Table 1. Patient Accounting: Accounting of Patients in ITT and PA Populations

	Double-Blind	Open Label		
Set	Protocol (Treatment)	Protocol (Treatment)	ITT[1]	PA[2]
1	CAN-19 (Risperidone)		5 (0.7)	1 (0.2)
2	CAN-19 (Risperidone)	CAN-20 (Risperidone)	38 (5.4)	24 (4.1)
3	CAN-19 (Placebo)	CAN-20 (Risperidone)	39 (5.6)	28 (4.7)
4	CAN-19 (Risperidone)	INT-41 (Risperidone)	10 (1.4)	10 (1.7)
5	CAN-19 (Placebo)	INT-41 (Risperidone)	13 (1.9)	12 (2.0)
6	USA-93 (Risperidone)		7 (1.0)	0 (0.0)
7	USA-93 (Risperidone)	USA-97 (Risperidone)	48 (6.9)	45 (7.6)
8	USA-93 (Placebo)	USA-97 (Risperidone)	59 (8.4)	55 (9.3)
9		INT-41 (Risperidone)	481 (68.7)	417 (70.4)
	Total Number of Patients		700	592

[1]Intent-to-Treat Population (ITT): Patients who took at least one dose of study medication

[2]Primary Analysis Population (PA): Patients with pre-dose and at least one post-dose prolactin observation at or after week 4

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Table 2. Patient Accounting: Accounting of Patients in PA Population

			N (%) of Patients in PA Population[1]						
	Double-Blind	Open Label	Weeks Post First Risperidone Dose						
Set	Protocol (Treatment)	Protocol (Treatment)	Pre-dose	4 to 7	8 to 12	16 to 24	28 to 36	40 to 48	52 to 55
1	CAN-19 (Risperidone)		1 (0.2)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
2	CAN-19 (Risperidone)	CAN-20 (Risperidone)	24 (4.1)	20 (3.6)	21 (4.2)	20 (4.5)	18 (4.6)	17 (4.7)	16 (38.1)
3	CAN-19 (Placebo)	CAN-20 (Risperidone)	28 (4.7)	26 (4.7)	22 (4.4)	21 (4.8)	17 (4.3)	18 (5.0)	0 (0.0)
4	CAN-19 (Risperidone)	INT-41 (Risperidone)	10 (1.7)	10 (1.8)	9 (1.8)	9 (2.0)	7 (1.8)	9 (2.5)	8 (19.0)
5	CAN-19 (Placebo)	INT-41 (Risperidone)	12 (2.0)	8 (1.5)	12 (2.4)	10 (2.3)	10 (2.5)	8 (2.2)	0 (0.0)
6	USA-93 (Risperidone)		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
7	USA-93 (Risperidone)	USA-97 (Risperidone)	45 (7.6)	39 (7.1)	42 (8.4)	33 (7.5)	28 (7.1)	16 (4.5)	18 (42.9)
8	USA-93 (Placebo)	USA-97 (Risperidone)	55 (9.3)	49 (8.9)	42 (8.4)	27 (6.1)	17 (4.3)	19 (5.3)	0 (0.0)
9		INT-41 (Risperidone)	417 (70.4)	397 (72.2)	351 (70.3)	321 (72.8)	297 (75.4)	271 (75.7)	0 (0.0)
	Total Number of Patients		592	550	499	441	394	358	42

[1]Primary Analysis Population (PA): Patients with pre-dose and at least one post-dose prolactin observation at or after week 4

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Table 3. Demographic Variables and Prolactin Levels: Patient Data Listing (ITT Population)

						Pre-dose					Prolactin [ng/mL]						
												Weeks Post Risperidone Dose					
Set	Patient ID	Flag	Gender	Retardation DSM-IV Axis II	IQ	Age	Tanner Stage	Height [cm]	Weight [kg]	BMI	Pre-dose	4 - 7	8 - 12	16 - 24	28 - 36	40 - 48	52 - 55
1	A3646	PA	Male	Mild	61	10	0	138.9	36.9	19.1	5.0	23.0					
	A3631	ITT	Male	Borderline	78	10	1	131.1	27.0	15.7							
	A3647	ITT	Male	Mild	69	6	0	115.1	23.0	17.4	10.0						
	A3694	ITT	Male	Borderline	77	9		131.1	26.1	15.2							
	A3702	ITT	Male	Borderline	79	6		110.0	18.6	15.4							
2	A3501	PA	Male	Borderline	84	9		127.0	33.6	20.8	5.0		35.0				
	A3502	PA	Male	Mild	62	13	1	140.0	32.1	16.4	9.0	55.0		52.0	49.0		
	A3503	PA	Male	Borderline	71	6	1	116.1	17.1	12.7	4.0	66.0			12.0	13.0	16.0
	A3508	PA	Male	Borderline	76	6	1	122.9	22.5	14.9	4.0		11.0				
	A3523	PA	Female	Moderate	49	8	1	119.1	30.9	21.8	4.0	14.0	19.0	10.0		4.0	
	A3524	PA	Male	Borderline	71	10	1	151.9	38.5	16.7	4.0	6.0	6.0	11.0	18.0	17.0	13.0
	A3525	PA	Male	Moderate	40	11	1	131.1	29.9	17.4	9.0		8.0	13.0	14.0	15.0	11.0
	A3530	PA	Female	Mild	70	8	1	126.0	21.0	13.2	39.0	50.0	15.0	28.0	2.0	9.0	5.0
	A3532	PA	Female	Mild	61	10	1	142.0	48.9	24.3	6.0	19.0	22.0	9.0	3.0	5.0	6.0
	A3619	PA	Male	Mild	70	11	1	132.1	25.1	14.4	2.0	10.0	103.0	25.0	31.0	17.0	4.0
	A3620	PA	Male	Moderate	45	13		142.0	32.8	16.3	8.0	25.0	6.0	6.0	13.0	16.0	29.0
	A3638	PA	Male	Moderate	49	6	1	110.0	16.0	13.2	4.0	12.0	18.0	5.0		2.0	3.0
	A3641	PA	Female	Borderline	71	7	1	118.1	18.0	12.9	8.0	18.0	11.0	12.0	13.0	28.0	11.0
	A3645	PA	Male	Borderline	70	9	1	151.9	61.4	26.6	9.0	33.0	54.0	22.0	36.0	28.0	
	A3651	PA	Male	Borderline	78	8	1	140.0	25.9	13.2	5.0		15.0	6.0	2.0		2.0
	A3652	PA	Male	Borderline	83	5	1	113.0	18.0	14.1	11.0	17.0	31.0	8.0	7.0	7.0	4.0
	A3654	PA	Female	Moderate	45	9	1	150.9	41.0	18.0	13.0	40.0				43.0	33.0
	A3657	PA	Male	Borderline	75	9		125.0	26.1	16.7	16.0	63.0	10.0	34.0	17.0		
	A3663	PA	Male	Borderline	78	10		135.9	30.4	16.5	5.0	15.0	10.0	3.0	8.0		7.0
	A3665	PA	Female	Mild	70	10	2	130.0	40.3	23.8	3.0	23.0	8.0	9.0	10.0	12.0	10.0
	A3679	PA	Male	Mild	53	12	2	142.0	34.9	17.3	8.0	29.0	18.0	19.0			
	A3681	PA	Male	Borderline	78	10	1	134.1	38.2	21.2	9.0	31.0	83.0	8.0	11.0	51.0	16.0
	A3683	PA	Female	Mild	51	9	1	122.9	23.5	15.6	13.0	28.0	25.0	20.0	21.0	38.0	11.0
	A3698	PA	Female	Borderline	81	7		119.1	23.8	16.8	6.0	51.0	26.0	25.0	41.0	44.0	
	A3513	ITT	Male	Borderline	80	10		137.9	33.9	17.8		42.0	19.0	14.0			
	A3514	ITT	Male	Borderline	81	8	1	134.9	26.6	14.6					19.0	37.0	48.0
	A3516	ITT	Male	Mild	54	10	1	136.9	27.3	14.6							
	A3518	ITT	Male	Borderline	74	11	1	125.0	22.0	14.1							
	A3520	ITT	Male	Borderline	78	7	1	121.9	20.0	13.5							
	A3521	ITT	Female	Borderline	73	11	2	145.0	39.9	19.0			34.0	15.0			
	A3541	ITT	Male	Borderline	80	9	0	144.0	30.9	14.9				8.0			
	A3548	ITT	Female	Mild	52	9		119.1	24.1	17.0							
	A3611	ITT	Male	Moderate	48	10		118.1	31.4	22.5							
	A3612	ITT	Female	Moderate	59	8		150.1	33.9	15.0							

Note. Primary Analysis Population (PA): Patients with pre-dose and at least one post-dose prolactin observation at or after week 4

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Table 3. Demographic Variables and Prolactin Levels: Patient Data Listing (ITT Population) -(continued)

						Pre-dose					Prolactin [ng/mL]						
												Weeks Post Risperidone Dose					
Set	Patient ID	Flag	Gender	Retardation DSM-IV Axis II	IQ	Age	Tanner Stage	Height [cm]	Weight [kg]	BMI	Pre-dose	4 - 7	8 - 12	16 - 24	28 - 36	40 - 48	52 - 55
2	A3623	ITT	Male	Borderline	72	8	1	135.9	36.9	20.0					27.0		
	A3624	ITT	Male	Mild	68	12	1	160.0	60.9	23.8					16.0		11.0
	A3655	ITT	Male	Borderline	82	10		129.0	27.5	16.5		18.0					
	A3656	ITT	Female	Borderline	83	11		151.9	38.5	16.7	12.0						
3	A3504	PA	Male	Borderline	77	6	1	126.0	33.5	21.1	8.0	65.0	36.0	26.0			
	A3505	PA	Female	Mild	70	7	1	120.9	21.0	14.4	6.0	62.0	36.0	4.0	23.0	9.0	
	A3506	PA	Male	Borderline	79	11	1	143.0	31.9	15.6	2.0	36.0	42.0	5.0		9.0	
	A3522	PA	Male	Mild	59	8	1	118.1	22.5	16.1	8.0	17.0	7.0	45.0	13.0	30.0	
	A3536	PA	Female	Mild	69	12	2	150.9	38.9	17.1	7.0	40.0	30.0	11.0	27.0	30.0	
	A3545	PA	Male	Borderline	84	6	1	118.1	33.5	24.0	7.0	18.0	7.0	24.0			
	A3610	PA	Male	Mild	66	11		144.0	30.9	14.9	5.0	3.0					
	A3615	PA	Male	Moderate	63	12	1		32.4		4.0	35.0	27.0		11.0	18.0	
	A3618	PA	Male	Mild	57	11	1	145.0	34.6	16.5	5.0	27.0	11.0	8.0		21.0	
	A3621	PA	Male	Borderline	73	11	0	142.0	45.4	22.5	7.0	31.0	36.0	13.0	13.0	14.0	
	A3639	PA	Male	Moderate	43	9	1	124.0	26.9	17.5	3.0	24.0		12.0	4.0	39.0	
	A3643	PA	Male	Mild	60	8	1	126.0	28.4	17.9	5.0	20.0	9.0			2.0	
	A3648	PA	Female	Mild	66	10	0	134.9	43.9	24.1	6.0				72.0		
	A3649	PA	Male	Borderline	76	7	0	117.1	23.5	17.1	4.0	50.0					
	A3650	PA	Female	Borderline	83	10	2	141.0	35.9	18.1	2.0	14.0	43.0	12.0	21.0	5.0	
	A3653	PA	Male	Borderline	81	6	1	124.0	27.9	18.1	7.0	23.0	19.0	10.0	32.0	9.0	
	A3658	PA	Male	Mild	62	9	1	125.0	22.0	14.1	5.0	27.0	12.0	6.0	4.0	24.0	
	A3659	PA	Male	Mild	55	10	1	138.9	28.9	15.0	3.0	54.0	5.0	18.0	17.0		
	A3660	PA	Female	Borderline	80	6	1	122.9	21.0	13.9	4.0	43.0	3.0	7.0	21.0	2.0	
	A3661	PA	Male	Borderline	77	6	1	110.0	18.0	14.9	3.0	23.0	41.0	12.0	5.0	6.0	
	A3662	PA	Male	Mild	52	10	1		21.4		6.0	11.0	6.0	9.0	13.0	8.0	
	A3664	PA	Female	Moderate	36	13	4	145.0	52.0	24.7	25.0	39.0	39.0	25.0	16.0	25.0	
	A3666	PA	Male	Borderline	78	9	1	127.0	33.4	20.7	7.0	11.0	17.0	12.0	13.0	11.0	
	A3680	PA	Male	Mild	65	12	2	134.9	30.3	16.7	7.0	51.0	5.0	26.0			
	A3682	PA	Male	Borderline	73	10	1	135.9	45.7	24.7	9.0		14.0	4.0	10.0	12.0	
	A3696	PA	Male	Moderate	48	7		115.1	21.0	15.9	4.0	26.0					
	A3697	PA	Male	Mild	64	7	1	115.1	20.4	15.4	8.0	22.0	12.0				
	A3699	PA	Male	Borderline	77	9		133.1	21.5	12.1	5.0	36.0		18.0			
	A3515	ITT	Male	Borderline	74	9	1	132.1	27.9	16.0				40.0	11.0		
	A3517	ITT	Female	Mild	63	10	1		24.4								
	A3519	ITT	Male	Borderline	71	8	1	120.9	24.9	17.0							
	A3533	ITT	Male	Moderate	36	12	1	136.9	29.1	15.5			54.0	53.0	39.0	29.0	
	A3542	ITT	Male	Mild	66	8	1	120.9	21.5	14.7		14.0				6.0	
	A3543	ITT	Male	Borderline	78	9	1	147.1	50.7	23.4		29.0					
	A3613	ITT	Male	Borderline	71	7		125.0	22.3	14.3							

Note. Primary Analysis Population (PA): Patients with pre-dose and at least one post-dose prolactin observation at or after week 4

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Table 3. Demographic Variables and Prolactin Levels: Patient Data Listing (ITT Population) -(continued)

						Pre-dose					Prolactin [ng/mL]						
												Weeks Post Risperidone Dose					
Set	Patient ID	Flag	Gender	Retardation DSM-IV Axis II	IQ	Age	Tanner Stage	Height [cm]	Weight [kg]	BMI	Pre-dose	4 - 7	8 - 12	16 - 24	28 - 36	40 - 48	52 - 55
3	A3622	ITT	Male	Borderline	74	11	2	130.0	25.8	15.3				44.0	29.0	22.0	
	A3625	ITT	Female	Borderline	74	12	4	142.0	30.0	14.9					6.0		
	A3692	ITT	Male	Mild	68	11		136.9									
	A3693	ITT	Male	Mild	55	8		128.0	33.4	20.4							
4	A3578	PA	Male	Mild	57	8	1	119.9	22.3	15.5	2.0	10.0	3.8	3.3	12.4	6.3	7.3
	A3585	PA	Male	Borderline	81	7	1	118.1	21.9	15.7	2.0	14.0	3.5	3.9		4.9	6.2
	A3588	PA	Male	Borderline	71	11	1	137.9	33.8	17.8	2.0	2.0	18.8				
	A3590	PA	Male	Moderate	49	12	1	133.1	23.8	13.4	6.0	26.0	18.6	14.2	14.7	19.2	12.3
	A3592	PA	Male	Mild	70	6	1	115.1	20.5	15.5	7.0	27.0	23.3	16.0	13.9	7.9	21.9
	A3606	PA	Male	Borderline	76	7	1	120.9	22.5	15.4	7.0	24.0	18.9	9.3	9.4	11.3	10.3
	A3608	PA	Male	Borderline	81	12	2	147.1	45.9	21.2	5.0	39.0	18.5	19.4	15.8	15.0	
	A3709	PA	Male	Borderline	73	10	1	140.0	31.9	16.3	4.0	26.0	15.0	19.0	22.0	22.0	25.3
	A3711	PA	Male	Mild	53	11	1	150.1	29.4	13.0	6.0	27.0		22.0		19.0	6.0
	A3720	PA	Male	Borderline	77	11	1	144.0	34.9	16.8	7.0	20.0	12.0	5.0	17.0	28.0	8.2
5	A3581	PA	Female	Mild	70	11	3	150.1	39.9	17.7	7.0	21.0	11.9	7.7	5.4	5.3	
	A3586	PA	Male	Borderline	72	5	1	110.0	20.5	16.9	8.0	8.3	9.1	6.9	13.1		
	A3587	PA	Male	Borderline	74	5	1	109.0	19.6	16.5	7.0	21.7	10.8	3.0			
	A3594	PA	Male	Mild	59	9	1	136.9	39.9	21.3	4.0	2.9	3.7	16.3	2.7	2.0	
	A3598	PA	Female	Mild	55	12	5	154.9	51.9	21.6	18.0		5.9				
	A3602	PA	Male	Mild	61	8	1	128.0	25.6	15.6	5.0		21.1	14.2	16.1	12.2	
	A3607	PA	Male	Borderline	81	9	1	130.0	27.4	16.2	5.0	11.9	9.1	4.7	27.5	3.3	
	A3609	PA	Male	Mild	53	10	1	130.0	25.4	15.0	14.0	27.0	7.0	31.7	27.7	61.0	
	A3700	PA	Male	Borderline	83	9	1	140.0	31.8	16.2	3.0		20.0		9.0	15.0	
	A3704	PA	Male	Borderline	77	9	1	136.0	38.3	20.7	9.0	29.0	21.0	16.0	6.0	8.0	
	A3708	PA	Male	Mild	70	11	1	142.0	32.1	15.9	9.0	35.0	11.0	21.0	22.0		
	A3710	PA	Female	Mild	59	12	3	154.9	41.9	17.5	8.0		78.0	46.0	71.0	160.9	
	A3599	ITT	Female	Mild	65	10	1	125.0	32.4	20.7	8.0						
6	A3036	ITT	Male	Borderline	79	9	1	134.6	30.8	17.0	4.0						
	A3103	ITT	Male	Borderline	73	7	1	119.4	21.5	15.1	2.0						
	A3130	ITT	Male	Mild	63	6	1		20.9		5.0						
	A3139	ITT	Male	Borderline	75	11	1	144.8	36.3	17.3	6.0						
	A3152	ITT	Male	Borderline	84	6	1	109.2	18.7	15.7	3.0						
	A3181	ITT	Male	Borderline	84	10	2	139.7	33.3	17.1	5.0						
	A3182	ITT	Male	Borderline	75	11	2	147.3	40.8	18.8	8.0						
7	A3003	PA	Male	Borderline	73	12	1	144.8	49.0	23.4	19.0	11.0	11.0	18.0			
	A3008	PA	Male	Borderline	76	9	1	119.4	20.9	14.7	3.0	17.0	14.0				6.0

Note, Primary Analysis Population (PA): Patients with pre-dose and at least one post-dose prolactin observation at or after week 4

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Table 3. Demographic Variables and Prolactin Levels: Patient Data Listing (ITT Population) -(continued)

						Pre-dose					Prolactin [ng/mL]						
												Weeks Post Risperidone Dose					
Set	Patient ID	Flag	Gender	Retardation DSM-IV Axis II	IQ	Age	Tanner Stage	Height [cm]	Weight [kg]	BMI	Pre-dose	4 - 7	8 - 12	16 - 24	28 - 36	40 - 48	52 - 55
7	A3010	PA	Female	Borderline	83	6	2	124.5	25.9	16.7	6.0	22.0	4.0	13.0	6.0		10.0
	A3012	PA	Male	Mild	60	10	1	137.2	28.1	14.9	9.0		39.0	11.0			
	A3021	PA	Male	Moderate	64	9	1	132.1	39.5	22.6	7.0	27.0	46.0	14.0	8.0	14.0	
	A3022	PA	Male	Moderate	44	10	1	149.9	33.1	14.7	6.0	15.0		16.0			15.0
	A3033	PA	Male	Borderline	84	8	1	127.0	22.8	14.1	9.0	10.0	3.0				
	A3038	PA	Male	Borderline	84	11	1	132.1	25.5	14.6	5.0	4.0	12.0	27.0	17.0		14.0
	A3043	PA	Male	Mild	54	9	1	142.2	32.7	16.2	2.0	4.0	18.0	23.0	12.0	23.0	2.0
	A3045	PA	Male	Borderline	77	6	1	114.3	21.5	16.5	16.0	27.0		31.0	59.0		
	A3047	PA	Male	Borderline	83	12		142.2	32.2	15.9	5.0	11.0	66.0	48.0			6.0
	A3054	PA	Male	Borderline	71	9	1	132.1	27.7	15.9	8.0	40.0	18.0	4.0	5.0		
	A3055	PA	Female	Borderline	81	7	1	114.3	17.9	13.7	5.0	12.0		8.0	3.0		
	A3061	PA	Male	Mild	65	11	1	142.2	33.4	16.5	6.0	63.0	61.0	46.0			
	A3063	PA	Male	Mild	65	11	1	127.0	23.6	14.6	4.0	25.0	12.0	2.0	3.0		
	A3067	PA	Male	Moderate	49	9	1	121.9	32.4	21.8	9.0	18.0	27.0				
	A3069	PA	Male	Moderate	36	13	1	154.9	38.9	16.2	10.0	15.0	33.0		9.0	11.0	13.0
	A3072	PA	Female	Mild	68	9	1	137.2	30.6	16.3	7.0		28.0				
	A3073	PA	Male	Borderline	76	12	2	147.3	39.5	18.2	8.0	65.0	4.0	33.0			
	A3075	PA	Male	Mild	62	10	1	137.2	33.6	17.8	6.0	22.0	14.0				
	A3077	PA	Male	Mild	58	9	1	124.5	25.4	16.4	5.0		38.0				
	A3082	PA	Male	Borderline	75	12	1	149.9	54.0	24.0	5.0	10.0	29.0	20.0	4.0	2.0	
	A3083	PA	Female	Mild	68	9	1	124.5	29.5	19.0	20.0		39.0	30.0	32.0	13.0	17.0
	A3086	PA	Female	Mild	69	10	2	152.4	71.2	30.7	6.0	3.0	17.0	39.0	27.0	7.0	
	A3091	PA	Male	Borderline	73	7	1	127.0	29.5	18.3	7.0	82.0	39.0	3.0	2.0	2.0	3.0
	A3092	PA	Male	Borderline	76	12	2	154.9	44.0	18.3	7.0	52.0	12.0	5.0	6.0	14.0	13.0
	A3096	PA	Male	Borderline	71	7	1	134.6	44.9	24.8	3.0	26.0	32.0	24.0	13.0	30.0	
	A3097	PA	Female	Mild	66	12	2	167.6	71.2	25.3	23.0	43.0	29.0				
	A3099	PA	Female	Borderline	78	8	1	124.5	31.8	20.5	9.0	18.0	29.0			23.0	
	A3104	PA	Male	Mild	53	12	1	152.4	39.0	16.8	14.0	68.0	44.0	50.0	25.0		
	A3105	PA	Male	Borderline	83	9	1	134.6	36.1	19.9	4.0	4.0	11.0	25.0			
	A3107	PA	Male	Borderline	84	9	1	134.6	29.0	16.0	6.0	74.0	27.0		47.0		
	A3122	PA	Female	Mild	69	11	2	147.3	61.0	28.1	12.0	24.0	37.0	19.0	21.0		
	A3126	PA	Male	Mild	68	5	1		16.0		4.0	37.0	31.0	13.0	35.0	14.0	9.0
	A3134	PA	Male	Borderline	80	6	1	119.4	25.4	17.8	6.0	37.0	33.0	6.0	15.0		20.0
	A3137	PA	Male	Borderline	76	8	1	134.6	41.8	23.1	3.0	31.0	33.0	34.0	22.0	12.0	
	A3140	PA	Male	Mild	65	8	1	132.1	25.2	14.4	6.0	12.0	6.0	8.0	10.0	9.0	5.0
	A3153	PA	Male	Borderline	84	10	1	144.8	59.7	28.5	7.0	16.0	4.0	9.0	5.0		
	A3162	PA	Male	Borderline	75	7	1	162.6	23.2	8.8	7.0	65.0	76.0	83.0	102.0	32.0	88.0
	A3166	PA	Male	Borderline	78	9	1	129.5	23.6	14.1	3.0	42.0	34.0	30.0			9.0
	A3170	PA	Male	Borderline	81	5	1	109.2	20.5	17.2	5.0		18.0				
	A3176	PA	Male	Borderline	73	8	1	124.5	25.4	16.4	5.0	3.0	8.0	3.0	3.0		

Note. Primary Analysis Population (PA): Patients with pre-dose and at least one post-dose prolactin observation at or after week 4

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Table 3. Demographic Variables and Prolactin Levels: Patient Data Listing (ITT Population) -(continued)

					Pre-dose					Prolactin [ng/mL]						
											Weeks Post Risperidone Dose					
Set	Patient ID	Flag	Gender	Retardation DSM-IV Axis II	IQ	Age	Tanner Stage	Height [cm]	Weight [kg]	BMI	Pre-dose	4 - 7	8 - 12	16 - 24	28 - 36	40 - 48	52 - 55
7	A3177	PA	Male	Moderate	46	10	1	134.6	31.3	17.3	6.0	3.0	12.0		15.0	3.0	4.0
	A3185	PA	Male	Mild	58	12	2	142.2	59.9	29.6	5.0	28.0	32.0	31.0	27.0		28.0
	A3195	PA	Male	Borderline	80	8	1	127.0	33.1	20.5	3.0		8.0	8.0	7.0	7.0	4.0
	A3042	ITT	Male	Borderline	77	11	1	147.3	48.5	22.4		14.0	6.0	28.0			
	A3052	ITT	Male	Moderate	42	12	1	121.9	20.4	13.7			33.0	8.0	22.0		
	A3053	ITT	Male	Moderate	62	8	1	137.2	34.9	18.5		11.0	10.0	9.0			
8	A3007	PA	Male	Mild	60	6	1	109.2	18.4	15.4	8.0	14.0				3.0	
	A3011	PA	Male	Mild	69	8	1	127.0	39.0	24.2	7.0	33.0	24.0	26.0	9.0	10.0	
	A3024	PA	Male	Moderate	44	13	5	160.0	59.9	23.4	7.0	9.0		13.0			
	A3025	PA	Male	Moderate	36	10	1	124.5	24.5	15.8	16.0	9.0	9.0				
	A3031	PA	Male	Mild	53	12	2	149.9	61.2	27.2	8.0	25.0	30.0	31.0			
	A3034	PA	Male	Borderline	83	11	1	154.9	44.1	18.4	4.0	28.0	33.0	17.0	36.0	2.0	
	A3035	PA	Female	Mild	68	7	1	116.8	20.1	14.7	11.0		4.0				
	A3040	PA	Male	Moderate	50	8	1	114.3	19.5	14.9	6.0	12.0	3.0				
	A3048	PA	Male	Mild	64	13	1	142.2	46.0	22.7	38.0		2.0	6.0			
	A3056	PA	Female	Moderate	50	7		109.2	20.0	16.8	12.0	26.0	5.0				
	A3058	PA	Male	Borderline	76	7	1	119.4	22.7	15.9	9.0	21.0					
	A3060	PA	Female	Borderline	78	8	1	129.5	30.4	18.1	6.0	22.0					
	A3062	PA	Female	Mild	56	8	1	132.1	38.1	21.8	8.0		15.0	18.0		14.0	
	A3064	PA	Male	Mild	70	8	1		34.1		3.0	33.0	47.0	8.0	3.0	4.0	
	A3066	PA	Male	Moderate	49	12	1	127.0	26.8	16.6	8.0	20.0	19.0	18.0		10.0	
	A3068	PA	Male	Moderate	38	10	1	134.6	28.8	15.9	2.0	22.0	23.0	13.0	31.0	16.0	
	A3071	PA	Male	Borderline	62	7	1	116.8	21.3	15.6	5.0	47.0	23.0			34.0	
	A3074	PA	Male	Mild	58	6	1	119.4	24.0	16.8	6.0	4.0	2.0				
	A3076	PA	Male	Borderline	76	6	1	111.8	19.5	15.6	9.0	55.0	66.0			35.0	
	A3079	PA	Male	Borderline	77	12	2	154.9	48.1	20.0	3.0	63.0	34.0				
	A3080	PA	Female	Moderate	50	13	2	149.9	45.8	20.4	15.0	26.0	30.0			10.0	
	A3081	PA	Male	Borderline	71	7	1	111.8	25.4	20.3	8.0	47.0	52.0	44.0	35.0	6.0	
	A3084	PA	Male	Mild	69	10	2	139.7	56.0	28.7	6.0		14.0				
	A3085	PA	Female	Borderline	82	5	1	116.8	27.6	20.2	15.0	50.0					
	A3087	PA	Male	Borderline	71	13	1	149.9	59.4	26.4	8.0	33.0	28.0				
	A3088	PA	Female	Borderline	75	7	1	124.5	24.5	15.8	7.0	3.0	7.0				
	A3089	PA	Male	Mild	70	7	1	129.5	26.2	15.6	35.0	39.0	8.0	31.0	17.0	7.0	
	A3093	PA	Female	Borderline	71	9	1	137.2	30.8	16.4	7.0	23.0	15.0	7.0	10.0	10.0	
	A3094	PA	Male	Mild	54	10	1	121.9	27.7	18.6	3.0	33.0	28.0	13.0			
	A3095	PA	Male	Mild	57	8	1	134.6	34.5	19.0	4.0	15.0	16.0	11.0			
	A3098	PA	Female	Mild	68	6	1	114.3	18.6	14.2	6.0	36.0	31.0	27.0	17.0		
	A3101	PA	Male	Borderline	71	9	1	124.5	24.5	15.8	3.0		35.0	25.0	6.0		
	A3102	PA	Male	Borderline	76	12	3	160.0	58.1	22.7	4.0	3.0	9.0	5.0			

Note. Primary Analysis Population (PA): Patients with pre-dose and at least one post-dose prolactin observation at or after week 4

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Table 3. Demographic Variables and Prolactin Levels: Patient Data Listing (ITT Population) -(continued)

						Pre-dose				Prolactin [ng/mL]						
											Weeks Post Risperidone Dose					
Set	Patient ID	Flag	Gender	Retardation DSM-IV Axis II	IQ	Age	Tanner Stage	Height [cm]	Weight [kg]	BMI	Pre-dose	4 - 7	8 - 12	16 - 24	28 - 36	40 - 48	52 - 55
8	A3106	PA	Male	Borderline	83	8	1	116.8	23.6	17.3	4.0	32.0	6.0	26.0			
	A3108	PA	Male	Borderline	83	12	1	147.3	41.7	19.2	7.0	10.0	5.0	3.0			
	A3109	PA	Female	Mild	64	10	2	144.8	53.4	25.5	9.0	7.0	12.0	7.0			
	A3110	PA	Male	Moderate	50	9	1	144.8	38.1	18.2	6.0	47.0	9.0	23.0	14.0	19.0	
	A3121	PA	Male	Mild	55	9	1	132.1	58.3	33.4	10.0	31.0	17.0	10.0			
	A3132	PA	Male	Borderline	80	5	1	99.1	16.0	16.3	10.0	39.0	25.0				
	A3135	PA	Female	Borderline	84	8	1	121.9	25.8	17.4	5.0	14.0	5.0	10.0	4.0		
	A3136	PA	Male	Borderline	84	7	1	129.5	36.7	21.9	5.0	11.0	17.0	17.0	8.0	7.0	
	A3151	PA	Male	Borderline	75	9	1	127.0	25.4	15.7	5.0	27.0	22.0		2.0	4.0	
	A3161	PA	Male	Borderline	75	5	1		19.3		5.0	58.0	9.0	15.0	18.0	3.0	
	A3164	PA	Male	Mild	64	8	1	134.6	29.0	16.0	5.0	99.0					
	A3167	PA	Male	Borderline	83	13	3	139.7	38.1	19.5	5.0	44.0					
	A3168	PA	Male	Mild	69	9	1	144.8	39.0	18.6	4.0	35.0	32.0		19.0	27.0	
	A3169	PA	Female	Borderline	82	10	4	154.9	48.5	20.2	5.0	13.0					
	A3171	PA	Male	Moderate	43	5		106.7	20.0	17.6	4.0	3.0					
	A3173	PA	Male	Moderate	41	6	1	116.8	20.9	15.3	8.0				6.0	9.0	
	A3179	PA	Male	Moderate	49	9	1	129.5	23.6	14.1	4.0	22.0					
	A3183	PA	Female	Mild	58	6	1	111.8	25.4	20.3	9.0	27.0					
	A3184	PA	Male	Mild	62	9	1	132.1	27.4	15.7	5.0	9.0					
	A3198	PA	Male	Mild	70	8	1	129.5	39.5	23.6	6.0	11.0	34.0	3.0			
	A3199	PA	Male	Borderline	75	6	1	101.6	17.7	17.1	6.0	48.0	43.0	35.0	30.0		
	A3200	PA	Male	Borderline	78	5	1	111.8	24.5	19.6	3.0	24.0	3.0				
	A3009	ITT	Male	Moderate	36	12	3	142.2	41.1	20.3	10.0						
	A3023	ITT	Male	Moderate	36	11	2	132.1	34.0	19.5	45.0						
	A3100	ITT	Male	Borderline	73	8	1	137.2	33.6	17.8	8.0						
	A3187	ITT	Male	Mild	66	8	2	124.5	26.5	17.1	29.0						
9	A03001	PA	Male	Borderline	82	9	1		24.3		2.0			2.0	29.6	25.9	
	A03002	PA	Male	Mild	64	12	1	157.0	42.0	17.0	2.4	19.5	11.0	11.4	10.2	4.4	
	A03004	PA	Male	Mild	60	9	1	143.0	40.4	19.8	11.2			29.0		35.4	
	A03005	PA	Male	Mild	67	10	1		47.0		5.3	9.2				6.1	
	A03006	PA	Male	Borderline	81	7	1	134.0	30.0	16.7	2.8	11.6	10.2		12.8	5.7	
	A03007	PA	Male	Mild	67	7	1	126.0	22.0	13.9	3.9	19.4		17.6	27.2	13.8	
	A03008	PA	Male	Mild	62	9	1	138.0	28.0	14.7	4.5	36.8	21.5	43.4		3.6	
	A03009	PA	Male	Mild	71	8	1	128.0	22.0	13.4	40.2	36.5	27.1		46.0	33.8	
	A03010	PA	Male	Mild	73	7	1	137.0	27.0	14.4	6.2	33.0		38.8	42.9	29.3	
	A03012	PA	Male	Mild	64	12	2	156.0	42.9	17.6	22.6	44.5	54.8	48.8		36.4	
	A03014	PA	Male	Mild	59	8	1	131.0	27.7	16.1	19.2	41.1					
	A03015	PA	Male	Mild	62	7	1	121.0	21.5	14.7	6.4	57.8	28.7		52.7		
	A03016	PA	Male	Mild	62	8	1	130.0	29.0	17.2	13.6			15.5		28.9	

Note. Primary Analysis Population (PA): Patients with pre-dose and at least one post-dose prolactin observation at or after week 4

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Table 3. Demographic Variables and Prolactin Levels: Patient Data Listing (ITT Population) -(continued)

