

Table 14.2.2.7.1.7 Summary of study specific quality of life questionnaire by order of vulvovaginitis episode and treatment (PPS)

Variable	VV episode order	Statistics	IMUNOR		PLACEBO	
			Value	Change from BL	Value	Change from BL
Number of days unable to work/study due to VV	Episode 1	n / missing	23 / 2	22 / 3	9 / 8	9 / 8
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
		Median	0.0	0.0	0.0	0.0
		IQR	0.0	0.0	0.0	0.0
		Q1 / Q3	0.0 / 0.0	0.0 / 0.0	0.0 / 0.0	0.0 / 0.0
		Min / Max	0 / 0	0 / 0	0 / 0	0 / 0
	Episode 2	n / missing	13 / 0	13 / 0	6 / 6	6 / 6
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
		Median	0.0	0.0	0.0	0.0
		IQR	0.0	0.0	0.0	0.0
		Q1 / Q3	0.0 / 0.0	0.0 / 0.0	0.0 / 0.0	0.0 / 0.0
		Min / Max	0 / 0	0 / 0	0 / 0	0 / 0
	Episode 3	n / missing	4 / 0	4 / 0	6 / 0	6 / 0
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.5 (1.22)	0.5 (1.22)
		Median	0.0	0.0	0.0	0.0
		IQR	0.0	0.0	0.0	0.0
		Q1 / Q3	0.0 / 0.0	0.0 / 0.0	0.0 / 0.0	0.0 / 0.0
		Min / Max	0 / 0	0 / 0	0 / 3	0 / 3
	Episode 4	n / missing	2 / 0	2 / 0	3 / 0	3 / 0
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
		Median	0.0	0.0	0.0	0.0
		IQR	0.0	0.0	0.0	0.0
		Q1 / Q3	0.0 / 0.0	0.0 / 0.0	0.0 / 0.0	0.0 / 0.0
		Min / Max	0 / 0	0 / 0	0 / 0	0 / 0
	Episode 5	n / missing	1 / 0	1 / 0		
		Mean (SD)	N/A	N/A		
		Median	0.0	0.0		
		IQR	N/A	N/A		
		Q1 / Q3	N/A	N/A		
		Min / Max	N/A	N/A		
	Episode 6	n / missing	1 / 0	1 / 0		
		Mean (SD)	N/A	N/A		
		Median	0.0	0.0		
		IQR	N/A	N/A		
		Q1 / Q3	N/A	N/A		
		Min / Max	N/A	N/A		

BL = Baseline; IQR = Interquartile range; Max = Maximum; Min = Minimum; n = Number of subjects with available value; N/A = Not applicable; missing = Number of subjects at visit with missing value; PPS = Per Protocol Set; Q1 = lower quartile (25th percentile); Q3 = upper quartile (75th percentile); SD = Standard deviation; VV = Vulvovaginitis.

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Table 14.2.2.7.1.7 Summary of study specific quality of life questionnaire by order of vulvovaginitis episode and treatment (PPS)

Variable	VV episode order	Statistics	IMUNOR		PLACEBO	
			Value	Change from BL	Value	Change from BL
Number of days of partial work/study restriction due to VV	Episode 1	n / missing	23 / 2	22 / 3	9 / 8	9 / 8
		Mean (SD)	0.1 (0.42)	-0.6 (1.26)	0.4 (1.33)	-0.2 (2.54)
		Median	0.0	0.0	0.0	0.0
		IQR	0.0	0.0	0.0	0.0
		Q1 / Q3	0.0 / 0.0	0.0 / 0.0	0.0 / 0.0	0.0 / 0.0
		Min / Max	0 / 2	-4 / 0	0 / 4	-6 / 4
	Episode 2	n / missing	13 / 0	13 / 0	6 / 6	6 / 6
		Mean (SD)	0.2 (0.55)	-0.6 (1.26)	0.7 (1.63)	0.0 (2.53)
		Median	0.0	0.0	0.0	0.0
		IQR	0.0	0.0	0.0	0.0
		Q1 / Q3	0.0 / 0.0	0.0 / 0.0	0.0 / 0.0	0.0 / 0.0
		Min / Max	0 / 2	-4 / 0	0 / 4	-4 / 4
	Episode 3	n / missing	4 / 0	4 / 0	6 / 0	6 / 0
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.5 (1.22)	0.5 (1.22)
		Median	0.0	0.0	0.0	0.0
		IQR	0.0	0.0	0.0	0.0
		Q1 / Q3	0.0 / 0.0	0.0 / 0.0	0.0 / 0.0	0.0 / 0.0
		Min / Max	0 / 0	0 / 0	0 / 3	0 / 3
	Episode 4	n / missing	2 / 0	2 / 0	3 / 0	3 / 0
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
		Median	0.0	0.0	0.0	0.0
		IQR	0.0	0.0	0.0	0.0
		Q1 / Q3	0.0 / 0.0	0.0 / 0.0	0.0 / 0.0	0.0 / 0.0
		Min / Max	0 / 0	0 / 0	0 / 0	0 / 0
	Episode 5	n / missing	1 / 0	1 / 0		
		Mean (SD)	N/A	N/A		
		Median	0.0	0.0		
		IQR	N/A	N/A		
		Q1 / Q3	N/A	N/A		
		Min / Max	N/A	N/A		
	Episode 6	n / missing	1 / 0	1 / 0		
		Mean (SD)	N/A	N/A		
		Median	0.0	0.0		
		IQR	N/A	N/A		
		Q1 / Q3	N/A	N/A		
		Min / Max	N/A	N/A		

