Table 21. Prolactin-related Side Effects by Prolactin Levels [ng/mL] at or above Upper Limit of Normal (ULN) (PAP - As Observed): Frequency Tables

Time Period	Prolactin-related Side Effects	N	Prolactin		Chi-Square Test p-Value
			Above ULN*	Normal	
Pre-dose	Yes		2 (6.9)	28 (5.0)	0.6452
	No		27 (93.1)	535 (95.0)	
	Total	592	29	563	
Weeks 4 to 7	Yes		21 (5.4)	6 (3.7)	0.3979
	No		367 (94.6)	156 (96.3)	
	Total	550	388	162	
Weeks 8 to 12	Yes		20 (7.8)	7 (2.9)	0.0158
	No		237 (92.2)	235 (97.1)	
	Total	499	257	242	
Weeks 16 to 24	Yes		9 (5.1)	17 (6.4)	0.5699
	No		167 (94.9)	248 (93.6)	
	Total	441	176	265	
Weeks 28 to 36	Yes		7 (4.7)	16 (6.5)	0.4669
	No		141 (95.3)	230 (93.5)	
	Total	394	148	246	
Weeks 40 to 48	Yes		6 (5.5)	14 (5.6)	0.9422
	No		104 (94.5)	234 (94.4)	
	Total	358	110	248	

*ULN: The upper limit of normal for prolactin levels is 18 for males and 30 for females

Note 1) Prolactin-related side effects are adverse events classified under System Organ Class as "Endocrine disorders" or "Reproductive disorders"

2) Prolactin-related side effects 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" and "Vaginitis Atrophic" were not included

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