						Pre-dose					Prolactin [ng/mL]						
												Weeks Post Risperidone Dose					
Set	Patient ID	Flag	Gender	Retardation DSM-IV Axis II	IQ	Age	Tanner Stage	Height [cm]	Weight [kg]	BMI	Pre-dose	4 - 7	8 - 12	16 - 24	28 - 36	40 - 48	52 - 55
9	A03021	PA	Male	Borderline	74	7	1	116.0	20.0	14.9	4.8	23.9					
	A03025	PA	Male	Mild	67	15	3	165.0	55.0	20.2	4.3	21.5	22.2	15.4	16.9		
	A03028	PA	Male	Borderline	79	13	3	162.0	57.3	21.8	2.0	27.4	16.2	23.2			
	A03030	PA	Male	Borderline	78	10	1	136.0	27.0	14.6	3.1	20.3	11.5	7.5	14.0	16.0	
	A03034	PA	Male	Mild	72	12	2	140.0	40.0	20.4	14.0	31.1	26.2	15.3	23.0	20.4	
	A03038	PA	Male	Mild	73	10			39.0		3.7	26.7	22.0	14.4	13.8	6.5	
	A03040	PA	Male	Mild	69	11	2	151.0	40.0	17.5	4.7	41.9	40.5	41.2			
	A03041	PA	Male	Mild	64	11	1	159.0	62.0	24.5	2.2	47.7	48.0	34.3	39.1	29.7	
	A03042	PA	Male	Mild	63	11	3	156.0	48.0	19.7	5.3	12.7	17.3	12.9	8.8	14.5	
	A03043	PA	Female	Mild	69	14	4	163.0	69.5	26.2	4.6	50.3	37.3	38.9	35.0	37.3	
	A03044	PA	Male	Borderline	79	12	2	154.0	39.0	16.4	3.1	33.0	29.2	17.6	15.1	12.0	
	A03045	PA	Male	Borderline	79	11	1	156.0	62.0	25.5	4.1	29.5	31.0				
	A03048	PA	Male	Mild	56	9	1	137.0	29.9	15.9	8.5	16.7	47.2	24.7	16.5		
	A03049	PA	Female			8	1	120.0	26.3	18.3	16.7	43.9					
	A03050	PA	Male	Mild	70	13	2	150.0	40.7	18.1	3.2	21.2	3.5				
	A03051	PA	Male	Mild	71	10	2	150.0	40.7	18.1	6.7	41.0	33.6	40.0		30.3	
	A03052	PA	Male	Mild	62	10	1	146.0	46.1	21.6	2.5	47.7	32.0	31.2	18.7	27.3	
	A03053	PA	Male	Mild	59	12	1	138.0	30.6	16.1	9.9	42.8					
	A03055	PA	Male	Borderline	71	12	1	145.0	31.7	15.1	3.2	27.8	11.3	26.0	17.1	15.5	
	A03056	PA	Male	Mild	53	11	1	140.0	36.2	18.5	4.2	45.9	46.0	64.3	45.9	48.5	
	A03057	PA	Male	Moderate	46	6	1	133.0	30.1	17.0	3.5	50.4	33.6	26.8	23.8	20.6	
	A03059	PA	Male	Borderline	71	15	5	172.0	56.5	19.1	3.5	24.6	27.0	22.5	20.3	15.0	
	A03060	PA	Female	Mild	62	13	3	162.0	60.0	22.9	6.1	17.2	6.1	9.3	9.6	5.1	
	A03065	PA	Male	Mild	53	13	4	170.0	65.0	22.5	6.2	22.7	28.5	19.0	33.0	28.0	
	A03067	PA	Male	Mild	59	13	1		41.0		7.1	21.7	4.6			6.0	
	A03068	PA	Female	Mild	59	11	1	134.0	39.0	21.7	3.9			18.8	30.3		
	A03069	PA	Male	Borderline	75	11	1	143.0	35.0	17.1	3.0	14.3	19.3	10.2	16.8	6.8	
	A03070	PA	Female	Mild	53	10	1	131.0	30.4	17.7	4.5	33.9					
	A03071	PA	Male	Borderline	71	11	2	148.0	36.0	16.4	5.3	26.9	30.2	26.9	22.0	11.0	
	A03073	PA	Male	Moderate	42	10	1	140.0	34.0	17.3	3.3	35.0	23.7	28.4		3.9	
	A03075	PA	Male	Borderline	75	7	1	114.0	16.0	12.3	6.1	18.0	11.7	9.6	12.0	7.0	
	A03077	PA	Male	Borderline	71	11	1	140.0	32.0	16.3	3.3	31.3	25.6	6.2	22.0	4.5	
	A03080	PA	Female	Moderate	40	12	2	152.0	61.5	26.6	13.3	24.8	16.9	21.2	22.2	34.0	
	A03081	PA	Male	Mild	62	8	1	129.0	26.2	15.7	2.9	29.0	18.0				
	A03093	PA	Male	Moderate	50	9	1	125.0	28.0	17.9	10.0	42.4	49.4	33.6	34.2	30.7	
	A03096	PA	Male	Borderline	83	10	1	152.0	40.0	17.3	3.0	51.0	35.8	34.1	28.3	32.3	
	A03100	PA	Male	Borderline	74	12	3	154.0	43.0	18.1	17.1	30.6	36.8	32.2	22.2	30.0	
	A03101	PA	Female	Borderline	81	8	1	128.0	34.0	20.8	7.4	11.3	21.4	9.8	9.9	3.3	
	A03105	PA	Male	Borderline	73	9	1	137.0	35.0	18.6	8.4	23.9	6.0	16.2	15.3	9.6	
	A03106	PA	Male	Borderline	72	11	1	146.0	40.0	18.8	47.7	150.0	95.3	90.9	87.7		

Note. Primary Analysis Population (PA): Patients with pre-dose and at least one post-dose prolactin observation at or after week 4

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Table 3. Demographic Variables and Prolactin Levels: Patient Data Listing (ITT Population) -(continued)

						Pre-dose					Prolactin [ng/mL]						
												Weeks Post Risperidone Dose					
Set	Patient ID	Flag	Gender	Retardation DSM-IV Axis II	IQ	Age	Tanner Stage	Height [cm]	Weight [kg]	BMI	Pre-dose	4 - 7	8 - 12	16 - 24	28 - 36	40 - 48	52 - 55
9	A03108	PA	Male	Borderline	71	11	1	152.0	47.0	20.3	2.2	30.7	17.0	20.9	28.6	21.9	
	A03110	PA	Male	Borderline	78	13	1	144.0	34.0	16.4	4.4	18.7	25.9	24.1	23.6		
	A03181	PA	Male	Moderate	47	12	2		36.5		7.0	22.0	6.6	13.1	22.4	14.3	
	A03182	PA	Male	Mild	59	11	1		51.5		2.8	25.6	11.0	7.2	14.8	4.8	
	A03183	PA	Female	Moderate	40	13	5		70.0		10.6	46.9	49.4	46.5	40.1	37.2	
	A03184	PA	Male	Mild	58	13	3	149.0	45.0	20.3	15.6	36.5	8.0	25.4	30.2	21.3	
	A03185	PA	Male	Mild	69	12	2	153.0	42.5	18.2	4.0	27.1	23.0	14.2	15.9	2.5	
	A03186	PA	Male	Mild	57	7	1	122.0	22.0	14.8	14.0	39.5	2.4	20.4	20.9	5.7	
	A03187	PA	Female	Mild	68	11	1	149.0	40.0	18.0	11.3	12.4	17.9	7.0	8.4	13.7	
	A03188	PA	Male	Mild	65	9	1	134.0	39.4	21.9	2.9	14.1	7.7	8.8	13.1	4.3	
	A03189	PA	Female	Moderate	42	8	2	133.0	55.2	31.2	3.7	31.4	4.5				
	A03190	PA	Male	Borderline	73	8	1	123.0	23.5	15.5	7.8	34.3	24.8	3.9	11.9	2.5	
	A03191	PA	Male	Mild	54	13	2	146.0	39.7	18.6	10.3	15.8			16.8		
	A03192	PA	Male	Borderline	79	6	1	123.0	25.0	16.5	4.1	13.8	12.2	13.8	12.6	12.4	
	A03193	PA	Male	Borderline	74	7	1		24.0		3.9	8.6	5.0	3.0	7.2	22.4	
	A03196	PA	Female	Moderate	40	13	3	144.0	39.2	18.9	17.2	30.7		36.8	21.0	20.0	
	A03197	PA	Male	Moderate	44	6	1	116.0	20.0	14.9	3.1	8.2	5.0	8.5	6.8	6.0	
	A03205	PA	Male	Mild	54	8	1	128.0	25.0	15.3	6.0	31.0	7.0	6.0		5.0	
	A03208	PA	Male	Mild	56	11	2	140.0	45.0	23.0	4.0	19.0	13.0				
	A03210	PA	Male	Moderate	42	10	1	130.0	27.5	16.3	16.0	51.0	42.0	21.0	15.0	4.0	
	A03211	PA	Male	Mild	70	7	1	120.0	25.0	17.4	14.0	40.0	1.0	20.0	5.0	16.0	
	A03212	PA	Female	Moderate	44	9	1	142.0	36.5	18.1	7.0	5.0					
	A03213	PA	Male	Mild	60	12	2	164.0	45.0	16.7	5.0	45.0	27.0	20.0	25.0	9.0	
	A03223	PA	Male	Moderate	40	10	1	129.0	33.0	19.8	3.0	31.0	10.0	17.0	14.0	10.0	
	A03225	PA	Male	Moderate	44	8	1	124.0	24.0	15.6	17.0	19.0	21.0	8.0	11.0	5.0	
	A03226	PA	Male	Moderate	50	7	1	119.0	21.0	14.8	4.0	18.0	45.0	15.0	16.0	8.0	
	A03227	PA	Male	Moderate	45	12	2	147.0	34.5	16.0	4.0	13.0	15.0	3.0	9.0	7.0	
	A03228	PA	Male	Mild	55	7	1	118.0	21.0	15.1	9.0	55.0	88.0	27.0	37.0		
	A03229	PA	Male	Moderate	47	10	1	122.0	25.0	16.8	5.0	16.0	10.0	5.0	5.0		
	A03230	PA	Female	Moderate	47	6	1	105.0	18.5	16.8	28.0			38.0	18.0		
	A03231	PA	Male	Moderate	46	9	1	130.0	28.0	16.6	7.0	50.0	36.0	22.0	11.0		
	A03232	PA	Male	Mild	54	6	1	116.0	18.0	13.4	4.0	28.0	43.0		28.0		
	A03233	PA	Female	Moderate	40	10	1	123.0	26.0	17.2	3.0	24.0	18.0		4.0		
	A03235	PA	Male	Borderline	79	6	1	114.0	19.0	14.6	28.0		2.0				
	A03245	PA	Male	Moderate	44	12	1	128.0	26.0	15.9	7.0	24.0		29.8			
	A03249	PA	Male	Mild	56	9	1	127.0	24.0	14.9	6.0	31.0	34.0	14.0	23.0	13.0	
	A03250	PA	Male	Moderate	48	12	1	131.0	24.5	14.3	5.0	39.0	30.0	24.0	27.0	24.0	
	A03251	PA	Male	Moderate	40	9	1	136.0	31.0	16.8	4.0	53.0	58.0	29.0	26.0	20.0	
	A03252	PA	Male	Mild	61	8	1	129.0	25.5	15.3	26.0	48.0	41.0	39.0	39.0	17.0	
	A03253	PA	Male	Mild	54	5	1	111.0	20.0	16.2	8.0	53.0					

Note. Primary Analysis Population (PA): Patients with pre-dose and at least one post-dose prolactin observation at or after week 4

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Table 3. Demographic Variables and Prolactin Levels: Patient Data Listing (ITT Population) -(continued)

						Pre-dose				Prolactin [ng/mL]						
											Weeks Post Risperidone Dose					
Set	Patient ID	Flag	Gender	Retardation DSM-IV Axis II	IQ	Age	Tanner Stage	Height [cm]	Weight [kg]	BMI	Pre-dose	4 - 7	8 - 12	16 - 24	28 - 36	40 - 48	52 - 55
9	A03254	PA	Male	Borderline	75	8	1	124.0	24.0	15.6	12.0	49.0	37.0	27.0	20.0	4.0	
	A03255	PA	Male	Mild	59	9	1	134.0	28.5	15.9	10.0	16.0	20.0	16.0			
	A03259	PA	Male	Mild	63	15	2	164.0	43.0	16.0	12.0	47.0	45.0	88.0	22.2	35.1	
	A03260	PA	Male	Borderline	75	8	1	132.0	32.5	18.7	6.0	34.0	33.0	17.2	26.2	5.9	
	A03261	PA	Male	Moderate	50	7	1	123.0	36.5	24.1	7.0	19.0	39.0	24.0	10.0	32.0	
	A03262	PA	Male	Mild	61	9	1	126.5	30.0	18.7	7.0	24.0	22.0		13.0	24.3	
	A03266	PA	Male	Mild	70	11	1		32.0		7.0	29.0	55.0	4.0	25.0	21.0	
	A03268	PA	Male	Moderate	49	9	1	124.0	23.5	15.3	10.0	65.0	68.0	55.0		44.0	
	A03269	PA	Male	Mild	52	8	1	120.0	24.0	16.7	10.0	42.0	30.0	27.0	19.0	16.0	
	A03272	PA	Female	Mild	68	9	1	130.0	31.3	18.5	16.0	70.0	32.0	42.0	36.0	30.0	
	A03273	PA	Male	Mild	52	11	1	139.0	34.2	17.7	6.0	40.0	26.0	35.0	22.0	28.4	
	A03276	PA	Male	Borderline	75	7	1	120.0	20.0	13.9	5.0		8.0	3.0	13.0	2.0	
	A03277	PA	Male	Mild	54	6	1	122.0	22.5	15.1	6.0	13.0	10.0	7.0	6.0	15.0	
	A03278	PA	Male	Mild	52	7	1	127.0	28.0	17.4	5.0	26.0	33.0				
	A03279	PA	Male	Moderate	40	11	1	135.0	29.0	15.9	47.0	27.0	11.0	5.0	5.0	3.0	
	A03280	PA	Male	Mild	56	12	1	151.0	42.3	18.6	6.0	34.0	27.0	25.0	30.0	16.0	
	A03281	PA	Female	Moderate	42	10	3	150.0	37.8	16.8	8.0	64.0	22.0	25.0	43.0	16.0	
	A03282	PA	Female	Moderate	40	15	4	150.0	43.6	19.4	15.0	66.0	37.0	27.0	19.0	10.6	
	A03283	PA	Female	Moderate	50	13	1	157.0	47.8	19.4	15.0	56.0	47.0	32.2			
	A03284	PA	Male	Mild	57	11	1	155.0	33.2	13.8	41.0	32.0	30.2	5.8			
	A03285	PA	Male	Moderate	42	11	2	142.0	30.0	14.9	2.0	29.0	7.0	2.0	5.0		
	A03288	PA	Male	Moderate	40	10	1	134.0	26.5	14.8	24.0	36.0	14.0	16.0			
	A03289	PA	Male	Moderate	42	10	1	127.0	31.5	19.5	4.0				13.0		
	A03290	PA	Male	Mild	54	15	4	163.0	47.5	17.9	7.0	20.0	29.0		7.0	7.0	
	A03291	PA	Female	Moderate	44	10	2	131.0	34.5	20.1	3.0	21.0	2.0		4.0		
	A03293	PA	Female	Mild	64	10	1	144.0	34.1	16.4	6.0	45.0	40.0	36.8			
	A03294	PA	Female	Moderate	50	14	2	149.0	42.7	19.2	10.0	33.0	61.0	40.9	28.8		
	A03295	PA	Female	Mild	51	9	1	136.0	36.3	14.2	16.4	25.3	20.4	7.7	11.4	9.6	
	A03296	PA	Female	Moderate	47	10	2	143.0	39.2	19.2	4.0		17.7	13.9	15.9	13.7	
	A03298	PA	Male	Borderline	80	9	1	136.0	33.5	18.1	10.9	25.4	14.6	14.7	12.1	11.0	
	A03299	PA	Male	Borderline	77	14	5	171.0	53.7	18.4	2.8	24.7					
	A03300	PA	Female	Mild	67	6	1	116.0	19.1	14.2	2.5	24.4	11.5	3.9	5.2	3.7	
	A03301	PA	Male	Borderline	81	7	1	136.0	28.6	15.5	2.5	25.8	14.9	30.1	18.9	21.1	
	A03302	PA	Female	Borderline	72	8	1	138.0	27.5	14.4	16.3	29.3	22.6	15.6	13.9	14.3	
	A03303	PA	Female	Mild	53	15	4	164.0	66.0	24.5	7.4	36.8	29.2	19.0	35.0		
	A03304	PA	Male	Moderate	45	14	3	166.0	50.1	18.2	2.0	23.5	23.7	26.1	12.5	8.6	
	A03305	PA	Male	Borderline	74	13	1	150.0	37.1	16.5	3.8	15.6		20.0	12.1	10.7	
	A03306	PA	Male	Mild	68	13	1	155.0	42.9	17.9	6.0	42.7					
	A03309	PA	Male	Borderline	75	11	2	149.0	52.0	23.4	10.7	45.1	36.0	31.9	24.9	15.8	
	A03311	PA	Male	Borderline	76	12	1	144.0	29.8	14.4	5.5	29.7					

Note. Primary Analysis Population (PA): Patients with pre-dose and at least one post-dose prolactin observation at or after week 4

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Table 3. Demographic Variables and Prolactin Levels: Patient Data Listing (ITT Population) -(continued)

						Pre-dose					Prolactin [ng/mL]						
											Weeks Post Risperidone Dose						
Set	Patient ID	Flag	Gender	Retardation DSM-IV Axis II	IQ	Age	Tanner Stage	Height [cm]	Weight [kg]	BMI	Pre-dose	4 - 7	8 - 12	16 - 24	28 - 36	40 - 48	52 - 55
9	A03313	PA	Male	Borderline	79	9	1	148.0	29.9	13.7	8.9	29.5	26.1	13.9	13.4	6.7	
	A03314	PA	Male	Mild	62	11	1	161.0	64.4	24.8	2.1	27.8	18.4	3.6			
	A03315	PA	Male	Mild	61	8	1	129.0	27.0	16.2	17.4	48.8	43.3	37.9	25.1		
	A03316	PA	Male	Moderate	45	10	1	123.0	24.1	15.9	12.9	23.0	19.9		20.4	22.8	
	A03317	PA	Female	Moderate	47	14	3	144.0	32.0	15.4	20.7	83.6	61.3	81.3	61.1	34.0	
	A03318	PA	Male	Mild	59	11	1	145.0	32.2	15.3	5.0	19.6	34.9	14.1	2.4	17.9	
	A03319	PA	Male	Moderate	47	10	1	138.0	39.8	20.9	2.8	22.1	14.8				
	A03320	PA	Male	Mild	69	6	1	114.0	23.0	17.7	3.1	32.5					
	A03321	PA	Male	Mild	59	10	1	134.0	25.0	13.9	3.1	48.2					
	A03322	PA	Male	Borderline	81	9	1	146.0	40.3	18.9	4.6	26.9	35.7	16.7	21.8	11.3	
	A03325	PA	Male	Borderline	72	11	1	145.0	41.0	19.5	2.9	11.0	6.6		2.0		
	A03326	PA	Male	Borderline	84	7	1	127.0	27.1	16.8	7.8	18.9		5.2	4.8	12.3	
	A03327	PA	Male	Borderline	80	10	2	142.0	35.5	17.6	17.8	33.4	32.0	25.0	14.6	61.6	
	A03328	PA	Male	Borderline	79	8	1	131.0	25.5	14.9	25.5	35.6	21.4	9.7	11.7	8.6	
	A03329	PA	Male	Borderline	72	5			24.7		5.0	38.9	31.3	13.5	10.5	8.3	
	A03330	PA	Male	Mild	62	10	1	131.0	22.3	13.0	17.2	61.6	45.5	39.8	33.8	30.2	
	A03331	PA	Male	Mild	52	10	1	132.0	26.6	15.3	6.4	36.4	31.2	27.6	28.5	33.9	
	A03333	PA	Male	Borderline	74	10	1	144.0	43.0	20.7	4.8	47.1	10.3	7.9	3.5	40.5	
	A03335	PA	Male	Borderline	83	13	4	166.0	51.3	18.6	3.7	14.2	7.0	4.5	5.3	7.0	
	A03336	PA	Male	Mild	70	12	1	156.0	46.0	18.9	2.7	20.6	15.5	10.2	7.6	3.0	
	A03337	PA	Male	Borderline	75	12	1	161.0	63.3	24.4	6.4	36.6	41.2	10.2			
	A03338	PA	Male	Moderate	37	11	1	132.0	39.1	22.4	3.0	26.8	25.9	36.3		23.9	
	A03339	PA	Male	Moderate	44	12	2	152.0	45.6	19.7	3.2	16.7	20.0	8.9	9.6	18.2	
	A03340	PA	Male	Borderline	83	13	1	150.0	44.6	19.8	6.1	28.6	25.0	22.9	21.6	22.7	
	A03341	PA	Male	Mild	52	8	1	135.0	29.4	16.1	7.4	41.7	5.1				
	A03342	PA	Male	Mild	65	8	1	126.0	22.0	13.9	5.1	47.7	36.6	27.3	27.3	21.5	
	A03343	PA	Male	Borderline	72	11	1	144.0	36.0	17.4	3.2	46.7	37.2	36.3	46.2	3.0	
	A03344	PA	Female	Mild	64	14	3	165.0	45.6	16.7	50.7	95.2	63.1	77.5			
	A03345	PA	Male	Borderline	77	12	2	150.0	48.5	21.6	23.4	42.0	153.0	83.4			
	A03346	PA	Male	Mild	68	13	1	176.0	65.4	21.1	5.1	35.7	28.0	2.5	28.6	11.4	
	A03347	PA	Male	Mild	65	11	1	139.0	29.8	15.4	2.4	35.0	26.3	16.1	20.2	21.7	
	A03348	PA	Male	Borderline	82	10	1	150.0	38.8	17.2	5.5	41.3	39.3	40.2	28.9		
	A03350	PA	Male	Moderate	46	10	1	136.0	36.7	19.8	8.7	28.9	25.4	14.9	15.1	16.1	
	A03351	PA	Female	Borderline	79	8	1	144.0	43.2	20.8	3.6	38.6	30.1				
	A03352	PA	Male	Borderline	71	15	2	176.0	67.2	21.7	19.0	48.9	28.0				
	A03353	PA	Male	Borderline	83	11	1	151.0	37.0	16.2	4.7	26.9	27.8	16.1	8.0	14.9	
	A03354	PA	Male	Mild	65	10	1	127.0	23.0	14.3	3.2	13.3	5.4	5.0	4.0	3.0	
	A03355	PA	Male	Borderline	72	12	2	155.0	61.4	25.6	3.2	13.0	13.6			7.2	
	A03357	PA	Male	Borderline	81	8	1	135.0	44.5	24.4	8.2	14.4	27.2		29.1	11.0	
	A03358	PA	Male	Mild	66	7	1	131.0	22.5	13.1	4.4	29.8	18.4	3.2	2.9	16.4	

Note. Primary Analysis Population (PA): Patients with pre-dose and at least one post-dose prolactin observation at or after week 4

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Table 3. Demographic Variables and Prolactin Levels: Patient Data Listing (ITT Population) -(continued)

						Pre-dose					Prolactin [ng/mL]						
												Weeks Post Risperidone Dose					
Set	Patient ID	Flag	Gender	Retardation DSM-IV Axis II	IQ	Age	Tanner Stage	Height [cm]	Weight [kg]	BMI	Pre-dose	4 - 7	8 - 12	16 - 24	28 - 36	40 - 48	52 - 55
9	A03359	PA	Male	Mild	69	10	1	136.0	29.0	15.7	5.7	26.9				13.2	
	A03360	PA	Male	Mild	64	7	1	120.0	19.0	13.2	25.5	33.5		28.2	21.6		
	A03363	PA	Male	Borderline	73	15	2		70.0		13.7	13.8		19.6	16.7		
	A03364	PA	Male	Mild	68	10	1	124.0	24.3	15.8	7.8		52.9	40.0	5.5		
	A03365	PA	Female	Borderline	78	11	1	148.0	32.5	14.8	7.2	23.8		10.8	18.7		
	A03366	PA	Male	Borderline	78	11	1	144.0	39.5	19.0	6.7	25.0	25.1	20.1		17.9	
	A03367	PA	Male	Borderline	84	8	1	131.0	29.0	16.9	4.4	20.8	23.3	11.3	20.4		
	A03368	PA	Male	Mild	57	12	1	148.0	50.0	22.8	4.1		24.2	28.0	26.1	7.8	
	A03369	PA	Male	Mild	61	7	1	122.0	18.5	12.4	8.0	35.6	5.2	35.6	4.2	7.5	
	A03370	PA	Male	Borderline	77	10	1	144.0	28.5	13.7	2.4	25.0		22.0	15.9	19.5	
	A03372	PA	Male	Borderline	74	15	2	169.0	56.0	19.6	76.5	18.6	7.5				
	A03375	PA	Male	Borderline	74	10	1	138.0	27.5	14.4	4.4				28.3		
	A03376	PA	Female	Borderline	75	7	1	118.0	19.5	14.0	4.9	47.5	37.6	36.9	19.4	26.0	
	A03377	PA	Male	Borderline	78	8	1	124.0	21.0	13.7	5.2	34.7	31.1	52.1	15.8	24.7	
	A03378	PA	Male	Borderline	71	11	1	148.0	45.0	20.5	6.3		21.0				
	A03379	PA	Male	Mild	63	10	1	149.0	38.0	17.1	5.1	31.6	28.4	34.0	26.5	24.0	
	A03381	PA	Male	Mild	76	10	1	141.0	34.4	17.3	17.3	24.0	18.4				
	A03382	PA	Male	Mild	62	8	1	143.0	32.6	15.9	2.5	31.0	14.4	20.8	14.0		
	A03384	PA	Female	Mild	58	10	2	138.0	36.0	18.9	7.0	17.3	9.7	6.4	7.7		
	A03385	PA	Male	Borderline	72	14	2	159.0	60.0	23.7	3.9	24.2	19.0	26.7			
	A03395	PA	Female	Mild	59	15	5	166.0	54.0	19.6	7.9	70.7	64.2	63.8	79.8	49.6	
	A03396	PA	Male	Mild	66	14	4	173.0	66.5	22.2	8.8	37.3	16.9	31.9	31.1	27.4	
	A03398	PA	Male	Mild	52	14	2	156.0	73.0	30.0	3.9	21.9	26.4	32.8	29.3		
	A03399	PA	Male	Borderline	71	15	3	169.0	71.0	24.9	4.8	65.1	31.4	35.1	29.2	29.9	
	A03406	PA	Male	Mild	65	14	3	157.0	40.0	16.2	3.0	17.7	7.8	10.4	14.9	5.1	
	A03407	PA	Male	Mild	60	10	1	137.0	25.5	13.6	13.8	27.0	25.4	4.1	7.8	21.5	
	A03409	PA	Male	Borderline	82	8	1	137.0	29.0	15.5	2.5	30.0	31.0	22.2	7.7	12.5	
	A03410	PA	Male	Borderline	71	10	1	153.0	43.0	18.4	2.8	13.3	5.7	6.0	5.9	9.4	
	A03411	PA	Male	Mild	68	10	2	148.0	31.0	14.2	4.1	24.3	13.1	19.0	6.4	14.9	
	A03412	PA	Male	Mild	75	9	1	134.0	30.0	16.7	5.1	40.3	23.8	36.7	3.1	3.0	
	A03413	PA	Male	Borderline	79	12	1	148.0	34.0	15.5	2.6	16.4	2.4	11.4			
	A03414	PA	Male	Mild	64	9	1	135.0	25.0	13.7	2.7	43.7	35.9	27.9	20.8	32.5	
	A03415	PA	Male	Mild	62	12	1	139.0	36.1	18.7	2.9	30.8	35.8	27.6	18.9	15.9	
	A03416	PA	Male	Moderate	44	14	2	165.0	46.3	17.0	3.1	24.5	13.1	17.9	24.6	26.8	
	A03417	PA	Female	Mild	54	13	4	165.0	66.3	24.4	4.2	36.8	42.0	40.9	37.7	26.0	
	A03418	PA	Male	Moderate	50	13	4	165.0	46.4	17.0	3.0	30.9	29.4	27.3	20.1	16.9	
	A03419	PA	Male	Mild	68	11	1	137.0	27.6	14.7	17.7	36.5	40.5	2.7	26.2	18.8	
	A03420	PA	Male	Mild	61	11	1	133.0	24.6	13.9	4.6	38.9	3.5				
	A03421	PA	Male	Mild	63	6	1	122.0	24.2	16.3	10.2	41.8	38.5	32.8	27.2	26.3	
	A03422	PA	Male	Moderate	45	11	1	134.0	31.1	17.3	2.8	17.1	18.8	13.4	9.1	11.4	

Note. Primary Analysis Population (PA): Patients with pre-dose and at least one post-dose prolactin observation at or after week 4

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Table 3. Demographic Variables and Prolactin Levels: Patient Data Listing (ITT Population) -(continued)

						Pre-dose					Prolactin [ng/mL]					
												Weeks Post Risperidone Dose				
Set	Patient ID	Flag	Gender	Retardation DSM-IV Axis II	IQ	Age	Tanner Stage	Height [cm]	Weight [kg]	BMI	Pre-dose	4 - 7	8 - 12	16 - 24	28 - 36	40 - 48	52 - 55
9	A03423	PA	Male	Moderate	47	13	2	145.0	34.6	16.5	2.9	29.4	29.0	13.8	22.3	23.0	
	A03424	PA	Male	Mild	65	13	2	155.0	41.4	17.2	2.5	22.6	10.7				
	A03425	PA	Male	Borderline	77	8	1	118.0	21.7	15.6	20.2	13.7		20.8	18.4	13.9	
	A03426	PA	Male	Mild	70	8	1	124.0	24.0	15.6	5.7	7.1	7.9				
	A03427	PA	Male	Mild	57	5	1	113.0	31.2	24.4	8.5	20.1	19.7		30.7	23.1	
	A03428	PA	Female	Borderline	79	9	1	122.0	23.2	15.6	4.4	19.5	20.0	13.6	19.0	17.6	
	A03430	PA	Male	Moderate	44	15	3	161.0	49.0	18.9	3.0	24.0	24.9	27.2	19.6	20.5	
	A03431	PA	Male	Borderline	82	8	1	122.0	24.5	16.5	2.4	9.6	4.3	10.9		12.4	
	A03432	PA	Female	Borderline	78	10	1	135.0	26.5	14.5	3.1	31.5	3.7	3.3	2.4	23.1	
	A03434	PA	Male	Mild	59	13	3	164.0	46.5	17.3	5.5		27.5	16.7	19.6	19.8	
	A03435	PA	Male	Borderline	80	10	1	130.0	25.0	14.8	7.2	24.4	26.3	16.9	29.8	9.8	
	A03436	PA	Male	Borderline	72	7	1	120.0	24.0	16.7	2.2	3.6	18.3	17.5	10.4	13.6	
	A03437	PA	Male	Mild	63	13	1	150.0	30.0	13.3	11.6	8.1	3.5	12.6	12.2	14.8	
	A03438	PA	Male	Borderline	83	8	1	125.0	25.0	16.0	4.3	25.5	23.8	15.1	15.3	30.6	
	A03439	PA	Male	Borderline	84	11	2	139.0	27.5	14.2	2.7	36.4	3.6	2.0	2.8	3.1	
	A03440	PA	Male	Mild	66	9	1	136.0	28.0	15.1	3.0	21.2	7.8	7.6	7.8	11.4	
	A03441	PA	Male	Borderline	77	7	1	121.0	23.0	15.7	3.4	32.7	19.7	6.1	18.5	18.4	
	A03442	PA	Female	Borderline	78	7	1	122.0	20.0	13.4	9.4	14.8	25.0	29.1	4.8	4.0	
	A03443	PA	Male	Borderline	73	7	1	119.0	19.0	13.4	3.0	8.9	11.6	4.7	6.2	11.0	
	A03445	PA	Male	Mild	68	11	1	145.0	32.0	15.2	3.1	57.9		21.8	5.4	3.8	
	A03446	PA	Male	Borderline	82	12	1	146.0	38.0	17.8	5.1	34.6	15.7	11.1			
	A03449	PA	Male	Borderline	73	9	1	131.0	26.0	15.2	3.3	29.2		6.9			
	A03451	PA	Female	Mild	62	6	1	112.0	16.0	12.8	9.8	21.0	12.5	13.3	6.6	3.3	
	A03452	PA	Male	Borderline	79	5	1	112.0	21.0	16.7	7.2	29.3	3.9	2.9	3.5		
	A03454	PA	Male	Borderline	77	8	1	118.0	22.0	15.8	25.4	18.4		3.3	3.5	2.5	
	A03455	PA	Male	Borderline	72	11	2	153.0	31.0	13.2	10.0	29.9	18.2	11.8	20.5		
	A03456	PA	Male	Mild	58	13	2	148.0	33.0	15.1	6.6	17.5	6.6	4.1	9.9		
	A03457	PA	Male	Borderline	71	12	2	157.0	52.0	21.1	20.1	26.6	31.4	22.5	19.8	26.6	
	A03458	PA	Male	Mild	55	13	5	164.0	55.0	20.4	4.8	30.7	38.3	33.0	27.7	28.3	
	A03459	PA	Male	Mild	69	9	2	132.0	22.0	12.6	6.7	13.2	20.8	11.6	14.6	8.7	
	A03460	PA	Male	Borderline	84	11	1	145.0	33.0	15.7	4.5	25.3	15.9	5.8	19.7		
	A03461	PA	Male	Moderate	40	12	2	161.0	42.5	16.4	3.2	27.6	26.2	26.0		18.8	
	A03462	PA	Male	Moderate	36	10	1	142.0	24.0	11.9	13.8	37.4	31.5	31.1		26.8	
	A03463	PA	Female	Mild	55	9	1	115.0	23.0	17.4	18.0	30.5	30.9	21.0	29.5	23.5	
	A03464	PA	Female	Mild	52	11	3	145.0	35.0	16.6	5.0	33.6	31.5	18.5	31.9	20.2	
	A03465	PA	Male	Mild	67	15	4	174.0	71.0	23.5	5.5	20.2	27.6	5.4			
	A03466	PA	Male	Mild	82	15	4	165.0	61.0	22.4	11.3	25.0	16.9	7.0	6.3	10.2	
	A03468	PA	Male	Mild	38	11	1	142.0	38.0	18.8	8.4	22.9	38.5	25.0	41.3	7.0	
	A03474	PA	Male	Borderline	82	12	2	169.0	50.0	17.5	5.1	30.0	5.9	4.1	7.4	8.8	
	A03475	PA	Male	Mild	63	14	4	168.0	52.0	18.4	4.3	15.3	3.6	2.7	10.8	11.1	

Note. Primary Analysis Population (PA): Patients with pre-dose and at least one post-dose prolactin observation at or after week 4

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Table 3. Demographic Variables and Prolactin Levels: Patient Data Listing (ITT Population) -(continued)

