

14.4.2 Summary statistics and changes from baseline of COVID-19 symptom score

----- Result -----										Baseline				---- Change from baseline ----							
Visit	n	95%		95%	Median	SD	Min	Max	Mean	95%		95%	Mean	95%		SD	Min	Max			
		ICI	uCI	ICI						uCI	ICI	uCI									
Baseline (D1)	2	4.5	-1.9	10.9	4.5	0.71	4	5													
Day 2	2	3.5	-2.9	9.9	3.5	0.71	3	4	4.5	-1.9	10.9	4.5	-1.0			-1.0	0.00	-1	-1		
Day 3	2	2.5	-3.9	8.9	2.5	0.71	2	3	4.5	-1.9	10.9	4.5	-2.0	-14.7	10.7	-2.0	1.41	-3	-1		
Day 4	2	2.0			2.0	0.00	2	2	4.5	-1.9	10.9	4.5	-2.5	-8.9	3.9	-2.5	0.71	-3	-2		
Day 5	2	2.0			2.0	0.00	2	2	4.5	-1.9	10.9	4.5	-2.5	-8.9	3.9	-2.5	0.71	-3	-2		
Day 6	2	2.5	-3.9	8.9	2.5	0.71	2	3	4.5	-1.9	10.9	4.5	-2.0			-2.0	0.00	-2	-2		
Day 7	2	2.5	-3.9	8.9	2.5	0.71	2	3	4.5	-1.9	10.9	4.5	-2.0			-2.0	0.00	-2	-2		
Day 8	2	2.5	-3.9	8.9	2.5	0.71	2	3	4.5	-1.9	10.9	4.5	-2.0			-2.0	0.00	-2	-2		
Day 9	2	2.5	-16.6	21.6	2.5	2.12	1	4	4.5	-1.9	10.9	4.5	-2.0	-14.7	10.7	-2.0	1.41	-3	-1		
Day 10	2	1.0			1.0	0.00	1	1	4.5	-1.9	10.9	4.5	-3.5	-9.9	2.9	-3.5	0.71	-4	-3		
Day 11	2	1.0			1.0	0.00	1	1	4.5	-1.9	10.9	4.5	-3.5	-9.9	2.9	-3.5	0.71	-4	-3		
Day 12	2	1.0			1.0	0.00	1	1	4.5	-1.9	10.9	4.5	-3.5	-9.9	2.9	-3.5	0.71	-4	-3		
Day 13	2	1.0			1.0	0.00	1	1	4.5	-1.9	10.9	4.5	-3.5	-9.9	2.9	-3.5	0.71	-4	-3		
Day 14	2	2.0	-10.7	14.7	2.0	1.41	1	3	4.5	-1.9	10.9	4.5	-2.5	-8.9	3.9	-2.5	0.71	-3	-2		
Day 15	2	1.5	-4.9	7.9	1.5	0.71	1	2	4.5	-1.9	10.9	4.5	-3.0			-3.0	0.00	-3	-3		
Day 16	2	1.5	-4.9	7.9	1.5	0.71	1	2	4.5	-1.9	10.9	4.5	-3.0			-3.0	0.00	-3	-3		
Day 17	2	1.0			1.0	0.00	1	1	4.5	-1.9	10.9	4.5	-3.5	-9.9	2.9	-3.5	0.71	-4	-3		
Day 18	2	2.5	-16.6	21.6	2.5	2.12	1	4	4.5	-1.9	10.9	4.5	-2.0	-14.7	10.7	-2.0	1.41	-3	-1		
Day 19	2	2.5	-16.6	21.6	2.5	2.12	1	4	4.5	-1.9	10.9	4.5	-2.0	-14.7	10.7	-2.0	1.41	-3	-1		
Day 20	2	1.5	-4.9	7.9	1.5	0.71	1	2	4.5	-1.9	10.9	4.5	-3.0			-3.0	0.00	-3	-3		
Day 21	2	1.5	-4.9	7.9	1.5	0.71	1	2	4.5	-1.9	10.9	4.5	-3.0			-3.0	0.00	-3	-3		
Day 22	2	1.5	-4.9	7.9	1.5	0.71	1	2	4.5	-1.9	10.9	4.5	-3.0			-3.0	0.00	-3	-3		
Day 23	2	2.0	-10.7	14.7	2.0	1.41	1	3	4.5	-1.9	10.9	4.5	-2.5	-8.9	3.9	-2.5	0.71	-3	-2		
Day 24	2	1.5	-17.6	20.6	1.5	2.12	0	3	4.5	-1.9	10.9	4.5	-3.0	-15.7	9.7	-3.0	1.41	-4	-2		
Day 25	2	1.0	-11.7	13.7	1.0	1.41	0	2	4.5	-1.9	10.9	4.5	-3.5	-9.9	2.9	-3.5	0.71	-4	-3		
Day 26	2	1.0	-11.7	13.7	1.0	1.41	0	2	4.5	-1.9	10.9	4.5	-3.5	-9.9	2.9	-3.5	0.71	-4	-3		
Day 27	2	1.0	-11.7	13.7	1.0	1.41	0	2	4.5	-1.9	10.9	4.5	-3.5	-9.9	2.9	-3.5	0.71	-4	-3		
EoS (Day 21-28)	3	0.7	-2.2	3.5	0.0	1.15	0	2	4.5	-1.9	10.9	4.5	-3.5	-9.9	2.9	-3.5	0.71	-4	-3		

