

**Appendix Table F61. Clinical outcomes after fesoterodine vs. placebo, secondary data from post hoc and pooled analyses**

Outcome	Reference daily dose mg/day	Active n/N	Control n/N	Relative risk (95% CI)	Absolute risk difference (95% CI)	Number needed to treat (95% CI)	Attributable events/1000 treated (95% CI)
Response to treatment	Sand, 2009 <sup>372</sup> 4 mg/day	251/434	167/430	1.49 (1.29; 1.72)	0.190 (0.125; 0.255)	5 (4; 8)	190 (125; 255)
Response to treatment	Sand, 2009 <sup>372</sup> 8 mg/day	291/452	167/430	1.66 (1.45; 1.90)	0.255 (0.192; 0.319)	4 (3; 5)	255 (192; 319)
Discontinuation	Sand, 2009 <sup>372</sup> 8 mg/day	14/287	6/283	2.30 (0.90; 5.90)	0.028 (-0.002; 0.058)		
Discontinuation due to adverse effects	Khullar, 2008 <sup>330</sup> 4 mg/day	27/554	19/554	1.42 (0.80; 2.53)	0.014 (-0.009; 0.038)		
Discontinuation due to adverse effects	Khullar, 2008 <sup>330</sup> 8 mg/day	41/566	19/554	2.11 (1.24; 3.59)	0.038 (0.012; 0.064)	26 (16; 84)	38 (12; 64)
Back pain	Sand, 2009 <sup>372</sup> mg/day	9/434	1/430	8.92 (1.13; 70.08)	0.018 (0.004; 0.033)	54 (31; 235)	18 (4; 33)
Back pain	Sand, 2009 <sup>372</sup> 8 mg/day	4/421	1/430	4.09 (0.46; 36.40)	0.007 (-0.003; 0.018)		
Constipation	Sand, 2009 <sup>372</sup> 4 mg/day	20/434	10/430	1.98 (0.94; 4.18)	0.023 (-0.002; 0.047)		
Constipation	Khullar, 2008 <sup>330</sup> 4 mg/day	23/554	11/554	2.09 (1.03; 4.25)	0.022 (0.001; 0.042)	46 (24; 719)	22 (1; 42)
Constipation	Chapple, 2008 <sup>260</sup> 8 mg/day	13/287	4/283	3.20 (1.06; 9.71)	0.031 (0.003; 0.059)	32 (17; 290)	31 (3; 59)
Constipation	Sand, 2009 <sup>372</sup> 4 mg/day	24/421	10/430	2.45 (1.19; 5.06)	0.034 (0.007; 0.060)	30 (17; 135)	34 (7; 60)
Constipation	Khullar, 2008 <sup>330</sup> 8 mg/day	34/566	11/554	3.03 (1.55; 5.91)	0.040 (0.017; 0.063)	25 (16; 57)	40 (17; 63)
Cough	Sand, 2009 <sup>372</sup> 4 mg/day	7/434	3/430	2.31 (0.60; 8.88)	0.009 (-0.005; 0.023)		
Cough	Sand, 2009 <sup>372</sup> 4 mg/day	5/421	3/430	1.70 (0.41; 7.08)	0.005 (-0.008; 0.018)		
Diarrhea	Sand, 2009 <sup>372</sup> 4 mg/day	7/434	10/430	0.69 (0.27; 1.81)	-0.007 (-0.026; 0.011)		
Diarrhea	Sand, 2009 <sup>372</sup> 4 mg/day	6/421	10/430	0.61 (0.22; 1.67)	-0.009 (-0.027; 0.009)		
Dizziness	Sand, 2009 <sup>372</sup> 4 mg/day	4/434	9/430	0.44 (0.14; 1.42)	-0.012 (-0.028; 0.005)		
Dizziness	Sand, 2009 <sup>372</sup> 4 mg/day	5/421	9/430	0.57 (0.19; 1.68)	-0.009 (-0.026; 0.008)		

**Appendix Table F61. Clinical outcomes after fesoterodine vs. placebo, secondary data from post hoc and pooled analyses (continued)**

