**Appendix Table D56. Adverse effects with divalproex sodium vs. placebo in children (results from low risk of bias randomized controlled clinical trial)**5

| **Outcome** | **Dose** | **Events/**  **randomized [rate, %] with drug** | **Events/**  **randomized [rate, %] with placebo** | **Relative risk**  **(95% CI)** | **Absolute risk difference**  **(95% CI)** |
| --- | --- | --- | --- | --- | --- |
| Abdominal pain | 1000mg | 3/75 [4.0] | 1/73 [1.4] | 2.9 (0.3 to 27.4) | 0.03 (-0.03 to 0.08) |
| Abdominal pain | 250mg | 1/83 [1.2] | 1/73 [1.4] | 0.9 (0.1 to 13.8) | 0.00 (-0.04 to 0.03) |
| Abdominal pain | 500mg | 6/74 [8.1] | 1/73 [1.4] | 5.9 (0.7 to 48.0) | 0.07 (0.00 to 0.14) |
| Ammonia increased | 1000mg | 4/75 [5.3] | 0/73 [0.0] | 8.8 (0.5 to 159.9) | 0.05 (0.00 to 0.11) |
| Ammonia increased | 1000mg | 8/75 [10.7] | 5/73 [6.8] | 1.6 (0.5 to 4.5) | 0.04 (-0.05 to 0.13) |
| Ammonia increased | 250mg | 2/83 [2.4] | 0/73 [0.0] | 4.4 (0.2 to 90.3) | 0.02 (-0.02 to 0.06) |
| Ammonia increased | 250mg | 4/83 [4.8] | 5/73 [6.8] | 0.7 (0.2 to 2.5) | -0.02 (-0.09 to 0.05) |
| Ammonia increased | 500mg | 1/74 [1.4] | 0/73 [0.0] | 3.0 (0.1 to 71.5) | 0.01 (-0.02 to 0.05) |
| Ammonia increased | 500mg | 2/74 [2.7] | 5/73 [6.8] | 0.4 (0.1 to 2.0) | -0.04 (-0.11 to 0.03) |
| Cough | 1000mg | 2/75 [2.7] | 3/73 [4.1] | 0.6 (0.1 to 3.8) | -0.01 (-0.07 to 0.04) |
| Cough | 250mg | 1/83 [1.2] | 3/73 [4.1] | 0.3 (0.0 to 2.8) | -0.03 (-0.08 to 0.02) |
| Cough | 500mg | 4/74 [5.4] | 3/73 [4.1] | 1.3 (0.3 to 5.7) | 0.01 (-0.06 to 0.08) |
| Discontinued due to lack of efficacy | 1000mg | 0/75 [0.0] | 1/73 [1.4] | 0.3 (0.0 to 7.8) | -0.01 (-0.05 to 0.02) |
| Discontinued due to lack of efficacy | 250mg | 1/83 [1.2] | 1/73 [1.4] | 0.9 (0.1 to 13.8) | 0.00 (-0.04 to 0.03) |
| Discontinued due to lack of efficacy | 500mg | 3/74 [4.1] | 1/73 [1.4] | 3.0 (0.3 to 27.8) | 0.03 (-0.03 to 0.08) |
| Fatigue | 1000mg | 6/75 [8.0] | 4/73 [5.5] | 1.5 (0.4 to 5.0) | 0.03 (-0.06 to 0.11) |
| Fatigue | 250mg | 1/83 [1.2] | 4/73 [5.5] | 0.2 (0.0 to 1.9) | -0.04 (-0.10 to 0.01) |
| Fatigue | 500mg | 1/74 [1.4] | 4/73 [5.5] | 0.2 (0.0 to 2.2) | -0.04 (-0.10 to 0.02) |
| Gastroenteritis viral | 1000mg | 4/75 [5.3] | 1/73 [1.4] | 3.9 (0.4 to 34.0) | 0.04 (-0.02 to 0.10) |
| Gastroenteritis viral | 250mg | 4/83 [4.8] | 1/73 [1.4] | 3.5 (0.4 to 30.8) | 0.03 (-0.02 to 0.09) |
| Gastroenteritis viral | 500mg | 1/74 [1.4] | 1/73 [1.4] | 1.0 (0.1 to 15.5) | 0.00 (-0.04 to 0.04) |
| Influenza | 1000mg | 3/75 [4.0] | 5/73 [6.8] | 0.6 (0.1 to 2.4) | -0.03 (-0.10 to 0.04) |
| Influenza | 250mg | 1/83 [1.2] | 5/73 [6.8] | 0.2 (0.0 to 1.5) | -0.06 (-0.12 to 0.01) |
