

Appendix Table F53. Clinical outcomes after different doses and clinical formulations of tolterodine

| Outcome | Reference design | Active vs. control | Active events/ randomized | Control events/ randomized | Relative risk (95% CI) | Absolute risk difference (95% CI) | Number needed to treat (95% CI) | Attributable events/1000 treated (95% CI) |
|--------------------------------|---|-------------------------------------|------------------------------|-------------------------------|---------------------------|---|--|--|
| Improvement in UI | Appell, 1997 ²²⁹ Pooled analysis | 1mg twice daily vs. 2mg daily | 50/121 | 246/474 | 0.80 (0.63; 1.00) | -0.11 (-0.20; -0.01) | -9 (-139; -5) | -106 (-204; -7) |
| Completed the study | Malone-Lee, 2006 ³⁴⁶ RCT | 1mg twice daily vs. 2mg twice daily | 53/61 | 64/73 | 0.99 (0.87; 1.13) | -0.01 (-0.12; 0.11) | | |
| Withdrew from study | Appell, 1997 ²²⁹ Pooled analysis | 1mg twice daily vs. 2mg daily | 7/121 | 63/474 | 0.44 (0.20; 0.93) | -0.08 (-0.13; -0.02) | -13 (-43; -8) | -75 (-127; -23) |
| Withdrew from study | Van Kerrebroeck, 2001 ³⁹⁴ RCT | 4mg once daily vs. 2mg twice daily | 27/507 | 28/514 | 0.98 (0.58; 1.63) | 0.00 (-0.03; 0.03) | | |
| Withdrew due to adverse events | Appell, 1997 ²²⁹ Pooled analysis | 1mg twice daily vs. 2mg daily | 2/121 | 38/474 | 0.21 (0.05; 0.84) | -0.06 (-0.10; -0.03) | -16 (-33; -10) | -64 (-97; -30) |
| Withdrew due to adverse events | Armstrong, 2007 ²³² Pooled analysis | 2mg qd vs. 4mg qd | 15/193 | 19/399 | 1.63 (0.85; 3.14) | 0.03 (-0.01; 0.07) | | |
| Withdrew due to adverse events | Malone-Lee, 2001 ³⁴⁶ RCT | 1mg twice daily vs. 2mg twice daily | 4/61 | 7/73 | 0.68 (0.21; 2.23) | -0.03 (-0.12; 0.06) | | |
| Withdrew due to adverse events | Jacquetin, 2001 ³¹⁶ RCT | 1mg twice daily vs. 2mg twice daily | 3/97 | 2/103 | 1.59 (0.27; 9.33) | 0.01 (-0.03; 0.06) | | |
| All adverse events | Jacquetin, 2001 ³¹⁶ RCT | 1mg twice daily vs. 2mg twice daily | 78/97 | 84/103 | 0.99 (0.86; 1.13) | -0.01 (-0.12; 0.10) | | |
| All adverse events | Jacquetin, 2001 ³¹⁶ RCT | 1mg twice daily vs. 2mg twice daily | 39/97 | 55/103 | 0.75 (0.56; 1.02) | -0.13 (-0.27; 0.01) | | |

Appendix Table F53. Clinical outcomes after different doses and clinical formulations of tolterodine (continued)