Set	Patient ID	Flag	Gender	Retardation DSM-IV Axis II	IQ	Pre-dose Age	Tanner Stage	Height [cm]	Weight [kg]	BMI	Prolactin [ng/mL] Pre-dose	Weeks Post Risperidone Dose 4 - 7	8 - 12	16 - 24	28 - 36	40 - 48	52 - 55
9	A03476	PA	Male	Mild	63	11	1	138.0	35.0	18.4	4.3	50.0	56.3	44.5	12.6	11.0	
	A03477	PA	Male	Mild	68	10	1	134.0	25.0	13.9	6.0	67.1	66.9	65.7	8.3	6.8	
	A03479	PA	Male	Moderate	45	9	1	136.0	26.0	14.1	3.5	33.3	20.5	16.5	15.2	8.4	
	A03480	PA	Male	Borderline	78	11	1	148.0	55.0	25.1	5.1	15.3	13.7	12.7	10.7	13.7	
	A03481	PA	Male	Moderate	42	7	1	131.0	27.5	16.0	4.5	13.3	7.8	13.7	16.6	6.4	
	A03482	PA	Female	Mild	73	10	2	145.0	38.0	18.1	5.7	20.1	21.9	9.0	42.7	43.5	
	A03483	PA	Male	Mild	58	13	2	168.0	53.5	19.0	2.8	17.9	22.8	18.6	23.0	18.1	
	A03484	PA	Male	Borderline	83	13	4	176.0	57.9	18.7	5.0	35.5	22.3	37.3	28.5	15.4	
	A03485	PA	Male	Borderline	84	9	1	137.0	42.7	22.8	4.0	25.8	13.9	22.9	16.6	4.3	
	A03486	PA	Male	Borderline	76	11	1	151.0	66.6	29.2	5.1	24.0	9.4	19.3	20.7	2.8	
	A03487	PA	Male	Moderate	40	11	2	152.0	33.0	14.3	8.7	8.8	10.1	8.8	6.6	11.8	
	A03489	PA	Male	Moderate	42	12	2	147.0	35.0	16.2	3.5	39.0	42.0	5.5	23.7	11.7	
	A03490	PA	Male	Mild	41	7	1	117.0	31.2	22.8	11.4	19.8	22.8	25.1	18.3	19.2	
	A03491	PA	Male	Mild	64	7	1	122.0	24.8	16.7	6.7	35.0	24.5		10.0	26.9	
	A03492	PA	Female	Borderline	81	8	1	138.0	30.8	16.2	4.2	21.2	45.5	19.4	11.0	13.7	
	A03493	PA	Male	Mild	54	13	1	144.0	36.6	17.7	7.3	35.8	18.8	29.3	24.7	23.4	
	A03494	PA	Male	Mild	65	12	2	160.0	47.0	18.4	12.3	32.8	31.3	14.7	30.7	12.1	
	A03496	PA	Male	Mild	55	12	1	164.0	80.5	29.9	6.3	19.4	16.5	21.2	17.2	10.6	
	A03497	PA	Male	Mild	64	11	1	142.0	30.8	15.3	11.4	46.1	40.0	33.4	36.9	16.6	
	A03498	PA	Male	Mild	59	7	1	115.0	19.6	14.8	5.1	14.6					
	A03499	PA	Male	Moderate	47	11	1	145.0	34.5	16.4	3.9	20.4	5.5	17.5	12.7	7.8	
	A03500	PA	Male	Borderline	84	12	2	150.0	40.0	17.8	3.6	14.9	36.6		12.7	20.8	
	A03501	PA	Male	Borderline	84	14	2	168.0	58.0	20.5	9.1	30.9	32.2	9.6			
	A03502	PA	Female	Mild	57	7	1	118.0	20.0	14.4	4.6	47.6	41.1	22.0	20.3	13.6	
	A03503	PA	Male	Mild	60	11	1	150.0	33.6	14.9	3.2	18.6	5.5	8.0	15.9	9.8	
	A03504	PA	Male	Borderline	77	12	2	156.0	44.4	18.2	4.2	10.0	15.6	18.9	8.6	18.2	
	A03505	PA	Male	Mild	68	14	2	160.0	48.6	19.0	17.8	7.1	19.3	27.0	12.3	6.5	
	A03506	PA	Male	Mild	66	12	1	147.0	35.0	16.2	5.4	46.2	47.9	39.0	22.4	34.2	
	A03507	PA	Male	Borderline	79	13	1	148.0	40.2	18.4	2.7	14.6	14.5	16.1	4.5	12.3	
	A03508	PA	Female	Moderate	40	12	2	142.0	40.6	20.1	5.2	29.7	23.2	17.0	16.9	25.8	
	A03509	PA	Female	Mild	58	13	3	150.0	54.4	24.2	3.3	25.1	28.0	20.5	14.9	19.4	
	A03510	PA	Male	Borderline	79	13	4	167.0	55.7	20.0	6.9	27.9	27.8	25.7	17.9	22.7	
	A03511	PA	Male	Mild	70	8	1	132.0	27.8	16.0	2.7	16.0	11.5	17.6	8.1	3.7	
	A03512	PA	Male	Mild	62	6	1	105.0	14.0	12.7	10.4	31.6	6.0	52.1	27.8	22.0	
	A03513	PA	Male	Moderate	45	11	1	124.0	24.0	15.6	5.9	33.0	5.8	30.0	3.6	25.6	
	A03514	PA	Male	Borderline	84	14	4	167.0	69.2	24.8	5.1	24.7	31.4	5.6	19.6	14.9	
	A03515	PA	Female	Borderline	83	11	1	135.0	36.2	19.9	6.5	24.8	23.4				
	A03516	PA	Male	Borderline	81	12	1	152.0	55.8	24.2	7.5	37.2	26.6	14.6	20.9	2.7	
	A03517	PA	Female	Mild	61	13	2	155.0	49.5	20.6	24.4	65.3	55.4	39.1	44.1	21.0	
	A03518	PA	Male	Mild	64	13	1	159.0	60.5	23.9	5.9	8.5	16.5	3.8	13.9	3.1	

Note. Primary Analysis Population (PA): Patients with pre-dose and at least one post-dose prolactin observation at or after week 4

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Table 3. Demographic Variables and Prolactin Levels: Patient Data Listing (ITT Population) -(continued)

						Pre-dose					Prolactin [ng/mL]						
												Weeks Post Risperidone Dose					
Set	Patient ID	Flag	Gender	Retardation DSM-IV Axis II	IQ	Age	Tanner Stage	Height [cm]	Weight [kg]	BMI	Pre-dose	4 - 7	8 - 12	16 - 24	28 - 36	40 - 48	52 - 55
9	A03519	PA	Male	Moderate	41	12	2	132.0	25.4	14.6	32.5	55.2	66.3	46.8	50.1	29.8	
	A03520	PA	Male	Moderate	39	6	1	119.0	21.0	14.8	2.4	51.2	14.6	16.9	9.8	2.8	
	A03521	PA	Male	Mild	70	8	1	133.0	27.5	15.5	6.1	20.5	12.5	30.6	8.8	27.9	
	A03522	PA	Male	Moderate	36	7	1	125.0	24.0	15.4	46.8	29.9	4.7	5.4	30.2	31.3	
	A03523	PA	Male	Moderate	47	13	1	144.0	33.2	16.0	4.3	23.2	16.9	16.8	3.2	6.5	
	A03524	PA	Male	Mild	60	8	1	132.0	25.0	14.3	7.1	26.4	30.3	23.3	14.8	15.0	
	A03525	PA	Male	Borderline	80	8	1	140.0	45.3	22.2	3.9	22.1	8.1	19.6	14.4	4.0	
	A03526	PA	Male	Borderline	72	8	1	127.0	24.9	15.4	3.7	25.1	12.1	5.5	19.5	11.0	
	A03527	PA	Male	Borderline	84	9	1	126.0	23.0	14.5	4.8	28.0	33.6	30.2	29.6	4.0	
	A03528	PA	Male	Mild	65	7	1	112.0	18.2	14.5	15.7	53.8	43.2	32.5	27.5	21.7	
	A03533	PA	Male	Moderate	40	8	1	115.0	27.0	20.4	2.9	32.6	42.6	3.7	15.7	4.4	
	A03537	PA	Male	Mild	70	6	1		29.5		3.7	40.1	39.5	28.1	30.4	28.7	
	A03539	PA	Male	Moderate	40	12	2	148.0	39.5	18.0	5.2	15.0	5.7	8.8	30.2	4.0	
	A03541	PA	Male	Moderate	40	15	3	160.0	52.0	20.3	18.4	20.3		16.1	16.6	19.0	
	A03543	PA	Male	Moderate	40	11	1	126.0	24.5	15.4	5.8		17.4	12.8	35.5	9.2	
	A03548	PA	Female	Moderate	37	8	1	112.0	26.4	21.0	24.4	36.8	43.7	9.4			
	A03559	PA	Male	Mild	54	10	1	126.0	29.0	18.3	17.8	20.6					
	A03561	PA	Male	Moderate	47	13	3	150.0	40.0	17.8	12.9	63.8	24.0		6.8	10.0	
	A03562	PA	Male	Borderline	75	7	1	119.0	18.5	13.1	19.3	17.7	17.9	10.9	22.0	21.0	
	A03563	PA	Female	Borderline	76	14	5	164.0	73.6	27.4	3.4	14.6					
	A03565	PA	Male	Mild	64	14	4	192.0	82.2	22.3	5.3	13.8	7.2	5.1	5.2	18.6	
	A03570	PA	Male	Moderate	42	10	1	137.0	28.0	14.9	2.7	18.9	37.5	11.0	4.9	5.1	
	A03572	PA	Male	Moderate	46	11	2	153.0	49.2	21.0	6.0	9.5	3.5	3.5	4.4	5.8	
	A03574	PA	Male	Mild	56	11	1	151.0	40.3	17.7	3.7	31.1	4.8		7.7		
	A03576	PA	Male	Borderline	71	15	3	165.0	66.0	24.2	5.2	11.7	3.1	5.9			
	A03581	PA	Male	Mild	68	9	1	130.0	26.0	15.4	4.6	4.9	6.7	6.3	4.4	6.2	
	A03594	PA	Male	Borderline	82	10	3	158.0	54.0	21.6	11.3	23.0	22.0	6.7	5.2	11.0	
	A03597	PA	Male	Mild	51	14	3	162.0	48.3	18.4	3.5	35.6		10.8			
	A03611	PA	Male	Mild	56	12	1	148.0	32.0	14.6	3.9	20.1	3.0	10.6		2.4	
	A03612	PA	Male	Moderate	50	10	1	135.0	27.5	15.1	7.9	32.2	8.9				
	A03616	PA	Male	Mild	51	13	1	167.0	75.5	27.1	4.9	32.4	18.2				
	A03617	PA	Male	Borderline	71	13	1	141.0	31.0	15.6	5.1	29.5	17.1	20.9	3.1	2.1	
	A03619	PA	Male	Borderline	81	11	1	141.0	34.5	17.4	3.6	23.9	16.1	10.9			
	A03622	PA	Male	Borderline	73	8	1	125.0	23.5	15.0	5.5	13.1					
	A03624	PA	Male	Moderate	40	9	2	130.0	26.0	15.4	2.8	11.7	8.3	7.0	9.4	11.0	
	A03634	PA	Male	Mild	54	11	1	139.0	30.0	15.5	18.8	21.9					
	A03636	PA	Male	Mild	59	10	1	143.0	47.0	23.0	2.8	16.0	14.9	13.0			
	A03637	PA	Male	Moderate	46	15	4	158.0	46.0	18.4	5.1	15.2	9.8				
	A03639	PA	Female	Mild	79	8	1	129.0	29.0	17.4	4.0	3.2		19.0			
	A03640	PA	Male	Mild	57	10	1	142.0	48.0	23.8	7.1	10.3	11.0	14.0			

Note. Primary Analysis Population (PA): Patients with pre-dose and at least one post-dose prolactin observation at or after week 4

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Table 3. Demographic Variables and Prolactin Levels: Patient Data Listing (ITT Population) -(continued)

						Pre-dose					Prolactin [ng/mL]						
												Weeks Post Risperidone Dose					
Set	Patient ID	Flag	Gender	Retardation DSM-IV Axis II	IQ	Age	Tanner Stage	Height [cm]	Weight [kg]	BMI	Pre-dose	4 - 7	8 - 12	16 - 24	28 - 36	40 - 48	52 - 55
9	A03641	PA	Female	Moderate	40	13	2	152.0	40.0	17.3	18.9	26.7	17.4		3.8		
	A03642	PA	Male	Borderline	76	14	4	164.0	55.5	20.6	8.2	47.3	17.1	3.3		21.0	
	A03644	PA	Female	Moderate	36	12	3	152.0	48.5	21.0	8.2	46.1	31.0		24.0		
	A03646	PA	Male	Mild	70	11	2	151.0	44.0	19.3	3.0	47.2	36.6	24.4		29.0	
	A03648	PA	Male	Mild	65	15	3	173.0	59.5	19.9	3.5	3.0	14.7	7.3	13.0	11.0	
	A03649	PA	Male	Borderline	82	9	1	136.0	36.0	19.5	9.9	32.2	4.7	4.7	5.0		
	A03650	PA	Female	Mild	64	14	4	160.0	70.0	27.3	8.5	40.6	32.0	37.0	5.0		
	A03662	PA	Male	Moderate	44	12	3	142.0	33.0	16.4	3.1	24.6		12.0		13.0	
	A03664	PA	Male	Moderate	41	12	1	124.0	24.0	15.6	3.7	48.9	15.0	44.0	39.0	43.0	
	A03665	PA	Male	Mild	55	8	2	128.0	25.0	15.3	6.4	31.2	45.0	17.0			
	A03671	PA	Male	Mild	64	9	1	116.0	18.9	14.0	9.6	33.7					
	A03672	PA	Female	Moderate	46	13	1	146.0	56.0	26.3	6.3	19.3	18.3		11.0	14.0	
	A03673	PA	Male	Mild	42	13	1	151.0	52.2	22.9	3.9	16.8	11.3				
	A03674	PA	Male	Mild	55	8	1	122.0	26.0	17.5	3.8	42.1				16.0	
	A03676	PA	Male	Borderline	72	7	1	126.0	30.0	18.9	5.6	35.5	24.9		12.0	16.0	
	A03677	PA	Male	Borderline	82	9	1	129.0	26.0	15.6	2.6	23.9				16.0	
	A03681	PA	Female	Moderate	41	13	3	138.0	42.0	22.1	6.6	43.6		14.9	15.0	17.0	
	A03706	PA	Male	Borderline	82	6	1	113.0	21.5	16.8	16.0	37.0	8.0	21.0	26.7	4.7	
	A03710	PA	Male	Mild	68	11	1	149.0	39.0	17.6	4.0		35.5	20.7		2.6	
	A03712	PA	Female	Mild	66	8	1	135.0	30.0	16.5	6.0	63.0	53.0	40.0	26.8	12.5	
	A03733	PA	Male	Borderline	83	11	1	147.0	49.3	22.8	4.0	37.5	22.6	11.8	12.8	11.5	
	A03734	PA	Male	Mild	59	11	1	142.0	36.9	18.3	4.8	35.4	28.5				
	A03735	PA	Male	Borderline	84	13	2	156.0	42.8	17.6	3.7	23.4	17.3	14.8	15.5	16.0	
	A03736	PA	Male	Borderline	81	10	1	146.0	36.8	17.3	3.3	33.2	26.7				
	A03738	PA	Female	Borderline	82	14	3	164.0	66.0	24.5	22.7	51.6	20.8	37.0	36.0		
	A03739	PA	Male	Borderline	84	12	1	147.0	36.4	16.8	4.0	19.8	15.1	9.5	6.7	8.1	
	A03740	PA	Male	Mild	68	10	1	140.0	34.8	17.8	2.6	26.4	15.6	12.2			
	A03741	PA	Male	Mild	70	13					3.3		17.5	6.2	3.2	21.5	
	A03742	PA	Male	Mild	68	10	2	155.0	63.7	26.5	3.7	52.3	28.5	33.5	41.2		
	A03743	PA	Male	Borderline	80	12	1	152.0	47.9	20.7	4.7	27.6	14.0	11.9	21.8	12.0	
	A03744	PA	Male	Mild	68	8	1	135.0	29.3	16.1	7.4	15.3	16.1	13.5	8.6	13.0	
	A03745	PA	Male	Mild	64	12	1	155.0	62.1	25.8	3.8	43.5					
	A03746	PA	Male	Borderline	71	12	1	147.0	45.6	21.1	12.3	27.7	26.6				
	A03747	PA	Male	Mild	68	15	1	162.0	68.0	25.9	3.8	21.5	22.5	17.1	9.7		
	A03748	PA	Male	Borderline	83	10	1	150.0	49.5	22.0	3.3	21.9	16.7				
	A03749	PA	Male	Borderline	78	12	1	146.0	49.2	23.1	3.8	15.1	14.6	10.4			
	A03750	PA	Male	Borderline	84	9	1	137.0	34.9	18.6	3.1	24.7	13.6				
	A03820	PA	Male	Mild	56	9	1	133.0	26.0	14.7	3.1	17.7	6.4	14.4	12.7	2.7	
	A03821	PA	Male	Mild	57	9	1	124.0	26.5	17.2	6.2	33.4	38.2	33.3	27.9	15.8	
	A03901	PA	Male	Borderline	77	13	2	154.9	48.8	20.3	3.7	20.1	21.3	8.1			

Note. Primary Analysis Population (PA): Patients with pre-dose and at least one post-dose prolactin observation at or after week 4

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Table 3. Demographic Variables and Prolactin Levels: Patient Data Listing (ITT Population) -(continued)

						Pre-dose					Prolactin [ng/mL]						
												Weeks Post Risperidone Dose					
Set	Patient ID	Flag	Gender	Retardation DSM-IV Axis II	IQ	Age	Tanner Stage	Height [cm]	Weight [kg]	BMI	Pre-dose	4 - 7	8 - 12	16 - 24	28 - 36	40 - 48	52 - 55
9	A03905	PA	Female	Mild	68	9	2	129.5	27.2	16.2	5.5	46.3			18.9		
	A03912	PA	Male	Borderline	75	7	1	129.5	28.6	17.1	6.3	20.7	3.5				
	A03913	PA	Female	Borderline	74	6	1	114.3	22.5	17.2	7.4	5.6					
	A03914	PA	Male	Borderline	81	8	1	116.8	20.0	14.7	3.9	18.9	29.1		26.2	7.5	
	A03915	PA	Male	Borderline	77	10	1	129.5	27.2	16.2	3.1	2.9	3.1				
	A03922	PA	Male	Borderline	84	13	4	170.2	55.8	19.3	6.2	17.1	4.8	10.9	5.0	2.7	
	A03923	PA	Male	Borderline	78	9	1	129.5	28.8	17.2	2.6	22.1	19.7	11.4	5.2	7.4	
	A03924	PA	Female	Borderline	83	6	1	113.0	20.4	16.0	5.2	8.4	3.2				
	A03926	PA	Female	Moderate	46	10		142.2	33.3	16.5	14.2	29.3					
	A03929	PA	Male	Mild	52	10		129.5	25.6	15.3	13.5	33.8					
	A03931	PA	Male	Borderline	83	6	1	106.7	17.5	15.4	5.7	46.6					
	A03933	PA	Female	Borderline	59	14	3	162.6	49.9	18.9	10.8	39.3	33.5	32.0	26.9		
	A03934	PA	Male	Mild	64	7	1	121.9	26.3	17.7	7.1	19.7	21.8	9.7	25.8		
	A03935	PA	Male	Borderline	84	13	3	154.9	42.6	17.8	4.4	25.7		15.2			
	A03936	PA	Male	Borderline	73	8	1	132.1	29.4	16.8	4.2	59.5	82.4	17.6	12.3	10.1	
	A03938	PA	Male	Mild	52	8	1	121.9	25.4	17.1	7.0	24.0	19.3	4.6	7.5	13.1	
	A03939	PA	Male	Mild	68	11	1	127.0	21.5	13.3	6.0	48.2	7.9		21.5	13.2	
	A03940	PA	Male	Moderate	39	11	1	129.5	24.4	14.5	14.6		23.0	4.9	4.0	10.0	
	A03941	PA	Female	Moderate	47	15	3	157.5	42.0	16.9	7.4	37.3	25.1	28.7	18.6		
	A03944	PA	Male	Borderline	84	8	1		34.3		5.1	17.3	15.6	4.8	4.0		
	A03945	PA	Male	Mild	70	10	1	127.0	23.6	14.6	9.2	30.5	17.5	8.0			
	A03966	PA	Male	Borderline	83	12	3	149.9	42.6	19.0	7.1	27.6					
	A03971	PA	Female	Borderline	69	8	1	124.5	24.9	16.1	4.1	45.1					
	A03974	PA	Male	Borderline	76	7	1	116.8	23.9	17.5	8.0	101.8		21.1	20.6		
	A03977	PA	Male	Mild	57	10	1	144.8	36.7	17.5	3.9	39.8	5.5	4.4			
	A03978	PA	Male	Mild	52	8	1	134.6	34.5	19.0	4.6	22.8					
	A03980	PA	Male	Borderline	71	10	1	137.2	25.2	13.4	5.1	30.2					
	A03981	PA	Male	Borderline	81	9	1	134.6	32.7	18.0	6.7	12.4	9.9	5.2	2.6	4.9	
	A03982	PA	Male	Mild	67	6	1	116.8	18.4	13.5	18.1	23.4					
	A03984	PA	Female	Mild	67	14	5	162.6	87.8	33.2	24.3	49.0	41.6	38.3	63.8	21.0	
	A03989	PA	Male	Mild	69	7		121.9	25.9	17.4	3.7	9.4	25.5	5.1	11.9		
	A03991	PA	Male	Borderline	78	7	1	129.5	29.7	17.7	6.2	23.6					
	A03992	PA	Male	Moderate	44	15	3	172.7	67.6	22.7	8.2		29.4	24.6	28.7	16.9	
	A03994	PA	Male	Moderate	50	6	1	109.2	22.0	18.4	3.7		19.7	6.7	5.6	13.6	
	A03995	PA	Male	Borderline	80	6	1	114.3	28.1	21.5	3.0	22.3					
	A04001	PA	Male	Borderline	84	14	4	160.0	64.0	25.0	13.9	21.0	21.2	25.9	27.2	22.7	
	A04004	PA	Male	Borderline	84	13	1	154.9	42.7	17.8	9.4	14.3	10.9	18.4	13.4		
	A04005	PA	Male	Mild	68	6	1	116.8	21.5	15.8	19.5	38.0	57.5	41.8	35.9	23.4	
	A04006	PA	Male	Mild	68	10	1	134.6	26.9	14.8	2.3	24.3	5.6	2.6	3.8	1.9	
	A04017	PA	Male	Borderline	78	11	2	137.2	34.9	18.5	2.6	22.6	8.8	17.9	13.1	2.7	

Note. Primary Analysis Population (PA): Patients with pre-dose and at least one post-dose prolactin observation at or after week 4

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Table 3. Demographic Variables and Prolactin Levels: Patient Data Listing (ITT Population) -(continued)

						Pre-dose					Prolactin [ng/mL]						
												Weeks Post Risperidone Dose					
Set	Patient ID	Flag	Gender	Retardation DSM-IV Axis II	IQ	Age	Tanner Stage	Height [cm]	Weight [kg]	BMI	Pre-dose	4 - 7	8 - 12	16 - 24	28 - 36	40 - 48	52 - 55
9	A04018	PA	Male	Borderline	76	12	1	152.4	38.7	16.7	4.5	35.5					
	A04021	PA	Male	Borderline	76	6	1	111.8	20.0	16.0	8.8	23.4					
	A04039	PA	Male	Borderline	84	7	1	111.8	21.1	16.9	4.1	5.8	28.6				
	A04041	PA	Male	Borderline	80	11	1	127.0	25.4	15.7	6.8	66.8	23.4				
	A03011	ITT	Female	Borderline	75	10	1	131.0	23.9	13.9		28.0	26.6	27.5		19.9	
	A03013	ITT	Male	Mild	55	6	1	117.0	21.0	15.3	24.4						
	A03107	ITT	Male	Borderline	77	11	1	134.0	26.0	14.5							
	A03206	ITT	Male	Mild	69	13	2	154.0	41.5	17.5		61.0	48.0	61.0	58.0	45.0	
	A03214	ITT	Male	Moderate	55	8	1	122.0	23.5	15.8		23.0	25.0	21.0	14.0	3.0	
	A03215	ITT	Female	Moderate	40	14	4	152.0	54.0	23.4		70.0	29.0				
	A03216	ITT	Female	Moderate	40	11	3	142.0	38.4	19.0		41.0	22.0	25.0	19.0	31.0	
	A03217	ITT	Female	Moderate	44	11	1	129.0	28.0	16.8		28.0	20.0	17.0	19.0	28.0	
	A03218	ITT	Male	Mild	60	12	1	156.0	41.0	16.8		45.0	31.0	16.0	22.0	23.0	
	A03219	ITT	Female	Moderate	47	13	1	136.0	26.0	14.1		4.0	3.0	4.0	3.0	3.0	
	A03220	ITT	Male	Mild	58	6	1	117.0	22.0	16.1		41.0	24.0	38.0	19.0	19.0	
	A03221	ITT	Female	Moderate	40	15	4	155.0	46.2	19.2		34.0	29.0		21.0	20.0	
	A03222	ITT	Male	Mild	56	14	3	161.0	55.0	21.2		22.0	24.0	3.0			
	A03265	ITT	Male	Mild	56	7	1	128.0	28.0	17.1		26.0	11.0	13.0	19.0	13.0	
	A03270	ITT	Male	Moderate	47	10	1	143.0	34.4	16.8		5.0	22.0	10.0	9.0	10.0	
	A03271	ITT	Male	Moderate	49	7	1	121.0	37.0	25.3		29.0	19.0	15.0	24.0	11.0	
	A03287	ITT	Female	Moderate	42	12	2	132.0	30.5	17.5	9.0						
	A03297	ITT	Male	Mild	59	11	1	143.0	31.3	15.3		34.9	16.7	15.2	15.3	9.8	
	A03310	ITT	Male	Moderate	44	10	1	147.0	71.7	33.2		19.2	21.9	17.2	15.9	18.1	
	A03361	ITT	Male	Borderline	74	9	1	128.0	26.0	15.9				12.8	30.6		
	A03362	ITT	Female	Mild	42	5	1	120.0	20.0	13.9					11.7	13.9	
	A03371	ITT	Male	Borderline	74	9	1	126.0	27.0	17.0		11.3		2.5	20.9		
	A03373	ITT	Male	Borderline	75	8	1	131.0	32.0	18.6	6.1						
	A03374	ITT	Female	Mild	67	9	1	131.0	24.5	14.3	2.2						
	A03429	ITT	Male	Borderline	79	13	3	160.0	46.2	18.0	6.0						
	A03447	ITT	Male	Moderate	35	15	4	163.0	41.0	15.4		23.4	36.2	20.5	18.8	7.0	
	A03450	ITT	Male	Mild	56	12	2	155.0	36.0	15.0	7.3						
	A03453	ITT	Male	Borderline	83	8	1	138.0	55.0	28.9	5.2						
	A03530	ITT	Male	Moderate	40	11	1	137.0	32.0	17.0		84.3	55.6	62.7	46.8	31.0	
	A03560	ITT	Male	Mild	52	6	1	125.0	30.0	19.2		19.7	4.1	5.4	3.7	4.0	
	A03569	ITT	Male	Mild	50	14	3	154.0	37.3	15.7		20.3	31.6	31.6	23.7	28.0	
	A03631	ITT	Female	Moderate	45	6	1	121.0	23.0	15.7	46.8						
	A03633	ITT	Female	Moderate	45	11	3	145.0	35.0	16.6	10.0						
	A03638	ITT	Male	Mild	59	9	1	120.0	25.0	17.4		18.2	16.9	17.0			
	A03645	ITT	Male	Borderline	81	12	2	153.0	41.0	17.5	3.2						
	A03661	ITT	Male	Borderline	76	8	2	133.0	32.0	18.1	3.0						

Note. Primary Analysis Population (PA): Patients with pre-dose and at least one post-dose prolactin observation at or after week 4

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Table 3. Demographic Variables and Prolactin Levels: Patient Data Listing (ITT Population) -(continued)

						Pre-dose					Prolactin [ng/mL]						
												Weeks Post Risperidone Dose					
Set	Patient ID	Flag	Gender	Retardation DSM-IV Axis II	IQ	Age	Tanner Stage	Height [cm]	Weight [kg]	BMI	Pre-dose	4 - 7	8 - 12	16 - 24	28 - 36	40 - 48	52 - 55
9	A03663	ITT	Female	Mild	70	9	3	138.0	39.0	20.5	4.4						
	A03719	ITT	Male	Borderline	81	8	1	119.0	20.5	14.5		3.0	17.0	2.0			
	A03737	ITT	Male	Borderline	74	13	1	149.0	40.0	18.0		47.0	35.8	30.5	26.0		
	A03780	ITT	Male	Borderline	84	12	1	147.0	35.5	16.4						17.7	
	A03782	ITT	Male	Mild	58	10	1	127.0	26.0	16.1		10.8		11.4			
	A03783	ITT	Male	Mild	61	8	1	116.0	20.5	15.2		5.2		3.0			
	A03788	ITT	Male	Mild	63	12	1	142.0	34.5	17.1		9.6					
	A03903	ITT	Male	Mild	65	12	2	147.3	45.8	21.1	6.9						
	A03916	ITT	Male	Borderline	81	14	4	172.7	61.5	20.6							
	A03917	ITT	Male	Borderline	79	14	1	149.9	39.5	17.6							
	A03918	ITT	Male	Borderline	81	11	1	152.4	82.1	35.3							
	A03919	ITT	Male	Borderline	74	7	1	119.4	23.6	16.6							
	A03920	ITT	Female	Borderline	75	10	2	139.7	38.6	19.8							
	A03948	ITT	Male	Mild	56	12	1	149.9	39.0	17.4							
	A03954	ITT	Male	Mild	67	9	1	144.8	46.7	22.3		30.5	22.4	20.2	13.7	22.5	
	A03970	ITT	Female	Mild	65	6	1	101.6	13.6	13.2	11.3						
	A03972	ITT	Male	Mild	68	5	1	121.9	44.0	29.6	12.9						
	A03975	ITT	Male	Borderline	80	6	1	106.7	17.7	15.5		38.7		23.1	5.7	2.9	
	A03976	ITT	Male	Moderate	46	8		132.1	48.1	27.6		17.4		4.7			
	A03979	ITT	Male	Borderline	73	7	1	114.3	16.6	12.7	3.1						
	A03996	ITT	Female	Borderline	84	8	1	132.1	27.7	15.9							
	A03997	ITT	Female	Borderline	75	10	1	149.9	38.6	17.2							
	A03998	ITT	Male	Mild	63	10	1	144.8	36.3	17.3							
	A03999	ITT	Male	Borderline	75	10	1	139.7	39.5	20.2							
	A04002	ITT	Male	Borderline	74	13	3	167.6	48.8	17.4	6.3						
	A04003	ITT	Male	Borderline	75	10	1	142.2	34.6	17.1	7.6						
	A04016	ITT	Male	Borderline	84	11	4	165.1	50.6	18.6	7.3						
	A04019	ITT	Male	Borderline	81	8	1	134.6	32.0	17.7	2.8						

Note. Primary Analysis Population (PA): Patients with pre-dose and at least one post-dose prolactin observation at or after week 4

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Table 4. Patient Demographics and Pre-dose Characteristics: Comparability of PA vs Non-PA Populations

Variable	ITT N	ITT Stats	PA N	PA Stats	Non-PA N	Non-PA Stats	P-value[1]
Gender: N (%)	700		592		108		
Male		574 (82.0)		489 (82.6)		85 (78.7)	0.3323
Female		126 (18.0)		103 (17.4)		23 (21.3)	
Race: N (%)	700		592		108		
Caucasian		550 (78.7)		475 (80.2)		75 (70.1)	0.0318
Black		78 (11.2)		57 (9.6)		21 (19.6)	
Hispanic		12 (1.7)		11 (1.9)		1 (0.9)	
Oriental		3 (0.4)		3 (0.5)		0 (0.0)	
Other		56 (8.0)		46 (7.8)		10 (9.3)	
NA		1		0		1	
Tanner Stage: N (%)	700		592		108		
0		6 (0.9)		4 (0.7)		2 (2.1)	0.4230
1		487 (72.6)		420 (73.0)		67 (69.8)	
2		96 (14.3)		83 (14.4)		13 (13.5)	
3		44 (6.6)		36 (6.3)		8 (8.3)	
4		29 (4.3)		23 (4.0)		6 (6.3)	
5		9 (1.3)		9 (1.6)		0 (0.0)	
NA		29		17		12	
DSM-IV Axis II: N (%)	700		592		108		
Borderline Mental Retardation		288 (41.2)		236 (39.9)		52 (48.1)	0.1202
Mild Mental Retardation		282 (40.3)		248 (42.0)		34 (31.5)	
Moderate Mental Retardation		129 (18.5)		107 (18.1)		22 (20.4)	
NA		1		1		0	
Age [years]	700		592		108		
Mean		9.9		9.9		9.7	0.4147
SD		2.4		2.5		2.3	
Median		9.9		9.9		9.8	
Minimum		5.0		5.1		5.0	
Maximum		15.0		15.0		14.7	
IQ Rating	699		591		108		
Mean		65.1		65.1		65.4	0.8133
SD		13.4		13.3		14.0	
Median		68.0		68.0		69.0	
Minimum		35.0		36.0		35.0	
Maximum		84.0		84.0		84.0	

[1]To compare populations (PA vs Non-PA):
Chi-square test is used for the following categorical variables: gender, race, Tanner stage and DSM-IV Axis II
Student's t-test is used for the following continuous variables: age, IQ rating, height, weight and BMI

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Table 4. Patient Demographics and Pre-dose Characteristics: Comparability of PA vs Non-PA Populations -(continued)

Variable	ITT N	ITT Stats	PA N	PA Stats	Non-PA N	Non-PA Stats	P-value[1]
Height [cm]	679		573		106		
Mean		137.5		137.8		135.9	0.2492
SD		15.6		15.9		14.3	
Median		136.9		137.0		136.0	
Minimum		99.1		99.1		101.6	
Maximum		192.0		192.0		172.7	
Weight [kg]	698		591		107		
Mean		35.1		35.4		33.6	0.2040
SD		13.2		13.4		11.7	
Median		32.0		32.1		32.0	
Minimum		13.6		14.0		13.6	
Maximum		87.8		87.8		82.1	
BMI	678		573		105		
Mean		18.0		18.0		17.9	0.7697
SD		3.7		3.7		3.9	
Median		17.1		17.1		17.1	
Minimum		8.8		8.8		12.7	
Maximum		35.3		33.4		35.3	

[1]To compare populations (PA vs Non-PA):
Chi-square test is used for the following categorical variables: gender, race, Tanner stage and DSM-IV Axis II
Student's t-test is used for the following continuous variables: age, IQ rating, height, weight and BMI

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Table 5. Study Drug Dosing Information: Comparability of PA vs Non-PA Populations

	ITT		PA		Non-PA		
Study Drug Dosing Variable	N	Stats	N	Stats	N	Stats	P-value*
Study Drug Exposure [mg][1]	700		592		108		
Mean		396.93		410.05		325.01	0.0081
SD		274.48		265.94		308.79	
Median		393.95		411.00		276.93	
Minimum		0.30		0.40		0.30	
Maximum		1305.80		1305.80		1274.80	
Study Drug Duration [days][2]	700		592		108		
Mean		307.87		319.40		244.66	<0.0001
SD		116.14		101.26		163.42	
Median		359.00		361.00		336.00	
Minimum		1.00		28.00		1.00	
Maximum		505.00		505.00		498.00	
Average Daily Dose [mg/day][3]	700		592		108		
Mean		1.23		1.26		1.05	0.0051
SD		0.72		0.70		0.77	
Median		1.20		1.22		0.96	
Minimum		0.00		0.00		0.02	
Maximum		4.17		4.17		3.48	

[1]Study drug exposure = Area under the Dose x Time curve
[2]Study drug duration = Date of last dose - Date of first dose + 1
[3]Average daily dose = Exposure / Study drug duration

Note. No dose was recorded for the following two patient (PA):
-patient A03306 from 28MAY1998 to 16JUN1998
-patient A03974 from 17JAN2000 to 20JAN2000
*Student's t-test is used to calculate the difference in exposure/duration/average daily dose between populations (PA vs Non-PA)

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Table 6. Prolactin Levels at Pre-dose by Gender and Tanner Stage: Descriptive Statistics (PA - As Observed)

Prolactin [ng/mL]

