**Appendix Table D138. Adverse effects with carbamazepine vs. placebo for migraine prevention in adults, results from medium risk of bias randomized controlled clinical trial86**

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| --- | --- | --- | --- | --- | --- | --- | --- |
| **Adverse Effect** | **Events/****Randomized with Active Drug** | **Events/****Randomized with Placebo** | **Rate, % with Active Drug [Placebo]** | **Relative Risk****(95% CI)** | **Absolute Risk Difference****(95% CI)** | **Number Needed to Treat to Harm****(95% CI)** | **Attributable Events per 1000 Treated****(95% CI)** |
| **Drowsiness** | **5/48** | **0/48** | **10.4 [0.0]** | **11.0 (0.6 to 193.6)** | **0.10 (0.01 to 0.20)** | **10 (5 to 88)** | **104 (11 to 197)** |
| **Vertigo or giddiness** | **23/48** | **2/48** | **47.9 [4.2]** | **11.5 (2.9 to 46.1)** | **0.44 (0.29 to 0.59)** | **2 (2 to 4)** | **438 (285 to 590)** |
| **Total** | **30/48** | **11/48** | **62.5 [22.9]** | **2.7 (1.6 to 4.8)** | **0.40 (0.21 to 0.58)** | **3 (2 to 5)** | **396 (214 to 577)** |
| **Necessitating reduction of dosage** | **6/48** | **0/48** | **12.5 [0.0]** | **13.0 (0.8 to 224.5)** | **0.13 (0.03 to 0.22)** | **8 (4 to 39)** | **125 (26 to 224)** |
| Nausea | 4/48 | 3/48 | 8.3 [6.3] | 1.3 (0.3 to 5.6) | 0.02 (-0.08 to 0.12) | NS | NS |
| Dry mouth | 2/48 | 0/48 | 4.2 [0.0] | 5.0 (0.2 to 101.5) | 0.04 (-0.03 to 0.11) | NS | NS |
| Heavy eyes | 2/48 | 0/48 | 4.2 [0.0] | 5.0 (0.2 to 101.5) | 0.04 (-0.03 to 0.11) | NS | NS |
| Constipation | 2/48 | 0/48 | 4.2 [0.0] | 5.0 (0.2 to 101.5) | 0.04 (-0.03 to 0.11) | NS | NS |
| Vomiting | 1/48 | 0/48 | 2.1 [0.0] | 3.0 (0.1 to 71.9) | 0.02 (-0.04 to 0.08) | NS | NS |
| Weight gain | 1/48 | 1/48 | 2.1 [2.1] | 1.0 (0.1 to 15.5) | 0.00 (-0.06 to 0.06) | NS | NS |
| Sweating | 1/48 | 0/48 | 2.1 [0.0] | 3.0 (0.1 to 71.9) | 0.02 (-0.04 to 0.08) | NS | NS |
| Transient rash | 1/48 | 0/48 | 2.1 [0.0] | 3.0 (0.1 to 71.9) | 0.02 (-0.04 to 0.08) | NS | NS |
| Dysuria | 1/48 | 0/48 | 2.1 [0.0] | 3.0 (0.1 to 71.9) | 0.02 (-0.04 to 0.08) | NS | NS |
| Blacked nose | 0/48 | 1/48 | 0.0 [2.1] | 0.3 (0.0 to 8.0) | -0.02 (-0.08 to 0.04) | NS | NS |
| Lack of drive | 0/48 | 1/48 | 0.0 [2.1] | 0.3 (0.0 to 8.0) | -0.02 (-0.08 to 0.04) | NS | NS |
| Flushing | 0/48 | 1/48 | 0.0 [2.1] | 0.3 (0.0 to 8.0) | -0.02 (-0.08 to 0.04) | NS | NS |
| Blunted feeling | 0/48 | 1/48 | 0.0 [2.1] | 0.3 (0.0 to 8.0) | -0.02 (-0.08 to 0.04) | NS | NS |
| Heavy head | 0/48 | 1/48 | 0.0 [2.1] | 0.3 (0.0 to 8.0) | -0.02 (-0.08 to 0.04) | NS | NS |

Bold = significant at 95% confidence limit when 95% CI of relative risk estimates do not include 1 and 95% CI of absolute risk difference estimates do not include 0

CI = confidence level; NS= not significant; Number needed to treat and number of attributable events were calculated for statistically significant differences