

Table 2  
 Adverse Events  
 Safety Population

| System Organ Class<br>Preferred Term               | Severity | Denvax<br>N =328 |          |
|--|----------|------------------|----------|
|  |          | n                | %        |
| Number of subjects with at least one adverse event | Total    | 212              | ( 64.6%) |
|  | Mild     | 173              | ( 52.7%) |
|  | Moderate | 38               | ( 11.6%) |
|  | Severe   | 1                | ( 0.3%)  |
| Total Adverse Events                               | Total    | 388              |          |
|  | Mild     | 304              |          |
|  | Moderate | 83               |          |
|  | Severe   | 1                |          |
| Blood and lymphatic system disorders               | Total    | 3                | ( 0.9%)  |
|  | Mild     | 2                | ( 0.6%)  |
|  | Moderate | 1                | ( 0.3%)  |
|  | Severe   | 0                | ( 0.0%)  |

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|                                      |          | n                | %       |
| Anaemia                              | Total    | 3                | ( 0.9%) |
|                                      | Mild     | 2                | ( 0.6%) |
|                                      | Moderate | 1                | ( 0.3%) |
|                                      | Severe   | 0                | ( 0.0%) |
| Gastrointestinal disorders           | Total    | 2                | ( 0.6%) |
|                                      | Mild     | 2                | ( 0.6%) |
|                                      | Moderate | 0                | ( 0.0%) |
|                                      | Severe   | 0                | ( 0.0%) |
| Abdominal pain                       | Total    | 1                | ( 0.3%) |
|                                      | Mild     | 1                | ( 0.3%) |
|                                      | Moderate | 0                | ( 0.0%) |
|                                      | Severe   | 0                | ( 0.0%) |

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|  |          | n                | %        |
| Vomiting   | Total    | 1                | ( 0.3%)  |
|  | Mild     | 1                | ( 0.3%)  |
|  | Moderate | 0                | ( 0.0%)  |
|  | Severe   | 0                | ( 0.0%)  |
| General disorders and administration site conditions | Total    | 208              | ( 63.4%) |
|  | Mild     | 170              | ( 51.8%) |
|  | Moderate | 37               | ( 11.3%) |
|  | Severe   | 1                | ( 0.3%)  |
| Asthenia   | Total    | 61               | ( 18.6%) |
|  | Mild     | 48               | ( 14.6%) |
|  | Moderate | 13               | ( 4.0%)  |
|  | Severe   | 0                | ( 0.0%)  |

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|                                      |          | n                | %        |
| Chills                               | Total    | 35               | ( 10.7%) |
|                                      | Mild     | 5                | ( 1.5%)  |
|                                      | Moderate | 30               | ( 9.1%)  |
|                                      | Severe   | 0                | ( 0.0%)  |
| Pain                                 | Total    | 2                | ( 0.6%)  |
|                                      | Mild     | 0                | ( 0.0%)  |
|                                      | Moderate | 1                | ( 0.3%)  |
|                                      | Severe   | 1                | ( 0.3%)  |
| Pyrexia                              | Total    | 207              | ( 63.1%) |
|                                      | Mild     | 194              | ( 59.1%) |
|                                      | Moderate | 13               | ( 4.0%)  |
|                                      | Severe   | 0                | ( 0.0%)  |

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|                                      |          | n                | %        |
| Nervous system disorders             | Total    | 36               | ( 11.0%) |
|                                      | Mild     | 28               | ( 8.5%)  |
|                                      | Moderate | 8                | ( 2.4%)  |
|                                      | Severe   | 0                | ( 0.0%)  |
| Coma                                 | Total    | 1                | ( 0.3%)  |
|                                      | Mild     | 0                | ( 0.0%)  |
|                                      | Moderate | 1                | ( 0.3%)  |
|                                      | Severe   | 0                | ( 0.0%)  |
| Lethargy                             | Total    | 35               | ( 10.7%) |
|                                      | Mild     | 28               | ( 8.5%)  |
|                                      | Moderate | 7                | ( 2.1%)  |
|                                      | Severe   | 0                | ( 0.0%)  |

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|  |          | n                | %       |
| Renal and urinary disorders            | Total    | 3                | ( 0.9%) |
|  | Mild     | 0                | ( 0.0%) |
|  | Moderate | 3                | ( 0.9%) |
|  | Severe   | 0                | ( 0.0%) |
| Haematuria                             | Total    | 3                | ( 0.9%) |
|  | Mild     | 0                | ( 0.0%) |
|  | Moderate | 3                | ( 0.9%) |
|  | Severe   | 0                | ( 0.0%) |
| Skin and subcutaneous tissue disorders | Total    | 2                | ( 0.6%) |
|  | Mild     | 2                | ( 0.6%) |
|  | Moderate | 0                | ( 0.0%) |
|  | Severe   | 0                | ( 0.0%) |

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|                                      |          | n                | %       |
| Pruritus                             | Total    | 2                | ( 0.6%) |
|                                      | Mild     | 2                | ( 0.6%) |
|                                      | Moderate | 0                | ( 0.0%) |
|                                      | Severe   | 0                | ( 0.0%) |

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