Outcome	Reference daily dose mg/day	Active n/N	Control n/N	Relative risk (95% CI)	Absolute risk difference (95% CI)	Number needed to treat (95% CI)	Attributable events/1000 treated (95% CI)
Dry eye	Sand, 2009 <sup>372</sup> 4 mg/day	6/434	0/430	12.88 (0.73; 227.94)	0.014 (0.002; 0.026)		
Dry eye	Chapple, 2008 <sup>260</sup> 8 mg/day	12/287	0/283	24.65 (1.47; 414.40)	0.042 (0.018; 0.066)	24 (15; 56)	42 (18; 66)
Dry eye	Sand, 2009 <sup>372</sup> 4 mg/day	10/421	0/430	21.45 (1.26; 364.85)	0.024 (0.009; 0.039)	42 (26; 117)	24 (9; 39)
Dry mouth	Sand, 2009 <sup>372</sup> 4 mg/day	89/434	32/430	2.76 (1.88; 4.03)	0.131 (0.085; 0.176)	8 (6; 12)	131 (85; 176)
Dry mouth	Khullar, 2008 <sup>330</sup> 4 mg/day	104/554	39/554	2.67 (1.88; 3.78)	0.117 (0.078; 0.156)	9 (6; 13)	117 (78; 156)
Dry mouth	Chapple, 2008 <sup>260</sup> 8 mg/day	97/287	20/283	4.78 (3.04; 7.52)	0.267 (0.205; 0.330)	4 (3; 5)	267 (205; 330)
Dry mouth	Sand, 2009 <sup>372</sup> 4 mg/day	155/421	32/430	4.95 (3.47; 7.06)	0.294 (0.241; 0.346)	3 (3; 4)	294 (241; 346)
Dry mouth	Khullar, 2008 <sup>330</sup> 8 mg/day	196/566	39/554	4.92 (3.56; 6.80)	0.276 (0.231; 0.321)	4 (3; 4)	276 (231; 321)
Dry throat	Sand, 2009 <sup>372</sup> 4 mg/day	4/434	0/430	8.92 (0.48; 165.12)	0.009 (-0.001; 0.019)		
Dry throat	Khullar, 2008 <sup>330</sup> 4 mg/day	5/554	2/554	2.50 (0.49; 12.83)	0.005 (-0.004; 0.015)		
Dry throat	Chapple, 2008 <sup>260</sup> 8 mg/day	8/287	0/283	16.76 (0.97; 289.07)	0.028 (0.008; 0.048)	36 (21; 129)	28 (8; 48)
Dry throat	Sand, 2009 <sup>372</sup> 4 mg/day	10/421	0/430	21.45 (1.26; 364.85)	0.024 (0.009; 0.039)	42 (26; 117)	24 (9; 39)
Dry throat	Khullar, 2008 <sup>330</sup> 8 mg/day	13/566	2/554	6.36 (1.44; 28.06)	0.019 (0.006; 0.033)	52 (31; 165)	19 (6; 33)
Dyspepsia	Khullar, 2008 <sup>330</sup> 4 mg/day	9/554	3/554	3.00 (0.82; 11.02)	0.011 (-0.001; 0.023)		
Dyspepsia	Khullar, 2008 <sup>330</sup> 8 mg/day	13/566	3/554	4.24 (1.22; 14.80)	0.018 (0.004; 0.031)		
Fatigue	Sand, 2009 <sup>372</sup> 4 mg/day	5/434	2/430	2.48 (0.48; 12.70)	0.007 (-0.005; 0.019)		
Fatigue	Chapple, 2008 <sup>260</sup> 8 mg/day	1/287	1/283	0.99 (0.06; 15.69)	0.000 (-0.010; 0.010)		
Fatigue	Sand, 2009 <sup>372</sup> 4 mg/day	1/421	2/430	0.51 (0.05; 5.61)	-0.002 (-0.010; 0.006)		

**Appendix Table F61. Clinical outcomes after fesoterodine vs. placebo, secondary data from post hoc and pooled analyses (continued)**