Variable	Gender/Stage Category	N	Mean	SD	Percentile					Minimum	Maximum	90% CI		95% CI	
					10th	25th	50th	75th	90th			Lower	Upper	Lower	Upper
Gender	Male	489	7.3	7.0	2.9	3.8	5.1	8.0	14.0	2.0	76.5	-4.3	18.9	-6.5	21.1
	Female	103	10.0	7.8	3.9	5.0	7.0	13.0	20.0	2.0	50.7	-2.9	22.9	-5.5	25.5
Tanner Stage	0	4	5.5	1.3	4.0	4.5	5.5	6.5	7.0	4.0	7.0	2.5	8.5	1.4	9.6
	1	420	7.5	6.7	2.9	3.9	5.7	8.0	14.8	2.0	47.7	-3.5	18.5	-5.7	20.7
	2	83	8.7	9.8	3.0	3.7	5.7	10.0	18.9	2.0	76.5	-7.5	25.0	-10.7	28.1
	3	36	9.2	9.0	3.0	4.2	6.4	11.1	18.4	2.0	50.7	-6.0	24.4	-9.1	27.5
	4	23	7.6	4.9	4.2	5.0	6.2	8.5	13.9	3.0	25.0	-0.7	16.0	-2.5	17.7
	5	9	8.9	7.1	2.8	3.5	7.0	10.6	24.3	2.8	24.3	-4.4	22.2	-7.6	25.4

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Table 7. Prolactin Levels in Each Period: Descriptive Statistics (PA - As Observed)

Study Period	N	Mean	SD	Median	Minimum	Maximum
Pre-dose	592	7.8	7.2	5.7	2.0	76.5
Weeks 4 to 7	550	29.4	16.5	26.9	2.0	150.0
Weeks 8 to 12	499	23.4	17.0	20.5	1.0	153.0
Weeks 16 to 24	441	19.6	14.5	16.7	2.0	90.9
Weeks 28 to 36	394	18.5	13.5	15.9	2.0	102.0
Weeks 40 to 48	358	16.1	13.2	13.7	1.9	160.9
Weeks 52 to 55	42	13.0	14.1	10.0	2.0	88.0

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Table 8. Incidence of Prolactin Levels at or above Upper Limit of Normal (ULN) in Each Period: Frequency Table (PA - As Observed)

Study Period	N	Incidence of Prolactin	
		Above ULN[1]	Normal
Pre-dose	592	29 (4.9)	563 (95.1)
Weeks 4 to 7	550	388 (70.5)	162 (29.5)
Weeks 8 to 12	499	257 (51.5)	242 (48.5)
Weeks 16 to 24	441	176 (39.9)	265 (60.1)
Weeks 28 to 36	394	148 (37.6)	246 (62.4)
Weeks 40 to 48	358	110 (30.7)	248 (69.3)
Weeks 52 to 55	42	7 (16.7)	35 (83.3)

[1]ULN: The upper limit of normal for prolactin levels is 18 [ng/mL] for males and 30 [ng/mL] for females

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Table 9. Prolactin Levels in Each Period: Descriptive Statistics (PA - Fixed N Subsets)

Fixed N Subset[1]	Study Period	N	Mean	SD	Median	Minimum	Maximum
Pre-dose and Weeks 4 to 7	Pre-dose	550	7.7	7.2	5.7	2.0	76.5
	Weeks 4 to 7	550	29.4	16.5	26.9	2.0	150.0
Pre-dose, Weeks 4 to 7 and 8 to 12	Pre-dose	466	7.7	7.5	5.7	2.0	76.5
	Weeks 4 to 7	466	29.5	16.3	27.0	2.0	150.0
	Weeks 8 to 12	466	23.5	17.0	20.8	1.0	153.0
Pre-dose, Weeks 4 to 7, 8 to 12 and 16 to 24	Pre-dose	385	7.6	7.0	5.5	2.0	50.7
	Weeks 4 to 7	385	30.1	16.5	27.6	2.9	150.0
	Weeks 8 to 12	385	24.5	17.8	21.3	1.0	153.0
	Weeks 16 to 24	385	19.8	14.9	16.7	2.0	90.9
Pre-dose, Weeks 4 to 7, 8 to 12, 16 to 24 and 28 to 36	Pre-dose	318	7.5	6.7	5.4	2.0	47.7
	Weeks 4 to 7	318	30.1	16.4	27.4	2.9	150.0
	Weeks 8 to 12	318	24.3	16.6	22.0	1.0	103.0
	Weeks 16 to 24	318	19.7	14.4	16.9	2.0	90.9
	Weeks 28 to 36	318	18.4	13.0	15.9	2.0	102.0
Pre-dose, Weeks 4 to 7, 8 to 12, 16 to 24, 28 to 36 and 40 to 48	Pre-dose	269	7.4	6.6	5.2	2.0	47.0
	Weeks 4 to 7	269	29.7	14.9	27.0	2.9	83.6
	Weeks 8 to 12	269	24.3	16.1	22.0	1.0	103.0
	Weeks 16 to 24	269	19.6	14.0	16.7	2.0	88.0
	Weeks 28 to 36	269	18.4	12.8	15.7	2.0	102.0
	Weeks 40 to 48	269	15.8	11.0	13.6	1.9	61.6

[1]To be included in a subset, observations had to exist at every study period in that subset

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Table 10. Incidence of Prolactin Levels at or above Upper Limit of Normal (ULN) in Each Period: Frequency Table (PA - Fixed N Subsets)

Fixed N Subset[1]	Study Period	N	Incidence of Prolactin: Above ULN[2]	Incidence of Prolactin: Normal
Pre-dose and Weeks 4 to 7	Pre-dose	550	27 (4.9)	523 (95.1)
	Weeks 4 to 7	550	388 (70.5)	162 (29.5)
Pre-dose, Weeks 4 to 7 and 8 to 12	Pre-dose	466	20 (4.3)	446 (95.7)
	Weeks 4 to 7	466	327 (70.2)	139 (29.8)
	Weeks 8 to 12	466	241 (51.7)	225 (48.3)
Pre-dose, Weeks 4 to 7, 8 to 12 and 16 to 24	Pre-dose	385	17 (4.4)	368 (95.6)
	Weeks 4 to 7	385	275 (71.4)	110 (28.6)
	Weeks 8 to 12	385	204 (53.0)	181 (47.0)
	Weeks 16 to 24	385	155 (40.3)	230 (59.7)
Pre-dose, Weeks 4 to 7, 8 to 12, 16 to 24 and 28 to 36	Pre-dose	318	11 (3.5)	307 (96.5)
	Weeks 4 to 7	318	227 (71.4)	91 (28.6)
	Weeks 8 to 12	318	170 (53.5)	148 (46.5)
	Weeks 16 to 24	318	127 (39.9)	191 (60.1)
	Weeks 28 to 36	318	121 (38.1)	197 (61.9)
Pre-dose, Weeks 4 to 7, 8 to 12, 16 to 24, 28 to 36 and 40 to 48	Pre-dose	269	10 (3.7)	259 (96.3)
	Weeks 4 to 7	269	193 (71.7)	76 (28.3)
	Weeks 8 to 12	269	146 (54.3)	123 (45.7)
	Weeks 16 to 24	269	106 (39.4)	163 (60.6)
	Weeks 28 to 36	269	104 (38.7)	165 (61.3)
	Weeks 40 to 48	269	80 (29.7)	189 (70.3)

[1]To be included in a subset, observations had to exist at every study period in that subset

[2]ULN: The upper limit of normal for prolactin levels is 18 [ng/mL] for males and 30 [ng/mL] for females

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Table 11. Comparability of Prolactin Levels in Patients Continuing vs Discontinuing in the Trial: Descriptive Statistics (PA - Fixed N Subsets)

Fixed N Subset	N	Mean	SD	Median	Minimum	Maximum
All Patients						
Pre-dose	550	7.7	7.2	5.7	2.0	76.5
Weeks 4 to 7	550	29.4	16.5	26.9	2.0	150.0
Weeks 8 to 12	466	23.5	17.0	20.8	1.0	153.0
Weeks 16 to 24	385	19.8	14.9	16.7	2.0	90.9
Weeks 28 to 36	318	18.4	13.0	15.9	2.0	102.0
Weeks 40 to 48	269	15.6	11.0	13.6	1.9	61.6
Patients Continuing						
Weeks 4 to 7	466	29.5	16.3	27.0	2.0	150.0
Weeks 8 to 12	385	24.5	17.8	21.3	1.0	153.0
Weeks 16 to 24	318	19.7	14.4	16.9	2.0	90.9
Weeks 28 to 36	269	18.4	12.8	15.7	2.0	102.0
Weeks 40 to 48	22	17.7	11.9	15.0	2.0	51.0
Patients Discontinuing						
Weeks 4 to 7	84	29.4	17.6	25.4	3.0	101.8
Weeks 8 to 12	81	18.6	11.7	18.3	2.0	66.0
Weeks 16 to 24	67	20.4	17.0	14.0	3.0	83.4
Weeks 28 to 36	49	18.3	14.4	17.0	3.0	87.7
Weeks 40 to 48	247	15.4	10.9	13.0	1.9	61.6

Note 1) Patients "continuing" refers to those who had a prolactin observation in the succeeding study period
2) Patients "discontinuing" refers to those who did not have a prolactin observation in the succeeding study period

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Table 12. Prolactin Levels [ng/mL] by Gender and Study Period: Descriptive Statistics (PA - As Observed)

	Prolactin											
	Males						Females					
Study Period	N	Mean	SD	Median	Minimum	Maximum	N	Mean	SD	Median	Minimum	Maximum
Pre-dose	489	7.3	7.0	5.1	2.0	76.5	103	10.0	7.8	7.0	2.0	50.7
Weeks 4 to 7	457	28.8	16.0	26.7	2.0	150.0	93	32.7	18.3	29.3	3.0	95.2
Weeks 8 to 12	417	22.8	17.0	19.3	1.0	153.0	82	26.6	16.5	25.0	2.0	78.0
Weeks 16 to 24	369	18.9	14.0	16.1	2.0	90.9	72	23.5	16.2	19.2	3.3	81.3
Weeks 28 to 36	323	17.6	12.3	15.1	2.0	102.0	71	22.5	17.4	19.0	2.0	79.8
Weeks 40 to 48	303	15.1	10.4	13.0	1.9	61.6	55	21.4	22.7	16.0	2.0	160.9
Weeks 52 to 55	34	13.0	15.1	9.0	2.0	88.0	8	12.9	8.9	10.5	5.0	33.0

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Table 13. Prolactin Levels [ng/mL] by Age Group [years] and Study Period: Descriptive Statistics (PA - As Observed)

		Prolactin					
Age Group	Study Period	N	Mean	SD	Median	Minimum	Maximum
5 to 7	Pre-dose	114	8.0	6.6	6.2	2.0	46.8
	Weeks 4 to 7	106	29.9	17.9	26.0	3.0	101.8
	Weeks 8 to 12	87	21.5	17.3	18.3	1.0	88.0
	Weeks 16 to 24	73	18.4	14.2	15.0	2.9	83.0
	Weeks 28 to 36	76	18.8	15.4	15.5	2.0	102.0
	Weeks 40 to 48	65	14.6	10.3	12.4	2.0	44.0
	Weeks 52 to 55	12	16.9	23.3	10.2	3.0	88.0
8 to 9	Pre-dose	146	7.6	6.3	5.5	2.0	40.2
	Weeks 4 to 7	133	28.5	15.9	27.0	2.9	99.0
	Weeks 8 to 12	122	23.5	14.7	21.1	3.0	82.4
	Weeks 16 to 24	108	18.1	11.5	16.1	2.0	55.0
	Weeks 28 to 36	97	15.5	10.0	13.4	2.0	47.0
	Weeks 40 to 48	95	14.4	10.3	12.0	2.0	44.0
	Weeks 52 to 55	11	9.2	9.0	6.0	2.0	33.0
10 to 11	Pre-dose	162	6.9	6.7	5.0	2.0	47.7
	Weeks 4 to 7	148	29.0	17.0	26.9	2.0	150.0
	Weeks 8 to 12	141	23.0	17.2	18.4	2.0	103.0
	Weeks 16 to 24	123	18.3	14.4	14.0	2.0	90.9
	Weeks 28 to 36	107	18.2	14.3	15.0	2.0	87.7
	Weeks 40 to 48	94	16.2	12.4	13.7	1.9	61.6
	Weeks 52 to 55	13	10.7	6.0	10.0	4.0	25.3
12 to 15	Pre-dose	170	8.6	8.7	6.0	2.0	76.5
	Weeks 4 to 7	163	30.3	15.7	27.6	3.0	95.2
	Weeks 8 to 12	149	24.9	18.2	23.0	2.0	153.0
	Weeks 16 to 24	137	22.7	16.3	19.0	2.5	88.0
	Weeks 28 to 36	114	20.9	13.7	19.3	3.1	79.8
	Weeks 40 to 48	104	18.4	17.2	16.0	2.0	160.9
	Weeks 52 to 55	6	16.9	9.4	13.0	6.0	29.0

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Table 14. Prolactin Levels [ng/mL] by Gender and Age Group [years]: Descriptive Statistics (PA - As Observed)

			Prolactin [ng/mL]					
Study Period	Gender	Age Category	N	Mean	SD	Median	Minimum	Maximum
Pre-dose	Male	>= 10	234	7.3	8.0	5.0	2.0	76.5
		< 10	255	7.3	6.0	5.7	2.0	46.8
		Total	489	7.3	7.0	5.1	2.0	76.5
	Female	>= 9	59	10.3	8.2	7.2	2.0	50.7
		< 9	44	9.7	7.3	7.0	2.5	39.0
		Total	103	10.0	7.8	7.0	2.0	50.7
Weeks 4 to 7	Male	>= 10	222	28.6	15.8	26.3	2.0	150.0
		< 10	235	29.0	16.3	26.9	2.9	101.8
		Total	457	28.8	16.0	26.7	2.0	150.0
	Female	>= 9	54	34.6	19.1	31.1	3.0	95.2
		< 9	39	29.9	17.1	26.0	3.0	70.0
		Total	93	32.7	18.3	29.3	3.0	95.2
Weeks 8 to 12	Male	>= 10	209	22.9	17.4	19.3	2.0	153.0
		< 10	208	22.8	16.6	19.7	1.0	88.0
		Total	417	22.8	17.0	19.3	1.0	153.0
	Female	>= 9	48	30.0	17.4	29.1	2.0	78.0
		< 9	34	21.8	13.9	20.9	3.0	53.0
		Total	82	26.6	16.5	25.0	2.0	78.0
Weeks 16 to 24	Male	>= 10	191	19.5	14.7	16.8	2.0	90.9
		< 10	178	18.2	13.2	15.1	2.0	83.0
		Total	369	18.9	14.0	16.1	2.0	90.9
	Female	>= 9	43	26.9	18.2	21.2	3.3	81.3
		< 9	29	18.5	11.1	15.6	3.9	42.0
		Total	72	23.5	16.2	19.2	3.3	81.3
Weeks 28 to 36	Male	>= 10	156	18.4	11.9	16.9	2.0	87.7
		< 10	167	16.8	12.7	13.8	2.0	102.0
		Total	323	17.6	12.3	15.1	2.0	102.0
	Female	>= 9	46	26.1	19.4	21.0	2.4	79.8
		< 9	25	15.8	10.4	13.9	2.0	41.0
		Total	71	22.5	17.4	19.0	2.0	79.8
Weeks 40 to 48	Male	>= 10	149	14.8	9.1	14.5	1.9	48.5
		< 10	154	15.4	11.6	12.3	2.0	61.6
		Total	303	15.1	10.4	13.0	1.9	61.6

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Table 14. Prolactin Levels [ng/mL] by Gender and Age Group [years]: Descriptive Statistics (PA - As Observed) -(continued)

			Prolactin [ng/mL]					
Study Period	Gender	Age Category	N	Mean	SD	Median	Minimum	Maximum
Weeks 40 to 48	Female	>= 9	31	25.3	27.7	20.2	5.0	160.9
		< 9	24	16.2	12.6	13.3	2.0	44.0
		Total	55	21.4	22.7	16.0	2.0	160.9
Weeks 52 to 55	Male	>= 10	16	13.1	8.0	12.7	4.0	29.0
		< 10	18	12.9	19.7	6.8	2.0	88.0
		Total	34	13.0	15.1	9.0	2.0	88.0
	Female	>= 9	2	8.0	2.8	8.0	6.0	10.0
		< 9	6	14.5	9.8	11.0	5.0	33.0
		Total	8	12.9	8.9	10.5	5.0	33.0

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Table 15. Correlation between Prolactin Levels (Log-Scale) [ng/mL] vs Age [years] (PA - As Observed)

				Log (10) Scale			Transformed to Original Scale		
					Slope 95% CI			Slope 95% CI	
Study Period	N[1]	Correlation Coefficient	R-Square[2]	Slope[3]	Lower	Upper	Slope[3]	Lower	Upper
Pre-dose	592	0.0076	0.0001	0.0009	-0.0083	0.0100	1.0020	0.9811	1.0233
Weeks 4 to 7	550	0.0439	0.0019	0.0049	-0.0045	0.0143	1.0114	0.9897	1.0336
Weeks 8 to 12	499	0.1112	0.0124	0.0159	0.0034	0.0284	1.0373	1.0078	1.0676
Weeks 16 to 24	441	0.1215	0.0148	0.0171	0.0040	0.0302	1.0402	1.0092	1.0721
Weeks 28 to 36	394	0.1150	0.0132	0.0156	0.0022	0.0289	1.0365	1.0051	1.0689
Weeks 40 to 48	358	0.1326	0.0176	0.0193	0.0043	0.0343	1.0455	1.0099	1.0823

[1]All data points were included

[2]Interpretation of R-Square: eg. At weeks 40 to 48, 1.76% of the variation in prolactin levels can be explained by age

[3]Interpretation of Slope: eg. At weeks 40 to 48, for every year there is a 10**(0.0193)=1.05 [1.01 - 1.08] ng/mL expected increase in mean prolactin

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Table 18. Incidence of Prolactin-related Side Effects (SHAP): Frequency Table (PA vs Non-PA)

Class Generic Name	Number (%) of Patients ITT	PA	Non-PA
Total number of patients	700	592	108
Number of patients with at least one SHAP	14 (2.0)	13 (2.2)	1 (0.9)
ENDOCRINE DISORDERS	5 (0.7)	5 (0.8)	0 (0.0)
GYNAECOMASTIA	5 (0.7)	5 (0.8)	0 (0.0)
REPRODUCTIVE DISORDERS, FEMALE	9 (1.3)	8 (1.4)	1 (0.9)
AMENORRHOEA	4 (0.6)	3 (0.5)	1 (0.9)
MENORRHAGIA	3 (0.4)	3 (0.5)	0 (0.0)
BREAST ENLARGEMENT	1 (0.1)	1 (0.2)	0 (0.0)
LACTATION NONPUERPERAL	1 (0.1)	1 (0.2)	0 (0.0)
MENSTRUAL DISORDER	1 (0.1)	1 (0.2)	0 (0.0)
VAGINAL HAEMORRHAGE	1 (0.1)	1 (0.2)	0 (0.0)

Note 1) SHAP are adverse events classified under System Organ Class as "Endocrine disorders" or "Reproductive disorders"
2) SHAP classified under Preferred Term as "Balanoposthitis", "Dysmenorrhoea", "Growth Hormone Excess", Hernia Inguinal", "Hyperprolactinaemia", "Penis Disorder", "Sexual Function Abnormal", "Sialoadenitis", "Testis Disorder", "Thyroiditis", "Thyroid Stim. Hormone Decreased" or "Vaginitis Atrophic" are not included
3) Patients with >= 1 week of Amenorrhoea, females with >= 31 days of Gynaecomastia and males < 10 years of age with Gynaecomastia are included
4) If SHAP was ongoing, duration of SHAP was calculated using last visit date
5) Multiple occurrences of a side effect within a patient are counted only once

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Table 17. Onset of Prolactin-related Side Effects (SHAP): Descriptive Statistics (PA - As Observed)

	Duration [days] from Pre-dose[1]						
Number of Patients with SHAP	Mean	SD	25th	50th	75th	Minimum	Maximum
13	98.8	105.3	10	34	197	1	254

[1]Onset of first prolactin-related side effect

Note 1) SHAP are adverse events classified under System Organ Class as "Endocrine disorders" or "Reproductive disorders"
2) SHAP classified under Preferred Term as "Balanoposthitis", "Dysmenorrhoea", "Growth Hormone Excess", Hernia Inguinal", "Hyperprolactinaemia", "Penis Disorder", "Sexual Function Abnormal", "Sialoadenitis", "Testis Disorder", "Thyroiditis", "Thyroid Stim. Hormone Decreased" or "Vaginitis Atrophic" are not included
3) Patients with >= 1 week of Amenorrhoea, females with >= 31 days of Gynaecomastia and males < 10 years of age with Gynaecomastia are included
4) If SHAP was ongoing, duration of SHAP was calculated using last visit date
5) Multiple occurrences of a side effect within a patient are counted only once

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Table 18. Prolactin Levels [ng/mL] in Each Period by Prolactin-related Side Effects (SHAP): Descriptive Statistics (PA - As Observed)

	Patients with SHAP (at any time)						Patients without SHAP					
Time Period	N	Mean	SD	Median	Minimum	Maximum	N	Mean	SD	Median	Minimum	Maximum
Pre-dose	13	12.3	12.6	8.0	5.0	50.7	579	7.7	7.0	5.5	2.0	76.5
Weeks 4 to 7	11	35.3	21.8	33.6	14.4	85.2	539	29.3	16.4	26.8	2.0	150.0
Weeks 8 to 12	12	35.2	21.8	30.3	6.1	78.0	487	23.1	16.7	20.0	1.0	153.0
Weeks 16 to 24	12	25.4	20.9	18.8	3.9	77.5	429	19.4	14.2	16.5	2.0	90.9
Weeks 28 to 36	11	23.4	19.0	16.0	6.0	71.0	383	18.3	13.3	15.8	2.0	102.0
Weeks 40 to 48	9	30.7	50.0	11.0	2.5	160.9	349	15.7	10.8	13.7	1.9	61.6
Weeks 52 to 55	0	0.0	0.0	0.0	0.0	0.0	42	13.0	14.1	10.0	2.0	88.0

Note 1) SHAP are adverse events classified under System Organ Class as "Endocrine disorders" or "Reproductive disorders"

2) SHAP classified under Preferred Term as "Balanoposthitis", "Dysmenorrhoea", "Growth Hormone Excess", Hernia Inguinal", "Hyperprolactinaemia", "Penis Disorder", "Sexual Function Abnormal", "Sialoadenitis", "Testis Disorder", "Thyroiditis", "Thyroid Stim. Hormone Decreased" or "Vaginitis Atrophic" are not included

3) Patients with >= 1 week of Amenorrhoea, females with >= 31 days of Gynaecomastia and males < 10 years of age with Gynaecomastia are included

4) If SHAP was ongoing, duration of SHAP was calculated using last visit date

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Table 19. Study Drug Dosing Information by Prolactin-related Side Effects (SHAP): Descriptive Statistics (PA - As Observed)

	Patients with Side Effects (at any time)						Patients without Side Effects					
Study Drug Dosing Variable	N	Mean	SD	Median	Minimum	Maximum	N	Mean	SD	Median	Minimum	Maximum
Study Drug Exposure [mg][1]	13	458.18	201.42	438.00	40.22	780.70	579	408.97	267.24	406.10	0.400	1305.80
Study Drug Duration [days][2]	13	358.54	31.16	365.00	288.00	414.00	579	318.52	102.12	360.00	28.000	505.00
Average Daily Dose [mg/day][3]	13	1.29	0.60	1.20	0.12	2.29	579	1.26	0.71	1.23	0.001	4.17

[1]Study drug exposure = Area under the Dose x Time curve
[2]Study drug duration = Date of last dose - Date of first dose + 1
[3]Average daily dose = Exposure / Study drug duration

Note 1) SHAP are adverse events classified under System Organ Class as "Endocrine disorders" or "Reproductive disorders"
2) SHAP classified under Preferred Term as "Balanoposthitis", "Dysmenorrhoea", "Growth Hormone Excess", Hernia Inguinal", "Hyperprolactinaemia", "Penis Disorder", "Sexual Function Abnormal", "Sialoadenitis", "Testis Disorder", "Thyroiditis", "Thyroid Stim. Hormone Decreased" or "Vaginitis Atrophic" are not included
3) Patients with >= 1 week of Amenorrhoea, females with >= 31 days of Gynaecomastia and males < 10 years of age with Gynaecomastia are included
4) If SHAP was ongoing, duration of SHAP was calculated using last visit date 27SEP02 14:35
5) No dose recorded for patient A03306 from 28MAY98 TO 16JUN98 and patient A03974 from 17JAN00 TO 20JAN00 s:\428\c\analysis\des_dosese.sas

Table 20. Prolactin-related Side Effects (SHAP) by Prolactin Levels [ng/mL] at or above Upper Limit of Normal (ULN): Frequency Table (PA - As Observed

Time Period	SHAP	N	Prolactin		P-value[2]
			Above ULN[1]	Normal	
Pre-dose	Yes		1 (3.4)	12 (2.1)	0.6370
	No		28 (96.6)	551 (97.9)	
	Total	592	29	563	
Weeks 4 to 7	Yes		8 (2.1)	3 (1.9)	0.8726
	No		380 (97.9)	159 (98.1)	
	Total	550	388	162	
Weeks 8 to 12	Yes		9 (3.5)	3 (1.2)	0.0992
	No		248 (96.5)	239 (98.8)	
	Total	499	257	242	
Weeks 16 to 24	Yes		4 (2.3)	8 (3.0)	0.6372
	No		172 (97.7)	257 (97.0)	
	Total	441	176	265	
Weeks 28 to 36	Yes		4 (2.7)	7 (2.8)	0.9336
	No		144 (97.3)	239 (97.2)	
	Total	394	148	246	
Weeks 40 to 48	Yes		2 (1.8)	7 (2.8)	0.5754
	No		108 (98.2)	241 (97.2)	
	Total	358	110	248	

[1]ULN: The upper limit of normal for prolactin levels is 18 [ng/mL] for males and 30 [ng/mL] for females
[2]Pearson's chi-square test is used to calculate the association between patients with SHAP (Yes vs No) and levels (Above ULN vs Normal)

Note 1) SHAP are adverse events classified under System Organ Class as "Endocrine disorders" or "Reproductive disorders"
2) SHAP classified under Preferred Term as "Balanoposthitis", "Dysmenorrhoea", "Growth Hormone Excess", Hernia Inguinal", "Hyperprolactinaemia", "Penis Disorder", "Sexual Function Abnormal", "Sialoadenitis", "Testis Disorder", "Thyroiditis", "Thyroid Stim. Hormone Decreased" or "Vaginitis Atrophic" are not included
3) Patients with >= 1 week of Amenorrhoea, females with >= 31 days of Gynaecomastia and males < 10 years of age with Gynaecomastia are included
4) If SHAP was ongoing, duration of SHAP was calculated using last visit date

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Table 21. Prolactin-related Side Effects (SHAP): Number [%] of Events (ITT vs PA)

	Age Group	Preferred Term	Severity	Outcome	ITT[1]	PA[2]
Number of Events					16	15
MALE	< 10	GYNAECOMASTIA	MILD	NOT YET RECOVERED	1 (6.3)	1 (6.7)
				RECOVERED FROM THIS AE	2 (12.5)	2 (13.3)
			MODERATE	NOT YET RECOVERED	2 (12.5)	2 (13.3)
FEMALE	>= 9	AMENORRHOEA	MILD	RECOVERED FROM THIS AE	3 (18.8)	2 (13.3)
			MODERATE	RECOVERED FROM THIS AE	1 (6.3)	1 (6.7)
		BREAST ENLARGEMENT	MILD	RECOVERED FROM THIS AE	1 (6.3)	1 (6.7)
		LACTATION NONPUERPERAL	MODERATE	RECOVERED FROM THIS AE	1 (6.3)	1 (6.7)
		MENORRHAGIA	MILD	RECOVERED FROM THIS AE	2 (12.5)	2 (13.3)
			MODERATE	RECOVERED FROM THIS AE	1 (6.3)	1 (6.7)
		MENSTRUAL DISORDER	MILD	NOT YET RECOVERED	1 (6.3)	1 (6.7)
		VAGINAL HAEMORRHAGE	MILD	RECOVERED FROM THIS AE	1 (6.3)	1 (6.7)

Only 2 patients did not recover from SHAP

Note. Number of Patients with SHAP: 14 in the ITT population and 13 in the PA population

[1]There were 16 SHAP in the ITT population; the following 2 patients had 2 of the same events:
-patient A3625/A-E had 2 events of amenorrheoea, mild, recovered from this AE
-patient A3664/MFC had 2 events of menstrual disorder, mild, not yet recovered

[2]There were 16 SHAP in the PA population; the following 2 patients had 2 of the same events:
-patient A3664/MFC had 2 events of menstrual disorder, mild, not yet recovered

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Table 22. Prolactin-related Side Effects (SHAP): Patient Data Listing (ITT Population)

Set	Patient ID	Flag	Gender	Risperidone Dosing Period		Prolactin-related Side Effect							
				Start Date	End Date	Event	Preferred Term	Onset Date	End Date	Serious	Severity	Relationship	Action Taken	Outcome
3	A3625	ITT	FEMALE	22OCT98	22SEP99	AMENORRHEA	AMENORRHOEA	12JAN99	25APR99	NO	MILD	NONE	NONE	RECOVERED FROM THIS AE
						MISSED MENSES	AMENORRHOEA	20MAY99	30JUN99	NO	MILD	NONE	NONE	RECOVERED FROM THIS AE
	A3664	PA	FEMALE	18APR98	21APR99	AMENORRHEA	AMENORRHOEA	27APR98	02JUL98	NO	MODERATE	POSSIBLE	DOSE ADJUSTED	RECOVERED FROM THIS AE
						MENSTRUAL IRREGULARITY (IRREGULAR CYCLES 20-40 DAYS)	MENSTRUAL DISORDER	01OCT98	ONGOING	NO	MILD	POSSIBLE	NONE	NOT YET RECOVERED
								01OCT98	ONGOING	NO	MILD	POSSIBLE	NONE	NOT YET RECOVERED
5	A3704	PA	MALE	25MAR99	28FEB00	INCREASED BREASTS GYNAECOMASTIA	GYNAECOMASTIA	17APR99	20MAY99	NO	MILD	VERY LIKELY	NONE	RECOVERED FROM THIS AE
	A3710	PA	FEMALE	29JAN99	28JAN00	EXCESSIVE MENSTRUAL BLEED	MENORRHAGIA	17MAR99	29MAR99	NO	MILD	DOUBTFUL	NONE	RECOVERED FROM THIS AE
9	A03004	PA	MALE	21SEP97	09OCT98	GYNECOMASTIC	GYNAECOMASTIA	15APR98	ONGOING	NO	MODERATE	PROBABLE	NONE	NOT YET RECOVERED
	A03060	PA	FEMALE	17NOV99	16NOV00	NO MENSTRUAL BLEEDING	AMENORRHOEA	14FEB00	21FEB00	NO	MILD	PROBABLE	NONE	RECOVERED FROM THIS AE
	A03190	PA	MALE	19MAY99	05JUL00	LOCAL OEDEMA IN THE LEFT BREAST	GYNAECOMASTIA	29SEP99	31OCT99	NO	MILD	NONE	NONE	RECOVERED FROM THIS AE

Note 1) SHAP are adverse events classified under System Organ Class as "Endocrine disorders" or "Reproductive disorders"

2) SHAP classified under Preferred Term as "Balanoposthitis", "Dysmenorrhoea", "Growth Hormone Excess", Hernia Inguinal", "Hyperprolactinaemia", "Penis Disorder", "Sexual Function Abnormal", "Sialoadenitis", "Testis Disorder", "Thyroiditis", "Thyroid Stim. Hormone Decreased" or "Vaginitis Atrophic" are not included

3) Patients with >= 1 week of Amenorrhoea, females with >= 31 days of Gynaecomastia and males < 10 years of age with Gynaecomastia are included

4) If SHAP was ongoing, duration of SHAP was calculated using last visit date

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Table 22. Prolactin-related Side Effects (SHAP): Patient Data Listing (ITT Population) -(continued)

Set	Patient ID	Flag	Gender	Risperidone Dosing Period		Prolactin-related Side Effect								
				Start Date	End Date	Event	Preferred Term	Onset Date	End Date	Serious	Severity	Relationship	Action Taken	Outcome
0	A03294	PA	FEMALE	26AUG99	24AUG00	MENORRHAGIA	MENORRHAGIA	18OCT99	27OCT99	NO	MODERATE	NONE	NONE	RECOVERED FROM THIS AE
	A03303	PA	FEMALE	29JAN98	06DEC98	AMENORRHOEA	AMENORRHOEA	15FEB98	26OCT98	NO	MILD	VERY LIKELY	NONE	RECOVERED FROM THIS AE
	A03329	PA	MALE	21MAY99	17MAY00	SLIGHT BREAST ENLARGEM	GYNAECOMASTIA	26APR00	ONGOING	NO	MILD	DOUBTFUL	NONE	NOT YET RECOVERED
	A03344	PA	FEMALE	05NOV98	19AUG99	GALACTORRHOEA	LACTATION NONPUERPERAL	04FEB99	19AUG99	NO	MODERATE	DOUBTFUL	NONE	RECOVERED FROM THIS AE
	A03357	PA	MALE	21JAN00	26JAN01	GYNECOMASTIA	GYNAECOMASTIA	30MAY00	ONGOING	NO	MODERATE	PROBABLE	PERMANENT STOP	NOT YET RECOVERED
	A03384	PA	FEMALE	09FEB00	06FEB01	BREAST MORE VOLUMINOUS	BREAST ENLARGEMENT	08JUN00	06FEB01	NO	MILD	PROBABLE	NONE	RECOVERED FROM THIS AE
	A03464	PA	FEMALE	03MAR99	23FEB00	MENORRHEA	MENORRHAGIA	15AUG99	17AUG99	NO	MILD	NONE	NONE	RECOVERED FROM THIS AE
						VAGINAL BLEEDING	VAGINAL HAEMORRHAGE	24JUL99	27JUL99	NO	MILD	NONE	TEMPORARY STOP	RECOVERED FROM THIS AE

Note 1) SHAP are adverse events classified under System Organ Class as "Endocrine disorders" or "Reproductive disorders"

2) SHAP classified under Preferred Term as "Balanoposthitis", "Dysmenorrhoea", "Growth Hormone Excess", Hernia Inguinal", "Hyperprolactinaemia", "Penis Disorder", "Sexual Function Abnormal", "Sialoadenitis", "Testis Disorder", 'Thyroiditis", "Thyroid Stim. Hormone Decreased" or "Vaginitis Atrophic" are not included

3) Patients with >= 1 week of Amenorrhoea, females with >= 31 days of Gynaecomastia and males < 10 years of age with Gynaecomastia are included

4) If SHAP was ongoing, duration of SHAP was calculated using last visit date

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Table 23. Concomitant Medication Use in Patients with Prolactin-related Side Effects (SHAP): Patient Data Listing (ITT Population)

