

Table 14.2.2.7.1.6 Mean EQ-5D summary index and EQ-VAS assessment during vulvovaginitis episodes between treatments (PPS)

Variable	Statistics	IMUNOR N = 52	PLACEBO N = 21	Comparison
EQ Overall Health (VAS)	Number of vulvovaginitis episodes with QoL assessment	44	25	
	Mean EQ Overall Health (VAS)	69.68	66.82	
	Difference in mean EQ Overall Health (VAS) (95% CI)			2.861 (-6.298, 12.019)
	p-value			0.5295
EQ-5D Summary Index	Number of vulvovaginitis episodes with QoL assessment	44	24	
	Mean EQ-5D Summary Index	0.95	0.90	
	Difference in mean EQ-5D Summary Index (95% CI)			0.051 (-0.005, 0.107)
	p-value			0.0724

CI = Confidence interval; N = Total number of subjects; PPS = Per Protocol Set; QoL = Quality of life; VAS = Visual analogue scale

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

Mean QoL assessment, difference in mean QoL assessment with corresponding confidence interval and p-value were obtained from mixed-effects model with QoL assessment as dependent variable, treatment group as independent variable and subject as random effect.

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Table 14.2.2.7.2.6 Mean EQ-5D summary index and EQ-VAS assessment during vulvovaginitis episodes between treatments (FAS)

Variable	Statistics	IMUNOR N = 90	PLACEBO N = 46	Comparison
EQ Overall Health (VAS)	Number of vulvovaginitis episodes with QoL assessment	75	45	
	Mean EQ Overall Health (VAS)	68.75	66.94	
	Difference in mean EQ Overall Health (VAS) (95% CI)			1.811 (-5.579, 9.200)
	p-value			0.6248
EQ-5D Summary Index	Number of vulvovaginitis episodes with QoL assessment	75	44	
	Mean EQ-5D Summary Index	0.92	0.90	
	Difference in mean EQ-5D Summary Index (95% CI)			0.024 (-0.020, 0.069)
	p-value			0.2794

CI = Confidence interval; FAS = Full Analysis Set; N = Total number of subjects; QoL = Quality of life; VAS = Visual analogue scale.

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

Mean QoL assessment, difference in mean QoL assessment with corresponding confidence interval and p-value were obtained from mixed-effects model with QoL assessment as dependent variable, treatment group as independent variable and subject as random effect.

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