BL = Baseline; IQR = Interquartile range; Max = Maximum; Min = Minimum; n = Number of subjects with available value; N/A = Not applicable; missing = Number of subjects at visit with missing value; PPS = Per Protocol Set; Q1 = lower quartile (25th percentile); Q3 = upper quartile (75th percentile); SD = Standard deviation; VV = Vulvovaginitis.

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Table 14.2.2.7.1.7 Summary of study specific quality of life questionnaire by order of vulvovaginitis episode and treatment (PPS)

Variable	VV episode order	Statistics	IMUNOR		PLACEBO	
			Value	Change from BL	Value	Change from BL
Quality of Life during actual episode/visit	Episode 1	n / missing	23 / 2	22 / 3	10 / 7	10 / 7
		Mean (SD)	5.0 (1.80)	1.0 (1.68)	4.3 (2.26)	0.5 (1.78)
		Median	5.0	0.5	5.0	0.0
		IQR	3.0	2.0	3.0	1.0
		Q1 / Q3	4.0 / 7.0	0.0 / 2.0	3.0 / 6.0	0.0 / 1.0
		Min / Max	2 / 8	-2 / 5	0 / 7	-2 / 4
	Episode 2	n / missing	13 / 0	13 / 0	6 / 6	6 / 6
		Mean (SD)	5.7 (2.18)	1.7 (2.14)	5.0 (1.67)	0.8 (1.83)
		Median	6.0	1.0	4.5	1.0
		IQR	2.0	4.0	3.0	2.0
		Q1 / Q3	5.0 / 7.0	0.0 / 4.0	4.0 / 7.0	0.0 / 2.0
		Min / Max	1 / 9	-1 / 5	3 / 7	-2 / 3
	Episode 3	n / missing	4 / 0	4 / 0	6 / 0	6 / 0
		Mean (SD)	4.5 (3.32)	1.0 (2.94)	5.5 (1.52)	0.5 (1.64)
		Median	3.5	0.5	5.5	0.5
		IQR	5.0	4.0	2.0	1.0
		Q1 / Q3	2.0 / 7.0	-1.0 / 3.0	5.0 / 7.0	0.0 / 1.0
		Min / Max	2 / 9	-2 / 5	3 / 7	-2 / 3
	Episode 4	n / missing	2 / 0	2 / 0	3 / 0	3 / 0
		Mean (SD)	5.0 (0.00)	2.0 (1.41)	6.7 (0.58)	0.3 (0.58)
		Median	5.0	2.0	7.0	0.0
		IQR	0.0	2.0	1.0	1.0
		Q1 / Q3	5.0 / 5.0	1.0 / 3.0	6.0 / 7.0	0.0 / 1.0
		Min / Max	5 / 5	1 / 3	6 / 7	0 / 1
	Episode 5	n / missing	1 / 0	1 / 0		
		Mean (SD)	N/A	N/A		
		Median	7.0	5.0		
		IQR	N/A	N/A		
		Q1 / Q3	N/A	N/A		
		Min / Max	N/A	N/A		
	Episode 6	n / missing	1 / 0	1 / 0		
		Mean (SD)	N/A	N/A		
		Median	7.0	5.0		
		IQR	N/A	N/A		
		Q1 / Q3	N/A	N/A		
		Min / Max	N/A	N/A		

BL = Baseline; IQR = Interquartile range; Max = Maximum; Min = Minimum; n = Number of subjects with available value; N/A = Not applicable; missing = Number of subjects at visit with missing value; PPS = Per Protocol Set; Q1 = lower quartile (25th percentile); Q3 = upper quartile (75th percentile); SD = Standard deviation; VV = Vulvovaginitis.