| Outcome | Reference design | Active vs. control | Active events/ randomized | Control events/ randomized | Relative risk (95% CI) | Absolute risk difference (95% CI) | Number needed to treat (95% CI) | Attributable events/1000 treated (95% CI) |
|---|---|-------------------------------------|------------------------------|-------------------------------|---------------------------|---|--|--|
| All adverse events | Jonas, 1997 ³¹⁸ RCT | 1mg twice daily vs. 2mg twice daily | 34/99 | 43/99 | 0.79 (0.56; 1.13) | -0.09 (-0.23; 0.04) | | |
| All adverse events | Jonas, 1997 ³¹⁸ RCT | 1mg twice daily vs. 2mg twice daily | 31/99 | 32/99 | 0.97 (0.64; 1.46) | -0.01 (-0.14; 0.12) | | |
| At least one adverse event | Armstrong, 2007 ²³² Pooled analysis | 2mg qd vs. 4mg qd | 152/193 | 254/399 | 1.24 (1.11; 1.37) | 0.15 (0.08; 0.23) | 7 (4; 13) | 151 (76; 226) |
| At least one adverse event | Millard, 1999 ³⁴⁹ RCT | 1mg twice daily vs. 2mg twice daily | 8/129 | 2/123 | 3.81 (0.83; 17.61) | 0.05 (0.00; 0.09) | | |
| At least one adverse event | Appell, 1997 ²²⁹ Pooled analysis | 1mg twice daily vs. 2mg daily | 94/121 | 351/474 | 1.05 (0.94; 1.17) | 0.04 (-0.05; 0.12) | | |
| Adverse events of severe intensity | Malone-Lee, 2001 ³⁴⁶ RCT | 1mg twice daily vs. 2mg twice daily | 5/61 | 6/73 | 1.00 (0.32; 3.11) | 0.00 (-0.09; 0.09) | | |
| Mild adverse events related to study medication | Armstrong, 2007 ²³² Pooled analysis | 2mg qd vs. 4mg qd | 81/193 | 123/399 | 1.36 (1.09; 1.70) | 0.11 (0.03; 0.19) | 9 (5; 35) | 111 (28; 194) |
| Mild adverse events not related to study medication | Armstrong, 2007 ²³² Pooled analysis | 2mg qd vs. 4mg qd | 57/193 | 117/399 | 1.01 (0.77; 1.31) | 0.00 (-0.08; 0.08) | | |
| Moderate adverse events related to study medication | Armstrong, 2007 ²³² Pooled analysis | 2mg qd vs. 4mg qd | 46/193 | 84/399 | 1.13 (0.83; 1.55) | 0.03 (-0.04; 0.10) | | |

Appendix Table F53. Clinical outcomes after different doses and clinical formulations of tolterodine (continued)

| Outcome | Reference design | Active vs. control | Active events/ randomized | Control events/ randomized | Relative risk (95% CI) | Absolute risk difference (95% CI) | Number needed to treat (95% CI) | Attributable events/1000 treated (95% CI) |
|---|---|-------------------------------------|------------------------------|-------------------------------|---------------------------|---|--|--|
| Moderate adverse events not related to study medication | Armstrong, 2007 ²³² Pooled analysis | 2mg qd vs. 4mg qd | 35/193 | 40/399 | 1.81 (1.19; 2.75) | 0.08 (0.02; 0.14) | 12 (7; 52) | 81 (19; 143) |
| Severe adverse events related to study medication | Armstrong, 2007 ²³² Pooled analysis | 2mg qd vs. 4mg qd | 7/193 | 9/399 | 1.61 (0.61; 4.25) | 0.01 (-0.02; 0.04) | | |
| Severe adverse events not related to study medication | Armstrong, 2007 ²³² Pooled analysis | 2mg qd vs. 4mg qd | 5/193 | 6/399 | 1.72 (0.53; 5.57) | 0.01 (-0.01; 0.04) | | |
| Serious adverse event | Malone-Lee, 2001 ³⁴⁶ RCT | 1mg twice daily vs. 2mg twice daily | 2/61 | 1/73 | 2.39 (0.22; 25.76) | 0.02 (-0.03; 0.07) | | |
| Serious adverse event | Millard, 1999 ³⁴⁹ RCT | 1mg twice daily vs. 2mg twice daily | 5/129 | 7/123 | 0.68 (0.22; 2.09) | -0.02 (-0.07; 0.03) | | |
| Serious adverse event | Van Kerrebroeck, 2001 ³⁹⁴ RCT | 4mg once daily vs. 2mg once daily | 7/507 | 12/514 | 0.59 (0.23; 1.49) | -0.01 (-0.03; 0.01) | | |
| Abdominal pain | Swift, 2003 ³⁸² RCT | 4mg once daily vs. 2mg twice daily | 18/417 | 12/408 | 1.47 (0.72; 3.01) | 0.01 (-0.01; 0.04) | | |
| Abdominal pain | Jacquetin, 2007 ³¹⁶ RCT | 1mg twice daily vs. 2mg twice daily | 6/97 | 4/103 | 1.59 (0.46; 5.47) | 0.02 (-0.04; 0.08) | | |
| Abdominal pain | Malone-Lee, 2001 ³⁴⁶ RCT | 1mg twice daily vs. 2mg twice daily | 3/61 | 6/73 | 0.60 (0.16; 2.29) | -0.03 (-0.12; 0.05) | | |