| Influenza | 500mg | 5/74 [6.8] | 5/73 [6.8] | 1.0 (0.3 to 3.3) | 0.00 (-0.08 to 0.08) |
| Nasopharyngitis | 1000mg | 3/75 [4.0] | 6/73 [8.2] | 0.5 (0.1 to 1.9) | -0.04 (-0.12 to 0.03) |
| Nasopharyngitis | 250mg | 5/83 [6.0] | 6/73 [8.2] | 0.7 (0.2 to 2.3) | -0.02 (-0.10 to 0.06) |
| Nasopharyngitis | 500mg | 5/74 [6.8] | 6/73 [8.2] | 0.8 (0.3 to 2.6) | -0.01 (-0.10 to 0.07) |
| Nausea | 1000mg | 7/75 [9.3] | 3/73 [4.1] | 2.3 (0.6 to 8.4) | 0.05 (-0.03 to 0.13) |
| Nausea | 250mg | 5/83 [6.0] | 3/73 [4.1] | 1.5 (0.4 to 5.9) | 0.02 (-0.05 to 0.09) |
| Nausea | 500mg | 6/74 [8.1] | 3/73 [4.1] | 2.0 (0.5 to 7.6) | 0.04 (-0.04 to 0.12) |
| Pharyngolaryngeal pain | 1000mg | 1/75 [1.3] | 3/73 [4.1] | 0.3 (0.0 to 3.0) | -0.03 (-0.08 to 0.02) |
| Pharyngolaryngeal pain | 250mg | 1/83 [1.2] | 3/73 [4.1] | 0.3 (0.0 to 2.8) | -0.03 (-0.08 to 0.02) |
| Pharyngolaryngeal pain | 500mg | 5/74 [6.8] | 3/73 [4.1] | 1.6 (0.4 to 6.6) | 0.03 (-0.05 to 0.10) |
| Somnolence | 1000mg | 4/75 [5.3] | 1/73 [1.4] | 3.9 (0.4 to 34.0) | 0.04 (-0.02 to 0.10) |
| Somnolence | 250mg | 2/83 [2.4] | 1/73 [1.4] | 1.8 (0.2 to 19.0) | 0.01 (-0.03 to 0.05) |
| Somnolence | 500mg | 4/74 [5.4] | 1/73 [1.4] | 3.9 (0.5 to 34.5) | 0.04 (-0.02 to 0.10) |
| Treatment discontinuation | 1000mg | 13/75 [17.3] | 6/73 [8.2] | 2.1 (0.8 to 5.3) | 0.09 (-0.02 to 0.20) |
| Treatment discontinuation | 250mg | 8/83 [9.6] | 6/73 [8.2] | 1.2 (0.4 to 3.2) | 0.01 (-0.08 to 0.10) |
| Treatment discontinuation | 500mg | 12/74 [16.2] | 6/73 [8.2] | 2.0 (0.8 to 5.0) | 0.08 (-0.03 to 0.18) |
| Upper respiratory tract infection | 1000mg | 4/75 [5.3] | 5/73 [6.8] | 0.8 (0.2 to 2.8) | -0.02 (-0.09 to 0.06) |
| Upper respiratory tract infection | 250mg | 12/83 [14.5] | 5/73 [6.8] | 2.1 (0.8 to 5.7) | 0.08 (-0.02 to 0.17) |
| Upper respiratory tract infection | 500mg | 3/74 [4.1] | 5/73 [6.8] | 0.6 (0.1 to 2.4) | -0.03 (-0.10 to 0.05) |
| Viral infection | 1000mg | 0/75 [0.0] | 2/73 [2.7] | 0.2 (0.0 to 4.0) | -0.03 (-0.07 to 0.02) |
| Viral infection | 250mg | 3/83 [3.6] | 2/73 [2.7] | 1.3 (0.2 to 7.7) | 0.01 (-0.05 to 0.06) |
| Viral infection | 500mg | 4/74 [5.4] | 2/73 [2.7] | 2.0 (0.4 to 10.4) | 0.03 (-0.04 to 0.09) |
| Vomiting | 1000mg | 3/75 [4.0] | 1/73 [1.4] | 2.9 (0.3 to 27.4) | 0.03 (-0.03 to 0.08) |
| Vomiting | 250mg | 2/83 [2.4] | 1/73 [1.4] | 1.8 (0.2 to 19.0) | 0.01 (-0.03 to 0.05) |
| Vomiting | 500mg | 4/74 [5.4] | 1/73 [1.4] | 3.9 (0.5 to 34.5) | 0.04 (-0.02 to 0.10) |
| Weight gain | 1000mg | 5/75 [6.7] | 1/73 [1.4] | 4.9 (0.6 to 40.7) | 0.05 (-0.01 to 0.12) |
| Weight gain | 250mg | 5/83 [6.0] | 1/73 [1.4] | 4.4 (0.5 to 36.8) | 0.05 (-0.01 to 0.10) |
| Weight gain | 500mg | 1/74 [1.4] | 1/73 [1.4] | 1.0 (0.1 to 15.5) | 0.00 (-0.04 to 0.04) |