n = Number of subjects, CI = Confidence interval, ICI = Lower limit of CI, uCI = Upper limit of CI, SD = Standard deviation.

Baseline is defined as the last value measured prior to the study treatment start.

14.4.3 Frequency table of COVID-19 symptoms

Visit	Question	Answer	Bazedoxifene (N = 3) n (%)
Baseline (D1)	Q1: Fever (morning)	37-37,4 °C	0
		37,5-38 °C	0
		over 38 °C	0
	Q2: Fever (evening)	37-37,4 °C	0
		37,5-38 °C	0
		over 38 °C	0
	Q3: Cough (day)	Slight cough	2 (100%)
		Hacking cough	0
	Q4: Cough (night)	Slight cough	0
		Waking up	0
	Q5: Fatigue	Mild	2 (100%)
		Moderate	0
	Q6: Taste perception	Decreased	2 (100%)
	Q7: Smell perception	Decreased	0
Day 2	Q1: Fever (morning)	Mild	0
		Moderate	0
		ATB	0
	Q10: Oxygenotherapy	Oxygenotherapy needed	2 (100%)
	Q11: Other symptoms	Headache	1 (50.0%)
	Q1: Fever (morning)	37-37,4 °C	0
		37,5-38 °C	0
		over 38 °C	0
	Q2: Fever (evening)	37-37,4 °C	0
		37,5-38 °C	0
		over 38 °C	0
	Q3: Cough (day)	Slight cough	2 (100%)
		Hacking cough	0
	Q4: Cough (night)	Slight cough	0
		Waking up	0
	Q5: Fatigue	Mild	2 (100%)
		Moderate	0
Day 3	Q6: Taste perception	Decreased	1 (50.0%)
	Q7: Smell perception	Decreased	0
	Q8: Diarrhea/ vomiting	Mild	0
		Moderate	0
	Q9: Need of antibiotics	ATB	0
	Q10: Oxygenotherapy	Oxygenotherapy needed	2 (100%)
	Q11: Other symptoms	Headache	0
	Q1: Fever (morning)	37-37,4 °C	0
		37,5-38 °C	0
		over 38 °C	0
	Q2: Fever (evening)	37-37,4 °C	0
		37,5-38 °C	0
		over 38 °C	0
	Q3: Cough (day)	Slight cough	2 (100%)
		Hacking cough	0
	Q4: Cough (night)	Slight cough	0
		Waking up	0
	Q5: Fatigue	Mild	2 (100%)
		Moderate	0
	Q6: Taste perception	Decreased	0
	Q7: Smell perception	Decreased	0
	Q8: Diarrhea/ vomiting	Mild	0
		Moderate	0
	Q9: Need of antibiotics	ATB	0
	Q10: Oxygenotherapy	Oxygenotherapy needed	1 (50.0%)
	Q11: Other symptoms	Headache	0