Outcome	Reference daily dose mg/day	Active n/N	Control n/N	Relative risk (95% CI)	Absolute risk difference (95% CI)	Number needed to treat (95% CI)	Attributable events/1000 treated (95% CI)
Headache	Sand, 2009 <sup>372</sup> 4 mg/day	21/434	18/430	1.16 (0.62; 2.14)	0.007 (-0.021; 0.034)		
Headache	Khullar, 2008 <sup>330</sup> 4 mg/day	24/554	23/554	1.04 (0.60; 1.83)	0.002 (-0.022; 0.026)		
Headache	Sand, 2009 <sup>372</sup> 4 mg/day	13/421	18/430	0.74 (0.37; 1.49)	-0.011 (-0.036; 0.014)		
Headache	Khullar, 2008 <sup>330</sup> 8 mg/day	15/566	23/554	0.64 (0.34; 1.21)	-0.015 (-0.036; 0.006)		
Increased alanine aminotransferase	Chapple, 2008 <sup>260</sup> 8 mg/day	6/287	1/283	5.92 (0.72; 48.83)	0.017 (-0.001; 0.035)		
Lacrimonal disorder	Khullar, 2008 <sup>330</sup> 4 mg/day	8/554	0/554	17.00 (0.98; 293.82)	0.014 (0.004; 0.025)	69 (40; 255)	14 (4; 25)
Lacrimonal disorder	Khullar, 2008 <sup>330</sup> 8 mg/day	21/566	0/554	42.09 (2.56; 693.13)	0.037 (0.021; 0.053)	27 (19; 47)	37 (21; 53)
Mild-constipation	Khullar, 2008 <sup>330</sup> 4 mg/day	8/554	1/554	8.00 (1.00; 63.75)	0.013 (0.002; 0.023)	79 (43; 478)	13 (2; 23)
Mild-constipation	Khullar, 2008 <sup>330</sup> 4 mg/day	14/554	8/554	1.75 (0.74; 4.14)	0.011 (-0.006; 0.027)		
Mild-constipation	Khullar, 2008 <sup>330</sup> 8 mg/day	14/566	1/554	13.70 (1.81; 103.86)	0.023 (0.010; 0.036)	44 (28; 104)	23 (10; 36)
Mild-constipation	Khullar, 2008 <sup>330</sup> 8 mg/day	18/566	8/554	2.20 (0.97; 5.02)	0.017 (0.000; 0.035)		
Mild-dry mouth	Khullar, 2008 <sup>330</sup> 4 mg/day	16/554	11/554	1.45 (0.68; 3.11)	0.009 (-0.009; 0.027)		
Mild-dry mouth	Khullar, 2008 <sup>330</sup> 4 mg/day	84/554	27/554	3.11 (2.05; 4.72)	0.103 (0.068; 0.138)	10 (7; 15)	103 (68; 138)
Mild-dry mouth	Khullar, 2008 <sup>330</sup> 8 mg/day	53/566	11/554	4.72 (2.49; 8.93)	0.074 (0.047; 0.100)	14 (10; 21)	74 (47; 100)
Mild-dry mouth	Khullar, 2008 <sup>330</sup> 8 mg/day	126/566	27/554	4.57 (3.07; 6.81)	0.174 (0.135; 0.213)	6 (5; 7)	174 (135; 213)
Mild-headache	Khullar, 2008 <sup>330</sup> 4 mg/day	6/554	3/554	2.00 (0.50; 7.96)	0.005 (-0.005; 0.016)		
Mild-headache	Khullar, 2008 <sup>330</sup> 4 mg/day	15/554	19/554	0.79 (0.41; 1.54)	-0.007 (-0.028; 0.013)		

**Appendix Table F61. Clinical outcomes after fesoterodine vs. placebo, secondary data from post hoc and pooled analyses (continued)**

Outcome	Reference daily dose mg/day	Active n/N	Control n/N	Relative risk (95% CI)	Absolute risk difference (95% CI)	Number needed to treat (95% CI)	Attributable events/1000 treated (95% CI)
Mild-headache	Khullar, 2008 <sup>330</sup> 8 mg/day	5/566	3/554	1.63 (0.39; 6.79)	0.003 (-0.006; 0.013)		
Mild-headache	Khullar, 2008 <sup>330</sup> 8 mg/day	9/566	19/554	0.46 (0.21; 1.02)	-0.018 (-0.037; 0.000)		
Mild-urinary tract infection	Khullar, 2008 <sup>330</sup> 4 mg/day	7/554	5/554	1.40 (0.45; 4.38)	0.004 (-0.009; 0.016)		
Mild-urinary tract infection	Khullar, 2008 <sup>330</sup> 4 mg/day	11/554	12/554	0.92 (0.41; 2.06)	-0.002 (-0.019; 0.015)		
Mild-urinary tract infection	Khullar, 2008 <sup>330</sup> 8 mg/day	8/566	5/554	1.57 (0.52; 4.76)	0.005 (-0.007; 0.018)		
Mild-urinary tract infection	Khullar, 2008 <sup>330</sup> 8 mg/day	15/566	12/554	1.22 (0.58; 2.59)	0.005 (-0.013; 0.023)		
Nasopharyngitis	Sand, Morrow, 2009 <sup>372</sup> 4 mg/day	14/434	12/430	1.16 (0.54; 2.47)	0.004 (-0.018; 0.027)		
Nasopharyngitis	Khullar, 2008 <sup>330</sup> 4 mg/day	18/554	14/554	1.29 (0.65; 2.56)	0.007 (-0.012; 0.027)		
Nasopharyngitis	Chapple, 2008 <sup>260</sup> 8 mg/day	5/287	7/283	0.70 (0.23; 2.19)	-0.007 (-0.031; 0.016)		
Nasopharyngitis	Sand, 2009 <sup>372</sup> 4 mg/day	6/421	12/430	0.51 (0.19; 1.35)	-0.014 (-0.033; 0.006)		
Nasopharyngitis	Khullar, 2008 <sup>330</sup> 8 mg/day	7/566	14/554	0.49 (0.20; 1.20)	-0.013 (-0.029; 0.003)		
Nausea	Sand, 2009 <sup>372</sup> 4 mg/day	4/434	5/430	0.79 (0.21; 2.93)	-0.002 (-0.016; 0.011)		
Nausea	Chapple, 2008 <sup>260</sup> 8 mg/day	4/287	1/283	3.94 (0.44; 35.07)	0.010 (-0.005; 0.026)		
Nausea	Sand, 2009 <sup>372</sup> 4 mg/day	11/421	5/430	2.25 (0.79; 6.41)	0.015 (-0.004; 0.033)		
Severe-constipation	Khullar, 2008 <sup>330</sup> 4 mg/day	1/554	2/554	0.50 (0.05; 5.50)	-0.002 (-0.008; 0.004)		
Severe-constipation	Khullar, 2008 <sup>330</sup> 8 mg/day	2/566	2/554	0.98 (0.14; 6.92)	0.000 (-0.007; 0.007)		
Severe-dry mouth	Khullar, 2008 <sup>330</sup> 4 mg/day	4/554	1/554	4.00 (0.45; 35.67)	0.005 (-0.002; 0.013)		

