

TABLE 14.2.3.10.1 Dyspnea severity (Likert scale) at fixed time points (Continued)  
FULL ANALYSIS SET

|   | Reparixin<br>N=182 |            | Placebo<br>N=88 |            |
|---|--------------------|------------|-----------------|------------|
|   | n (%)              | 95% CI     | n (%)           | 95% CI     |
| Number of patients with Dyspnea severity Likert scale |                    |            |                 |            |
| End of Treatment                                      |                    |            |                 |            |
| n   | 77                 |            | 38              |            |
| Score -3  | 3 (3.9%)           | 0.8; 11.0  | 0               | 0.0; 9.3   |
| Score -2  | 1 (1.3%)           | 0.0; 7.0   | 0               | 0.0; 9.3   |
| Score -1  | 0                  | 0.0; 4.7   | 1 (2.6%)        | 0.1; 13.8  |
| Score 0   | 4 (5.2%)           | 1.4; 12.8  | 0               | 0.0; 9.3   |
| Score 1   | 12 (15.6%)         | 8.3; 25.6  | 7 (18.4%)       | 7.7; 34.3  |
| Score 2   | 17 (22.1%)         | 13.4; 33.0 | 6 (15.8%)       | 6.0; 31.3  |
| Score 3   | 40 (51.9%)         | 40.3; 63.5 | 24 (63.2%)      | 46.0; 78.2 |
| Comparison Between Treatments (p-value[1]):           |                    |            |                 |            |
| Reparixin vs Placebo                                  |                    |            |                 | 0.242      |

Note 1: Comparison between treatment arms is performed by means of two-sample Mann-Whitney U test.

Note 2: 95% Confidence Interval is calculated using Clopper-Pearson's formula.

Cross-reference: Listing 16.2.6.1.4

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FULL ANALYSIS SET

|   | Reparixin<br>N=182 |            | Placebo<br>N=88 |            |
|---|--------------------|------------|-----------------|------------|
|   | n (%)              | 95% CI     | n (%)           | 95% CI     |
| Number of patients with Dyspnea severity Likert scale |                    |            |                 |            |
| Hospital Discharge                                    |                    |            |                 |            |
| n   | 38                 |            | 27              |            |
| Score -3  | 0                  | 0.0; 9.3   | 0               | 0.0; 12.8  |
| Score -2  | 0                  | 0.0; 9.3   | 1 (3.7%)        | 0.1; 19.0  |
| Score -1  | 0                  | 0.0; 9.3   | 0               | 0.0; 12.8  |
| Score 0   | 2 (5.3%)           | 0.6; 17.7  | 2 (7.4%)        | 0.9; 24.3  |
| Score 1   | 3 (7.9%)           | 1.7; 21.4  | 1 (3.7%)        | 0.1; 19.0  |
| Score 2   | 5 (13.2%)          | 4.4; 28.1  | 4 (14.8%)       | 4.2; 33.7  |
| Score 3   | 28 (73.7%)         | 56.9; 86.6 | 19 (70.4%)      | 49.8; 86.2 |
| Comparison Between Treatments (p-value[1]):           |                    |            |                 |            |
| Reparixin vs Placebo                                  |                    |            |                 | 0.722      |

Note 1: Comparison between treatment arms is performed by means of two-sample Mann-Whitney U test.

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Cross-reference: Listing 16.2.6.1.4

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