			Bazedoxifene (N = 3) n (%)
Visit	Question	Answer	
Day 4	Q1: Fever (morning)	37-37,4 °C	0
		37,5-38 °C	0
		over 38 °C	0
	Q2: Fever (evening)	37-37,4 °C	0
		37,5-38 °C	0
		over 38 °C	0
	Q3: Cough (day)	Slight cough	1 (50.0%)
		Hacking cough	0
	Q4: Cough (night)	Slight cough	0
		Waking up	0
	Q5: Fatigue	Mild	2 (100%)
		Moderate	0
	Q6: Taste perception	Decreased	0
	Q7: Smell perception	Decreased	0
Day 5	Q1: Fever (morning)	37-37,4 °C	0
		37,5-38 °C	0
		over 38 °C	0
	Q2: Fever (evening)	37-37,4 °C	0
		37,5-38 °C	0
		over 38 °C	0
	Q3: Cough (day)	Slight cough	1 (50.0%)
		Hacking cough	0
	Q4: Cough (night)	Slight cough	0
		Waking up	0
	Q5: Fatigue	Mild	2 (100%)
		Moderate	0
	Q6: Taste perception	Decreased	0
	Q7: Smell perception	Decreased	0
Day 6	Q1: Fever (morning)	37-37,4 °C	0
		37,5-38 °C	0
		over 38 °C	0
	Q2: Fever (evening)	37-37,4 °C	1 (50.0%)
		37,5-38 °C	0
		over 38 °C	0
	Q3: Cough (day)	Slight cough	1 (50.0%)
		Hacking cough	0
	Q4: Cough (night)	Slight cough	0
		Waking up	0
	Q5: Fatigue	Mild	2 (100%)
		Moderate	0
	Q6: Taste perception	Decreased	0
	Q7: Smell perception	Decreased	0

			Bazedoxifene (N = 3) n (%)
Visit	Question	Answer	
Day 7	Q1: Fever (morning)	37-37,4 °C	0
		37,5-38 °C	0
		over 38 °C	0
	Q2: Fever (evening)	37-37,4 °C	1 (50.0%)
		37,5-38 °C	0
		over 38 °C	0
	Q3: Cough (day)	Slight cough	1 (50.0%)
		Hacking cough	0
	Q4: Cough (night)	Slight cough	0
		Waking up	0
	Q5: Fatigue	Mild	2 (100%)
		Moderate	0
	Q6: Taste perception	Decreased	0
	Q7: Smell perception	Decreased	0
Day 8	Q1: Fever (morning)	37-37,4 °C	0
		37,5-38 °C	0
		over 38 °C	0
	Q2: Fever (evening)	37-37,4 °C	1 (50.0%)
		37,5-38 °C	0
		over 38 °C	0
	Q3: Cough (day)	Slight cough	1 (50.0%)
		Hacking cough	0
	Q4: Cough (night)	Slight cough	0
		Waking up	0
	Q5: Fatigue	Mild	2 (100%)
		Moderate	0
	Q6: Taste perception	Decreased	0
	Q7: Smell perception	Decreased	0
Day 9	Q1: Fever (morning)	37-37,4 °C	1 (50.0%)
		37,5-38 °C	0
		over 38 °C	0
	Q2: Fever (evening)	37-37,4 °C	1 (50.0%)
		37,5-38 °C	0
		over 38 °C	0
	Q3: Cough (day)	Slight cough	1 (50.0%)
		Hacking cough	0
	Q4: Cough (night)	Slight cough	0
		Waking up	0
	Q5: Fatigue	Mild	2 (100%)
		Moderate	0
	Q6: Taste perception	Decreased	0
	Q7: Smell perception	Decreased	0
	Q8: Diarrhea/ vomiting	Mild	0
		Moderate	0
	Q9: Need of antibiotics	ATB	0
	Q10: Oxygenotherapy	Oxygenotherapy needed	0
	Q11: Other symptoms	Headache	0