Appendix Table F53. Clinical outcomes after different doses and clinical formulations of tolterodine (continued)

| Outcome | Reference design | Active vs. control | Active events/ randomized | Control events/ randomized | Relative risk (95% CI) | Absolute risk difference (95% CI) | Number needed to treat (95% CI) | Attributable events/1000 treated (95% CI) |
|-----------------------------------|--|-------------------------------------|------------------------------|-------------------------------|---------------------------|---|--|--|
| Abdominal pain | Van Kerrebroeck, 2001 ³⁹⁴ RCT | 4mg once daily vs. 2mg once daily | 19/507 | 13/514 | 1.48 (0.74; 2.97) | 0.01 (-0.01; 0.03) | | |
| Abnormal accommodation | Malone-Lee, 2001 ³⁴⁶ RCT | 1mg twice daily vs. 2mg twice daily | 0/61 | 3/73 | 0.17 (0.01; 3.24) | -0.04 (-0.09; 0.01) | | |
| Abnormal accommodation | Jonas, 1997 ³¹⁸ RCT | 1mg twice daily vs. 2mg twice daily | 3/99 | 5/99 | 0.60 (0.15; 2.44) | -0.02 (-0.07; 0.03) | | |
| Abnormal vision | Swift, 2003 ³⁸² RCT | 4mg once daily vs. 2mg twice daily | 5/417 | 4/408 | 1.22 (0.33; 4.52) | 0.00 (-0.01; 0.02) | | |
| Abnormal vision | Van Kerrebroeck, 2001 ³⁹⁴ RCT | 4mg once daily vs. 2mg once daily | 6/507 | 4/514 | 1.52 (0.43; 5.36) | 0.00 (-0.01; 0.02) | | |
| Arthralgia | Takei, 2005 ³⁸⁴ RCT | 4mg/day vs. 4mg/day | 1/80 | 11/74 | 0.08 (0.01; 0.64) | -0.14 (-0.22; -0.05) | -7 (-19; -5) | -136 (-221; -52) |
| Arthritis | Swift, 2003 ³⁸² RCT | 4mg once daily vs. 2mg twice daily | 1/417 | 5/408 | 0.20 (0.02; 1.67) | -0.01 (-0.02; 0.00) | | |
| Autonomic nervous system | Jonas, 1997 ³¹⁸ RCT | 1mg twice daily vs. 2mg twice daily | 11/99 | 16/99 | 0.69 (0.34; 1.41) | -0.05 (-0.15; 0.04) | | |
| Autonomic nervous system disorder | Appell, 1997 ²²⁹ Pooled analysis | 1mg twice daily vs. 2mg daily | 35/121 | 204/474 | 0.67 (0.50; 0.91) | -0.14 (-0.23; -0.05) | -7 (-20; -4) | -141 (-233; -49) |
| Autonomic nervous system disorder | Millard, 1999 ³⁴⁹ RCT | 1mg twice daily vs. 2mg twice daily | 37/129 | 53/123 | 0.67 (0.47; 0.93) | -0.14 (-0.26; -0.03) | -7 (-37; -4) | -144 (-261; -27) |

Appendix Table F53. Clinical outcomes after different doses and clinical formulations of tolterodine (continued)

