

Table 14.2.2.7.1.5 Summary of EQ-5D summary index and EQ-VAS by order of vulvovaginitis episode and treatment (PPS)

Variable	VV episode order	Statistics	IMUNOR		PLACEBO	
			Value	Change from BL	Value	Change from BL
EQ Overall Health (VAS)	Episode 1	n / missing	23 / 2	22 / 3	10 / 7	10 / 7
		Mean (SD)	69.3 (16.55)	-14.0 (15.57)	66.0 (12.87)	-13.3 (14.14)
		Median	70.0	-10.0	70.0	-10.0
		IQR	20.0	17.0	25.0	30.0
		Q1 / Q3	60.0 / 80.0	-20.0 / -3.0	55.0 / 80.0	-30.0 / 0.0
		Min / Max	30 / 95	-50 / 5	45 / 80	-38 / 0
	Episode 2	n / missing	13 / 0	13 / 0	6 / 6	6 / 6
		Mean (SD)	69.6 (14.64)	-8.7 (20.20)	70.8 (12.81)	-7.2 (25.14)
		Median	70.0	0.0	67.5	-10.0
		IQR	20.0	23.0	20.0	35.0
		Q1 / Q3	60.0 / 80.0	-23.0 / 0.0	60.0 / 80.0	-25.0 / 10.0
		Min / Max	50 / 90	-50 / 30	60 / 90	-38 / 30
	Episode 3	n / missing	4 / 0	4 / 0	6 / 0	6 / 0
		Mean (SD)	67.5 (32.79)	-6.3 (41.91)	62.5 (7.58)	-15.5 (16.11)
		Median	72.5	-12.5	62.5	-17.5
		IQR	55.0	57.5	10.0	25.0
		Q1 / Q3	40.0 / 95.0	-35.0 / 22.5	60.0 / 70.0	-30.0 / -5.0
		Min / Max	30 / 95	-50 / 50	50 / 70	-33 / 10
	Episode 4	n / missing	2 / 0	2 / 0	3 / 0	3 / 0
		Mean (SD)	60.0 (42.43)	-25.0 (21.21)	68.3 (20.21)	-12.7 (19.14)
		Median	60.0	-25.0	65.0	-10.0
		IQR	60.0	30.0	40.0	38.0
		Q1 / Q3	30.0 / 90.0	-40.0 / -10.0	50.0 / 90.0	-33.0 / 5.0
		Min / Max	30 / 90	-40 / -10	50 / 90	-33 / 5
	Episode 5	n / missing	1 / 0	1 / 0		
		Mean (SD)	N/A	N/A		
		Median	70.0	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	65.0	-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; VAS = Visual analogue scale; VV = Vulvovaginitis.

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Variable	VV episode order	Statistics	IMUNOR		PLACEBO	
			Value	Change from BL	Value	Change from BL
EQ-5D Summary Index	Episode 1	n / missing	23 / 2	22 / 3	10 / 7	10 / 7
		Mean (SD)	0.939 (0.0733)	-0.031 (0.0718)	0.921 (0.1113)	-0.034 (0.0944)
		Median	0.937	0.000	0.961	0.000
		IQR	0.084	0.063	0.113	0.021
		Q1 / Q3	0.916 / 1.000	-0.063 / 0.000	0.887 / 1.000	-0.021 / 0.000
		Min / Max	0.72 / 1.00	-0.29 / 0.10	0.65 / 1.00	-0.24 / 0.06
	Episode 2	n / missing	13 / 0	13 / 0	5 / 7	5 / 7
		Mean (SD)	0.948 (0.0545)	0.003 (0.0524)	0.917 (0.0788)	-0.023 (0.0820)
		Median	0.937	0.000	0.892	0.000
		IQR	0.084	0.000	0.141	0.021
		Q1 / Q3	0.916 / 1.000	0.000 / 0.000	0.859 / 1.000	0.000 / 0.021
		Min / Max	0.86 / 1.00	-0.14 / 0.08	0.83 / 1.00	-0.17 / 0.03
	Episode 3	n / missing	4 / 0	4 / 0	6 / 0	6 / 0
		Mean (SD)	0.916 (0.0795)	-0.030 (0.1141)	0.872 (0.1097)	-0.067 (0.1044)
		Median	0.927	-0.003	0.851	-0.038
		IQR	0.106	0.138	0.217	0.107
		Q1 / Q3	0.863 / 0.969	-0.099 / 0.039	0.783 / 1.000	-0.107 / 0.000
		Min / Max	0.81 / 1.00	-0.19 / 0.08	0.75 / 1.00	-0.25 / 0.03
	Episode 4	n / missing	2 / 0	2 / 0	3 / 0	3 / 0
		Mean (SD)	0.969 (0.0445)	0.008 (0.0106)	0.880 (0.1040)	-0.073 (0.1010)
		Median	0.969	0.008	0.829	-0.030
		IQR	0.063	0.015	0.188	0.188
		Q1 / Q3	0.937 / 1.000	0.000 / 0.015	0.812 / 1.000	-0.188 / 0.000
		Min / Max	0.94 / 1.00	0.00 / 0.02	0.81 / 1.00	-0.19 / 0.00
	Episode 5	n / missing	1 / 0	1 / 0		
		Mean (SD)	N/A	N/A		
		Median	0.937	0.015		
		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	0.937	0.015		
		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; VAS = Visual analogue scale; VV = Vulvovaginitis.