			Bazedoxifene (N = 3) n (%)
Visit	Question	Answer	
Day 10	Q1: Fever (morning)	37-37,4 °C	0
		37,5-38 °C	0
		over 38 °C	0
	Q2: Fever (evening)	37-37,4 °C	0
		37,5-38 °C	0
		over 38 °C	0
	Q3: Cough (day)	Slight cough	0
		Hacking cough	0
	Q4: Cough (night)	Slight cough	0
		Waking up	0
	Q5: Fatigue	Mild	2 (100%)
		Moderate	0
	Q6: Taste perception	Decreased	0
	Q7: Smell perception	Decreased	0
Day 11	Q1: Fever (morning)	37-37,4 °C	0
		37,5-38 °C	0
		over 38 °C	0
	Q2: Fever (evening)	37-37,4 °C	0
		37,5-38 °C	0
		over 38 °C	0
	Q3: Cough (day)	Slight cough	0
		Hacking cough	0
	Q4: Cough (night)	Slight cough	0
		Waking up	0
	Q5: Fatigue	Mild	2 (100%)
		Moderate	0
	Q6: Taste perception	Decreased	0
	Q7: Smell perception	Decreased	0
Day 12	Q1: Fever (morning)	37-37,4 °C	0
		37,5-38 °C	0
		over 38 °C	0
	Q2: Fever (evening)	37-37,4 °C	0
		37,5-38 °C	0
		over 38 °C	0
	Q3: Cough (day)	Slight cough	0
		Hacking cough	0
	Q4: Cough (night)	Slight cough	0
		Waking up	0
	Q5: Fatigue	Mild	2 (100%)
		Moderate	0
	Q6: Taste perception	Decreased	0
	Q7: Smell perception	Decreased	0
	Q8: Diarrhea/ vomiting	Mild	0
		Moderate	0
	Q9: Need of antibiotics	ATB	0
	Q10: Oxygenotherapy	Oxygenotherapy needed	0
	Q11: Other symptoms	Headache	0

Visit	Question	Answer	Bazedoxifene
			(N = 3) n (%)
Day 13	Q1: Fever (morning)	37-37,4 °C	0
		37,5-38 °C	0
		over 38 °C	0
	Q2: Fever (evening)	37-37,4 °C	0
		37,5-38 °C	0
		over 38 °C	0
	Q3: Cough (day)	Slight cough	0
		Hacking cough	0
	Q4: Cough (night)	Slight cough	0
		Waking up	0
	Q5: Fatigue	Mild	2 (100%)
		Moderate	0
	Q6: Taste perception	Decreased	0
	Q7: Smell perception	Decreased	0
	Q8: Diarrhea/ vomiting	Mild	0
		Moderate	0
Day 14	Q1: Fever (morning)	37-37,4 °C	0
		37,5-38 °C	0
		over 38 °C	0
	Q2: Fever (evening)	37-37,4 °C	1 (50.0%)
		37,5-38 °C	0
		over 38 °C	0
	Q3: Cough (day)	Slight cough	1 (50.0%)
		Hacking cough	0
	Q4: Cough (night)	Slight cough	0
		Waking up	0
	Q5: Fatigue	Mild	2 (100%)
		Moderate	0
	Q6: Taste perception	Decreased	0
	Q7: Smell perception	Decreased	0
	Q8: Diarrhea/ vomiting	Mild	0
		Moderate	0
Day 15	Q1: Fever (morning)	37-37,4 °C	0
		37,5-38 °C	0
		over 38 °C	0
	Q2: Fever (evening)	37-37,4 °C	0
		37,5-38 °C	0
		over 38 °C	0
	Q3: Cough (day)	Slight cough	1 (50.0%)
		Hacking cough	0
	Q4: Cough (night)	Slight cough	0
		Waking up	0
	Q5: Fatigue	Mild	2 (100%)
		Moderate	0
	Q6: Taste perception	Decreased	0
	Q7: Smell perception	Decreased	0
	Q8: Diarrhea/ vomiting	Mild	0
		Moderate	0
	Q9: Need of antibiotics	ATB	0
	Q10: Oxygenotherapy	Oxygenotherapy needed	0
	Q11: Other symptoms	Headache	0