| Outcome | Reference design | Active vs. control | Active events/ randomized | Control events/ randomized | Relative risk (95% CI) | Absolute risk difference (95% CI) | Number needed to treat (95% CI) | Attributable events/1000 treated (95% CI) |
|----------------------------------|--|--|------------------------------|-------------------------------|---------------------------|---|--|--|
| Back pain | Takei, 2005 ³⁸⁴ RCT | 4mg/day vs. 4mg/day | 3/80 | 11/74 | 0.25 (0.07; 0.87) | -0.11 (-0.20; -0.02) | -9 (-50; -5) | -111 (-202; -20) |
| Body disorder as a whole | Armstrong, 2007 ²³² Pooled analysis | 2mg qd vs. 4mg qd | 61/193 | 85/399 | 1.48 (1.12; 1.96) | 0.10 (0.03; 0.18) | 10 (6; 38) | 103 (26; 180) |
| Cardiovascular adverse events | Appell, 1997 ²²⁹ Pooled analysis | 1mg twice daily vs. 2mg daily | 15/121 | 20/474 | 2.94 (1.55; 5.57) | 0.08 (0.02; 0.14) | 12 (7; 49) | 82 (20; 143) |
| Constipation | Swift, 2003 ³⁸² RCT | 4mg once daily vs. 2mg twice daily | 27/417 | 27/408 | 0.98 (0.58; 1.64) | 0.00 (-0.04; 0.03) | | |
| Constipation | Jacquetin, 2001 ³¹⁶ RCT | 1mg twice daily vs. 2mg twice daily | 4/97 | 2/103 | 2.12 (0.40; 11.33) | 0.02 (-0.03; 0.07) | | |
| Constipation | Jonas, 1997 ³¹⁸ RCT | 1mg twice daily vs. 2mg twice daily | 2/99 | 3/99 | 0.67 (0.11; 3.90) | -0.01 (-0.05; 0.03) | | |
| Constipation | Takei, 2005 ³⁸⁴ RCT | 4mg/day vs. 4mg/day | 12/80 | 16/74 | 0.69 (0.35; 1.37) | -0.07 (-0.19; 0.06) | | |
| Constipation | Malone-Lee, 2001 ³⁴⁶ RCT | 1mg twice daily vs. 2mg twice daily | 5/61 | 0/73 | 13.13 (0.74; 232.79) | 0.08 (0.01; 0.16) | 12 (6; 114) | 82 (9; 155) |
| Constipation | Van Kerrebroeck, 2001 ³⁹⁴ RCT | 4mg once daily vs. 2mg once daily | 30/507 | 35/514 | 0.87 (0.54; 1.39) | -0.01 (-0.04; 0.02) | | |
| Constipation | Armstrong, 2007 ²³² Pooled analysis | 2mg qd vs. 4mg qd | 12/193 | 31/399 | 0.80 (0.42; 1.52) | -0.02 (-0.06; 0.03) | | |
| Diarrhea | Malone-Lee, 2001 ³⁴⁶ RCT | 1mg twice daily vs. 2mg twice daily | 8/61 | 4/73 | 2.39 (0.76; 7.57) | 0.08 (-0.02; 0.18) | | |

Appendix Table F53. Clinical outcomes after different doses and clinical formulations of tolterodine (continued)

| Outcome | Reference design | Active vs. control | Active events/ randomized | Control events/ randomized | Relative risk (95% CI) | Absolute risk difference (95% CI) | Number needed to treat (95% CI) | Attributable events/1000 treated (95% CI) |
|------------------|---|-------------------------------------|------------------------------|-------------------------------|---------------------------|---|--|--|
| Diarrhea | Van Kerrebroeck, 2001 ³⁹⁴ RCT | 4mg once daily vs. 2mg once daily | 10/507 | 16/514 | 0.63 (0.29; 1.38) | -0.01 (-0.03; 0.01) | | |
| Diarrhea | Armstrong, 2007 ²³² pooled analysis | 2mg qd vs. 4mg qd | 9/193 | 25/399 | 0.74 (0.35; 1.56) | -0.02 (-0.05; 0.02) | | |
| Diarrhea | Swift, 2003 ³⁸² RCT | 4mg once daily vs. 2mg twice daily | 10/417 | 14/408 | 0.70 (0.31; 1.56) | -0.01 (-0.03; 0.01) | | |
| Diarrhea | Takei, 2005 ³⁸⁴ RCT | 4mg/day vs. 4mg/day | 6/80 | 12/74 | 0.46 (0.18; 1.17) | -0.09 (-0.19; 0.01) | | |
| Digestive system | Armstrong, 2007 ²³² Pooled analysis | 2mg qd vs. 4mg qd | 87/193 | 145/399 | 1.24 (1.01; 1.52) | 0.09 (0.00; 0.17) | 11 (6; 360) | 87 (3; 172) |
| Dizziness | Swift, 2003 ³⁸² RCT | 4mg once daily vs. 2mg twice daily | 7/417 | 7/408 | 0.98 (0.35; 2.76) | 0.00 (-0.02; 0.02) | | |
| Dizziness | Malone-Lee, 2001 ³⁴⁶ RCT | 1mg twice daily vs. 2mg twice daily | 5/61 | 4/73 | 1.50 (0.42; 5.33) | 0.03 (-0.06; 0.11) | | |
| Dizziness | Van Kerrebroeck, 2001 ³⁹⁴ RCT | 4mg once daily vs. 2mg once daily | 11/507 | 9/514 | 1.24 (0.52; 2.96) | 0.00 (-0.01; 0.02) | | |
| Dry mouth | Swift, 2003 ³⁸² RCT | 4mg once daily vs. 2mg twice daily | 105/417 | 127/408 | 0.81 (0.65; 1.01) | -0.06 (-0.12; 0.00) | | |
| Dry mouth | Jacquetin, 2001 ³¹⁶ RCT | 1mg twice daily vs. 2mg twice daily | 20/97 | 35/103 | 0.61 (0.38; 0.97) | -0.13 (-0.26; -0.01) | -7 (-85; -4) | -134 (-255; -12) |

