

[Page]

Protocols: RIS-CAN-19/RIS-CAN-20, RIS-USA-93/RIS-USA-97 and RIS-INT-41
 Janssen-Ortho Inc. - Confidential

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

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

²Pearson'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

27SEP02 14:35 s:\428\d\analysis\freq_seprouln.sas

SciAn Services Inc. ([Path] Long-term Risperidone vs Prolactin Pooled analysis - Manuscript Support. (Final) - 27Sep02.doc)

**PLAINTIFF'S
 EXHIBIT
 29A**

EXHIBIT
 P-29A
 Date: _____
 M.L. GRAY, CSR, RPR

JURE 03888769
 Confidential/Produced in Litigation Pursuant to Protective Order