			Bazedoxifene (N = 3) n (%)
Visit	Question	Answer	
Day 16	Q1: Fever (morning)	37-37,4 °C	0
		37,5-38 °C	0
		over 38 °C	0
	Q2: Fever (evening)	37-37,4 °C	0
		37,5-38 °C	0
		over 38 °C	0
	Q3: Cough (day)	Slight cough	1 (50.0%)
		Hacking cough	0
	Q4: Cough (night)	Slight cough	0
		Waking up	0
	Q5: Fatigue	Mild	2 (100%)
		Moderate	0
	Q6: Taste perception	Decreased	0
	Q7: Smell perception	Decreased	0
Day 17	Q1: Fever (morning)	37-37,4 °C	0
		37,5-38 °C	0
		over 38 °C	0
	Q2: Fever (evening)	37-37,4 °C	0
		37,5-38 °C	0
		over 38 °C	0
	Q3: Cough (day)	Slight cough	1 (50.0%)
		Hacking cough	0
	Q4: Cough (night)	Slight cough	0
		Waking up	0
	Q5: Fatigue	Mild	1 (50.0%)
		Moderate	0
	Q6: Taste perception	Decreased	0
	Q7: Smell perception	Decreased	0
Day 18	Q1: Fever (morning)	37-37,4 °C	1 (50.0%)
		37,5-38 °C	0
		over 38 °C	0
	Q2: Fever (evening)	37-37,4 °C	1 (50.0%)
		37,5-38 °C	0
		over 38 °C	0
	Q3: Cough (day)	Slight cough	1 (50.0%)
		Hacking cough	0
	Q4: Cough (night)	Slight cough	0
		Waking up	0
	Q5: Fatigue	Mild	2 (100%)
		Moderate	0
	Q6: Taste perception	Decreased	0
	Q7: Smell perception	Decreased	0
	Q8: Diarrhea/ vomiting	Mild	0
		Moderate	0
	Q9: Need of antibiotics	ATB	0
	Q10: Oxygenotherapy	Oxygenotherapy needed	0
	Q11: Other symptoms	Headache	0

			Bazedoxifene (N = 3) n (%)
Visit	Question	Answer	
Day 19	Q1: Fever (morning)	37-37,4 °C	1 (50.0%)
		37,5-38 °C	0
		over 38 °C	0
	Q2: Fever (evening)	37-37,4 °C	1 (50.0%)
		37,5-38 °C	0
		over 38 °C	0
	Q3: Cough (day)	Slight cough	1 (50.0%)
		Hacking cough	0
	Q4: Cough (night)	Slight cough	0
		Waking up	0
	Q5: Fatigue	Mild	2 (100%)
		Moderate	0
	Q6: Taste perception	Decreased	0
	Q7: Smell perception	Decreased	0
Day 20	Q1: Fever (morning)	37-37,4 °C	0
		37,5-38 °C	0
		over 38 °C	0
	Q2: Fever (evening)	37-37,4 °C	0
		37,5-38 °C	0
		over 38 °C	0
	Q3: Cough (day)	Slight cough	1 (50.0%)
		Hacking cough	0
	Q4: Cough (night)	Slight cough	0
		Waking up	0
	Q5: Fatigue	Mild	2 (100%)
		Moderate	0
	Q6: Taste perception	Decreased	0
	Q7: Smell perception	Decreased	0
Day 21	Q1: Fever (morning)	37-37,4 °C	0
		37,5-38 °C	0
		over 38 °C	0
	Q2: Fever (evening)	37-37,4 °C	0
		37,5-38 °C	0
		over 38 °C	0
	Q3: Cough (day)	Slight cough	1 (50.0%)
		Hacking cough	0
	Q4: Cough (night)	Slight cough	0
		Waking up	0
	Q5: Fatigue	Mild	2 (100%)
		Moderate	0
	Q6: Taste perception	Decreased	0
	Q7: Smell perception	Decreased	0
	Q8: Diarrhea/ vomiting	Mild	0
		Moderate	0
	Q9: Need of antibiotics	ATB	0
	Q10: Oxygenotherapy	Oxygenotherapy needed	0
	Q11: Other symptoms	Headache	0