Set	Patient ID	Flag	Gender	Preferred Term	Medication	Onset Date	End Date	Schedule	Indication
3	A3625	ITT	FEMALE	AMENORRHOEA	HYDROCORTISONE CREAM	PRIOR	ONGOING	PRN	ECZEMA
					TYLENOL	PRIOR	ONGOING	1-2 TABS ONCE A DAY PRN	MENSTRUAL CRAMPS
					AMOXICILLIN	PRIOR	25OCT98	750MG 250MG TID	EAR INFECTION
					BEN-GAY	23SEP98	23SEP98	PRN-1 DOSE	LEG CRAMPS
					AMOXICILLIN	15OCT98	ONGOING	750MG QD	EAR INFECTION
					ADVIL	01JAN99	ONGOING	400MG PRN 200-400MG PO PRN	MENSTRUAL CRAMPS
	A3664	PA	FEMALE	AMENORRHOEA	MULTIVITAMINS	PRIOR	ONGOING	1 TAB OD	NUTRITIONAL SUPPLEMENT
					VENTOLIN INHALER	PRIOR	ONGOING	PRN	BRONCHIAL SPASMS (? ASTHMA)
					VITAMINS	PRIOR	ONGOING	1 TAB PO OD	NUTRITIONAL SUPPLEMENT
					VENTOLIN INHALER	24MAR98	ONGOING	PRN	BRONCHIAL SPASMS (? ASTHMA)
					AMOXIL	24MAR98	03APR98	750MG	BRONCHIAL INFECTION
					NUAMOXIL	07APR98	14APR98	1500MG	LESION IN MOUTH
					NYADERM	07APR98	14APR98	QID	LESION IN MOUTH
					IMMUNIZATION	28APR98	28APR98	1 INJECTION 3RD DOSE HEPATITIS B	PREVENTATIVE GENERAL HEALTH
					GUAITUSSIN DM	31AUG98	06SEP98	3 TSP PO 1 TSP TID	CHEST (CONGESTION)
					NU-DOXYCYCLINE	31AUG98	06SEP98	200MG PO 100MG BID	CHEST (CONGESTIONS)
					XALATAN OPH. SOL'N	08OCT98	ONGOING	1 DROP LEFT EYE QHS	LEFT EYE (WEAK MUSCLE) PRE-EXISTING CONDITION
					NU-DOXYCYCLINE	08OCT98	15OCT98	200MG PO 100MG BID	CHEST INFECTION
					AMOXICILLIN	31OCT98	07NOV98	750MG 250MG PO TID	CHEST INFECTION
5	A3704	PA	MALE	GYNAECOMASTIA	RITALIN (METHYLPHENIDATE)	PRIOR	ONGOING	25MG QD AM	ADHD
					METHYLPHENIDATE	PRIOR	24JUN99	15 MG MANE 10 MG 10H30	ADHD
					TIMOLOL	11JUN99	15DEC99	EYE DROPS	GLAUCOMA
					CALAMINE	24JUN99	15JUL99	100 MG PRN	SKIN RASH
	A3710	PA	FEMALE	MENORRHAGIA	PANADO	23DEC98	24DEC98	1000MG 2 TABS QD	URTI
					DEPO-PROVERA	27JAN99	27JAN99	150MG IMI 12 WKLY	INABILITY TO HANDLE MENSES

Note 1) SHAP are adverse events classified under System Organ Class as "Endocrine disorders" or "Reproductive disorders"

2) SHAP classified under Preferred Term as "Balanoposthitis", "Dysmenorrhoea", "Growth Hormone Excess", Hernia Inguinal", "Hyperprolactinaemia", "Penis Disorder", "Sexual Function Abnormal", "Sialoadenitis", "Testis Disorder", "Thyroiditis", "Thyroid Stim. Hormone Decreased" or "Vaginitis Atrophic" are not included

3) Patients with >= 1 week of Amenorrhoea, females with >= 31 days of Gynaecomastia and males < 10 years of age with Gynaecomastia are included

4) If SHAP was ongoing, duration of SHAP was calculated using last visit date

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Table 23. Concomitant Medication Use in Patients with Prolactin-related Side Effects (SHAP): Patient Data Listing (ITT Population) -(continued)

Set	Patient ID	Flag	Gender	Preferred Term	Medication	Onset Date	End Date	Schedule	Indication
5	A3710	PA	FEMALE	MENORRHAGIA	DEPO-PROVERA	17FEB99	17FEB99	150MG IMI 12 WKLY	CONTRAGESTION + REGULATION OF MENSES
					DVRAL 28	17FEB99	24FEB99	1 TABLET	MENORRHAGIA
					OVRAL 28	17MAR99	19MAR99	BD 1 TABLET	BREAK THROUGH BLEEDING
					DEPO-PROVERA	19MAR99	19MAR99	150MG 12 WEEKLY	CONTRAGESTION + REGULATION OF MENSES
					NORDETTE	13APR99	ONGOING	1 TABLET	CONTRAGESTION + REGULATION OF MENSES
					CLEAR COUGH	20MAY99	21MAY99	10ML	COUGH
					CLEAR COUGH	07JUN99	10JUN99	10ML	COUGH
					VENTOLIN PUMP	07JUN99	11JUN99	2 PUFFS DLY	BRONCHOSPASM + COUGH
					PANADO	10JUN99	10JUN99	500MG	TUMMY ACHE
					PANADO TAB 500MG	28NOV99	28NOV99	T STAT	SORE THROAT
					VENTOLIN INHALER	06DEC99	29DEC99	1 PUFF AT NIGHT	COUGH DUE TO BRONCHOSPASM (OLD ASTHMA)
9	A03004	PA	MALE	GYNAECOMASTIA	ASPEGIC	27MAR98	29MAR98	2 X 250 MGR	VIRAL INFECTION
					ARTANE	09MAY98	02JUL98	2 MGR, 3 X 2 MGR	EPS
					ARTANE	03JUL98	10AUG98	5 MGR, 2 X 5 MGR	EPS
					ARTANE	11AUG98	13AUG98	5 MGR, 3 X 5 MGR	EPS
					ARTANE	14AUG98	08OCT98	5 MGR, 2 X 5 MGR	EPS
					ARTANE	09OCT98	ONGOING	5 MGR, 2 X 2.5 MGR	EPS
	A03060	PA	FEMALE	AMENORRHOEA	PARACETAMOL	20NOV99	20NOV99	TABL A 500 MG, 2X1/2 TABL	HEADACHE
					PARACETAMOL	30JAN00	18FEB00	TABL 500 MG, 4X500MG FROM 30/1 TO 18/2	INFLUENZA
					OTRIVIN	15MAR00	06APR00	NASAL DROPS 3-4 X	RHINITIS
					AMOXICILLINE	06APR00	13APR00	500 MG 3 DD 1	UPPER AIRWAY INFECTION
					DOXYCYCLINE	17APR00	25APR00	100 MG	UPPER AIRWAY INFECTION
					FLIXONASE	22MAY00	22JUN00	NOSE SPRAY,2 SPRAYS NOSTRIL 1X/DAY	ALLERGIC RHINITIS
	A03190	PA	MALE	GYNAECOMASTIA	IBUPROFENE	09OCT99	09OCT99	5 MG TID PO	COMMON COLD

Note 1) SHAP are adverse events classified under System Organ Class as "Endocrine disorders" or "Reproductive disorders"

2) SHAP classified under Preferred Term as "Balanoposthitis", "Dysmenorrhoea", "Growth Hormone Excess", Hernia Inguinal", "Hyperprolactinaemia", "Penis Disorder", "Sexual Function Abnormal", "Sialoadenitis", "Testis Disorder", "Thyroiditis", "Thyroid Stim. Hormone Decreased" or "Vaginitis Atrophic" are not included

3) Patients with >= 1 week of Amenorrhoea, females with >= 31 days of Gynaecomastia and males < 10 years of age with Gynaecomastia are included

4) If SHAP was ongoing, duration of SHAP was calculated using last visit date

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Table 23. Concomitant Medication Use in Patients with Prolactin-related Side Effects (SHAP): Patient Data Listing (ITT Population) -(continued)

Set	Patient ID	Flag	Gender	Preferred Term	Medication	Onset Date	End Date	Schedule	Indication
9	A03190	PA	MALE	GYNAECOMASTIA	AMOXICILINE	09OCT99	10OCT99	250 MG TID PO	COMMON COLD
					CLAVULANIC ACID	09OCT99	10OCT99	250 MG TID PO	COMMON COLD
					MEFENAMIC ACID (COSCAN)	10OCT99	10OCT99	250 MG BID PO	COMMON COLD
	A03294	PA	FEMALE	MENORRHAGIA	DEPOT PROVERA	06SEP99	06SEP99	IMI 1	PREGNANCY PROPHYLAXIS CONTRACEPTION
					BIFASIL	18OCT99	07NOV99	1 TAB D	MENORRHAGIA EXCESSIVE FLOW OF MENSES
					DISPRIN	26DEC99	26DEC99	1 TAB D	MILD LARYNGITIS
					PANADO	21AUG00	21AUG00	1 TAB	HEADACHE
					IMMODIUM	22AUG00	22AUG00	2 TABS	DIARRHOA
	A03303	PA	FEMALE	AMENORRHOEA	RITALIN	PRIOR	15FEB98	10 MG PO AS REQUIRED	AO/HD
					AKINETON RET.	10MAR98	11MAR98	4 MG 1/2-0-0 PO	DISTURBED ARTICULATION
					AKINETON RET.	12MAR98	19NOV98	4 MG 1-0-0 PO	DISTURBED ARTICULATION
					GUTRON	01APR98	02APR98	TRPF PO 5-0-5	ARTERIAL HYPOTENSION, TIREDNESS
					GUTRON	03APR98	06DEC98	TRPF PO 5-0-0	ARTERIAL HYPOTENSION, TIREDNESS
					RITALIN	08APR98	08APR98	10 MG PO	BREAKTHROUGH OF AGGRESSIVENESS
					RITALIN	15APR98	15APR98	10 MG PO	BREAKTHROUGH OF AGGRESSIVENESS
					SUPRACOMBIN	15MAY98	20MAY98	TBL 2XPER DAY PO	URINARY TRACT INFECTION
					BUSCOPAN - ZAPFCHEN	22JUN98	26JUN98	1-2/DAY RECTUM	ABDOMINAL PAIN
					SAB SIMPLEX	22JUN98	26JUN98	20 TRPF PO AS REQUIRED	ABDOMINAL PAIN
					HEPATITIS B VACCINATION	06JUL98	06JUL98	NAV MG IM	PROPHYLAXIS
					DIAZEPAM	05AUG98	05AUG98	10 MG IV	CONVULSION OF THE WHOLE BODY

Note 1) SHAP are adverse events classified under System Organ Class as "Endocrine disorders" or "Reproductive disorders"

2) SHAP classified under Preferred Term as "Balanoposthitis", "Dysmenorrhoea", "Growth Hormone Excess", Hernia Inguinal", "Hyperprolactinaemia", "Penis Disorder", "Sexual Function Abnormal", "Sialoadenitis", "Testis Disorder", "Thyroiditis", "Thyroid Stim. Hormone Decreased" or "Vaginitis Atrophic" are not included

3) Patients with >= 1 week of Amenorrhoea, females with >= 31 days of Gynaecomastia and males < 10 years of age with Gynaecomastia are included

4) If SHAP was ongoing, duration of SHAP was calculated using last visit date

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Table 23. Concomitant Medication Use in Patients with Prolactin-related Side Effects (SHAP): Patient Data Listing (ITT Population) -(continued)

Set	Patient ID	Flag	Gender	Preferred Term	Medication	Onset Date	End Date	Schedule	Indication
9	A03303	PA	FEMALE	AMENORRHOEA	CONCEPLAN	05OCT98	ONGOING	1X PO	AMENORRHOEA CONTRACEPTION
					AKINETON RET.	20NOV98	06DEC98	4 MG 0.5-0-0 PO	DISTURBED ARTICULATION
					VALIUM	02DEC98	ONGOING	5 MG 0-0-1 PO	PROPHYLACTIS OF CONVULSIONS
	A03329	PA	MALE	GYNAECOMASTIA	FLUORETTEN	PRIOR	ONGOING	0.5MG, 1	PREVENTING CARIES
					PARACETAMOL	27MAY99	30MAY99	SUPP 250 MG	HIGH TEMPERATURE
					ROXITHROMYCIN	25JAN00	30JAN00	200 MG	URTI UPPER RESPIRATORY TRACT INFECTION
	A03344	PA	FEMALE	LACTATION NONPUERPERAL	TRIGOA	PRIOR	ONGOING	1 TBL/D PO	CONTRACEPTION
					PULMICORT	PRIOR	28JAN99	INTRAPARYNGEAL 2X2 SPRAY(AS NEEDED)	ASTHMA BRONCHIALE
					NACL-INHALATION	25NOV98	02DEC98	2X10 MINUTES INHALATION	COLO AND FLU
					NASIVIN	26NOV98	29NOV98	1-2 DROPS INTRANASAL	RHINITIS
					KLACID	06DEC98	16DEC98	250 MG 2X1 TBL PO	BRONCHITIS
					PODOMEXEF	06DEC98	16DEC98	200 2X1 TLB PO	BRONCHITIS
					SALBUTAMOL	06DEC98	16DEC98	INTRAPHARYNGEAL 2X1 SPRAY	BRONCHITIS
					KLACID	13JAN99	23JAN99	250 MG 2X1 TBL PO	BRONCHITIS
					BRONUC	18JAN99	28JAN99	200 2X1 TBL PO	BRONCHITIS
					FLUTIDE DISKUS	29JAN99	19FEB99	250 (INTRAPHARYNGEAL)1X1 SPRAY	ASTHMA BRONCHIALE
					SINGULAIR	30JAN99	08FEB99	1X1 TBL PO	ASTHMA BRONCHIALE
					SALBUTAMOL	20FEB99	ONGOING	INTRAPHARYNGEAL 1X2 SPRAY	ASTHMA BRONCHIALE
					LOFTAN	20FEB99	27FEB99	8MG 1X1 TBL PO	ASTHMA BRONCHIALE
					SINGULAIR	09MAR99	ONGOING	1X1 TBL PO	ASTHMA BRONCHIALE
					CARBO MEDICINALIS	16MAY99	16MAY99	30 G	THERAPY OF INTOXICATION
					DICLOFENAC 50	16MAY99	16MAY99	1 G	SELF MEDICATION (INTOXICATION)
					EUVEGAL-N-TROPFEN	16MAY99	16MAY99	NAV	SELF MEDICATION (INTOXICATION)
					GRIPPOSTAD C	16MAY99	16MAY99	TABL NAV	SELF MEDICATION (INTOXICATION)

Note 1) SHAP are adverse events classified under System Organ Class as "Endocrine disorders" or "Reproductive disorders"

2) SHAP classified under Preferred Term as "Balanoposthitis", "Dysmenorrhoea", "Growth Hormone Excess", Hernia Inguinal", "Hyperprolactinaemia", "Penis Disorder", "Sexual Function Abnormal", "Sialoadenitis", "Testis Disorder", "Thyroiditis", "Thyroid Stim. Hormone Decreased" or "Vaginitis Atrophic" are not included

3) Patients with >= 1 week of Amenorrhoea, females with >= 31 days of Gynaecomastia and males < 10 years of age with Gynaecomastia are included

4) If SHAP was ongoing, duration of SHAP was calculated using last visit date

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Table 23. Concomitant Medication Use in Patients with Prolactin-related Side Effects (SHAP): Patient Data Listing (ITT Population) -(continued)

Set	Patient ID	Flag	Gender	Preferred Term	Medication	Onset Date	End Date	Schedule	Indication
9	A03344	PA	FEMALE	LACTATION NONPUERPERAL	IPECACUANHA SYRUP	16MAY99	16MAY99	30 ML	THERAPY OF INTOXICATION
					KRANIT-N TABL.	16MAY99	16MAY99	TABL NAV	SELF MEDICATION (INTOXICATION)
					MCP "ISIS"	16MAY99	16MAY99	10 MG NAV	SELF MEDICATION (INTOXICATION)
	A03357	PA	MALE	GYNAECOMASTIA	NORTUSSINE	PRIOR	19JAN00	2 SPOONS	COLD
					DIPIPERON SOLUTION	02JAN01	ONGOING	5-5-12,1MGR %	DROP OUT OF THE RISPERDAL STUDY
									CONDUCT DISORDER
	A03384	PA	FEMALE	BREAST ENLARGEMENT	NONE				
	A03464	PA	FEMALE	VAGINAL HAEMORRHAGE	MUKOSEPTONEX	25FEB99	01MAR99	5 DROPS	RHINITIS MUCOPURULENTA
					CILEST	27SEP99	ONGOING	1 TBL	CONTRACEPTION
					HYLAK	06FEB00	07FEB00	60 DROPS	DYSPEPSIA

Note 1) SHAP are adverse events classified under System Organ Class as "Endocrine disorders" or "Reproductive disorders"

2) SHAP classified under Preferred Term as "Balanoposthitis", "Dysmenorrhoea", "Growth Hormone Excess", Hernia Inguinal", "Hyperprolactinaemia", "Penis Disorder", "Sexual Function Abnormal", "Sialoadenitis", "Testis Disorder", "Thyroiditis", "Thyroid Stim. Hormone Decreased" or "Vaginitis Atrophic" are not included

3) Patients with >= 1 week of Amenorrhoea, females with >= 31 days of Gynaecomastia and males < 10 years of age with Gynaecomastia are included

4) If SHAP was ongoing, duration of SHAP was calculated using last visit date

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Table 24. Demographic Variables and Prolactin Levels in Patients with Prolactin-related Side Effects (SHAP): Patient Data Listing (ITT Population)

Set	Patient ID	Flag	Gender	Pre-dose Age	Retardation DSM-IV Axis II	IQ	Preferred Term	Prolactin [ng/ml]					
									Weeks Post Risperidone Dose				
								Pre-dose	4 - 7	8 - 12	16 - 24	28 - 36	40 - 48
3	A3625	ITT	Female	11.6	Borderline	74	AMENORRHOEA					6.0	
	A3664	PA	Female	12.9	Moderate	36	AMENORRHOEA	25.0	39.0	39.0	25.0	16.0	25.0
5	A3704	PA	Male	9.4	Borderline	77	GYNAECOMASTIA	9.0	29.0	21.0	16.0	6.0	8.0
	A3710	PA	Female	12.5	Mild	59	MENORRHAGIA	8.0		78.0	46.0	71.0	160.9
9	A03004	PA	Male	9.1	Mild	60	GYNAECOMASTIA	11.2			29.0		35.4
	A03060	PA	Female	13.5	Mild	62	AMENORRHOEA	6.1	17.2	6.1	9.3	9.6	5.1
	A03190	PA	Male	7.9	Borderline	73	GYNAECOMASTIA	7.8	34.3	24.8	3.9	11.9	2.5
	A03294	PA	Female	14.3	Moderate	50	MENORRHAGIA	10.0	33.0	61.0	40.9	28.8	
	A03303	PA	Female	14.8	Mild	53	AMENORRHOEA	7.4	36.8	29.2	19.0	35.0	
	A03329	PA	Male	5.1	Borderline	72	GYNAECOMASTIA	5.0	38.9	31.3	13.5	10.5	8.3
	A03344	PA	Female	14.0	Mild	64	LACTATION NONPUERPERAL	50.7	95.2	63.1	77.5		
	A03357	PA	Male	7.6	Borderline	81	GYNAECOMASTIA	8.2	14.4	27.2		29.1	11.0
	A03384	PA	Female	9.8	Mild	58	BREAST ENLARGEMENT	7.0	17.3	9.7	6.4	7.7	
	A03464	PA	Female	10.8	Mild	52	VAGINAL HAEMORRHAGE	5.0	33.6	31.5	18.5	31.9	20.2

Note 1) SHAP are adverse events classified under System Organ Class as "Endocrine disorders" or "Reproductive disorders"

2) SHAP classified under Preferred Term as "Balanoposthitis", "Dysmenorrhoea", "Growth Hormone Excess", Hernia Inguinal", "Hyperprolactinaemia", "Penis Disorder", "Sexual Function Abnormal", "Sialoadenitis", "Testis Disorder", "Thyroiditis", "Thyroid Stim. Hormone Decreased" or "Vaginitis Atrophic" are not included

3) Patients with >= 1 week of Amenorrhoea, females with >= 31 days of Gynaecomastia and males < 10 years of age with Gynaecomastia are included

4) If SHAP was ongoing, duration of SHAP was calculated using last visit date

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Table 25. Tanner Stage, Height [cm] and Weight [kg] in Patients with Prolactin-related Side Effects (SHAP): Patient Data Listing (ITT Population)

Set	Patient ID	Gender	Pre-dose Age	Preferred Term	Tanner Stage				Height [cm]					Weight [kg]					
						Weeks(s)				Week(s)					Weeks(s)				
					Pre-dose	6	24-31	48-56	Pre-dose	4-11	12-19	24-31	48-56	Pre-dose	4-7	8-12	16-24	28-36	40-48
3	A3625	Female	12	AMENORRHOEA	4	5			142.0					30.0	31.9	31.9	31.9	33.1	31.9
	A3664	Female	13	AMENORRHOEA	4			4	145.0					52.0	53.6	57.2	63.5	67.2	69.4
5	A3704	Male	9	GYNAECOMASTIA	1	1		1	136.0	136.0	137.0	139.0	141.0	39.0	42.2	45.6	47.6		47.8
	A3710	Female	12	MENORRHAGIA	3	4		4	154.9	157.0	154.0	156.0	158.0	41.9	45.0	49.0	56.0		59.5
9	A03004	Male	9	GYNAECOMASTIA	1	1		1	143.0	144.0	147.0	147.0	152.5	40.4	39.0	43.5	46.5		51.0
	A03060	Female	13	AMENORRHOEA	3	4		5	162.0	163.0	164.0	164.0	165.0	60.0	62.5	67.0	69.5		70.0
	A03190	Male	8	GYNAECOMASTIA	1	1		1	123.0	124.0	126.0	129.0	133.0	23.5	25.0	27.3	31.0		33.3
	A03294	Female	14	MENORRHAGIA	2	4		4	149.0	149.0	151.0	152.0	153.0	42.7	44.7	47.0	48.8		52.9
	A03303	Female	15	AMENORRHOEA	4	4			164.0	164.0	165.0	166.0		66.0	65.7	69.0	68.4	67.9	
	A03329	Male	5	GYNAECOMASTIA		1		1		120.0	122.0	124.0	128.0	24.7	26.5	29.0	30.6		31.4
	A03344	Female	14	LACTATION NONPUERPERAL	3	3			165.0	165.0	165.0	165.0		45.6	50.2	54.8	59.0		
	A03357	Male	8	GYNAECOMASTIA	1			1	135.0	137.0	137.0		142.0	44.5	48.0	52.0			57.0
	A03384	Female	10	BREAST ENLARGEMENT	2	2		2	138.0	138.0	140.0	141.0	145.0	36.0	37.0	39.0	41.5		40.0
	A03464	Female	11	VAGINAL HAEMORRHAGE	3	4		4	145.0	147.0	147.0	153.0	153.0	35.0	37.0	40.5	44.0		49.0

Note 1) SHAP are adverse events classified under System Organ Class as "Endocrine disorders" or "Reproductive disorders"

2) SHAP classified under Preferred Term as "Balanoposthitis", "Dysmenorrhoea", "Growth Hormone Excess", Hernia Inguinal", "Hyperprolactinaemia", "Penis Disorder", "Sexual Function Abnormal", "Sialoadenitis", "Testis Disorder", "Thyroiditis", "Thyroid Stim. Hormone Decreased" or "Vaginitis Atrophic" are not included

3) Patients with >= 1 week of Amenorrhoea, females with >= 31 days of Gynaecomastia and males < 10 years of age with Gynaecomastia are included

4) If SHAP was ongoing, duration of SHAP was calculated using last visit date

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Table 26. Incidence of Extrapyramidal Symptoms (EPS): Frequency Table (PA vs Non-PA)

Class Generic Name	Number (%) of Patients ITT	 PA	 Non-PA
Total number of patients	700	592	108
Number of patients with at least one EPS	147 (21.0)	129 (21.8)	18 (16.7)
CENTR & PERIPH NERVOUS SYSTEM DISORDERS	147 (21.0)	129 (21.8)	18 (16.7)
HYPERTONIA	37 (5.3)	34 (5.7)	3 (2.8)
TREMOR	33 (4.7)	27 (4.6)	6 (5.6)
EXTRAPYRAMIDAL DISORDER	29 (4.1)	28 (4.7)	1 (0.9)
HYPERKINESIA	24 (3.4)	22 (3.7)	2 (1.9)
HYPOKINESIA	22 (3.1)	19 (3.2)	3 (2.8)
MUSCLE CONTRACTIONS INVOLUNTARY	21 (3.0)	20 (3.4)	1 (0.9)
BRADYKINESIA	14 (2.0)	12 (2.0)	2 (1.9)
DYSTONIA	11 (1.6)	9 (1.5)	2 (1.9)
OCULOGYRIC CRISIS	6 (0.9)	4 (0.7)	2 (1.9)
DYSKINESIA TARDIVE	2 (0.3)	2 (0.3)	0 (0.0)
HYPOTONIA	1 (0.1)	1 (0.2)	0 (0.0)

Note 1) EPS are adverse events classified under System Organ Class as "Centr & Periph Nervous System Disorders"

2) EPS classified under Preferred Term as "Agitation" "Akathesia" "Bradykinesia" "Dyskinesia Tardive" "Dystonia" "Extrapyramidal Disorder" "Hyperkinesia" "Hyperreflexia" "Hypertonia" "Hypokinesia" "Hypotonia" "Muscle Contractions Involuntary" "Oculogyric Crisis" "Parkinsonism" "Rigidity" "Shuffling Gait" "Stiffness" "Tics" or "Tremor" are included

3) Multiple occurrences of a side effect within a patient are counted only once

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Table 27. Onset [days] of Extrapyramidal Symptoms (EPS): Descriptive Statistics (PA - As Observed)

	Duration [days] from Pre-dose[1]						
Number of Patients with EPS	Mean	SD	25th	50th	75th	Minimum	Maximum
129	64.3	99.3	4	22	69	1	369

[1]Onset of first extrapyramidal symptom

Note 1) EPS are adverse events classified under System Organ Class as "Centr & Periph Nervous System Disorders"
2) EPS classified under Preferred Term as "Agitation" "Akathesia" "Bradykinesia" "Dyskinesia Tardive" "Dystonia" "Extrapyramidal Disorder" "Hyperkinesia" "Hyperreflexia" "Hypertonia" "Hypokinesia" "Hypotonia" "Muscle Contractions Involuntary" "Oculogyric Crisis" "Parkinsonism" "Rigidity" "Shuffling Gait" "Stiffness" "Tics" or "Tremor" are included
3) If EPS was ongoing, duration of EPS was calculated using last visit date
4) Multiple occurrences of a side effect within a patient are counted only once

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Table 28. Prolactin Levels [ng/mL] in Each Period by Extrapyramidal Symptoms (EPS): Descriptive Statistics (PA - As Observed)

	Patients with EPS (at any time)						Patients without EPS					
Time Period	N	Mean	SD	Median	Minimum	Maximum	N	Mean	SD	Median	Minimum	Maximum
Pre-dose	129	8.9	9.0	6.0	2.0	47.7	463	7.4	6.6	5.5	2.0	76.5
Weeks 4 to 7	118	30.5	19.2	25.9	3.0	150.0	432	29.2	15.7	27.0	2.0	101.8
Weeks 8 to 12	116	26.6	20.0	21.1	3.0	103.0	383	22.5	15.8	20.0	1.0	153.0
Weeks 16 to 24	104	19.6	17.0	14.5	2.0	90.9	337	19.6	13.6	17.0	2.0	83.4
Weeks 28 to 36	94	19.5	16.3	13.9	2.0	87.7	300	18.1	12.5	16.0	2.0	102.0
Weeks 40 to 48	82	17.3	18.8	13.5	2.0	160.9	276	15.7	11.1	13.7	1.9	61.6
Weeks 52 to 55	11	6.3	3.4	5.0	3.0	13.0	31	15.3	15.6	11.0	2.0	88.0

Note 1) EPS are adverse events classified under System Organ Class as "Centr & Periph Nervous System Disorders"

2) EPS classified under Preferred Term as "Agitation" "Akathesia" "Bradykinesia" "Dyskinesia Tardive" "Dystonia" "Extrapyramidal Disorder" "Hyperkinesia" "Hyperreflexia" "Hypertonia" "Hypokinesia" "Hypotonia" "Muscle Contractions Involuntary" "Oculogyric Crisis" "Parkinsonism" "Rigidity" "Shuffling Gait" "Stiffness" "Tics" or "Tremor" are included

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Table 20. Extrapyramidal Symptoms (EPS) by Prolactin Levels [ng/mL] at or above Upper Limit of Normal (ULN): Frequency Table (PA - As Observed)

Time Period	EPS	N	Prolactin		P-value[2]
			Above ULN[1]	Normal	
Pre-dose	Yes		8 (27.6)	121 (21.5)	0.4382
	No		21 (72.4)	442 (78.5)	
	Total	592	29	563	
Weeks 4 to 7	Yes		84 (21.6)	34 (21.0)	0.8632
	No		304 (78.4)	128 (79.0)	
	Total	550	388	162	
Weeks 8 to 12	Yes		61 (23.7)	55 (22.7)	0.7899
	No		196 (76.3)	187 (77.3)	
	Total	499	257	242	
Weeks 16 to 24	Yes		39 (22.2)	65 (24.5)	0.5660
	No		137 (77.8)	200 (75.5)	
	Total	441	176	265	
Weeks 28 to 36	Yes		36 (24.3)	58 (23.6)	0.8662
	No		112 (75.7)	188 (76.4)	
	Total	394	148	246	
Weeks 40 to 48	Yes		23 (20.9)	59 (23.8)	0.5495
	No		87 (79.1)	189 (76.2)	
	Total	358	110	248	

[1]ULN: The upper limit of normal for prolactin levels is 18 [ng/mL] for males and 30 [ng/mL] for females
[2]Pearson's chi-square test is used to calculate the association between patients with EPS (Yes vs No) and levels (Above ULN vs Normal)
Note 1) EPS are adverse events classified under System Organ Class as "Centr & Periph Nervous System Disorders"
2) EPS classified under Preferred Term as "Agitation" "Akathesia" "Bradykinesia" "Dyskinesia Tardive" "Dystonia" "Extrapyramidal Disorder" "Hyperkinesia" "Hyperreflexia" "Hypertonia" "Hypokinesia" "Hypotonia" "Muscle contractions Involuntary" "Oculogyric Crisis" "Parkinsonism" "Rigidity" "Shuffling Gait" "Stiffness" "Tics" or "Tremor" are included
3) If EPS was ongoing, duration of EPS was calculated using last visit date
4) Multiple occurrences of a side effect within a patient are counted only once

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Table 30. Extrapyramidal Symptoms (EPS): Patient Data Listing (ITT Population)

				Risperidone Dosing Period		Prolactin-related Side Effect								
Set	Patient IO	Flag	Gender	Start Date	End Date	Event	Preferred Term	Onset Date	End Date	Serious	Severity	Relationship	Action Taken	Outcome
2	A3501	PA	MALE	04SEP98	28OCT99	(L) ARM SORE & STIFF	HYPERTONIA	04SEP98	12SEP98	NO	MILD	NONE	NONE	RECOVERED FROM THIS AE
						STIFF BACK	HYPERTONIA	11NOV98	11NOV98	NO	MILD	NONE	NONE	RECOVERED FROM THIS AE
	A3514	ITT	MALE	18SEP98	27SEP99	MUSCLE TIGHTNESS	HYPERTONIA	29SEP98	01OCT98	NO	MILD	POSSIBLE	DOSE ADJUSTED	RECOVERED FROM THIS AE
	A3530	PA	FEMALE	04FEB99	09FEB00	AKATHISIA	HYPERKINESIA	02APR99	17NOV99	NO	MILD	DEFINITE	DOSE ADJUSTED	RECOVERED FROM THIS AE
						RIGIDITY ALL 4 LIMBS	HYPERTONIA	17FEB99	ONGOING	NO	MILD	POSSIBLE	NONE	NOT YET RECOVERED
						RIGIDITY RT ARM	HYPERTONIA	04AUG99	25AUG99	NO	MILD	POSSIBLE	NONE	RECOVERED FROM THIS AE
	A3619	PA	MALE	29NOV97	10DEC98	AKATHISIA	HYPERKINESIA	05JAN98	09JAN98	NO	MILD	NONE	NONE	RECOVERED FROM THIS AE
	A3623	ITT	MALE	30APR98	18MAR99	RIGIDITY TO ARMS	HYPERTONIA	21MAY98	28MAY98	NO	MILD	POSSIBLE	DOSE ADJUSTED	RECOVERED FROM THIS AE
						RIGIDITY TO LEGS	HYPERTONIA	21MAY98	28MAY98	NO	MILD	POSSIBLE	DOSE ADJUSTED	RECOVERED FROM THIS AE
	A3624	ITT	MALE	05AUG98	19AUG99	SHAKINESS IN HANDS	TREMOR	16SEP98	24SEP98	NO	MILD	POSSIBLE	NONE	RECOVERED FROM THIS AE
	A3638	PA	MALE	18SEP97	30SEP98	STIFF NECK	HYPERTONIA	06JUN98	08JUN98	NO	MILD	POSSIBLE	NONE	RECOVERED FROM THIS AE
	A3641	PA	FEMALE	30OCT97	18NOV98	SHAKEY (HAND TREMOR)	TREMOR	22JAN98	18NOV98	NO	MILD	POSSIBLE	NONE	RECOVERED FROM THIS AE

Note 1) EPS are adverse events classified under System Organ Class as "Centr & Periph Nervous System Disorders"

2) EPS classified under Preferred Term as "Agitation" "Akathesia" "Bradykinesia" "Dyskinesia Tardive" "Dystonia" "Extrapyramidal Disorder" "Hyperkinesia" "Hyperreflexia" "Hypertonia" "Hypokinesia" "Hypotonia" "Muscle Contractions Involuntary" "Oculogyric Crisis" "Parkinsonism" "Rigidity" "Shuffling Gait" "Stiffness" "Tics" or "Tremor" are included

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Table 30. Extrapyramidal Symptoms (EPS): Patient Data Listing (ITT Population) -(continued)

				Risperidone Dosing Period		Prolactin-related Side Effect								
Set	Patient ID	Flag	Gender	Start Date	End Date	Event	Preferred Term	Onset Date	End Date	Serious	Severity	Relationship	Action Taken	Outcome
2	A3641	PA	FEMALE	30OCT97	18NOV98	STIFF LEGS	HYPERTONIA	20DEC97	20SEP98	NO	MILD	POSSIBLE	NONE	RECOVERED FROM THIS AE
						STIFF MOVEMENTS	HYPERTONIA	06DEC97	10DEC97	NO	MILD	POSSIBLE	NONE	RECOVERED FROM THIS AE
						STIFFNESS	HYPERTONIA	19NOV97	26NOV97	NO	MILD	POSSIBLE	DOSE ADJUSTED	RECOVERED FROM THIS AE
	A3645	PA	MALE	04APR98	28APR99	TWITCHING-HEAD & SHOULDERS	MUSCLE CONTRACTIONS INVOLUNTARY	26FEB99	01MAR99	NO	MILD	NONE	TEMPORARY STOP	RECOVERED FROM THIS AE
	A3652	PA	MALE	01JAN98	27JAN99	AKATHISIA	HYPERKINESIA	04NOV98	ONGOING	NO	MILD	POSSIBLE	DOSE ADJUSTED	NOT YET RECOVERED
	A3657	PA	MALE	12JUN98	05AUG99	INCREASED VOCAL & MOTOR TICS	MUSCLE CONTRACTIONS INVOLUNTARY	20AUG98	22OCT98	NO	MODERATE	POSSIBLE	NONE	RECOVERED FROM THIS AE
	A3663	PA	MALE	28FEB98	15APR99	STIFF NECK	HYPERTONIA	15APR98	18APR98	NO	MILD	NONE	NONE	RECOVERED FROM THIS AE
3	A3508	PA	MALE	15MAR99	07MAR00	HAND TREMOR	TREMOR	12JUL99	10AUG99	NO	MILD	NONE	NONE	RECOVERED FROM THIS AE
	A3533	ITT	MALE	19JUL99	19JUN00	BACK SPASMS	DYSTONIA	22JUL99	23JUL99	NO	MODERATE	POSSIBLE	DOSE ADJUSTED	RECOVERED FROM THIS AE
						RESTLESS, NERVOUS, UNABLE TO KEEP STILL	HYPERKINESIA	02OCT99	31OCT99	NO	MILD	POSSIBLE	NONE	RECOVERED FROM THIS AE
	A3536	PA	FEMALE	18JUN99	26MAY00	COGWHEEL RIGIDITY	EXTRAPYRAMIDAL DISORDER	30JUN99	ONGOING	NO	MILD	DEFINITE	DOSE ADJUSTED	NOT YET RECOVERED