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Table 14.2.2.7.2.5 Summary of EQ-5D summary index and EQ-VAS by order of vulvovaginitis episode and treatment (FAS)

Variable	VV episode order	Statistics	IMUNOR		PLACEBO	
			Value	Change from BL	Value	Change from BL
EQ Overall Health (VAS)	Episode 1	n / missing	42 / 3	41 / 4	23 / 10	23 / 10
		Mean (SD)	69.5 (17.56)	-14.1 (18.11)	63.9 (16.37)	-20.3 (18.53)
		Median	75.0	-10.0	60.0	-15.0
		IQR	15.0	17.0	30.0	34.0
		Q1 / Q3	65.0 / 80.0	-20.0 / -3.0	50.0 / 80.0	-38.0 / -4.0
		Min / Max	30 / 100	-65 / 25	30 / 95	-60 / 5
	Episode 2	n / missing	20 / 0	20 / 0	8 / 10	8 / 10
		Mean (SD)	66.8 (18.59)	-13.2 (20.80)	74.4 (12.94)	-9.0 (21.65)
		Median	70.0	-10.0	77.5	-14.5
		IQR	22.5	30.0	25.0	27.5
		Q1 / Q3	55.0 / 77.5	-30.0 / 0.0	60.0 / 85.0	-22.5 / 5.0
		Min / Max	20 / 90	-55 / 30	60 / 90	-38 / 30
	Episode 3	n / missing	7 / 0	7 / 0	9 / 2	9 / 2
		Mean (SD)	64.3 (25.57)	-15.0 (31.75)	64.4 (13.10)	-19.2 (17.37)
		Median	70.0	-20.0	65.0	-20.0
		IQR	55.0	25.0	10.0	20.0
		Q1 / Q3	40.0 / 95.0	-30.0 / -5.0	60.0 / 70.0	-30.0 / -10.0
		Min / Max	30 / 95	-50 / 50	45 / 90	-50 / 10
	Episode 4	n / missing	4 / 0	4 / 0	5 / 2	5 / 2
		Mean (SD)	57.5 (25.98)	-25.0 (12.25)	75.0 (17.32)	-11.6 (13.61)
		Median	55.0	-25.0	80.0	-10.0
		IQR	40.0	15.0	25.0	0.0
		Q1 / Q3	37.5 / 77.5	-32.5 / -17.5	65.0 / 90.0	-10.0 / -10.0
		Min / Max	30 / 90	-40 / -10	50 / 90	-33 / 5
	Episode 5	n / missing	1 / 0	1 / 0		
		Mean (SD)	N/A	N/A		
		Median	70.0	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	65.0	-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; VAS = Visual analogue scale; VV = Vulvovaginitis.

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Table 14.2.2.7.2.5 Summary of EQ-5D summary index and EQ-VAS by order of vulvovaginitis episode and treatment (FAS)

Variable	VV episode order	Statistics	IMUNOR		PLACEBO	
			Value	Change from BL	Value	Change from BL
EQ-5D Summary Index	Episode 1	n / missing	42 / 3	41 / 4	23 / 10	23 / 10
		Mean (SD)	0.932 (0.0700)	-0.037 (0.0722)	0.907 (0.1013)	-0.048 (0.0903)
		Median	0.937	0.000	0.922	0.000
		IQR	0.108	0.063	0.128	0.078
		Q1 / Q3	0.892 / 1.000	-0.063 / 0.000	0.872 / 1.000	-0.078 / 0.000
		Min / Max	0.72 / 1.00	-0.29 / 0.10	0.65 / 1.00	-0.26 / 0.06
	Episode 2	n / missing	20 / 0	20 / 0	7 / 11	7 / 11
		Mean (SD)	0.902 (0.1509)	-0.053 (0.1658)	0.920 (0.0764)	-0.036 (0.0817)
		Median	0.937	0.000	0.892	0.000
		IQR	0.128	0.067	0.141	0.162
		Q1 / Q3	0.873 / 1.000	-0.067 / 0.000	0.859 / 1.000	-0.141 / 0.021
		Min / Max	0.32 / 1.00	-0.68 / 0.08	0.83 / 1.00	-0.17 / 0.03
	Episode 3	n / missing	7 / 0	7 / 0	9 / 2	9 / 2
		Mean (SD)	0.892 (0.0633)	-0.047 (0.0930)	0.879 (0.1272)	-0.080 (0.1255)
		Median	0.866	-0.006	0.892	0.000
		IQR	0.078	0.141	0.217	0.107
		Q1 / Q3	0.859 / 0.937	-0.141 / 0.000	0.783 / 1.000	-0.107 / 0.000
		Min / Max	0.81 / 1.00	-0.19 / 0.08	0.68 / 1.00	-0.32 / 0.03
	Episode 4	n / missing	4 / 0	4 / 0	5 / 2	5 / 2
		Mean (SD)	0.859 (0.1479)	-0.071 (0.1378)	0.877 (0.0864)	-0.094 (0.0896)
		Median	0.888	-0.011	0.829	-0.063
		IQR	0.219	0.156	0.125	0.158
		Q1 / Q3	0.750 / 0.969	-0.149 / 0.008	0.812 / 0.937	-0.188 / -0.030
		Min / Max	0.66 / 1.00	-0.28 / 0.02	0.81 / 1.00	-0.19 / 0.00
	Episode 5	n / missing	1 / 0	1 / 0		
		Mean (SD)	N/A	N/A		
		Median	0.937	0.015		
		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	0.937	0.015		
		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; VAS = Visual analogue scale; VV = Vulvovaginitis.

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