

**Table 14.2.2.3.1 Comparison of number of vulvovaginitis episodes between treatments in patients with prevailing mycotic etiology (PPS)**

		IMUNOR N = 42	PLACEBO N = 18	Comparison
Number of vulvovaginitis episodes	0 episodes	23 (54.8%)	3 (16.7%)	
	1 episode	10 (23.8%)	5 (27.8%)	
	2 episodes	7 (16.7%)	6 (33.3%)	
	3 episodes		2 (11.1%)	
	4 episodes	1 (2.4%)	2 (11.1%)	
	6 episodes	1 (2.4%)		
Comparison of number of vulvovaginitis episodes	Mean episode count	0.81	1.72	
	Ratio of mean episode counts (95% CI)			0.470 (0.263, 0.839)
	p-value			0.0106

% = 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.

Produced on 30-OCT-2024

Page 1 of 1

**Table 14.2.2.3.2 Comparison of number of vulvovaginitis episodes between treatments in patients with prevailing mycotic etiology (FAS)**

		IMUNOR N = 51	PLACEBO N = 26	Comparison
Number of vulvovaginitis episodes	0 episodes	25 (49.0%)	5 (19.2%)	
	1 episode	15 (29.4%)	8 (30.8%)	
	2 episodes	8 (15.7%)	7 (26.9%)	
	3 episodes		2 (7.7%)	
	4 episodes	2 (3.9%)	4 (15.4%)	
	6 episodes	1 (2.0%)		
Comparison of number of vulvovaginitis episodes	Mean episode count	0.88	1.69	
	Ratio of mean episode counts (95% CI)			0.521 (0.321, 0.847)
	p-value			0.0086

% = 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.

Produced on 30-OCT-2024

Page 1 of 1