Appendix Table F53. Clinical outcomes after different doses and clinical formulations of tolterodine (continued)

| Outcome | Reference design | Active vs. control | Active events/ randomized | Control events/ randomized | Relative risk (95% CI) | Absolute risk difference (95% CI) | Number needed to treat (95% CI) | Attributable events/1000 treated (95% CI) |
|-----------|--|--|------------------------------|-------------------------------|---------------------------|---|--|--|
| Dry mouth | Jonas, 1997 ³¹⁸ RCT | 1mg twice daily vs. 2mg twice daily | 8/99 | 10/99 | 0.80 (0.33; 1.94) | -0.02 (-0.10; 0.06) | | |
| Dry mouth | Takei, 2005 ³⁸⁴ RCT | 4mg/day vs. 4mg/day | 42/80 | 63/74 | 0.62 (0.49; 0.78) | -0.33 (-0.46; -0.19) | -3 (-5; -2) | -326 (-463; -190) |
| Dry mouth | Malone-Lee, 2001 ³⁴⁶ RCT | 1mg twice daily vs. 2mg twice daily | 30/61 | 48/73 | 0.75 (0.55; 1.01) | -0.17 (-0.33; 0.00) | | |
| Dry mouth | Van Kerrebroeck, 2001 ³⁹⁴ RCT | 4mg once daily vs. 2mg once daily | 118/507 | 156/514 | 0.77 (0.62; 0.94) | -0.07 (-0.12; -0.02) | -14 (-60; -8) | -71 (-125; -17) |
| Dry mouth | Armstrong, 2007 ²³² Pooled analysis | 2mg qd vs. 4mg qd | 64/193 | 89/399 | 1.49 (1.13; 1.95) | 0.11 (0.03; 0.19) | 9 (5; 33) | 109 (31; 187) |
| Dry skin | Swift, 2003 ³⁸² RCT | 4mg once daily vs. 2mg twice daily | 2/417 | 5/408 | 0.39 (0.08; 2.01) | -0.01 (-0.02; 0.01) | | |
| Dry skin | Van Kerrebroeck, 2001 ³⁹⁴ RCT | 4mg once daily vs. 2mg once daily | 2/507 | 6/514 | 0.34 (0.07; 1.67) | -0.01 (-0.02; 0.00) | | |
| Dyspepsia | Swift, 2003 ³⁸² RCT | 4mg once daily vs. 2mg twice daily | 11/417 | 14/408 | 0.77 (0.35; 1.67) | -0.01 (-0.03; 0.02) | | |
| Dyspepsia | Malone-Lee, 2001 ³⁴⁶ RCT | 1mg twice daily vs. 2mg twice daily | 2/61 | 6/73 | 0.40 (0.08; 1.91) | -0.05 (-0.13; 0.03) | | |
| Dyspepsia | Van Kerrebroeck, 2001 ³⁹⁴ RCT | 4mg once daily vs. 2mg once daily | 15/507 | 16/514 | 0.95 (0.47; 1.90) | 0.00 (-0.02; 0.02) | | |