			Bazedoxifene (N = 3) n (%)
Visit	Question	Answer	
Day 22	Q1: Fever (morning)	37-37,4 °C	0
		37,5-38 °C	0
		over 38 °C	0
	Q2: Fever (evening)	37-37,4 °C	0
		37,5-38 °C	0
		over 38 °C	0
	Q3: Cough (day)	Slight cough	1 (50.0%)
		Hacking cough	0
	Q4: Cough (night)	Slight cough	0
		Waking up	0
	Q5: Fatigue	Mild	2 (100%)
		Moderate	0
	Q6: Taste perception	Decreased	0
	Q7: Smell perception	Decreased	0
Day 23	Q1: Fever (morning)	37-37,4 °C	0
		37,5-38 °C	0
		over 38 °C	0
	Q2: Fever (evening)	37-37,4 °C	1 (50.0%)
		37,5-38 °C	0
		over 38 °C	0
	Q3: Cough (day)	Slight cough	1 (50.0%)
		Hacking cough	0
	Q4: Cough (night)	Slight cough	0
		Waking up	0
	Q5: Fatigue	Mild	2 (100%)
		Moderate	0
	Q6: Taste perception	Decreased	0
	Q7: Smell perception	Decreased	0
Day 24	Q1: Fever (morning)	37-37,4 °C	0
		37,5-38 °C	0
		over 38 °C	0
	Q2: Fever (evening)	37-37,4 °C	1 (50.0%)
		37,5-38 °C	0
		over 38 °C	0
	Q3: Cough (day)	Slight cough	1 (50.0%)
		Hacking cough	0
	Q4: Cough (night)	Slight cough	0
		Waking up	0
	Q5: Fatigue	Mild	1 (50.0%)
		Moderate	0
	Q6: Taste perception	Decreased	0
	Q7: Smell perception	Decreased	0
	Q8: Diarrhea/ vomiting	Mild	0
		Moderate	0
	Q9: Need of antibiotics	ATB	0
	Q10: Oxygenotherapy	Oxygenotherapy needed	0
	Q11: Other symptoms	Headache	0

			Bazedoxifene (N = 3) n (%)
Visit	Question	Answer	
Day 25	Q1: Fever (morning)	37-37,4 °C	0
		37,5-38 °C	0
		over 38 °C	0
	Q2: Fever (evening)	37-37,4 °C	0
		37,5-38 °C	0
		over 38 °C	0
	Q3: Cough (day)	Slight cough	1 (50.0%)
		Hacking cough	0
	Q4: Cough (night)	Slight cough	0
		Waking up	0
	Q5: Fatigue	Mild	1 (50.0%)
		Moderate	0
	Q6: Taste perception	Decreased	0
	Q7: Smell perception	Decreased	0
Day 26	Q1: Fever (morning)	37-37,4 °C	0
		37,5-38 °C	0
		over 38 °C	0
	Q2: Fever (evening)	37-37,4 °C	0
		37,5-38 °C	0
		over 38 °C	0
	Q3: Cough (day)	Slight cough	1 (50.0%)
		Hacking cough	0
	Q4: Cough (night)	Slight cough	0
		Waking up	0
	Q5: Fatigue	Mild	1 (50.0%)
		Moderate	0
	Q6: Taste perception	Decreased	0
	Q7: Smell perception	Decreased	0
Day 27	Q1: Fever (morning)	37-37,4 °C	0
		37,5-38 °C	0
		over 38 °C	0
	Q2: Fever (evening)	37-37,4 °C	0
		37,5-38 °C	0
		over 38 °C	0
	Q3: Cough (day)	Slight cough	1 (50.0%)
		Hacking cough	0
	Q4: Cough (night)	Slight cough	0
		Waking up	0
	Q5: Fatigue	Mild	1 (50.0%)
		Moderate	0
	Q6: Taste perception	Decreased	0
	Q7: Smell perception	Decreased	0
	Q8: Diarrhea/ vomiting	Mild	0
		Moderate	0
	Q9: Need of antibiotics	ATB	0
	Q10: Oxygenotherapy	Oxygenotherapy needed	0
	Q11: Other symptoms	Headache	0

			Bazedoxifene (N = 3) n (%)
Visit	Question	Answer	
EoS (Day 21-28)	Q1: Fever (morning)	37-37,4 °C	0
		37,5-38 °C	0
		over 38 °C	0
	Q2: Fever (evening)	37-37,4 °C	0
		37,5-38 °C	0
		over 38 °C	0
	Q3: Cough (day)	Slight cough	1 (33.3%)
		Hacking cough	0
	Q4: Cough (night)	Slight cough	0
		Waking up	0
	Q5: Fatigue	Mild	1 (33.3%)
		Moderate	0
	Q6: Taste perception	Decreased	0
	Q7: Smell perception	Decreased	0
	Q8: Diarrhea/ vomiting	Mild	0
		Moderate	0
	Q9: Need of antibiotics	ATB	0
	Q10: Oxygenotherapy	Oxygenotherapy needed	0
	Q11: Other symptoms	Headache	0
n = Number of subjects experiencing the event, % = Percentage of subjects having the corresponding visit.			