

## 14.2 Efficacy Data

**Table 14.2.1.1 Primary endpoint: Comparison of number of vulvovaginitis episodes between treatments (PPS)**

		IMUNOR N = 52	PLACEBO N = 21	Comparison
Number of vulvovaginitis episodes	0 episodes	27 (51.9%)	4 (19.0%)	
	1 episode	12 (23.1%)	5 (23.8%)	
	2 episodes	9 (17.3%)	6 (28.6%)	
	3 episodes	2 (3.8%)	3 (14.3%)	
	4 episodes	1 (1.9%)	3 (14.3%)	
	6 episodes	1 (1.9%)		
Comparison of number of vulvovaginitis episodes	Mean episode count	0.88	1.81	
	Ratio of mean episode counts (95% CI)			0.489 (0.291, 0.822)
	p-value			0.0069

% = Percentage of subjects out of N; CI = Confidence interval; N = Total number of subjects in the treatment arm; PPS = Per Protocol Set.

Mean episode estimates, ratio of mean episode counts with corresponding confidence interval and p-value were obtained from negative binomial regression model with number of episodes as dependent variable and treatment group as independent variable.

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**Table 14.2.1.2 Sensitivity analysis of primary endpoint: Comparison of number of vulvovaginitis episodes between treatments (FAS)**

		IMUNOR N = 90	PLACEBO N = 46	Comparison
Number of vulvovaginitis episodes	0 episodes	45 (50.0%)	13 (28.3%)	
	1 episode	25 (27.8%)	15 (32.6%)	
	2 episodes	13 (14.4%)	7 (15.2%)	
	3 episodes	3 (3.3%)	4 (8.7%)	
	4 episodes	3 (3.3%)	7 (15.2%)	
	6 episodes	1 (1.1%)		
Comparison of number of vulvovaginitis episodes	Mean episode count	0.87	1.50	
	Ratio of mean episode counts (95% CI)			0.578 (0.389, 0.859)
	p-value			0.0067

% = Percentage of subjects out of N; CI = Confidence interval; FAS = Full Analysis Set; N = Total number of subjects in the treatment arm..

Mean episode estimates, ratio of mean episode counts with corresponding confidence interval and p-value were obtained from negative binomial regression model with number of episodes as dependent variable and treatment group as independent variable.

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