**Appendix Table F61. Clinical outcomes after fesoterodine vs. placebo, secondary data from post hoc and pooled analyses (continued)**

<b>Outcome</b>	<b>Reference daily dose mg/day</b>	<b>Active n/N</b>	<b>Control n/N</b>	<b>Relative risk (95% CI)</b>	<b>Absolute risk difference (95% CI)</b>	<b>Number needed to treat (95% CI)</b>	<b>Attributable events/1000 treated (95% CI)</b>
Severe-dry mouth	Khullar, 2008 <sup>330</sup> 8 mg/day	17/566	1/554	16.64 (2.22; 124.61)	0.028 (0.014; 0.043)	35 (23; 73)	28 (14; 43)
Severe-headache	Khullar, 2008 <sup>330</sup> 4 mg/day	3/554	1/554	3.00 (0.31; 28.75)	0.004 (-0.003; 0.011)		
Severe-headache	Khullar, 2008 <sup>330</sup> 8 mg/day	1/566	1/554	0.98 (0.06; 15.61)	0.000 (-0.005; 0.005)		
Severe-urinary tract infection	Khullar, 2008 <sup>330</sup> 4 mg/day	0/554	0/554	0.00 (0.00; 0.00)	0.000 (-0.004; 0.004)		
Severe-urinary tract infection	Khullar, 2008 <sup>330</sup> 8 mg/day	1/566	0/554	2.94 (0.12; 71.93)	0.002 (-0.003; 0.007)		
Upper respiratory tract infection	Sand, 2009 <sup>372</sup> 4 mg/day	12/434	9/430	1.32 (0.56; 3.10)	0.007 (-0.014; 0.027)		
Upper respiratory tract infection	Khullar, 2008 <sup>330</sup> 4 mg/day	14/554	12/554	1.17 (0.54; 2.50)	0.004 (-0.014; 0.021)		
Upper respiratory tract infection	Sand, 2009 <sup>372</sup> 4 mg/day	8/421	9/430	0.91 (0.35; 2.33)	-0.002 (-0.021; 0.017)		
Upper respiratory tract infection	Khullar, 2008 <sup>330</sup> 8 mg/day	10/566	12/554	0.82 (0.36; 1.87)	-0.004 (-0.020; 0.012)		
Urinary tract infection	Sand, 2009 <sup>372</sup> 4 mg/day	18/434	17/430	1.05 (0.55; 2.01)	0.002 (-0.024; 0.028)		
Urinary tract infection	Khullar, 2008 <sup>330</sup> 4 mg/day	18/554	17/554	1.06 (0.55; 2.03)	0.002 (-0.019; 0.022)		
Urinary tract infection	Sand, 2009 <sup>372</sup> 4 mg/day	24/421	17/430	1.44 (0.79; 2.64)	0.017 (-0.011; 0.046)		
Urinary tract infection	Khullar, 2008 <sup>330</sup> 8 mg/day	24/566	17/554	1.38 (0.75; 2.54)	0.012 (-0.010; 0.034)		