

TABLE 14.2.3.9 Clinical status at fixed time points either in hospital or at home (Continued)  
FULL ANALYSIS SET

	Reparixin N=182		Placebo N=88	
	n (%)	95% CI	n (%)	95% CI
Number of patients with clinical status				
End of Treatment				
n	164		77	
Score 1	3 (1.8%)	0.4; 5.3	2 (2.6%)	0.3; 9.1
Score 2	0	0.0; 2.2	0	0.0; 4.7
Score 3	92 (56.1%)	48.1; 63.8	36 (46.8%)	35.3; 58.5
Score 4	36 (22.0%)	15.9; 29.1	18 (23.4%)	14.5; 34.4
Score 5	25 (15.2%)	10.1; 21.7	15 (19.5%)	11.3; 30.1
Score 6	7 (4.3%)	1.7; 8.6	5 (6.5%)	2.1; 14.5
Score 7	1 (0.6%)	0.0; 3.4	1 (1.3%)	0.0; 7.0
Comparison Between Treatments (p-value[2]):				
Reparixin vs Placebo				0.193

Note 1: Clinical status is evaluated by 7-point WHO-OS score.

Note 2: Comparison between treatment arms is performed by means of two-sample Mann-Whitney U test.

Note 3: 95% Confidence Interval is calculated using Clopper-Pearson's formula.

Cross-reference: Listing 16.2.6.1.3

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TABLE 14.2.3.9 Clinical status at fixed time points either in hospital or at home (Continued)  
FULL ANALYSIS SET

	Reparixin N=182		Placebo N=88	
	n (%)	95% CI	n (%)	95% CI
Number of patients with clinical status				
Hospital Discharge				
n	134		61	
Score 1	11 (8.2%)	4.2; 14.2	6 (9.8%)	3.7; 20.2
Score 2	2 (1.5%)	0.2; 5.3	4 (6.6%)	1.8; 15.9
Score 3	109 (81.3%)	73.7; 87.5	48 (78.7%)	66.3; 88.1
Score 4	12 (9.0%)	4.7; 15.1	3 (4.9%)	1.0; 13.7
Score 5	0	0.0; 2.7	0	0.0; 5.9
Score 6	0	0.0; 2.7	0	0.0; 5.9
Score 7	0	0.0; 2.7	0	0.0; 5.9
Comparison Between Treatments (p-value[2]):				
Reparixin vs Placebo				0.131

Note 1: Clinical status is evaluated by 7-point WHO-OS score.

Note 2: Comparison between treatment arms is performed by means of two-sample Mann-Whitney U test.

Note 3: 95% Confidence Interval is calculated using Clopper-Pearson's formula.

Cross-reference: Listing 16.2.6.1.3

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