

**Table 14.2.2.2.1 Comparison of number of vulvovaginitis episodes between treatments in patients with prevailing bacterial etiology (PPS)**

|   |                                       | IMUNOR<br>N = 7 | PLACEBO<br>N = 1 | Comparison |
|---|---------------------------------------|-----------------|------------------|------------|
| Number of vulvovaginitis episodes               | 0 episodes                            | 4 (57.1%)       | 1 (100%)         |            |
|   | 1 episode                             | 1 (14.3%)       |                  |            |
|   | 2 episodes                            | 1 (14.3%)       |                  |            |
|   | 3 episodes                            | 1 (14.3%)       |                  |            |
| Comparison of number of vulvovaginitis episodes | Mean episode count                    | 0.86            | 0.00             |            |
|   | Ratio of mean episode counts (95% CI) |                 |                  | N/A        |
|   | p-value                               |                 |                  | N/A        |

% = Percentage of subjects out of N; CI = Confidence interval; N = Total number of subjects in the treatment arm; N/A = Not available; PPS = Per Protocol Set.  
 Comparison between treatments was not performed due to low number of patients in PLACEBO arm.

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**Table 14.2.2.2.2 Comparison of number of vulvovaginitis episodes between treatments in patients with prevailing bacterial etiology (FAS)**

|   |                                       | IMUNOR<br>N = 11 | PLACEBO<br>N = 1 | Comparison |
|---|---------------------------------------|------------------|------------------|------------|
| Number of vulvovaginitis episodes               | 0 episodes                            | 7 (63.6%)        | 1 (100%)         |            |
|   | 1 episode                             | 1 (9.1%)         |                  |            |
|   | 2 episodes                            | 2 (18.2%)        |                  |            |
|   | 3 episodes                            | 1 (9.1%)         |                  |            |
| Comparison of number of vulvovaginitis episodes | Mean episode count                    | 0.73             | 0.00             |            |
|   | Ratio of mean episode counts (95% CI) |                  |                  | N/A        |
|   | p-value                               |                  |                  | N/A        |

% = Percentage of subjects out of N; CI = Confidence interval; FAS = Full Analysis Set; N = Total number of subjects in the treatment arm; N/A = Not available.  
 Comparison between treatments was not performed due to low number of patients in PLACEBO arm.

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