Note 1) EPS are adverse events classified under System Organ Class as "Centr & Periph Nervous System Disorders"

2) EPS classified under Preferred Term as "Agitation" "Akathesia" "Bradykinesia" "Dyskinesia Tardive" "Dystonia" "Extrapyramidal Disorder" "Hyperkinesia" "Hyperreflexia" "Hypertonia" "Hypokinesia" "Hypotonia" "Muscle Contractions Involuntary" "Oculogyric Crisis" "Parkinsonism" "Rigidity" "Shuffling Gait" "Stiffness" "Tics" or "Tremor" are included

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Table 30. Extrapyramidal Symptoms (EPS): Patient Data Listing (ITT Population) -(continued)

				Risperidone Dosing Period		Prolactin-related Side Effect								
Set	Patient ID	Flag	Gender	Start Date	End Date	Event	Preferred Term	Onset Date	End Date	Serious	Severity	Relationship	Action Taken	Outcome
3	A3538	PA	FEMALE	18JUN99	26MAY00	LEFT HAND SLIGHTLY RIGID POSTURE	HYPERTONIA	28FEB00	ONGOING	NO	MILD	NONE	NONE	NOT YET RECOVERED
						SLOWER IN DOING TASKS	HYPOKINESIA	28FEB00	ONGOING	NO	MILD	NONE	NONE	NOT YET RECOVERED
	A3621	PA	MALE	28FEB98	26FEB99	MILD STIFFNESS IN ARM	HYPERTONIA	22MAY98	19JUN98	NO	MILD	POSSIBLE	NONE	RECOVERED FROM THIS AE
	A3622	ITT	MALE	29MAY98	30APR99	RIGIDITY OF ALL LIMBS	HYPERTONIA	25JUN98	24JUL98	NO	MILD	POSSIBLE	NONE	RECOVERED FROM THIS AE
	A3650	PA	FEMALE	11DEC97	18NOV98	STIFF NECK	HYPERTONIA	31AUG98	01SEP98	NO	MODERATE	POSSIBLE	NONE	RECOVERED FROM THIS AE
						STIFFNESS	HYPERTONIA	12DEC97	17DEC97	NO	MILD	POSSIBLE	NONE	RECOVERED FROM THIS AE
								22DEC97	29DEC97	NO	MILD	DEFINITE	DOSE ADJUSTED	RECOVERED FROM THIS AE
								12APR98	12APR98	NO	MILD	DEFINITE	NONE	RECOVERED FROM THIS AE
	A3658	PA	MALE	15AUG98	14JUL99	FACE TWITCHING	MUSCLE CONTRACTIONS INVOLUNTARY	04SEP98	30SEP98	NO	MODERATE	POSSIBLE	NONE	RECOVERED FROM THIS AE
	A3659	PA	MALE	30JUL98	30JUN99	FACIAL TICS	MUSCLE CONTRACTIONS INVOLUNTARY	30AUG98	26FEB99	NO	MILD	NONE	NONE	RECOVERED FROM THIS AE
						HEAD TIC	MUSCLE CONTRACTIONS INVOLUNTARY	08AUG98	13AUG98	NO	MILD	POSSIBLE	NONE	RECOVERED FROM THIS AE

Note 1) EPS are adverse events classified under System Organ Class as "Centr & Periph Nervous System Disorders"

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Table 30. Extrapyramidal Symptoms (EPS): Patient Data Listing (ITT Population) -(continued)

				Risperidone Dosing Period		Prolactin-related Side Effect								
Set	Patient ID	Flag	Gender	Start Date	End Date	Event	Preferred Term	Onset Date	End Date	Serious	Severity	Relationship	Action Taken	Outcome
3	A3661	PA	MALE	14JAN99	15DEC99	MOUTH TIC	MUSCLE CONTRACTIONS INVOLUNTARY	06OCT99	24NOV99	NO	MILD	POSSIBLE	NONE	RECOVERED FROM THIS AE
	A3682	PA	MALE	12MAR99	11FEB00	CRAMP IN SIDE	MUSCLE CONTRACTIONS INVOLUNTARY	07DEC99	09DEC99	NO	MILD	NONE	NONE	RECOVERED FROM THIS AE
4	A3585	PA	MALE	12MAR99	03APR00	INCREASED HYPERACTIVITY AT HOME	HYPERKINESIA	15SEP99	15NOV99	NO	MILD	NONE	NONE	RECOVERED FROM THIS AE
5	A3602	PA	MALE	06APR99	20MAR00	RIGIDITY OF RIGHT UPPER LIMB	HYPERTONIA	03MAY99	28MAY99	NO	MILD	POSSIBLE	NONE	RECOVERED FROM THIS AE
						TREMOR OF R + L UPPER LIMBS	TREMOR	17SEP99	06DEC99	NO	MILD	POSSIBLE	NONE	RECOVERED FROM THIS AE
	A3710	PA	FEMALE	29JAN99	28JAN00	PHYSICAL SLOWNESS	HYPOKINESIA	10FEB99	16FEB99	NO	MILD	DOUBTFUL	NONE	RECOVERED FROM THIS AE
7	A3012	PA	MALE	27MAR98	04SEP98	MUSCLE STIFFNESS, LEG	HYPERTONIA	31JUL98	31JUL98	NO	MILD	NONE	NONE	RECOVERED FROM THIS AE
	A3042	ITT	MALE	21JUN97	25AUG98	HANDS SHAKING	TREMOR	02DEC97	02DEC97	NO	MILD	NONE	NONE	RECOVERED FROM THIS AE
	A3045	PA	MALE	03JUL97	25AUG98	HANDS SHAKING	TREMOR	01DEC97	01DEC97	NO	MILD	NONE	NONE	RECOVERED FROM THIS AE
	A3061	PA	MALE	01MAY97	05NOV97	EXTRAPYRAMIDAL SYMPTOMS	EXTRAPYRAMIDAL DISORDER	29OCT97	30OCT97	YES	SEVERE	DEFINITE	PERMANENT STOP	RECOVERED FROM THIS AE
	A3069	PA	MALE	13MAY98	26MAY99	TREMORS IN ARMS AND HANDS	TREMOR	15JUN98	16JUN98	NO	MILD	POSSIBLE	NONE	RECOVERED FROM THIS AE

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Table 30. Extrapyramidal Symptoms (EPS): Patient Data Listing (ITT Population) -(continued)

				Risperidone Dosing Period		Prolactin-related Side Effect								
Set	Patient ID	Flag	Gender	Start Date	End Date	Event	Preferred Term	Onset Date	End Date	Serious	Severity	Relationship	Action Taken	Outcome
7	A3086	PA	FEMALE	19AUG98	20JUL99	STIFFNESS RIGHT ARM	HYPERTONIA	11OCT98	11OCT98	NO	MILD	POSSIBLE	NONE	RECOVERED FROM THIS AE
						TREMOR (FINE, EPISODIC)	TREMOR	31AUG98	31AUG98	NO	MILD	POSSIBLE	NONE	RECOVERED FROM THIS AE
						TREMOR-FINE, EPISODIC HANDS & LEGS	TREMOR	25AUG98	27AUG98	NO	MILD	POSSIBLE	DOSE ADJUSTED	RECOVERED FROM THIS AE
	A3091	PA	MALE	19APR97	06MAY98	INCREASED INTERMITTENT TICS	MUSCLE CONTRACTIONS INVOLUNTARY	14JUN97	21AUG97	NO	MODERATE	POSSIBLE	DOSE ADJUSTED	RECOVERED FROM THIS AE
	A3097	PA	FEMALE	09APR98	30JUN98	OCULOMOTOR DYSKINESIA	OCULOGYRIC CRISIS	06JUN98	06JUN98	NO	MILD	DEFINITE	DOSE ADJUSTED	RECOVERED FROM THIS AE
								18JUN98	29JUN98	NO	MILD	DEFINITE	NONE	RECOVERED FROM THIS AE
	A3166	PA	MALE	13MAR98	21APR99	TICS OF EYE	MUSCLE CONTRACTIONS INVOLUNTARY	09OCT98	09OCT98	NO	MODERATE	POSSIBLE	NONE	RECOVERED FROM THIS AE
						TWITCHING	MUSCLE CONTRACTIONS INVOLUNTARY	07OCT98	07OCT98	NO	MODERATE	NONE	NONE	RECOVERED FROM THIS AE
						VOCAL TICS	MUSCLE CONTRACTIONS INVOLUNTARY	13JAN99	16JAN99	NO	MILD	NONE	NONE	RECOVERED FROM THIS AE
								09MAR99	10MAR99	NO	MILD	NONE	NONE	RECOVERED FROM THIS AE
	A3195	PA	MALE	20JUN98	30JUN99	STIFFNESS LEGS AND FEET	HYPERTONIA	18JAN99	25JAN99	NO	MILD	POSSIBLE	NONE	RECOVERED FROM THIS AE

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Table 30. Extrapyramidal Symptoms (EPS): Patient Data Listing (ITT Population) -(continued)

				Risperidone Dosing Period		Prolactin-related Side Effect								
Set	Patient ID	Flag	Gender	Start Date	End Date	Event	Preferred Term	Onset Date	End Date	Serious	Severity	Relationship	Action Taken	Outcome
7	A3195	PA	MALE	20JUN98	30JUN99	STIFFNESS-MUSCLE	HYPERTONIA	18AUG98	18AUG98	NO	MILD	POSSIBLE	NONE	RECOVERED FROM THIS AE
						TREMOR-MUSCLE	TREMOR	14AUG98	14AUG98	NO	MILD	POSSIBLE	NONE	RECOVERED FROM THIS AE
8	A3009	ITT	MALE	26NOV97	02DEC97	DYSTONIC REACTION	DYSTONIA	27NOV97	28NOV97	NO	MODERATE	POSSIBLE	PERMANENT STOP	RECOVERED FROM THIS AE
	A3066	PA	MALE	04MAR98	08FEB99	ATAXIC TREMOR RIGHT FOOT	TREMOR	28MAR98	29MAR98	NO	MILD	POSSIBLE	NONE	RECOVERED FROM THIS AE
						INTENTIONAL TREMOR	TREMOR	21OCT98	01DEC98	NO	MILD	NONE	NONE	RECOVERED FROM THIS AE
	A3081	PA	MALE	06AUG98	12JUL99	TREMOR-BOTH HANDS	TREMOR	15JAN99	16JAN99	NO	MILD	POSSIBLE	NONE	RECOVERED FROM THIS AE
	A3084	PA	MALE	12SEP98	21DEC98	TICS NECK, EYE & LIP	MUSCLE CONTRACTIONS INVOLUNTARY	21NOV98	21DEC98	NO	MILD	POSSIBLE	NONE	RECOVERED FROM THIS AE
	A3093	PA	FEMALE	12JUL97	11JUN98	OCCASIONAL STIFFNESS	HYPERTONIA	26JUL97	25MAY98	NO	MILD	POSSIBLE	NONE	RECOVERED FROM THIS AE
	A3164	PA	MALE	26AUG98	05OCT98	TREMORS	TREMOR	16SEP98	16SEP98	NO	MILD	POSSIBLE	DOSE ADJUSTED	RECOVERED FROM THIS AE
	A3200	PA	MALE	02OCT98	23FEB99	STIFF LEG	HYPERTONIA	22OCT98	22OCT98	NO	MILD	NONE	NONE	RECOVERED FROM THIS AE
9	A03002	PA	MALE	13FEB98	12FEB99	EPS	EXTRAPYRAMIDAL DISORDER	15JUL98	16JUL98	NO	MODERATE	VERY LIKELY	TEMPORARY STOP	RECOVERED FROM THIS AE
	A03004	PA	MALE	21SEP97	09OCT98	DYSTONIA	DYSTONIA	09MAY98	20AUG98	NO	MODERATE	PROBABLE	NONE	RECOVERED FROM THIS AE

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Table 30. Extrapyramidal Symptoms (EPS): Patient Data Listing (ITT Population) -(continued)

Set	Patient ID	Flag	Gender	Risperidone Dosing Period Start Date	Risperidone Dosing Period End Date	Prolactin-related Side Effect Event	Preferred Term	Onset Date	End Date	Serious	Severity	Relationship	Action Taken	Outcome
9	A03004	PA	MALE	21SEP97	09OCT98	DYSTONIA	DYSTONIA	20AUG98	ONGOING	NO	MILD	PROBABLE	NONE	NOT YET RECOVERED
						DYSTONIA (EPS)	DYSTONIA	25NOV97	08MAY98	NO	MILD	PROBABLE	NONE	RECOVERED FROM THIS AE
						PARKINSOMISME	EXTRAPYRAMIDAL DISORDER	20AUG98	ONGOING	NO	MILD	PROBABLE	NONE	NOT YET RECOVERED
						PARKINSONISME	EXTRAPYRAMIDAL DISORDER	09MAY98	20AUG98	NO	MODERATE	PROBABLE	NONE	RECOVERED FROM THIS AE
	A03006	PA	MALE	13FEB98	12MAR99	EPS (CHRON.DYSTONIA UPPER LIMBS)	EXTRAPYRAMIDAL DISORDER	15MAY98	21JUL98	NO	MILD	PROBABLE	NONE	RECOVERED FROM THIS AE
	A03096	PA	MALE	23JUN98	21JUN99	DYSTONIA OF MEMBERS	DYSTONIA	15JUL98	25AUG98	NO	MILD	PROBABLE	NONE	RECOVERED FROM THIS AE
	A03106	PA	MALE	14JAN00	10JAN01	FROWN EYEBROW	MUSCLE CONTRACTIONS INVOLUNTARY	01APR00	02MAY00	NO	MILD	PROBABLE	NONE	RECOVERED FROM THIS AE
						WINKING LEFT EYELID	MUSCLE CONTRACTIONS INVOLUNTARY	03MAY00	08JUN00	NO	MODERATE	PROBABLE	NONE	RECOVERED FROM THIS AE
								09JUN00	10JUL00	NO	SEVERE	PROBABLE	NONE	RECOVERED FROM THIS AE
								11JUL00	04OCT00	NO	MILD	PROBABLE	NONE	RECOVERED FROM THIS AE
	A03181	PA	MALE	01APR98	16MAR99	BLINKING	MUSCLE CONTRACTIONS INVOLUNTARY	22JUL98	14DEC98	NO	MILD	PROBABLE	NONE	RECOVERED FROM THIS AE
						EXTRAPYRAMIDAL SYMPTOM	EXTRAPYRAMIDAL DISORDER	01APR98	08APR98	NO	MILD	NONE	NONE	RECOVERED FROM THIS AE

Note 1) EPS are adverse events classified under System Organ Class as "Centr & Periph Nervous System Disorders"

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Table 30. Extrapyramidal Symptoms (EPS): Patient Data Listing (ITT Population) -(continued)

				Risperidone Dosing Period		Prolactin-related Side Effect								
Set	Patient ID	Flag	Gender	Start Date	End Date	Event	Preferred Term	Onset Date	End Date	Serious	Severity	Relationship	Action Taken	Outcome
9	A03181	PA	MALE	01APR98	16MAR99	EXTRAPYRAMIDAL SYMPTOM	EXTRAPYRAMIDAL DISORDER	15APR98	22APR98	NO	MILD	DOUBTFUL	NONE	RECOVERED FROM THIS AE
						MOTORS TICS	MUSCLE CONTRACTIONS INVOLUNTARY	22JUL98	14DEC98	NO	MODERATE	DOUBTFUL	NONE	RECOVERED FROM THIS AE
						VOCALS TICS	MUSCLE CONTRACTIONS INVOLUNTARY	25FEB99	ONGOING	NO	MILD	POSSIBLE	NONE	NOT YET RECOVERED
	A03182	PA	MALE	08APR98	06APR99	BRADYKINESIA	BRADYKINESIA	17APR98	29APR98	NO	MILD	PROBABLE	DOSE ADJUSTED	RECOVERED FROM THIS AE
						MILD DECREASE OF PENDULAR ARM MOV	HYPOKINESIA	02SEP98	05OCT98	NO	MILD	PROBABLE	NONE	RECOVERED FROM THIS AE
						RIGIDITY RIGHT UPPER LIMB	HYPERTONIA	05OCT98	04JAN99	NO	MILD	PROBABLE	NONE	RECOVERED FROM THIS AE
	A03183	PA	FEMALE	06MAY98	21APR99	RIGIDITY LEFT UPPER LIMB	HYPERTONIA	20JAN99	21APR99	NO	MILD	PROBABLE	NONE	RECOVERED FROM THIS AE
	A03184	PA	MALE	22JUL98	14JUL99	AKATHISIA	HYPERKINESIA	22JUL98	28JUL98	NO	MILD	NONE	NONE	RECOVERED FROM THIS AE
						BRADYKINESIA	BRADYKINESIA	05AUG98	19AUG98	NO	MILD	PROBABLE	NONE	RECOVERED FROM THIS AE
								18NOV98	18DEC98	NO	MILD	PROBABLE	NONE	RECOVERED FROM THIS AE
								14JUL99	ONGOING	NO	MILD	PROBABLE	NONE	NOT YET RECOVERED
						SLOWNESS	HYPOKINESIA	29JUL98	18AUG98	NO	MILD	VERY LIKELY	NONE	RECOVERED FROM THIS AE
								18NOV98	18DEC98	NO	MILD	PROBABLE	NONE	RECOVERED FROM THIS AE

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Table 30. Extrapyramidal Symptoms (EPS): Patient Data Listing (ITT Population) -(continued)

Set	Patient ID	Flag	Gender	Risperidone Dosing Period Start Date	Risperidone Dosing Period End Date	Prolactin-related Side Effect: Event	Preferred Term	Onset Date	End Date	Serious	Severity	Relationship	Action Taken	Outcome
9	A03192	PA	MALE	23FEB00	21FEB01	HAND TREMOR	TREMOR	27FEB00	15MAR00	NO	MILD	PROBABLE	NONE	RECOVERED FROM THIS AE
	A03193	PA	MALE	18MAR98	17MAR99	GENERALIZED TREMOR (FOR 15')	TREMOR	28MAR98	28MAR98	NO	MILD	POSSIBLE	NONE	RECOVERED FROM THIS AE
	A03197	PA	MALE	18APR00	10MAY01	HYPOTONIA	HYPOTONIA	18APR01	09MAY01	NO	MILD	POSSIBLE	NONE	RECOVERED FROM THIS AE
	A03208	PA	MALE	16JUL97	23OCT97	EXTRAPYRAMIDAL SIDE EFFECTS	EXTRAPYRAMIDAL DISORDER	30JUL97	30JUL97	NO	MILD	POSSIBLE	NONE	RECOVERED FROM THIS AE
	A03212	PA	FEMALE	17NOV97	23DEC97	PAIN IN RIGHT ARM, ARM STIFF	HYPERTONIA	30NOV97	01DEC97	NO	MILD	NONE	NONE	RECOVERED FROM THIS AE
						STIFF MUSCLES	HYPERTONIA	15DEC97	19DEC97	YES	MILD	DOUBTFUL	PERMANENT STOP	RECOVERED FROM THIS AE
						STIFF POSTURE	HYPERTONIA	22DEC97	23DEC97	NO	MILD	DOUBTFUL	NONE	RECOVERED FROM THIS AE
	A03225	PA	MALE	12SEP97	26AUG98	? PARKINSONISM	EXTRAPYRAMIDAL DISORDER	04DEC97	ONGOING	NO	MILD	PROBABLE	DOSE ADJUSTED	NOT YET RECOVERED
	A03228	PA	MALE	23JAN98	28JAN99	AKATHISIA	HYPERKINESIA	14MAY98	12MAR99	NO	MILD	VERY LIKELY	DOSE ADJUSTED	RECOVERED FROM THIS AE
						MILD PARKINSONISM	EXTRAPYRAMIDAL DISORDER	29JAN98	ONGOING	NO	MILD	VERY LIKELY	NONE	NOT YET RECOVERED
	A03229	PA	MALE	06MAR98	08JAN99	BILATERAL MILD STIFFNESS	HYPERTONIA	06AUG98	03SEP98	NO	MILD	PROBABLE	DOSE ADJUSTED	RECOVERED FROM THIS AE
						R SIDED MILD PARKINSONISM	EXTRAPYRAMIDAL DISORDER	30APR98	08JAN99	NO	MILD	VERY LIKELY	NONE	RECOVERED FROM THIS AE

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Table 30. Extrapyramidal Symptoms (EPS): Patient Data Listing (ITT Population) -(continued)

Set	Patient ID	Flag	Gender	Risperidone Dosing Period Start Date	Risperidone Dosing Period End Date	Prolactin-related Side Effect Event	Preferred Term	Onset Date	End Date	Serious	Severity	Relationship	Action Taken	Outcome
9	A03229	PA	MALE	06MAR98	08JAN99	SPASMS IN ARMS	DYSTONIA	27JUN98	29JUN98	NO	MILD	POSSIBLE	NONE	RECOVERED FROM THIS AE
								23JUL98	20AUG98	NO	MILD	POSSIBLE	DOSE ADJUSTED	RECOVERED FROM THIS AE
	A03230	PA	FEMALE	19MAR98	08APR99	PARKINSONISM	EXTRAPYRAMIDAL DISORDER	27MAY98	01OCT98	NO	MILD	VERY LIKELY	NONE	RECOVERED FROM THIS AE
	A03231	PA	MALE	27MAR98	25MAR99	ACUTE TORSION DYSTONIA	DYSTONIA	17APR98	28MAY98	NO	MILD	VERY LIKELY	DOSE ADJUSTED	RECOVERED FROM THIS AE
						SLIGHT PARKINSONISM	EXTRAPYRAMIDAL DISORDER	16APR98	ONGOING	NO	MILD	VERY LIKELY	DOSE ADJUSTED	NOT YET RECOVERED
	A03232	PA	MALE	07SEP98	21SEP99	?; AKATHISIA	HYPERKINESIA	17DEC98	ONGOING	NO	MODERATE	PROBABLE	DOSE ADJUSTED	NOT YET RECOVERED
	A03233	PA	FEMALE	02OCT98	12OCT99	PARKINSONISM	EXTRAPYRAMIDAL DISORDER	09OCT98	ONGOING	NO	MILD	VERY LIKELY	NONE	NOT YET RECOVERED
						TARDIVE DYSKINESIA (RESTLESS LEGS)	DYSKINESIA TARDIVE	01AUG99	20DEC99	YES	SEVERE	VERY LIKELY	PERMANENT STOP	RECOVERED FROM THIS AE
	A03251	PA	MALE	10MAR98	22FEB99	EYEBALLS TURNING UP	OCULOGYRIC CRISIS	01JUN98	01JUN98	NO	MILD	PROBABLE	DOSE ADJUSTED	RECOVERED FROM THIS AE
						EYES PULLED UPWARDS	OCULOGYRIC CRISIS	11JUN98	11JUN98	NO	MODERATE	VERY LIKELY	DOSE ADJUSTED	RECOVERED FROM THIS AE
						EYES PULLING UP, SIDEWAYS DOWNWARDS	OCULOGYRIC CRISIS	08JUN98	08JUN98	NO	MODERATE	POSSIBLE	DOSE ADJUSTED	RECOVERED FROM THIS AE
	A03255	PA	MALE	13OCT98	21SEP99	TREMOR	TREMOR	03NOV98	30NOV98	NO	MILD	POSSIBLE	NONE	RECOVERED FROM THIS AE

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Table 30. Extrapyramidal Symptoms (EPS): Patient Data Listing (ITT Population) -(continued)

Set	Patient ID	Flag	Gender	Risperidone Dosing Period Start Date	Risperidone Dosing Period End Date	Prolactin-related Side Effect Event	Preferred Term	Onset Date	End Date	Serious	Severity	Relationship	Action Taken	Outcome
9	A03255	PA	MALE	13OCT98	21SEP99	TREMOR OF LEFT HAND	TREMOR	29JUN99	30SEP99	NO	MILD	POSSIBLE	NONE	RECOVERED FROM THIS AE
	A03259	PA	MALE	13APR99	18APR00	TREMOR (HAND)	TREMOR	26APR99	26APR99	NO	MILD	POSSIBLE	NONE	RECOVERED FROM THIS AE
	A03262	PA	MALE	02FEB99	07MAR00	AKATHISIA	HYPERKINESIA	20APR99	18MAY99	NO	MILD	DOUBTFUL	NONE	RECOVERED FROM THIS AE
	A03265	ITT	MALE	29JUL97	06JUL98	HAND TREMOR	TREMOR	29JUL97	05AUG97	NO	MILD	NONE	NONE	RECOVERED FROM THIS AE
	A03266	PA	MALE	15OCT97	22SEP98	STIFF LEG	HYPERTONIA	09DEC97	09DEC97	NO	MILD	DOUBTFUL	NONE	RECOVERED FROM THIS AE
	A03278	PA	MALE	14NOV97	16APR98	LIP TREMOR	TREMOR	04DEC97	11DEC97	NO	MILD	POSSIBLE	NONE	RECOVERED FROM THIS AE
						TARDIVE DYSKINESIA	DYSKINESIA TARDIVE	26MAR98	02APR98	NO	MILD	VERY LIKELY	PERMANENT STOP	RECOVERED FROM THIS AE
								02APR98	30APR98	YES	MODERATE	VERY LIKELY	NONE	RECOVERED FROM THIS AE
	A03279	PA	MALE	05DEC97	03DEC98	PARKINSONISM	EXTRAPYRAMIDAL DISORDER	14MAY98	ONGOING	NO	MILD	PROBABLE	NONE	NOT YET RECOVERED
	A03284	PA	MALE	06AUG99	19JAN00	MILD TREMOR	TREMOR	15AUG99	ONGOING	NO	MILD	DOUBTFUL	NONE	NOT YET RECOVERED
	A03285	PA	MALE	27FEB98	04MAR99	MILD PARKINSONISM	EXTRAPYRAMIDAL DISORDER	26MAR98	ONGOING	NO	MILD	VERY LIKELY	NONE	NOT YET RECOVERED
	A03288	PA	MALE	12JUN98	26NOV98	PARKINSONISM	EXTRAPYRAMIDAL DISORDER	18JUN98	01OCT98	NO	MILD	VERY LIKELY	NONE	RECOVERED FROM THIS AE
	A03290	PA	MALE	23OCT98	21OCT99	PARKINSONISM	EXTRAPYRAMIDAL DISORDER	04JUN99	23JUL99	NO	MILD	VERY LIKELY	DOSE ADJUSTED	RECOVERED FROM THIS AE

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2) EPS classified under Preferred Term as "Agitation" "Akathesia" "Bradykinesia" "Dyskinesia Tardive" "Dystonia" "Extrapyramidal Disorder" "Hyperkinesia" "Hyperreflexia" "Hypertonia" "Hypokinesia" "Hypotonia" "Muscle Contractions Involuntary" "Oculogyric Crisis" "Parkinsonism" "Rigidity" "Shuffling Gait" "Stiffness" "Tics" or "Tremor" are included

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Table 30. Extrapyramidal Symptoms (EPS): Patient Data Listing (ITT Population) -(continued)

Set	Patient ID	Flag	Gender	Risperidone Dosing Period Start Date	Risperidone Dosing Period End Date	Prolactin-related Side Effect Event	Preferred Term	Onset Date	End Date	Serious	Severity	Relationship	Action Taken	Outcome
9	AD3295	PA	FEMALE	27MAY97	04JUN98	INCREASED GRIMACING	MUSCLE CONTRACTIONS INVOLUNTARY	01JUL97	04JUN98	NO	MILD	DDUBTFUL	NDNE	RECOVERED FROM THIS AE
	A03297	ITT	MALE	02JUL97	06JUL98	TICS OF THE FACE AND THE NECK	MUSCLE CONTRACTIONS INVOLUNTARY	17JUL97	17JUL97	NO	MILD	DOUBTFUL	NONE	RECOVERED FROM THIS AE
								14AUG97	06JUL98	NO	MILD	DOUBTFUL	DOSE ADJUSTED	RECOVERED FROM THIS AE
	A03300	PA	FEMALE	04DEC97	27NOV98	TREMOR	TREMOR	24MAY98	24MAY98	NO	MILD	DOUBTFUL	NONE	RECOVERED FROM THIS AE
	AD3303	PA	FEMALE	29JAN98	06DEC98	FIXED MIMIC	EXTRAPYRAMIDAL DISORDER	10FEB98	26FEB98	NO	MODERATE	POSSIBLE	DOSE ADJUSTED	RECOVERED FRDM THIS AE
	A033D4	PA	MALE	13MAR98	09MAR99	EPS	EXTRAPYRAMIDAL DISORDER	14MAR98	14MAR98	YES	SEVERE	VERY LIKELY	NONE	RECOVERED FROM THIS AE
	A03305	PA	MALE	18MAR98	17MAR99	BRADYKINESIA "SCORE 1-2"	BRADYKINESIA	02SEP98	ONGOING	NO	MILD	POSSIBLE	NONE	NOT YET RECOVERED
						EXPRESSIVE AUTOMATIC MOVEMENTS "SCORE 3"	EXTRAPYRAMIDAL DISORDER	02SEP98	ONGOING	NO	MODERATE	POSSIBLE	NONE	NOT YET RECOVERED
	A03309	PA	MALE	23OCT99	27OCT00	AKATHISIA (SLIGHT)	HYPERKINESIA	04NOV99	10NOV99	NO	MODERATE	POSSIBLE	NONE	RECOVERED FROM THIS AE
	A03311	PA	MALE	16MAR98	18MAY98	DEFI, SLOWNESS IN MOVEMENTS	HYPOKINESIA	20APR98	ONGOING	NO	MODERATE	VERY LIKELY	PERMANENT STOP	NOT YET RECOVERED
						MILD DECREASE IN FACIAL EXPRESS	EXTRAPYRAMIDAL DISORDER	20APR98	ONGOING	NO	MILD	VERY LIKELY	PERMANENT STOP	NOT YET RECOVERED

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Table 30. Extrapyramidal Symptoms (EPS): Patient Data Listing (ITT Population) -(continued)

Set	Patient ID	Flag	Gender	Risperidone Dosing Period Start Date	Risperidone Dosing Period End Date	Prolactin-related Side Effect Event	Preferred Term	Onset Date	End Date	Serious	Severity	Relationship	Action Taken	Outcome
9	A03311	PA	MALE	16MAR98	18MAY98	MILD DECREASE OF PEND. ARM MOVEMENT	HYPOKINESIA	20APR98	ONGOING	NO	MILD	VERY LIKELY	PERMANENT STOP	NOT YET RECOVERED
						MILD RIGIDITY RIGHT/LEFT LOWER LIMB	HYPERTONIA	20APR98	ONGOING	NO	MODERATE	VERY LIKELY	PERMANENT STOP	NOT YET RECOVERED
						MILD RIGIDITY RIGHT/LEFT UPP. LIMB	HYPERTONIA	20APR98	ONGOING	NO	MODERATE	VERY LIKELY	PERMANENT STOP	NOT YET RECOVERED
	A03314	PA	MALE	01JUL98	12JAN99	BRADYKINESIA	BRADYKINESIA	27AUG98	09SEP98	NO	MILD	VERY LIKELY	DOSE ADJUSTED	RECOVERED FROM THIS AE
						RIGIDITY	HYPERTONIA	27AUG98	09SEP98	NO	MILD	VERY LIKELY	DOSE ADJUSTED	RECOVERED FROM THIS AE
	A03315	PA	MALE	13FEB98	18DEC98	STIFFNESS IN LEGS AND ARMS DURING THE DAY BUT LESS INTENSITY	HYPERTONIA	30OCT98	02DEC98	NO	MILD	NONE	NONE	RECOVERED FROM THIS AE
						STIFFNESS IN LEGS AND ARMS ESPECIALLY IN THE EVENING	HYPERTONIA	15SEP98	29SEP98	NO	MILD	PROBABLE	DOSE ADJUSTED	RECOVERED FROM THIS AE
	A03317	PA	FEMALE	03NOV98	09DEC99	AKATHISIE	HYPERKINESIA	08NOV98	07JAN99	NO	MODERATE	NONE	NONE	RECOVERED FROM THIS AE
								11MAY99	16AUG99	NO	MILD	NONE	NONE	RECOVERED FROM THIS AE
						RIGIDITY RIGHT/LEFT LOWER LIMB	HYPERTONIA	08NOV98	07JAN99	NO	MILD	NONE	NONE	RECOVERED FROM THIS AE

Note 1) EPS are adverse events classified under System Organ Class as "Centr & Periph Nervous System Disorders"

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Table 30. Extrapyramidal Symptoms (EPS): Patient Data Listing (ITT Population) -(continued)

				Risperidone Dosing Period		Prolactin-related Side Effect								
Set	Patient ID	Flag	Gender	Start Date	End Date	Event	Preferred Term	Onset Date	End Date	Serious	Severity	Relationship	Action Taken	Outcome
9	A03317	PA	FEMALE	03NOV98	09DEC99	RIGIDITY RIGHT/LEFT LOWER LIMB	HYPERTONIA	09FEB99	12APR99	NO	MILD	NONE	NONE	RECOVERED FROM THIS AE
						RIGIDITY RIGHT/LEFT UPPER LIMB	HYPERTONIA	19NOV98	30NOV98	NO	MILD	NONE	NONE	RECOVERED FROM THIS AE
						TREMOR RIGHT/LEFT UPPER LIMB	TREMOR	09DEC99	ONGOING	NO	MODERATE	NONE	NONE	NOT YET RECOVERED
	A03319	PA	MALE	31MAR99	06SEP99	STIFFNESS OF UPPER LEGS AND PAIN ,CHILD HITS AT UPPER LEGS	HYPERTONIA	07JUN99	ONGOING	NO	MILD	VERY LIKELY	NONE	NOT YET RECOVERED
	A03322	PA	MALE	09DEC98	07DEC99	LIGHT BRADYKINESIA	BRADYKINESIA	06MAY99	07JUN99	NO	MILD	POSSIBLE	NONE	RECOVERED FROM THIS AE
						LITTLE DECREASE OF MIMIC	EXTRAPYRAMIDAL DISORDER	06MAY99	07JUN99	NO	MILD	POSSIBLE	NONE	RECOVERED FROM THIS AE
						PATIENT TOLD ABOUT FEELING OF SLOWLINESS	HYPOKINESIA	09MAR99	07DEC99	NO	MILD	POSSIBLE	NONE	RECOVERED FROM THIS AE
						PATIENT TOLD ABOUT FEELING OF SLOWLINESS TREMOR AND INCREASED SALIVATION	HYPOKINESIA	08FEB99	09MAR99	NO	MILD	POSSIBLE	NONE	RECOVERED FROM THIS AE
						PATIENT TOLD ABOUT SHAKING AND TREMOR	TREMOR	06SEP99	06SEP99	NO	MILD	POSSIBLE	NONE	RECOVERED FROM THIS AE

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Table 30. Extrapyramidal Symptoms (EPS): Patient Data Listing (ITT Population) -(continued)

