

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]							
								Pre-dose	Weeks Post Risperidone Dose						
									4 - 7	8 - 12	16 - 24	28 - 36	40 - 48		
3	A3625	ITT	Female	11.6	Borderline	74	AMENORRHOEA								
	A3684	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	GYNÆCOMASTIA	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	GYNÆCOMASTIA	11.2			29.0		35.4		
	A03080	PA	Female	13.5	Mild	62	AMENORRHOEA	8.1	17.2	6.1	9.3	9.6	5.1		
	A03190	PA	Male	7.9	Borderline	73	GYNÆCOMASTIA	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	38.8	29.2	19.0	35.0			
	A03329	PA	Male	5.1	Borderline	72	GYNÆCOMASTIA	5.0	38.9	31.3	13.5	10.6	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	GYNÆCOMASTIA	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	10.6	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

27SEP02 14:35 s:\428\analysis\list_prose.sas

SciAn Services Inc. (K:\H-Bridgewater\Janssen\Risperidone\Child&Adoles AdBd\data\Prolactin\Long-term Risperidone vs Prolactin Pooled analysis - Manuscript Support (Final) - 27Sep02.doc)