Appendix Table F53. Clinical outcomes after different doses and clinical formulations of tolterodine (continued)

| Outcome | Reference design | Active vs. control | Active events/ randomized | Control events/ randomized | Relative risk (95% CI) | Absolute risk difference (95% CI) | Number needed to treat (95% CI) | Attributable events/1000 treated (95% CI) |
|---------------------------|---|--|------------------------------|-------------------------------|---------------------------|---|--|--|
| Dyspepsia | Armstrong, 2007 ²³² Pooled analysis | 2mg qd vs. 4mg qd | 10/193 | 11/399 | 1.88 (0.81; 4.35) | 0.02 (-0.01; 0.06) | | |
| Dysuria | Van Kerrebroeck, 2001 ³⁹⁴ RCT | 4mg once daily vs. 2mg once daily | 5/507 | 8/514 | 0.63 (0.21; 1.92) | -0.01 (-0.02; 0.01) | | |
| Fatigue | Van Kerrebroeck, 2001 ³⁹⁴ RCT | 4mg once daily vs. 2mg once daily | 11/507 | 6/514 | 1.86 (0.69; 4.99) | 0.01 (-0.01; 0.03) | | |
| Flatulence | Swift, 2003 ³⁸² RCT | 4mg once daily vs. 2mg twice daily | 8/417 | 11/408 | 0.71 (0.29; 1.75) | -0.01 (-0.03; 0.01) | | |
| Flatulence | Van Kerrebroeck, 2001 ³⁹⁴ RCT | 4mg once daily vs. 2mg once daily | 10/507 | 14/514 | 0.72 (0.32; 1.62) | -0.01 (-0.03; 0.01) | | |
| Gastrointestinal | Jonas, 1997 ³¹⁸ RCT | 1mg twice daily vs. 2mg twice daily | 5/99 | 6/99 | 0.83 (0.26; 2.64) | -0.01 (-0.07; 0.05) | | |
| Gastrointestinal disorder | Appell, 1997 ²²⁹ Pooled analysis | 1mg twice daily vs. 2mg daily | 27/121 | 123/474 | 0.86 (0.60; 1.24) | -0.04 (-0.12; 0.05) | | |
| General disorders | Jonas, 1997 ³¹⁸ RCT | 1mg twice daily vs. 2mg twice daily | 7/99 | 6/99 | 1.17 (0.41; 3.35) | 0.01 (-0.06; 0.08) | | |
| Headache | Swift, 2003 ³⁸² RCT | 4mg once daily vs. 2mg twice daily | 29/417 | 14/408 | 2.03 (1.09; 3.78) | 0.04 (0.01; 0.07) | 28 (15; 196) | 35 (5; 65) |
| Headache | Jacquetin, 2001 ³¹⁶ RCT | 1mg twice daily vs. 2mg twice daily | 3/97 | 3/103 | 1.06 (0.22; 5.14) | 0.00 (-0.05; 0.05) | | |

Appendix Table F53. Clinical outcomes after different doses and clinical formulations of tolterodine (continued)