				Risperidone Dosing Period		Prolactin-related Side Effect								
Set	Patient ID	Flag	Gender	Start Date	End Date	Event	Preferred Term	Onset Date	End Date	Serious	Severity	Relationship	Action Taken	Outcome
9	A03322	PA	MALE	09DEC98	07DEC99	PATIENT TOLD ABOUT SHAKING AND TREMOR	TREMOR	07DEC99	07DEC99	NO	MILD	POSSIBLE	NONE	RECOVERED FROM THIS AE
						TREMOR	TREMOR	30DEC98	07JAN99	NO	MILD	POSSIBLE	NONE	RECOVERED FROM THIS AE
	A03325	PA	MALE	11OCT99	09OCT00	RESLESSNESS (PATIENT TOLD ABOUT)	HYPERKINESIA	11OCT99	08NOV99	NO	MILD	DOUBTFUL	NONE	RECOVERED FROM THIS AE
						RESTLESSNESS (PATIENT REPORTED)	HYPERKINESIA	12APR00	ONGOING	NO	MILD	NONE	NONE	NOT YET RECOVERED
	A03330	PA	MALE	20MAY98	21APR99	AKINESIA	HYPOKINESIA	20MAY98	20MAY98	YES	MODERATE	VERY LIKELY	NONE	RECOVERED FROM THIS AE
	A03331	PA	MALE	31JUL98	14JUL99	TREMORS RIGHT/LEFT UPPER LIMB	TREMOR	26JAN99	20APR99	NO	MILD	POSSIBLE	NONE	RECOVERED FROM THIS AE
	A03335	PA	MALE	08FEB00	01FEB01	IMPRESSION OF SLOWNESS	HYPOKINESIA	07SEP00	06NOV00	NO	MODERATE	DOUBTFUL	DOSE ADJUSTED	RECOVERED FROM THIS AE
						TREMORS	TREMOR	27FEB00	08MAR00	NO	MILD	DOUBTFUL	NONE	RECOVERED FROM THIS AE
						TREMORS LEFT ARM AND LEG	TREMOR	03AUG00	06NOV00	NO	MILD	DOUBTFUL	NONE	RECOVERED FROM THIS AE
	A03336	PA	MALE	13AUG99	14AUG00	IMPRESSION OF SLOWNESS	HYPOKINESIA	07SEP99	10OCT99	NO	MILD	NONE	NONE	RECOVERED FROM THIS AE
						RESLESS	HYPERKINESIA	14AUG00	ONGOING	NO	MILD	NONE	NONE	NOT YET RECOVERED

Note 1) EPS are adverse events classified under System Organ Class as "Centr & Periph Nervous System Disorders"

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Table 30. Extrapyramidal Symptoms (EPS): Patient Data Listing (ITT Population) -(continued)

				Risperidone Dosing Period		Prolactin-related Side Effect								
Set	Patient ID	Flag	Gender	Start Date	End Date	Event	Preferred Term	Onset Date	End Date	Serious	Severity	Relationship	Action Taken	Outcome
9	A03336	PA	MALE	13AUG99	14AUG00	STIFFNESS	HYPERTONIA	07SEP99	10OCT99	NO	MILD	NONE	NONE	RECOVERED FROM THIS AE
	A03338	PA	MALE	12MAY99	09MAY00	BRADYKINESIA	BRADYKINESIA	13JUL99	10AUG99	NO	MILD	DOUBTFUL	NONE	RECOVERED FROM THIS AE
								07SEP99	18OCT99	NO	MILD	DOUBTFUL	NONE	RECOVERED FROM THIS AE
						IMPRESSION OF SLOWNESS	HYPOKINESIA	01JUN99	18OCT99	NO	MILD	DOUBTFUL	NONE	RECOVERED FROM THIS AE
						STIFFNESS (SLIGHT)	HYPERTONIA	01JUN99	10JUN99	NO	MILD	DOUBTFUL	NONE	RECOVERED FROM THIS AE
	A03350	PA	MALE	20SEP99	21AUG00	SLOWNESS	HYPOKINESIA	04OCT99	11OCT99	NO	MILD	DOUBTFUL	NONE	RECOVERED FROM THIS AE
	A03351	PA	FEMALE	18MAY99	02NOV99	SLOWINESS	HYPOKINESIA	28MAY99	06JUN99	NO	MILD	DOUBTFUL	NONE	RECOVERED FROM THIS AE
	A03354	PA	MALE	16DEC99	18DEC00	RESTLESSNESS (PATIENT REPORTED)	HYPERKINESIA	11MAY00	07JUN00	NO	MILD	NONE	NONE	RECOVERED FROM THIS AE
						RESTLESSNESS IN THE MORNING	HYPERKINESIA	14MAR00	10APR00	NO	MODERATE	NONE	DOSE ADJUSTED	RECOVERED FROM THIS AE
	A03361	ITT	MALE	04FEB00	19JAN01	SLIGHT FINE-MOTOR TREMOR OVER THE WHOLE BODY	TREMOR	30OCT00	ONGOING	NO	MILD	POSSIBLE	NONE	NOT YET RECOVERED
	A03367	PA	MALE	27DEC99	16FEB01	TIC	MUSCLE CONTRACTIONS INVOLUNTARY	19MAY00	19OCT00	NO	MILD	NONE	NONE	RECOVERED FROM THIS AE
								20OCT00	ONGOING	NO	MODERATE	NONE	NONE	NOT YET RECOVERED

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Table 30. Extrapyramidal Symptoms (EPS): Patient Data Listing (ITT Population) -(continued)

Set	Patient ID	Flag	Gender	Risperidone Dosing Period Start Date	Risperidone Dosing Period End Date	Prolactin-related Side Effect Event	Preferred Term	Onset Date	End Date	Serious	Severity	Relationship	Action Taken	Outcome
9	A03367	PA	MALE	27DEC99	16FEB01	TIC(SEE MEDICAL HISTORY)	MUSCLE CONTRACTIONS INVOLUNTARY	03MAR00	18MAY00	NO	MODERATE	NONE	NONE	RECOVERED FROM THIS AE
	A03385	PA	MALE	07APR00	10APR01	FEELING OF SLOWNESS	BRADYKINESIA	09APR00	14APR00	NO	MILD	VERY LIKELY	NONE	RECOVERED FROM THIS AE
						MORE TICS	MUSCLE CONTRACTIONS INVOLUNTARY	09APR00	20MAY00	NO	MODERATE	DOUBTFUL	NONE	RECOVERED FROM THIS AE
								30SEP00	15JAN01	NO	MILD	DOUBTFUL	NONE	RECOVERED FROM THIS AE
	A03396	PA	MALE	17DEC98	17DEC99	IMPRESSION OF SLOWNESS	HYPOKINESIA	30DEC98	15JAN99	NO	MILD	POSSIBLE	DOSE ADJUSTED	RECOVERED FROM THIS AE
	A03411	PA	MALE	21OCT98	15OCT99	MYOCLONUS (RIGHT SHOULDER)	MUSCLE CONTRACTIONS INVOLUNTARY	17FEB99	31MAY99	NO	MILD	POSSIBLE	NONE	RECOVERED FROM THIS AE
						MYOCLONUS - LIKE MOVEMENT OF RIGHT SHOULDER	MUSCLE CONTRACTIONS INVOLUNTARY	22SEP99	ONGOING	NO	MILD	DOUBTFUL	NONE	NOT YET RECOVERED
	A03416	PA	MALE	11FEB99	09FEB00	AKATHISIA	HYPERKINESIA	07APR99	06MAY99	NO	MILD	POSSIBLE	DOSE ADJUSTED	RECOVERED FROM THIS AE
	A03425	PA	MALE	23OCT98	13OCT99	HOSPITALISATION TO TREAT THE KNEE RIGIDITY	HYPERTONIA	23NOV98	ONGOING	YES	MODERATE	NONE	NONE	NOT YET RECOVERED
	A03432	PA	FEMALE	18JUN99	20JUN00	ACUT DYSTONIA	DYSTONIA	08SEP99	08SEP99	YES	MODERATE	VERY LIKELY	TEMPORARY STOP	RECOVERED FROM THIS AE
	A03437	PA	MALE	21DEC98	15DEC99	AKATHISIA	HYPERKINESIA	19MAR99	17APR99	NO	MODERATE	POSSIBLE	DOSE ADJUSTED	RECOVERED FROM THIS AE

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Table 30. Extrapyramidal Symptoms (EPS): Patient Data Listing (ITT Population) -(continued)

Set	Patient ID	Flag	Gender	Risperidone Dosing Period Start Date	Risperidone Dosing Period End Date	Prolactin-related Side Effect: Event	Preferred Term	Onset Date	End Date	Serious	Severity	Relationship	Action Taken	Outcome
9	A03437	PA	MALE	21DEC98	15DEC99	BRADYKINESIA	BRADYKINESIA	18JAN99	21JAN99	NO	MILD	POSSIBLE	DOSE ADJUSTED	RECOVERED FROM THIS AE
						SUSPESSION OF SLOWNESS	BRADYKINESIA	18JAN99	21JAN99	NO	MILD	PROBABLE	DOSE ADJUSTED	RECOVERED FROM THIS AE
	A03447	ITT	MALE	07JUL99	13JUL00	TREMORS	TREMOR	03DEC99	ONGOING	NO	MILD	POSSIBLE	NONE	NOT YET RECOVERED
	A03466	PA	MALE	11NOV98	08NOV99	BRADYKINESIA	BRADYKINESIA	13JAN99	20JAN99	NO	MILD	POSSIBLE	DOSE ADJUSTED	RECOVERED FROM THIS AE
	A03475	PA	MALE	16DEC98	08DEC99	BRADYKINESIA	BRADYKINESIA	30DEC98	05JAN99	NO	MILD	POSSIBLE	NONE	RECOVERED FROM THIS AE
	A03482	PA	FEMALE	12JAN99	25JAN00	ESRS TRANSIENTLY INCREASED	EXTRAPYRAMIDAL DISORDER	02FEB99	08FEB99	NO	MILD	VERY LIKELY	DOSE ADJUSTED	RECOVERED FROM THIS AE
	A03487	PA	MALE	21SEP98	28SEP99	HYPERK.	HYPERKINESIA	06APR99	29JUN99	NO	MODERATE	DOUBTFUL	NONE	RECOVERED FROM THIS AE
	A03489	PA	MALE	16SEP98	28SEP99	+ ESRS (MILD)	EXTRAPYRAMIDAL DISORDER	29JAN99	01MAR99	NO	MILD	PROBABLE	DOSE ADJUSTED	RECOVERED FROM THIS AE
						RIGIDITY	HYPERTONIA	29JAN99	01MAR99	NO	MILD	PROBABLE	DOSE ADJUSTED	RECOVERED FROM THIS AE
	A03490	PA	MALE	28JAN99	20JAN00	HYPOMIMIC	EXTRAPYRAMIDAL DISORDER	24JUN99	01AUG99	NO	MILD	VERY LIKELY	NONE	RECOVERED FROM THIS AE
	A03497	PA	MALE	07DEC98	02DEC99	IMPRESSION OF SLOWNESS IN MOVEMENTS	HYPOKINESIA	01JUN99	01JUN99	NO	MILD	VERY LIKELY	NONE	RECOVERED FROM THIS AE
	A03517	PA	FEMALE	27APR99	10APR00	HYPOMIMIA, BORDERLINE RIGIDITY	EXTRAPYRAMIDAL DISORDER	25MAY99	17JUL99	NO	MILD	VERY LIKELY	NONE	RECOVERED FROM THIS AE

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Table 30. Extrapyramidal Symptoms (EPS): Patient Data Listing (ITT Population) -(continued)

				Risperidone Dosing Period		Prolactin-related Side Effect								
Set	Patient ID	Flag	Gender	Start Date	End Date	Event	Preferred Term	Onset Date	End Date	Serious	Severity	Relationship	Action Taken	Outcome
9	A03522	PA	MALE	30NOV98	06DEC99	ES (EXTRAPYRAMID)	EXTRAPYRAMIDAL DISORDER	11SEP99	08NOV99	NO	MODERATE	VERY LIKELY	DOSE ADJUSTED	RECOVERED FROM THIS AE
						EXTRAPYRAM. SYMPT.	EXTRAPYRAMIDAL DISORDER	09DEC98	14DEC98	NO	MILD	VERY LIKELY	DOSE ADJUSTED	RECOVERED FROM THIS AE
	A03560	ITT	MALE	31MAR00	03APR01	BRADYKINESIA	BRADYKINESIA	01MAY00	26MAY00	NO	MILD	VERY LIKELY	NONE	RECOVERED FROM THIS AE
						PASSIVITY	HYPOKINESIA	01MAY00	26MAY00	NO	MILD	VERY LIKELY	NONE	RECOVERED FROM THIS AE
						SLOWNESS	HYPOKINESIA	01MAY00	26MAY00	NO	MILD	VERY LIKELY	NONE	RECOVERED FROM THIS AE
	A03576	PA	MALE	18NOV99	15JUN00	ACUTE DYSTONIA IN JAW	DYSTONIA	06DEC99	16DEC99	NO	MODERATE	POSSIBLE	OOSE ADJUSTED	RECOVERED FROM THIS AE
						RIGIDITY IN LIMBS	HYPERTONIA	06DEC99	09DEC99	NO	MILD	POSSIBLE	DOSE ADJUSTED	RECOVERED FROM THIS AE
						TREMOR IN RIGHT AND LEFT UPPER LIMB	TREMOR	06DEC99	16DEC99	NO	MILD	POSSIBLE	DOSE ADJUSTED	RECOVERED FROM THIS AE
	A03637	PA	MALE	07JUN00	23AUG00	(GETTING UP AND SITTING DOWN) REPETITIVE STEREOTYPY	HYPERKINESIA	05JUL00	23AUG00	NO	SEVERE	DOUBTFUL	PERMANENT STOP	RECOVERED FROM THIS AE
	A03640	PA	MALE	15JUN00	23MAY01	INCREASED TREMOR	TREMOR	01MAY01	ONGOING	NO	MODERATE	DOUBTFUL	NONE	NOT YET RECOVERED
	A03641	PA	FEMALE	27MAR00	30MAY01	RESTLESSNESS	HYPERKINESIA	03FEB01	01APR01	NO	MODERATE	DOUBTFUL	NONE	RECOVERED FROM THIS AE

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Table 30. Extrapyramidal Symptoms (EPS): Patient Data Listing (ITT Population) -(continued)

				Risperidone Dosing Period		Prolactin-related Side Effect								
Set	Patient ID	Flag	Gender	Start Date	End Date	Event	Preferred Term	Onset Date	End Date	Serious	Severity	Relationship	Action Taken	Outcome
9	A03650	PA	FEMALE	05JUL00	29MAR01	AKATISIA	HYPERKINESIA	14JUL00	25JUL00	NO	MODERATE	PROBABLE	NONE	RECOVERED FROM THIS AE
								26JUL00	ONGOING	NO	MILD	PROBABLE	NONE	NOT YET RECOVERED
	A03661	ITT	MALE	07JUN00	20JUN00	OCULOGYRIC CRISIS	OCULOGYRIC CRISIS	09JUN00	09JUN00	YES	MILD	VERY LIKELY	TEMPORARY STOP	RECOVERED FROM THIS AE
	A03663	ITT	FEMALE	07JUN00	20JUN00	OCULOGYRIC CRISIS	OCULOGYRIC CRISIS	09JUN00	09JUN00	YES	MILD	VERY LIKELY	TEMPORARY STOP	RECOVERED FROM THIS AE
	A03676	PA	MALE	27JUN00	26JUN01	PSYCHOMOTOR RETARDATION	HYPOKINESIA	22AUG00	05OCT00	NO	MODERATE	NONE	NONE	RECOVERED FROM THIS AE
	A03677	PA	MALE	25JUN00	08JUL01	DYSTANIA	DYSTONIA	06JUL00	06JUL00	NO	MODERATE	VERY LIKELY	NONE	RECOVERED FROM THIS AE
								09JUL00	09JUL00	NO	SEVERE	VERY LIKELY	NONE	RECOVERED FROM THIS AE
	A03681	PA	FEMALE	26JUN00	23JUL01	DYSTONIA	DYSTONIA	01NOV00	ONGOING	NO	MILD	VERY LIKELY	DOSE ADJUSTED	NOT YET RECOVERED
						HEAD TILTING	MUSCLE CONTRACTIONS INVOLUNTARY	08FEB01	ONGOING	NO	MODERATE	POSSIBLE	NONE	NOT YET RECOVERED
						RIGIDITY IN EXTREMITIES	HYPERTONIA	01JAN01	ONGOING	NO	MILD	VERY LIKELY	DOSE ADJUSTED	NOT YET RECOVERED
	A03710	PA	MALE	27AUG99	01SEP00	MILD NECK STIFFNESS	HYPERTONIA	21SEP99	22SEP99	NO	MILD	DOUBTFUL	NONE	RECOVERED FROM THIS AE
	A03733	PA	MALE	06OCT99	04OCT00	MILD TREMOR OF LEFT UPPER LIMB	TREMOR	04OCT00	ONGOING	NO	MILD	PROBABLE	NONE	NOT YET RECOVERED
						MILD TREMOR OF UPPER LIMBS BIL.	TREMOR	27OCT99	ONGOING	NO	MILD	PROBABLE	NONE	NOT YET RECOVERED

Note 1) EPS are adverse events classified under System Organ Class as "Centr & Periph Nervous System Disorders"

2) EPS classified under Preferred Term as "Agitation" "Akathesia" "Bradykinesia" "Dyskinesia Tardive" "Dystonia" "Extrapyramidal Disorder" "Hyperkinesia" "Hyperreflexia" "Hypertonia" "Hypokinesia" "Hypotonia" "Muscle Contractions Involuntary" "Oculogyric Crisis" "Parkinsonism" "Rigidity" "Shuffling Gait" "Stiffness" "Tics" or "Tremor" are included

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Table 30. Extrapyramidal Symptoms (EPS): Patient Data Listing (ITT Population) -(continued)

				Risperidone Dosing Period		Prolactin-related Side Effect								
Set	Patient ID	Flag	Gender	Start Date	End Date	Event	Preferred Term	Onset Date	End Date	Serious	Severity	Relationship	Action Taken	Outcome
9	A03734	PA	MALE	08DEC99	10MAY00	IMPRESSION OF SLOWNESS	HYPOKINESIA	29DEC99	05APR00	NO	MILD	PROBABLE	NONE	RECOVERED FROM THIS AE
	A03735	PA	MALE	22MAR00	28MAR01	IMPRESSION OF SLOWNESS	HYPOKINESIA	28JUN00	05SEP00	NO	MILD	PROBABLE	NONE	RECOVERED FROM THIS AE
						MODERATE TREMOR OF THE LEFT HAND	TREMOR	06SEP00	27MAR01	NO	MODERATE	PROBABLE	NONE	RECOVERED FROM THIS AE
						TREMOR OF LEFT HAND	TREMOR	28JUN00	05SEP00	NO	MILD	PROBABLE	NONE	RECOVERED FROM THIS AE
	A03737	ITT	MALE	24MAR00	14MAR01	AKATHISIA	HYPERKINESIA	18MAY00	09AUG00	NO	MODERATE	VERY LIKELY	NONE	RECOVERED FROM THIS AE
						AKATHISIA, SEVERITY VARYING	HYPERKINESIA	13APR00	09AUG00	NO	MILD	DOUBTFUL	NONE	RECOVERED FROM THIS AE
						SLOWNESS	BRADYKINESIA	18MAY00	12SEP00	NO	MODERATE	PROBABLE	NONE	RECOVERED FROM THIS AE
								13SEP00	13DEC00	NO	MILD	PROBABLE	NONE	RECOVERED FROM THIS AE
							HYPOKINESIA	20APR00	17MAY00	NO	MILD	PROBABLE	NONE	RECOVERED FROM THIS AE
	A03741	PA	MALE	20DEC99	05DEC00	BRADYKINESIA	BRADYKINESIA	10APR00	03SEP00	NO	MILD	PROBABLE	NONE	RECOVERED FROM THIS AE
						RIGIDITY LEFT LOWER LIMB	HYPERTONIA	04SEP00	04DEC00	NO	MILD	VERY LIKELY	NONE	RECOVERED FROM THIS AE
								05DEC00	ONGOING	NO	MODERATE	VERY LIKELY	NONE	NOT YET RECOVERED
						RIGIDITY RIGHT + LEFT LOWER LIMB	HYPERTONIA	14FEB00	09APR00	NO	SEVERE	VERY LIKELY	NONE	RECOVERED FROM THIS AE

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Table 30. Extrapyramidal Symptoms (EPS): Patient Data Listing (ITT Population) -(continued)

				Risperidone Dosing Period		Prolactin-related Side Effect								
Set	Patient ID	Flag	Gender	Start Date	End Date	Event	Preferred Term	Onset Date	End Date	Serious	Severity	Relationship	Action Taken	Outcome
9	A03741	PA	MALE	20DEC99	05DEC00	RIGIDITY RIGHT + LEFT LOWER LIMB	HYPERTONIA	10APR00	07MAY00	NO	MODERATE	VERY LIKELY	NONE	RECOVERED FROM THIS AE
								08MAY00	03SEP00	NO	MILD	VERY LIKELY	NONE	RECOVERED FROM THIS AE
						RIGIDITY RIGHT LOWER LIMB	HYPERTONIA	04SEP00	ONGOING	NO	MODERATE	VERY LIKELY	NONE	NOT YET RECOVERED
						STIFFNESS	HYPERTONIA	14MAR00	07MAY00	NO	MILD	PROBABLE	NONE	RECOVERED FROM THIS AE
	A03742	PA	MALE	01FEB00	09FEB01	AKATHISIA	HYPERKINESIA	08FEB00	20FEB00	NO	MILD	PROBABLE	NONE	RECOVERED FROM THIS AE
								27MAR00	02MAY00	NO	MODERATE	VERY LIKELY	DOSE ADJUSTED	RECOVERED FROM THIS AE
								03MAY00	10AUG00	NO	MILD	VERY LIKELY	NONE	RECOVERED FROM THIS AE
								11AUG00	ONGOING	NO	MODERATE	VERY LIKELY	NONE	NOT YET RECOVERED
						IMPRESSION OF SLOWNESS	HYPOKINESIA	23JUN00	10AUG00	NO	MILD	PROBABLE	NONE	RECOVERED FROM THIS AE
						OCULOGYRIC CRISIS	OCULOGYRIC CRISIS	27MAR00	02MAY00	NO	MILD	PROBABLE	DOSE ADJUSTED	RECOVERED FROM THIS AE
						RIGIDITY	HYPERTONIA	27MAR00	18JUL00	NO	MILD	VERY LIKELY	DOSE ADJUSTED	RECOVERED FROM THIS AE
						SLOWNESS	HYPOKINESIA	23JUN00	10AUG00	NO	MILD	PROBABLE	NONE	RECOVERED FROM THIS AE
						STIFFNESS	HYPERTONIA	27MAR00	18JUL00	NO	MILD	PROBABLE	DOSE ADJUSTED	RECOVERED FROM THIS AE
								10NOV00	08FEB01	NO	MILD	PROBABLE	NONE	RECOVERED FROM THIS AE

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Table 30. Extrapyramidal Symptoms (EPS): Patient Data Listing (ITT Population) -(continued)

				Risperidone Dosing Period		Prolactin-related Side Effect								
Set	Patient ID	Flag	Gender	Start Date	End Date	Event	Preferred Term	Onset Date	End Date	Serious	Severity	Relationship	Action Taken	Outcome
9	A03742	PA	MALE	01FEB00	09FEB01	TORSION DYSTONIA (JAW,TONGUE,LIPS)	DYSTONIA	28FEB00	26MAR00	NO	MILD	VERY LIKELY	NONE	RECOVERED FROM THIS AE
	A03923	PA	MALE	21MAY99	09JUN00	ABNORMAL EYE MOVEMENTS	OCULOGYRIC CRISIS	09SEP99	03FEB00	NO	MILD	POSSIBLE	DOSE ADJUSTED	RECOVERED FROM THIS AE
						BRADYKINESIA	BRADYKINESIA	09SEP99	03FEB00	NO	MILD	POSSIBLE	NONE	RECOVERED FROM THIS AE
	A03929	PA	MALE	29MAR00	17OCT00	NOSE/LIP TIC	MUSCLE CONTRACTIONS INVOLUNTARY	16AUG00	ONGOING	NO	MILD	POSSIBLE	NONE	NOT YET RECOVERED
	A03934	PA	MALE	17APR99	15MAR00	TREMORS	TREMOR	18MAY99	18MAY99	NO	MILD	POSSIBLE	NONE	RECOVERED FROM THIS AE
	A03935	PA	MALE	10MAY99	01DEC99	DIMINISHED FACIAL EXPRESSION	EXTRAPYRAMIDAL DISORDER	25MAY99	ONGOING	NO	MILD	PROBABLE	DOSE ADJUSTED	NOT YET RECOVERED
						EXTRAPYRAMIDAL SIDE EFFECTS	EXTRAPYRAMIDAL DISORDER	15NOV99	29NOV99	NO	MODERATE	VERY LIKELY	TEMPORARY STOP	RECOVERED FROM THIS AE
	A03936	PA	MALE	16MAR99	15MAR00	EYE BLINK	MUSCLE CONTRACTIONS INVOLUNTARY	21DEC99	ONGOING	NO	MILD	DOUBTFUL	NONE	NOT YET RECOVERED
						STIFF	HYPERTONIA	04JUL99	05JUL99	NO	MILD	DOUBTFUL	NONE	RECOVERED FROM THIS AE
	A03938	PA	MALE	27MAY99	24MAY00	AKINESIA	HYPOKINESIA	25AUG99	22OCT99	NO	MILD	PROBABLE	NONE	RECOVERED FROM THIS AE
						EYE TICK JERKING MOVEMENTS	MUSCLE CONTRACTIONS INVOLUNTARY	07OCT99	22OCT99	NO	MODERATE	VERY LIKELY	TEMPORARY STOP	RECOVERED FROM THIS AE

Note 1) EPS are adverse events classified under System Organ Class as "Centr & Periph Nervous System Disorders"

2) EPS classified under Preferred Term as "Agitation" "Akathesia" "Bradykinesia" "Dyskinesia Tardive" "Dystonia" "Extrapyramidal Disorder" "Hyperkinesia" "Hyperreflexia" "Hypertonia" "Hypokinesia" "Hypotonia" "Muscle Contractions Involuntary" "Oculogyric Crisis" "Parkinsonism" "Rigidity" "Shuffling Gait" "Stiffness" "Tics" or "Tremor" are included

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Table 30. Extrapyramidal Symptoms (EPS): Patient Data Listing (ITT Population) -(continued)

Set	Patient ID	Flag	Gender	Risperidone Dosing Period Start Date	Risperidone Dosing Period End Date	Prolactin-related Side Effect Event	Preferred Term	Onset Date	End Date	Serious	Severity	Relationship	Action Taken	Outcome
9	A03945	PA	MALE	01JUL99	22JUN00	INCREASED ACTIVITY LEVEL	HYPERKINESIA	21OCT99	07DEC99	NO	MILD	DOUBTFUL	NONE	RECOVERED FROM THIS AE
						SWINGS FEET AND LEGS WHEN SITTING	HYPERKINESIA	15AUG99	02SEP99	NO	MILD	DOUBTFUL	NONE	RECOVERED FROM THIS AE
	A03970	ITT	FEMALE	18DEC99	04JAN00	EXTRAPYRAMIDAL REACTION	EXTRAPYRAMIDAL DISORDER	20DEC99	21DEC99	NO	SEVERE	VERY LIKELY	PERMANENT STOP	RECOVERED FROM THIS AE
	A03975	ITT	MALE	16SEP99	07SEP00	HAND TREMORS	TREMOR	17FEB00	ONGOING	NO	MILD	POSSIBLE	NONE	NOT YET RECOVERED
	A03978	PA	MALE	27OCT99	20DEC00	INCREASED HYPERACTIVITY IN AM	HYPERKINESIA	08JAN00	17MAR00	NO	MODERATE	PROBABLE	DOSE ADJUSTED	RECOVERED FROM THIS AE
	A03979	ITT	MALE	26JAN00	16FEB00	INCREASED PASSIVITY	HYPOKINESIA	04FEB00	ONGOING	NO	MODERATE	POSSIBLE	DOSE ADJUSTED	NOT YET RECOVERED
	A03984	PA	FEMALE	24SEP99	22SEP00	TREMOR IN BOTH HANDS	TREMOR	21DEC99	26JAN00	NO	MILD	POSSIBLE	NONE	RECOVERED FROM THIS AE
	A04005	PA	MALE	20OCT99	18OCT00	BREATHING TICS	MUSCLE CONTRACTIONS INVOLUNTARY	06MAR00	04APR00	NO	MILD	NONE	DOSE ADJUSTED	RECOVERED FROM THIS AE
						VOCAL TICS / THROAT CLEARING	MUSCLE CONTRACTIONS INVOLUNTARY	15MAR00	04APR00	NO	MILD	NONE	NONE	RECOVERED FROM THIS AE

Note 1) EPS are adverse events classified under System Organ Class as "Centr & Periph Nervous System Disorders"

2) EPS classified under Preferred Term as "Agitation" "Akathesia" "Bradykinesia" "Dyskinesia Tardive" "Dystonia" "Extrapyramidal Disorder" "Hyperkinesia" "Hyperreflexia" "Hypertonia" "Hypokinesia" "Hypotonia" "Muscle Contractions Involuntary" "Oculogyric Crisis" "Parkinsonism" "Rigidity" "Shuffling Gait" "Stiffness" "Tics" or "Tremor" are included

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Table 31. Prolactin Levels [ng/mL] by Responders on the Conduct Problem Subscale of the NCBRF: Descriptive Statistics (PA - As Observed)

		Prolactin Levels for Responders						Prolactin Levels for Non-responders					
Response Criteria	Time Period	N	Mean	SD	Median	Minimum	Maximum	N	Mean	SD	Median	Minimum	Maximum
>= 25% vs < 25%	Prolactin at:												
	Weeks 4 to 7	271	29.6	15.3	27.0	3.0	83.6	64	28.9	12.5	27.0	2.9	70.7
	Weeks 8 to 12	266	24.8	16.7	22.0	2.4	103.0	64	21.9	11.3	21.3	1.0	55.0
	Weeks 16 to 24	252	19.9	14.2	17.0	2.0	88.0	67	17.9	12.5	15.6	2.5	63.8
	Weeks 28 to 36	251	19.0	12.8	15.9	2.0	102.0	65	15.5	12.7	13.0	2.0	79.8
	Weeks 40 to 48	288	16.2	13.9	13.6	1.9	160.9	66	15.6	10.2	14.9	2.0	44.0
>= 35% vs < 35%	Prolactin at:												
	Weeks 4 to 7	240	29.7	15.4	27.3	3.0	83.6	95	28.9	13.0	26.9	2.9	70.7
	Weeks 8 to 12	236	25.0	17.0	22.0	2.4	103.0	94	22.4	12.4	22.0	1.0	64.2
	Weeks 16 to 24	225	20.1	13.9	17.0	2.0	88.0	94	17.9	13.6	15.2	2.5	83.0
	Weeks 28 to 36	226	18.8	13.0	15.9	2.0	102.0	90	16.8	12.3	14.0	2.0	79.8
	Weeks 40 to 48	257	15.9	10.9	13.6	1.9	61.6	97	16.7	18.2	14.0	2.0	160.9
>= 50% vs < 50%	Prolactin at:												
	Weeks 4 to 7	202	31.1	15.8	29.0	3.0	83.6	133	27.0	12.8	25.3	2.9	70.7
	Weeks 8 to 12	195	25.2	17.2	22.0	3.0	103.0	135	22.9	13.5	22.0	1.0	76.0
	Weeks 16 to 24	177	20.1	13.9	16.9	2.0	88.0	142	18.6	13.8	16.2	2.5	83.0
	Weeks 28 to 36	185	19.0	13.6	15.3	2.6	102.0	131	17.2	11.6	15.3	2.0	79.8
	Weeks 40 to 48	213	16.4	11.3	13.7	2.0	61.6	141	15.8	15.9	13.6	1.9	160.9

Note 1) Patients were included in this analysis if they had pre-dose and weeks 40-48 prolactin observations

2) Improvement is a negative change from pre-dose

3) Improvement could not be calculated from the NCBRF for patient A3581/D-S who had a 0 score at pre-dose

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Table 32. Change from Pre-dose in Prolactin Levels [ng/mL] by Responders on the Conduct Problem Subscale of the NCBRF: Descriptive Statistics (PA)

		Change in Prolactin for Responders						Change in Prolactin for Non-responders					
Response Criteria	Time Period	N	Mean	SD	Median	Minimum	Maximum	N	Mean	SD	Median	Minimum	Maximum
>= 25% vs < 25%	Prolactin at:												
	Weeks 4 to 7	271	22.1	15.1	20.0	-16.9	75.0	64	21.7	13.2	21.5	-20.0	62.8
	Weeks 8 to 12	266	17.3	17.0	15.8	-42.1	101.0	64	15.1	12.9	14.6	-24.0	48.0
	Weeks 16 to 24	252	12.6	14.4	11.0	-42.0	76.0	67	10.1	12.9	8.2	-11.0	55.9
	Weeks 28 to 36	251	11.3	12.6	9.8	-21.9	95.0	65	8.1	15.4	7.4	-42.0	71.9
	Weeks 40 to 48	288	8.8	14.1	7.0	-28.0	152.9	66	8.5	12.7	7.3	-44.0	38.0
>= 35% vs < 35%	Prolactin at:												
	Weeks 4 to 7	240	22.4	15.3	20.6	-16.9	75.0	95	21.0	13.2	21.1	-20.0	62.8
	Weeks 8 to 12	236	17.4	17.3	15.8	-42.1	101.0	94	15.4	13.5	15.0	-24.0	56.3
	Weeks 16 to 24	225	12.7	14.3	11.4	-42.0	76.0	94	10.4	13.7	8.4	-11.0	76.0
	Weeks 28 to 36	226	11.2	12.9	9.6	-21.9	95.0	90	9.3	14.1	8.3	-42.0	71.9
	Weeks 40 to 48	257	8.4	11.0	7.0	-22.9	47.0	97	9.5	19.5	7.0	-44.0	152.9
>= 50% vs < 50%	Prolactin at:												
	Weeks 4 to 7	202	23.6	15.7	21.8	-16.9	75.0	133	19.5	12.8	18.9	-20.0	62.8
	Weeks 8 to 12	195	17.8	17.2	16.0	-42.1	101.0	135	15.5	14.8	14.2	-36.0	69.0
	Weeks 16 to 24	177	12.7	13.7	11.0	-41.4	76.0	142	11.2	14.6	9.1	-42.0	76.0
	Weeks 28 to 36	185	11.2	13.1	8.8	-21.9	95.0	131	9.9	13.4	9.8	-42.0	71.9
	Weeks 40 to 48	213	8.6	11.2	6.9	-22.9	47.0	141	8.8	17.1	7.0	-44.0	152.9

Note 1) Patients were included in this analysis if they had pre-dose and weeks 40-48 prolactin observations

2) Improvement is a negative change from pre-dose

3) Improvement could not be calculated from the NCBRF for patient A3581/D-S who had a 0 score at pre-dose

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Table 33. Responders on the Conduct Problem Subscale of the NCBRF by Prolactin Levels [ng/mL]: Frequency Table (PA - As Observed)

