

**Table 14.2.2.4.1 Comparison of mean duration of vulvovaginitis episodes between treatments (PPS)**

	IMUNOR N = 52	PLACEBO N = 21	Comparison
Number of vulvovaginitis episodes with known duration	20	13	
Mean episode duration	11.45	6.73	
Ratio of mean episode durations (95% CI)			1.701 (0.898, 3.221)
p-value			0.0951

CI = Confidence interval; N = Total number of subjects; PPS = Per Protocol Set.

Presented results should be interpreted with caution due to large amount of missing data on episode duration.

Mean episode duration estimates, ratio of mean episode durations with corresponding confidence interval and p-value were obtained from mixed-effects model with log-transformed episode duration as dependent variable, treatment group as independent variable and subject as random effect.

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**Table 14.2.2.4.2 Comparison of mean duration of vulvovaginitis episodes between treatments (FAS)**

	IMUNOR N = 90	PLACEBO N = 46	Comparison
Number of vulvovaginitis episodes with known duration	34	27	
Mean episode duration	11.51	7.22	
Ratio of mean episode durations (95% CI)			1.593 (1.012, 2.507)
p-value			0.0447

CI = Confidence interval; FAS = Full Analysis Set.

Presented results should be interpreted with caution due to large amount of missing data on episode duration.

Mean episode duration estimates, ratio of mean episode durations with corresponding confidence interval and p-value were obtained from mixed-effects model with log-transformed episode duration as dependent variable, treatment group as independent variable and subject as random effect.

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