| Outcome | Reference design | Active vs. control | Active events/ randomized | Control events/ randomized | Relative risk (95% CI) | Absolute risk difference (95% CI) | Number needed to treat (95% CI) | Attributable events/1000 treated (95% CI) |
|--------------------------------------|---|-------------------------------------|---------------------------|----------------------------|------------------------|-----------------------------------|---------------------------------|---|
| Headache | Jonas, 1997 ³¹⁸ RCT | 1mg twice daily vs. 2mg twice daily | 3/99 | 3/99 | 1.00 (0.21; 4.83) | 0.00 (-0.05; 0.05) | | |
| Headache | Takei, 2005 ³⁸⁴ RCT | 4mg/day vs. 4mg/day | 6/80 | 10/74 | 0.56 (0.21; 1.45) | -0.06 (-0.16; 0.04) | | |
| Headache | Malone-Lee, 2001 ³⁴⁶ RCT | 1mg twice daily vs. 2mg twice daily | 5/61 | 7/73 | 0.85 (0.29; 2.56) | -0.01 (-0.11; 0.08) | | |
| Headache | Van Kerrebroeck, 2001 ³⁹⁴ RCT | 4mg once daily vs. 2mg once daily | 32/507 | 19/514 | 1.71 (0.98; 2.97) | 0.03 (0.00; 0.05) | | |
| Headache | Armstrong, 2007 ²³² Pooled analysis | 2mg qd vs. 4mg qd | 18/193 | 24/399 | 1.55 (0.86; 2.79) | 0.03 (-0.01; 0.08) | | |
| Hypertension | Swift, 2003 ³⁸² RCT | 4mg once daily vs. 2mg twice daily | 6/417 | 4/408 | 1.47 (0.42; 5.16) | 0.00 (-0.01; 0.02) | | |
| Insomnia | Swift, 2003 ³⁸² RCT | 4mg once daily vs. 2mg twice daily | 7/417 | 2/408 | 3.42 (0.72; 16.39) | 0.01 (0.00; 0.03) | | |
| Insomnia | Van Kerrebroeck, 2001 ³⁹⁴ RCT | 4mg once daily vs. 2mg once daily | 7/507 | 2/514 | 3.55 (0.74; 17.00) | 0.01 (0.00; 0.02) | | |
| Metabolic and nutritional system | Armstrong, 2007 ²³² Pooled analysis | 2mg qd vs. 4mg qd | 17/193 | 21/399 | 1.67 (0.90; 3.10) | 0.04 (-0.01; 0.08) | | |
| Mild to-moderate intensity dry mouth | Jacquetin, 2001 ³¹⁶ RCT | 1mg twice daily vs. 2mg twice daily | 18/97 | 30/103 | 0.64 (0.38; 1.07) | -0.11 (-0.22; 0.01) | | |

Appendix Table F53. Clinical outcomes after different doses and clinical formulations of tolterodine (continued)

| Outcome | Reference design | Active vs. control | Active events/ randomized | Control events/ randomized | Relative risk (95% CI) | Absolute risk difference (95% CI) | Number needed to treat (95% CI) | Attributable events/1000 treated (95% CI) |
|---|---|-------------------------------------|------------------------------|-------------------------------|---------------------------|---|--|--|
| Minor noncholinergic and cholinergic adverse events | Millard, 1999 ³⁴⁹ RCT | 1mg twice daily vs. 2mg twice daily | 95/129 | 90/123 | 1.01 (0.87; 1.17) | 0.00 (-0.10; 0.11) | | |
| Moderate or severe dry mouth | Appell, 1997 ²²⁹ Pooled analysis | 1mg twice daily vs. 2mg daily | 5/121 | 81/474 | 0.24 (0.10; 0.58) | -0.13 (-0.18; -0.08) | -8 (-12; -6) | -130 (-179; -81) |
| Nasopharyngitis | Takei, 2005 ³⁸⁴ RCT | 4mg/day vs. 4mg/day | 6/80 | 50/74 | 0.11 (0.05; 0.24) | -0.60 (-0.72; -0.48) | -2 (-2; -1) | -601 (-722; -479) |
| Nausea | Swift, 2003 ³⁸² RCT | 4mg once daily vs. 2mg twice daily | 7/417 | 9/408 | 0.76 (0.29; 2.02) | -0.01 (-0.02; 0.01) | | |
| Nausea | Malone-Lee, 2001 ³⁴⁶ RCT | 1mg twice daily vs. 2mg twice daily | 2/61 | 3/73 | 0.80 (0.14; 4.62) | -0.01 (-0.07; 0.06) | | |
| Nausea | Van Kerrebroeck, 2001 ³⁹⁴ RCT | 4mg once daily vs. 2mg once daily | 7/507 | 10/514 | 0.71 (0.27; 1.85) | -0.01 (-0.02; 0.01) | | |
| Pain | Armstrong, 2007 ²³² Pooled analysis | 2mg qd vs. 4mg qd | 15/193 | 14/399 | 2.22 (1.09; 4.50) | 0.04 (0.00; 0.08) | 23 (12; 1303) | 43 (1; 84) |
| Palpitations | Appell, 1997 ²²⁹ Pooled analysis | 1mg twice daily vs. 2mg daily | 8/121 | 2/474 | 15.67 (3.37; 72.84) | 0.06 (0.02; 0.11) | 16 (9; 58) | 62 (17; 107) |
| Peripheral edema | Van Kerrebroeck, 2001 ³⁹⁴ RCT | 4mg once daily vs. 2mg once daily | 7/507 | 7/514 | 1.01 (0.36; 2.87) | 0.00 (-0.01; 0.01) | | |
| Peripheral edema | Armstrong, 2007 ²³² Pooled analysis | 2mg qd vs. 4mg qd | 11/193 | 13/399 | 1.75 (0.80; 3.83) | 0.02 (-0.01; 0.06) | | |
| Psychiatric adverse events | Jonas, 1997 ³¹⁸ RCT | 1mg twice daily vs. 2mg twice daily | 1/99 | 1/99 | 1.00 (0.06; 15.76) | 0.00 (-0.03; 0.03) | | |
| Respiratory adverse events | Jonas, 1997 ³¹⁸ RCT | 1mg twice daily vs. 2mg twice daily | 1/99 | 3/99 | 0.33 (0.04; 3.15) | -0.02 (-0.06; 0.02) | | |