Response Criteria	Time Period	Responders	N	Above ULN[1]	Normal	P-value[2]
>= 25% vs < 25%	Weeks 4 to 7	Yes		195 (80.2)	76 (82.6)	0.6236
		No		48 (19.8)	16 (17.4)	
		Total	335	243	92	
	Weeks 8 to 12	Yes		149 (81.4)	117 (79.6)	0.6762
		No		34 (18.6)	30 (20.4)	
		Total	330	183	147	
	Weeks 16 to 24	Yes		107 (84.9)	145 (75.1)	0.0358
		No		19 (15.1)	48 (24.9)	
		Total	319	126	193	
	Weeks 28 to 36	Yes		101 (83.5)	150 (76.9)	0.1616
		No		20 (16.5)	45 (23.1)	
		Total	316	121	195	
	Weeks 40 to 48	Yes		86 (78.9)	202 (82.4)	0.4286
		No		23 (21.1)	43 (17.6)	
		Total	354	109	245	
>= 35% vs < 35%	Weeks 4 to 7	Yes		173 (71.2)	67 (72.8)	0.7673
		No		70 (28.8)	25 (27.2)	
		Total	335	243	92	
	Weeks 8 to 12	Yes		132 (72.1)	104 (70.7)	0.7821
		No		51 (27.9)	43 (29.3)	
		Total	330	183	147	
	Weeks 16 to 24	Yes		97 (77.0)	128 (66.3)	0.0411
		No		29 (23.0)	65 (33.7)	
		Total	319	126	193	
	Weeks 28 to 36	Yes		88 (72.7)	138 (70.8)	0.7077
		No		33 (27.3)	57 (29.2)	
		Total	316	121	195	
	Weeks 40 to 48	Yes		76 (69.7)	181 (73.9)	0.4187
		No		33 (30.3)	64 (26.1)	
		Total	354	109	245	

[1]ULN: The upper limit of normal for prolactin levels is 18 [ng/mL] for males and 30 [ng/mL] for females
[2]Pearson's chi-square test is used to calculate the association between responders (Yes vs No) and prolactin levels (Above ULN vs Normal)

Note 1) Patients were included in this analysis if they had pre-dose and weeks 40-48 prolactin observations
2) Improvement is a negative change from pre-dose
3) Improvement could not be calculated from the NCBRF for patient A3581/0-S who had a 0 score at pre-dose

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Table 33. Responders on the Conduct Problem Subscale of the NCBRF by Prolactin Levels [ng/mL]: Frequency Table (PA - As Observed) -(continued)

Response Criteria	Time Period	Responders	N	Above ULN[1]	Normal	P-value[2]
>= 50% vs < 50%	Weeks 4 to 7	Yes		149 (61.3)	53 (57.6)	0.5358
		No		94 (38.7)	39 (42.4)	
		Total	335	243	92	
	Weeks 8 to 12	Yes		109 (59.6)	86 (58.5)	0.8457
		No		74 (40.4)	61 (41.5)	
		Total	330	183	147	
	Weeks 16 to 24	Yes		75 (59.5)	102 (52.8)	0.2410
		No		51 (40.5)	91 (47.2)	
		Total	319	126	193	
	Weeks 28 to 36	Yes		68 (56.2)	117 (60.0)	0.5049
		No		53 (43.8)	78 (40.0)	
		Total	316	121	195	
	Weeks 40 to 48	Yes		68 (62.4)	145 (59.2)	0.5700
		No		41 (37.6)	100 (40.8)	
		Total	354	109	245	

[1]ULN: The upper limit of normal for prolactin levels is 18 [ng/mL] for males and 30 [ng/mL] for females
[2]Pearson's chi-square test is used to calculate the association between responders (Yes vs No) and prolactin levels (Above ULN vs Normal)

Note 1) Patients were included in this analysis if they had pre-dose and weeks 40-48 prolactin observations
2) Improvement is a negative change from pre-dose
3) Improvement could not be calculated from the NCBRF for patient A3581/D-S who had a 0 score at pre-dose

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Table 34. Correlation between Conduct Problem Subscale Score of the NCBRF (Log-Scale) vs Prolactin Levels [ng/mL] (PA - As Observed)

Time Period	N[1]	Correlation Coefficient	R-Square[2]	Slope[3]	Slope 95% Confidence Interval	
					Lower	Upper
Pre-dose	592	0.0160	0.0003	0.4752	-1.9268	2.8772
Weeks 4 to 7	547	-0.0964	0.0093	-3.7370	-6.9829	-0.4911
Weeks 8 to 12	496	-0.0543	0.0029	-1.7141	-4.5024	1.0743
Weeks 16 to 24	438	-0.0439	0.0019	-1.4286	-4.4854	1.6282
Weeks 28 to 36	392	-0.0487	0.0024	-1.5426	-4.6911	1.6060
Weeks 40 to 48	355	-0.0378	0.0014	-1.1474	-4.3248	2.0299

[1]All data points were included

[2]Interpretation of R-Square: eg. At weeks 40 to 48, 0.14% the variation in the conduct disorder subscale score can be explained by prolactin levels

[3]Interpretation of Slope: eg. At weeks 40 to 48, for every tenfold ng/mL increase in prolactin there is a 1.1474 [-4.3248 - 2.0299] expected decrease in the mean conduct disorder subscale score on the NCBRF

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Figure 1. Prolactin Levels at Pre-dose by Gender

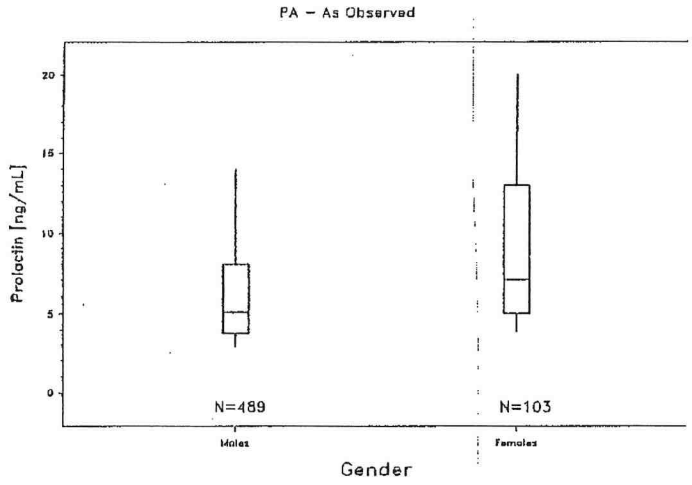

Figure 2. Prolactin Levels at Pre-dose by Tanner Stage

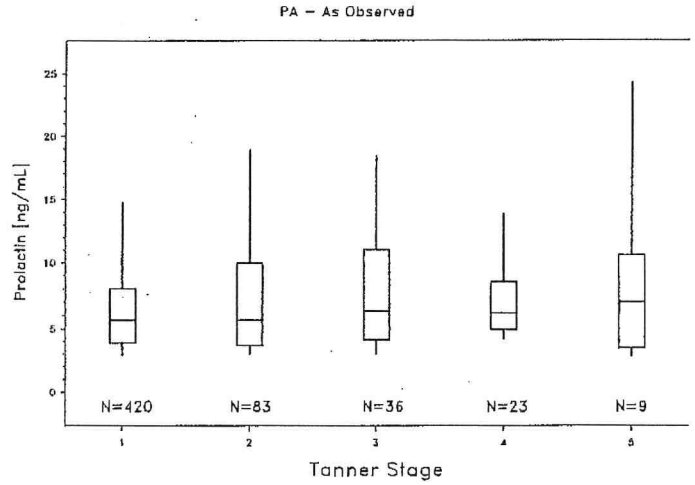

Figure 3. Prolactin Levels

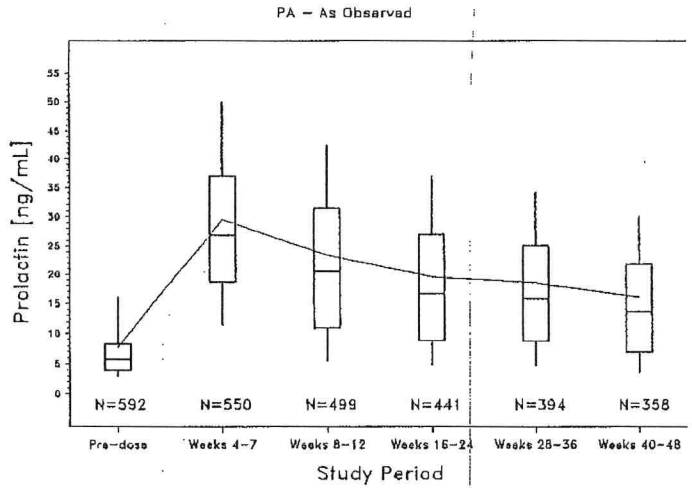

Figure 4. Mean Prolactin Levels

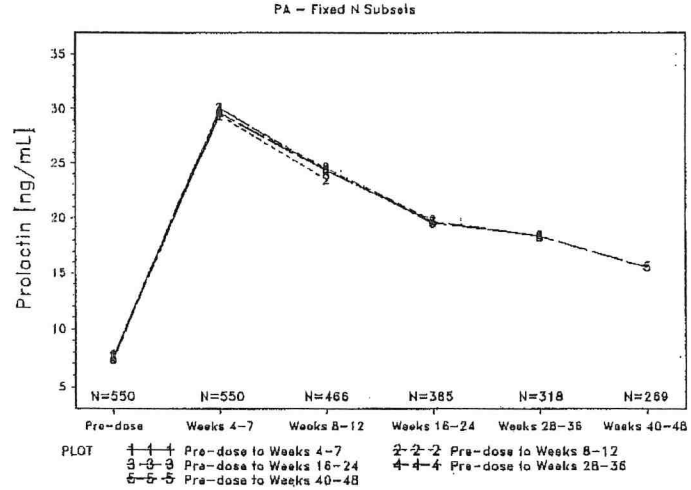

Figure 5. Prolactin Levels by Continuation Status

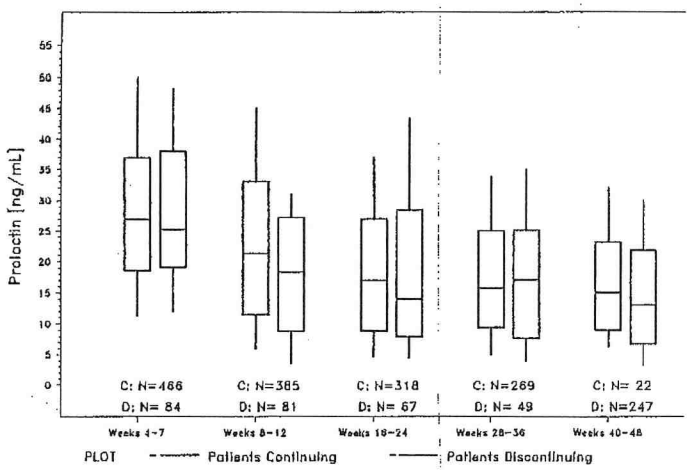

Figure 6. Mean Prolactin Levels by Gender

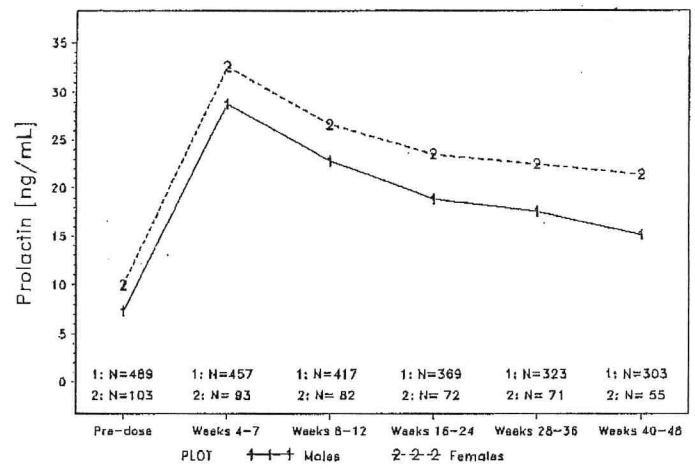

Figure 7. Mean Prolactin Levels by Age Group

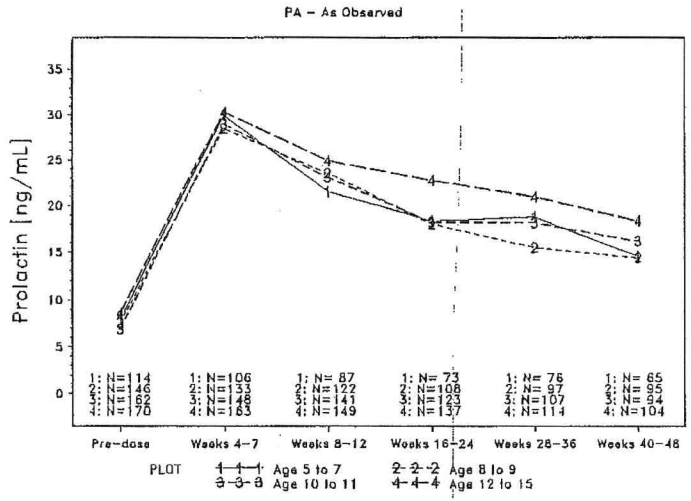

Figure 8. Mean Prolactin Levels by Gender and Age Group

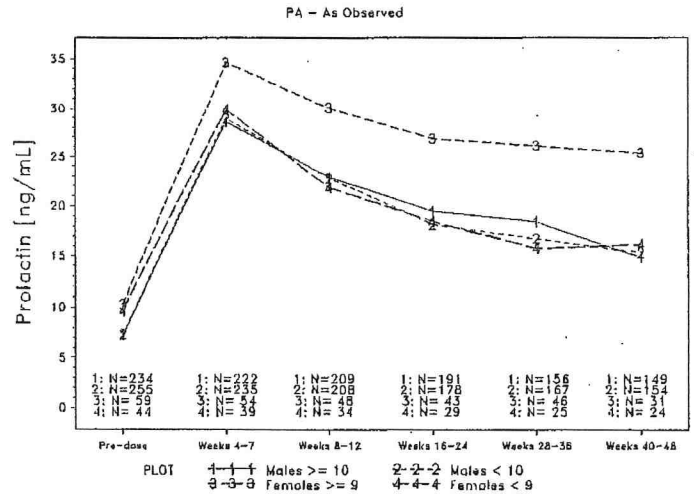

Figure 9. Prolactin Levels vs Age

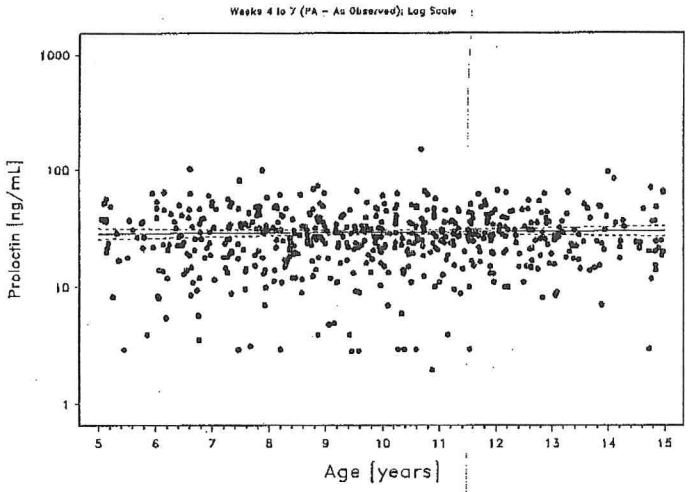

Figure 10. Prolactin Levels vs Age

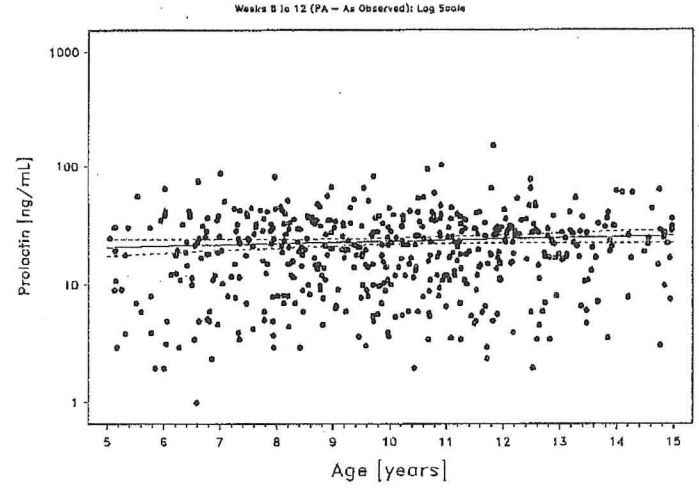

Figure 11. Prolactin Levels vs Age

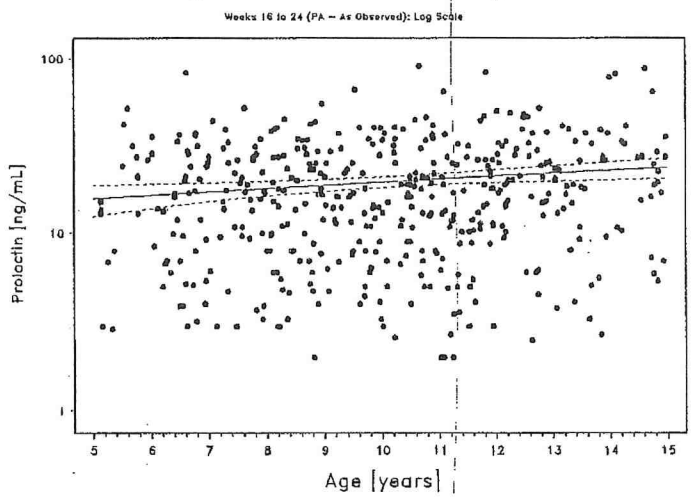

Figure 12. Prolactin Levels vs Age

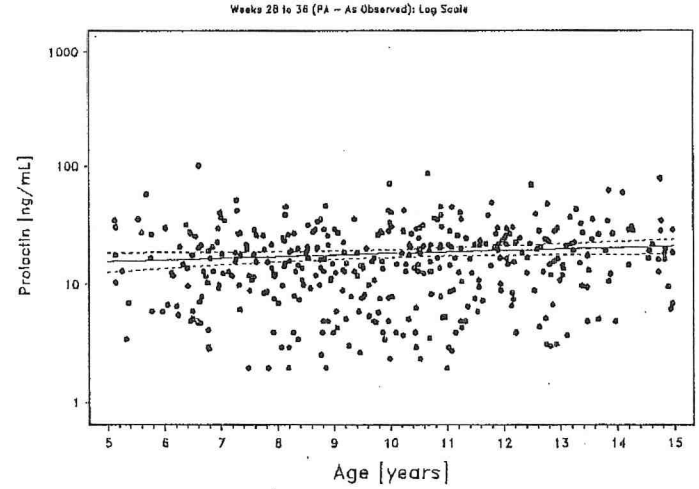

Figure 13. Prolactin Levels vs Age

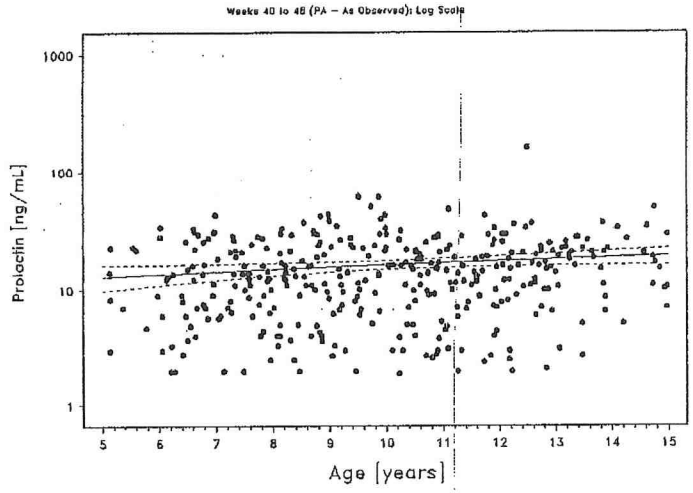

Figure 14. Mean Prolactin Levels by SHAP

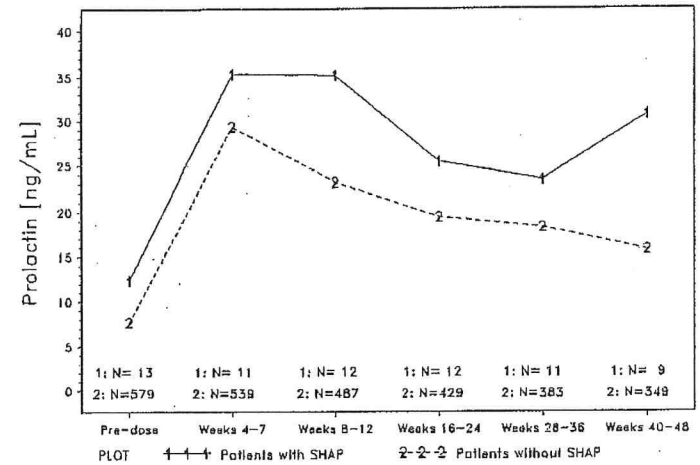

Figure 15. Percentage of Patients with SHAP at or above ULN

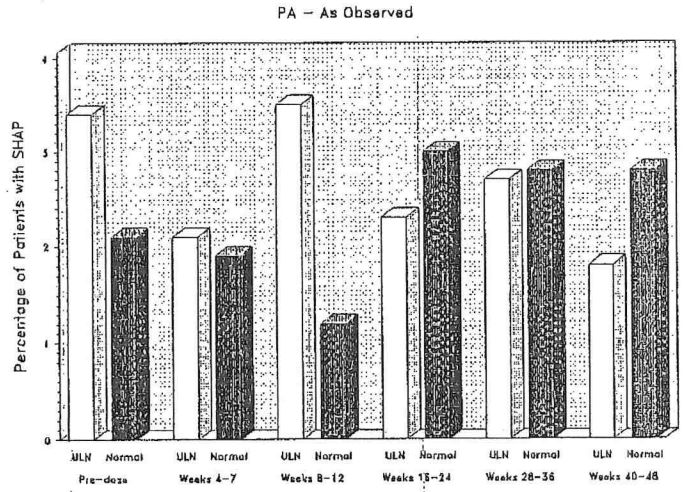

Figure 16. Mean Prolactin Levels by EPS

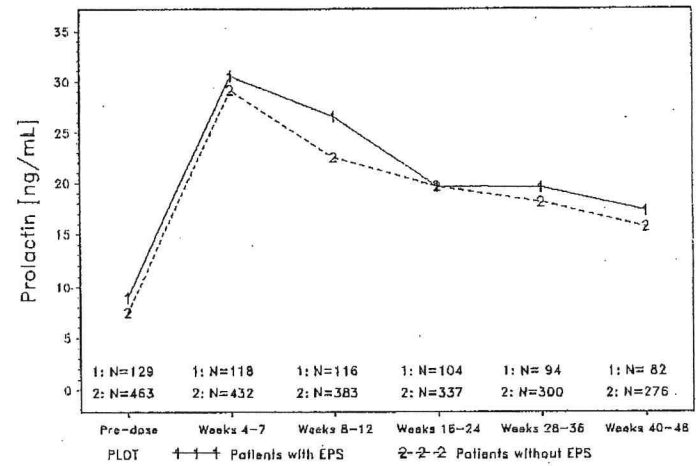

Figure 17. Percentage of Patients with EPS at or above ULN

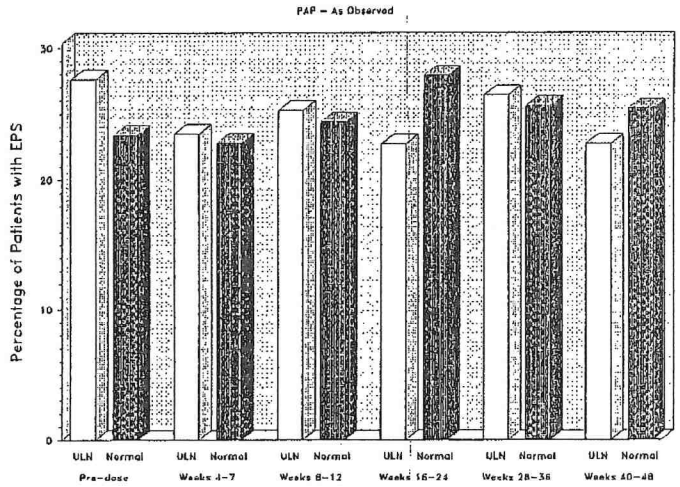

Figure 18. Mean Prolactin by Response Criterion (>= 25% vs < 25)

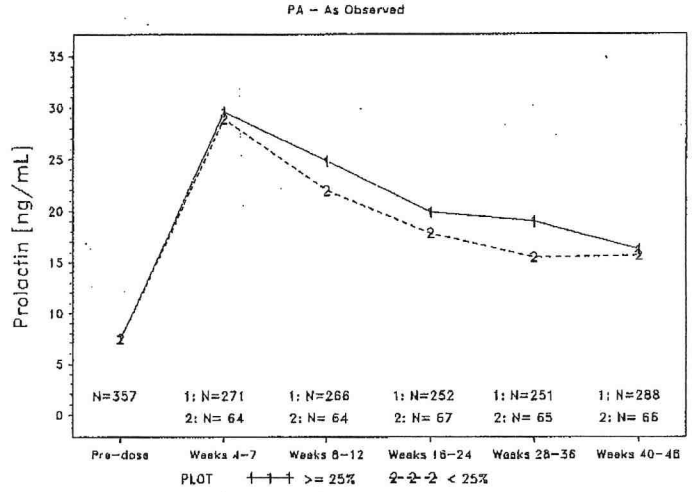

Figure 19. Mean Prolactin by Response Criterion (>= 35% vs < 35)

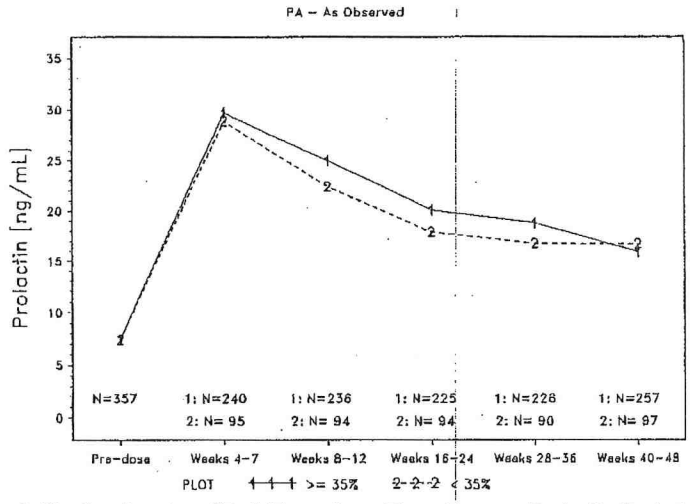

Figure 20. Mean Prolactin by Response Criterion (>= 50% vs < 50)

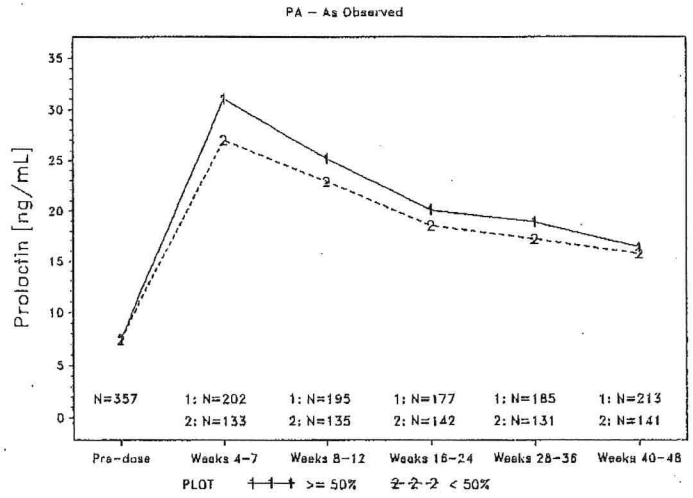

Figure 21. Percentage of Responders at or above ULN (>= 25% vs < 25)

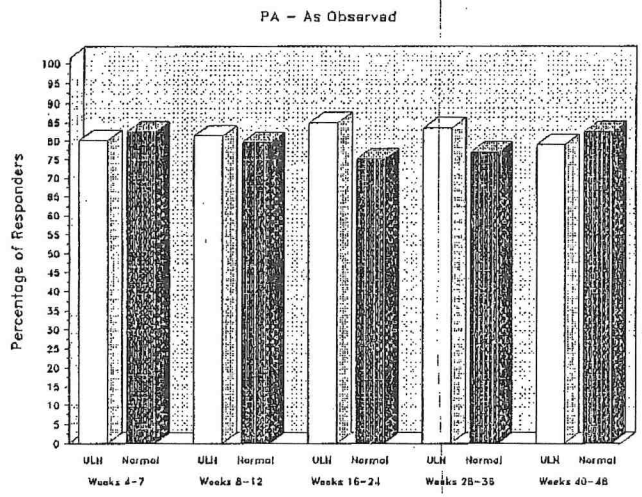

Figure 22. Percentage of Responders at or above ULN (>= 35% vs < 35)

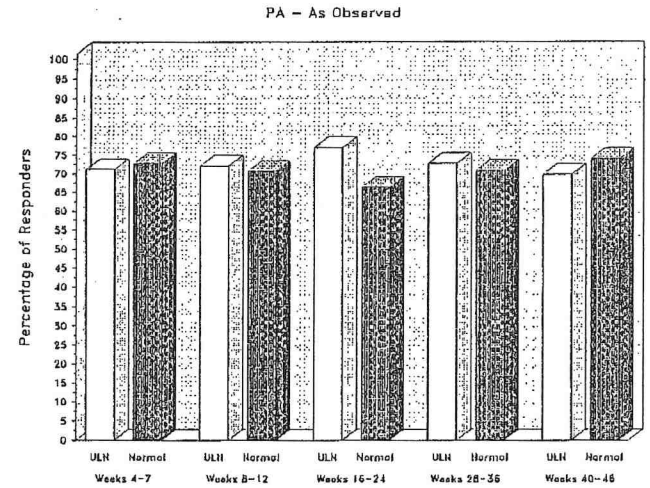

Figure 23. Percentage of Responders at or above ULN (>= 50% vs < 50)

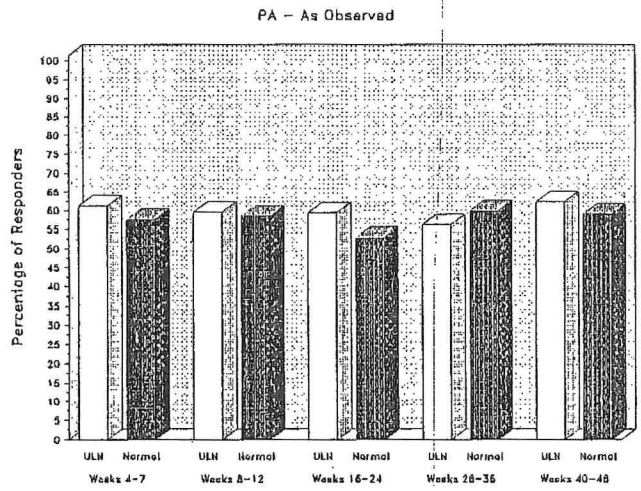

Figure 24. Conduct Problem Subscale Score vs Prolactin Levels

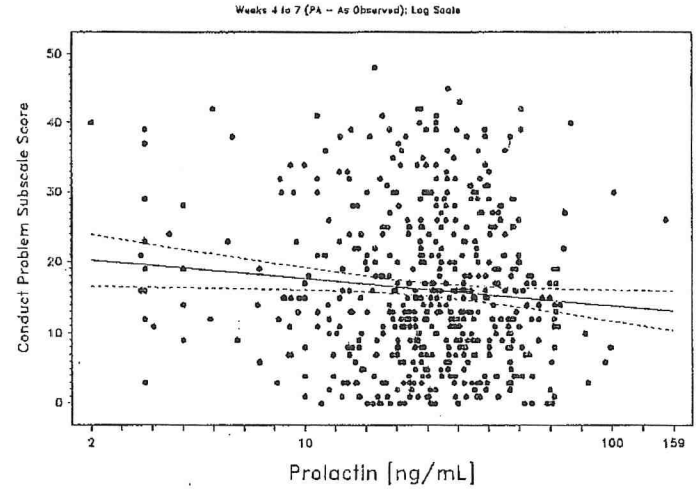

Figure 25. Conduct Problem Subscale Score vs Prolactin Levels

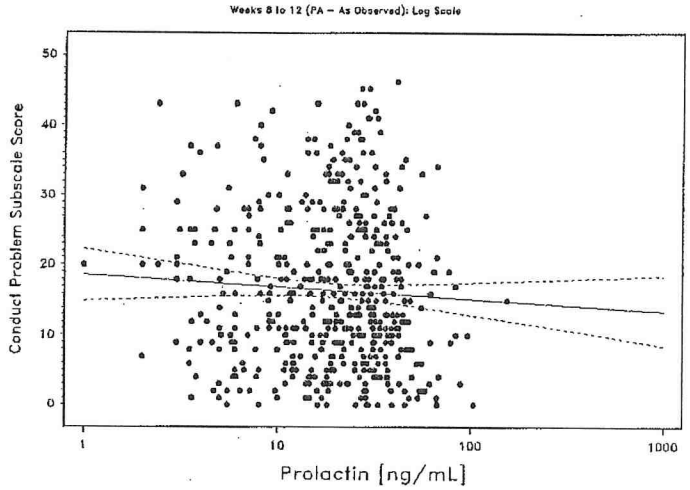

Figure 26. Conduct Problem Subscale Score vs Prolactin Levels

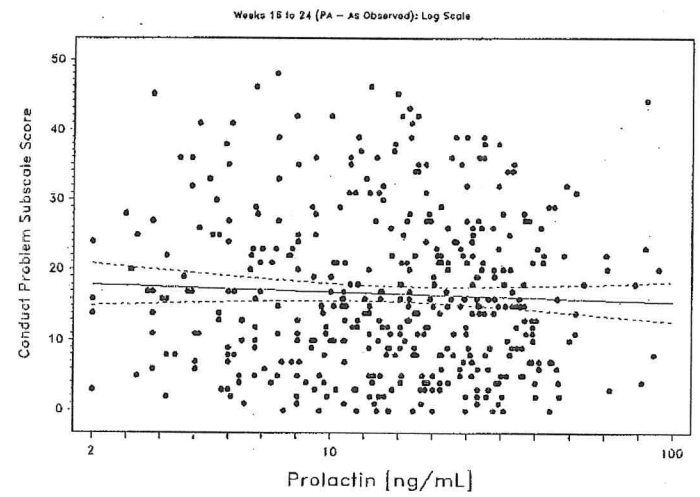

Figure 27. Conduct Problem Subscale Score vs Prolactin Levels

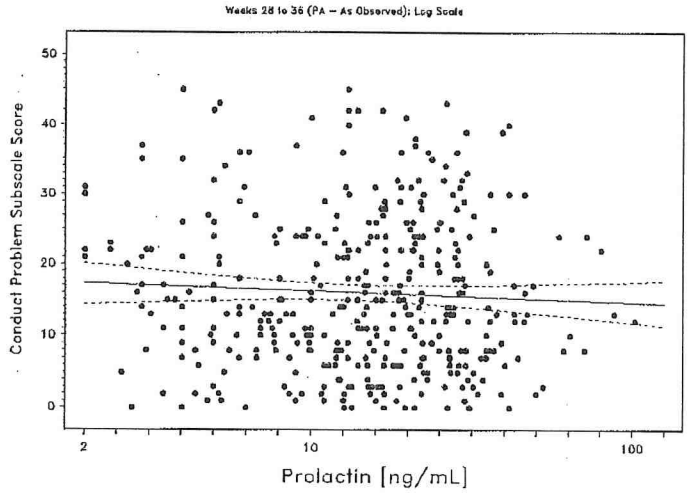

Figure 28. Conduct Problem Subscale Score vs Prolactin Levels