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Table 14.2.2.7.2.7 Summary of study specific quality of life questionnaire by order of vulvovaginitis episode and treatment (FAS)

Variable	VV episode order	Statistics	IMUNOR		PLACEBO	
			Value	Change from BL	Value	Change from BL
Number of days unable to work/study due to VV	Episode 1	n / missing	41 / 4	39 / 6	20 / 13	20 / 13
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.4 (1.09)	0.4 (1.09)
		Median	0.0	0.0	0.0	0.0
		IQR	0.0	0.0	0.0	0.0
		Q1 / Q3	0.0 / 0.0	0.0 / 0.0	0.0 / 0.0	0.0 / 0.0
		Min / Max	0 / 0	0 / 0	0 / 4	0 / 4
	Episode 2	n / missing	19 / 1	19 / 1	8 / 10	8 / 10
		Mean (SD)	0.1 (0.23)	0.1 (0.23)	0.0 (0.00)	0.0 (0.00)
		Median	0.0	0.0	0.0	0.0
		IQR	0.0	0.0	0.0	0.0
		Q1 / Q3	0.0 / 0.0	0.0 / 0.0	0.0 / 0.0	0.0 / 0.0
		Min / Max	0 / 1	0 / 1	0 / 0	0 / 0
	Episode 3	n / missing	7 / 0	7 / 0	9 / 2	9 / 2
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.4 (1.01)	0.4 (1.01)
		Median	0.0	0.0	0.0	0.0
		IQR	0.0	0.0	0.0	0.0
		Q1 / Q3	0.0 / 0.0	0.0 / 0.0	0.0 / 0.0	0.0 / 0.0
		Min / Max	0 / 0	0 / 0	0 / 3	0 / 3
	Episode 4	n / missing	4 / 0	4 / 0	5 / 2	5 / 2
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
		Median	0.0	0.0	0.0	0.0
		IQR	0.0	0.0	0.0	0.0
		Q1 / Q3	0.0 / 0.0	0.0 / 0.0	0.0 / 0.0	0.0 / 0.0
		Min / Max	0 / 0	0 / 0	0 / 0	0 / 0
	Episode 5	n / missing	1 / 0	1 / 0		
		Mean (SD)	N/A	N/A		
		Median	0.0	0.0		
		IQR	N/A	N/A		
		Q1 / Q3	N/A	N/A		
		Min / Max	N/A	N/A		
	Episode 6	n / missing	1 / 0	1 / 0		
		Mean (SD)	N/A	N/A		
		Median	0.0	0.0		
		IQR	N/A	N/A		
		Q1 / Q3	N/A	N/A		
		Min / Max	N/A	N/A		

BL = Baseline; FAS = Full Analysis Set; IQR = Interquartile range; Max = Maximum; Min = Minimum; n = Number of subjects with available value; N/A = Not applicable; missing = Number of subjects at visit with missing value; Q1 = lower quartile (25th percentile); Q3 = upper quartile (75th percentile); SD = Standard deviation; VV = Vulvovaginitis.

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Table 14.2.2.7.2.7 Summary of study specific quality of life questionnaire by order of vulvovaginitis episode and treatment (FAS)

Variable	VV episode order	Statistics	IMUNOR		PLACEBO	
			Value	Change from BL	Value	Change from BL
Number of days of partial work/study restriction due to VV	Episode 1	n / missing	41 / 4	39 / 6	20 / 13	20 / 13
		Mean (SD)	0.3 (1.28)	-0.7 (1.90)	0.7 (1.59)	-1.3 (3.84)
		Median	0.0	0.0	0.0	0.0
		IQR	0.0	1.0	0.0	1.5
		Q1 / Q3	0.0 / 0.0	-1.0 / 0.0	0.0 / 0.0	-1.5 / 0.0
		Min / Max	0 / 7	-6 / 4	0 / 5	-10 / 4
	Episode 2	n / missing	19 / 1	19 / 1	8 / 10	8 / 10
		Mean (SD)	1.4 (2.87)	0.1 (3.14)	0.5 (1.41)	-0.3 (2.25)
		Median	0.0	0.0	0.0	0.0
		IQR	2.0	2.0	0.0	1.0
		Q1 / Q3	0.0 / 2.0	-2.0 / 0.0	0.0 / 0.0	-1.0 / 0.0
		Min / Max	0 / 10	-4 / 10	0 / 4	-4 / 4
	Episode 3	n / missing	7 / 0	7 / 0	9 / 2	9 / 2
		Mean (SD)	0.3 (0.76)	-0.3 (1.25)	0.4 (1.01)	-1.2 (3.60)
		Median	0.0	0.0	0.0	0.0
		IQR	0.0	0.0	0.0	2.0
		Q1 / Q3	0.0 / 0.0	0.0 / 0.0	0.0 / 0.0	-2.0 / 0.0
		Min / Max	0 / 2	-3 / 1	0 / 3	-10 / 3
	Episode 4	n / missing	4 / 0	4 / 0	5 / 2	5 / 2
		Mean (SD)	0.8 (1.50)	0.5 (1.00)	0.0 (0.00)	-0.6 (0.89)
		Median	0.0	0.0	0.0	0.0
		IQR	1.5	1.0	0.0	1.0
		Q1 / Q3	0.0 / 1.5	0.0 / 1.0	0.0 / 0.0	-1.0 / 0.0
		Min / Max	0 / 3	0 / 2	0 / 0	-2 / 0
	Episode 5	n / missing	1 / 0	1 / 0		
		Mean (SD)	N/A	N/A		
		Median	0.0	0.0		
		IQR	N/A	N/A		
		Q1 / Q3	N/A	N/A		
		Min / Max	N/A	N/A		
	Episode 6	n / missing	1 / 0	1 / 0		
		Mean (SD)	N/A	N/A		
		Median	0.0	0.0		
		IQR	N/A	N/A		
		Q1 / Q3	N/A	N/A		
		Min / Max	N/A	N/A		