Appendix Table F53. Clinical outcomes after different doses and clinical formulations of tolterodine (continued)

| Outcome | Reference design | Active vs. control | Active events/ randomized | Control events/ randomized | Relative risk (95% CI) | Absolute risk difference (95% CI) | Number needed to treat (95% CI) | Attributable events/1000 treated (95% CI) |
|--|--|---|------------------------------|-------------------------------|---------------------------|---|--|--|
| Sinusitis | Swift, 2003 ³⁸² RCT | 4mg once daily vs. 2mg twice daily | 8/417 | 2/408 | 3.91 (0.84; 18.32) | 0.01 (0.00; 0.03) | | |
| Skin and appendages | Jonas, 1997 ³¹⁸ RCT | 1mg twice daily vs. 2mg twice daily | 1/99 | 1/99 | 1.00 (0.06; 15.76) | 0.00 (-0.03; 0.03) | | |
| Somnolence | Swift, 2003 ³⁸² RCT | 4mg once daily vs. 2mg twice daily | 12/417 | 11/408 | 1.07 (0.48; 2.39) | 0.00 (-0.02; 0.02) | | |
| Somnolence | Van Kerrebroeck, 2001 ³⁹⁴ RCT | 4mg once daily vs. 2mg once daily | 14/507 | 13/514 | 1.09 (0.52; 2.30) | 0.00 (-0.02; 0.02) | | |
| Urinary AE | Jonas, 1997 ³¹⁸ RCT | 1mg twice daily vs. 2mg twice daily | 6/99 | 5/99 | 1.20 (0.38; 3.80) | 0.01 (-0.05; 0.07) | | |
| Urinary tract infection | Swift, 2003 ³⁸² RCT | 4mg once daily vs. 2mg twice daily | 15/417 | 11/408 | 1.33 (0.62; 2.87) | 0.01 (-0.01; 0.03) | | |
| Urinary tract infection | Van Kerrebroeck, 2001 ³⁹⁴ RCT | 4mg once daily vs. 2mg once daily | 16/507 | 13/514 | 1.25 (0.61; 2.57) | 0.01 (-0.01; 0.03) | | |
| Urinary tract infection | Armstrong, 2007 ²³² Pooled analysis | 2mg qd vs. 4mg qd | 11/193 | 13/399 | 1.75 (0.80; 3.83) | 0.02 (-0.01; 0.06) | | |
| Urinary tract infection | Jonas, 1997 ³¹⁸ RCT | 1mg twice daily vs. 2mg twice daily | 5/99 | 2/99 | 2.50 (0.50; 12.58) | 0.03 (-0.02; 0.08) | | |
| Urogenital system adverse events | Armstrong, 2007 ²³² Pooled analysis | 2mg qd vs. 4mg qd campaign | 35/193 | 38/399 | 1.90 (1.24; 2.91) | 0.09 (0.02; 0.15) | 12 (7; 41) | 86 (25; 148) |
| Xerophthalmia | Swift, 2003 ³⁸² RCT | 4mg once daily vs. 2mg twice daily | 16/417 | 8/408 | 1.96 (0.85; 4.52) | 0.02 (0.00; 0.04) | | |
| Xerophthalmia | Van Kerrebroeck, 2001 ³⁹⁴ RCT | 4mg once daily vs. 2mg once daily | 17/507 | 12/514 | 1.44 (0.69; 2.98) | 0.01 (-0.01; 0.03) | | |