BL = Baseline; FAS = Full Analysis Set; IQR = Interquartile range; Max = Maximum; Min = Minimum; n = Number of subjects with available value; N/A = Not applicable; missing = Number of subjects at visit with missing value; Q1 = lower quartile (25th percentile); Q3 = upper quartile (75th percentile); SD = Standard deviation; VV = Vulvovaginitis.

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Table 14.2.2.7.2.7 Summary of study specific quality of life questionnaire by order of vulvovaginitis episode and treatment (FAS)

Variable	VV episode order	Statistics	IMUNOR		PLACEBO	
			Value	Change from BL	Value	Change from BL
Quality of Life during actual episode/visit	Episode 1	n / missing	42 / 3	40 / 5	23 / 10	23 / 10
		Mean (SD)	5.4 (2.03)	1.5 (1.96)	4.4 (2.06)	0.4 (1.83)
		Median	5.0	1.0	5.0	0.0
		IQR	3.0	3.0	2.0	3.0
		Q1 / Q3	4.0 / 7.0	0.0 / 3.0	3.0 / 5.0	-1.0 / 2.0
		Min / Max	1 / 9	-2 / 6	0 / 8	-3 / 4
	Episode 2	n / missing	20 / 0	19 / 1	8 / 10	8 / 10
		Mean (SD)	5.2 (2.09)	1.7 (2.14)	5.5 (2.33)	1.3 (1.91)
		Median	5.0	2.0	4.5	1.5
		IQR	2.5	4.0	3.0	2.5
		Q1 / Q3	4.0 / 6.5	0.0 / 4.0	4.0 / 7.0	0.0 / 2.5
		Min / Max	1 / 9	-2 / 5	3 / 10	-2 / 4
	Episode 3	n / missing	7 / 0	7 / 0	9 / 2	9 / 2
		Mean (SD)	5.0 (2.58)	1.6 (2.51)	5.7 (2.18)	0.6 (1.94)
		Median	5.0	1.0	5.0	0.0
		IQR	5.0	4.0	2.0	2.0
		Q1 / Q3	2.0 / 7.0	0.0 / 4.0	5.0 / 7.0	-1.0 / 1.0
		Min / Max	2 / 9	-2 / 5	3 / 10	-2 / 4
	Episode 4	n / missing	4 / 0	4 / 0	5 / 2	5 / 2
		Mean (SD)	5.3 (1.26)	3.0 (1.41)	6.2 (3.27)	0.2 (2.86)
		Median	5.0	3.5	7.0	0.0
		IQR	1.5	2.0	1.0	1.0
		Q1 / Q3	4.5 / 6.0	2.0 / 4.0	6.0 / 7.0	0.0 / 1.0
		Min / Max	4 / 7	1 / 4	1 / 10	-4 / 4
	Episode 5	n / missing	1 / 0	1 / 0		
		Mean (SD)	N/A	N/A		
		Median	7.0	5.0		
		IQR	N/A	N/A		
		Q1 / Q3	N/A	N/A		
		Min / Max	N/A	N/A		
	Episode 6	n / missing	1 / 0	1 / 0		
		Mean (SD)	N/A	N/A		
		Median	7.0	5.0		
		IQR	N/A	N/A		
		Q1 / Q3	N/A	N/A		
		Min / Max	N/A	N/A		

BL = Baseline; FAS = Full Analysis Set; IQR = Interquartile range; Max = Maximum; Min = Minimum; n = Number of subjects with available value; N/A = Not applicable; missing = Number of subjects at visit with missing value; Q1 = lower quartile (25th percentile); Q3 = upper quartile (75th percentile); SD = Standard deviation; VV = Vulvovaginitis.

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