

Appendix Table F57. Significant dose response association with clinical outcomes after darifenacin (individual RCTs)

Studies, reference	Active dose, mg/day	Control 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 (95% CI)
Adverse effects								
Hill, 2006 ⁴⁴	7.5	30	62/108	92/115	0.72 (0.60; 0.86)	-0.23 (-0.34; -0.11)	-4 (-9; -3)	-226 (-344; -107)
Withdrawals: adverse effects								
Hill, 2006 ⁴⁴	15	30	73/107	92/115	0.85 (0.73; 1.00)	-0.12 (-0.23; 0.00)	-8 (-314; -4)	-118 (-232; -3)
Hill, 2006 ⁴⁴	7.5	30	2/108	13/115	0.16 (0.04; 0.71)	-0.09 (-0.16; -0.03)	-11 (-32; -6)	-95 (-158; -31)
Chancellor, 2008 ²⁵⁶	7	15	21/205	6/190	3.24(1.34; 7.86)	0.07(0.02; 0.12)	14(8; 44)	71(22; 119)
Withdrawals due to lack of response								
Hill, 2006 ⁴⁴	7.5	15	1/108	2/107	0.50 (0.05; 5.38)	-0.01 (-0.04; 0.02)		
Hill, 2006 ⁴⁴	7.5	30	1/108	1/115	1.06 (0.07; 16.81)	0.00 (-0.02; 0.03)		
Hill, 2006 ⁴⁴	15	30	2/107	1/115	2.15 (0.20; 23.36)	0.01 (-0.02; 0.04)		
Constipation								
Steers, 2005 ⁴⁵	7.5	15	32/108	24/160	1.98 (1.24; 3.16)	0.15 (0.04; 0.25)	7 (4; 23)	146 (44; 249)
Hill, 2006 ⁴⁴	7.5	30	17/108	32/115	0.57 (0.33; 0.96)	-0.12 (-0.23; -0.01)	-8 (-72; -4)	-121 (-228; -14)
Chapple, 2004 ⁴⁷³	15	30	2/53	33/229	0.26 (0.06; 1.06)	-0.11 (-0.17; -0.04)	-9 (-26; -6)	-106 (-175; -38)
Chapple, 2004 ⁴⁷³	15	60	2/53	16/115	0.27 (0.06; 1.14)	-0.10 (-0.18; -0.02)	-10 (-50; -5)	-101 (-183; -20)
Dry mouth								
Steers, 2005 ⁴⁵	7.5	15	28/108	22/160	1.89 (1.14; 3.12)	0.12 (0.02; 0.22)	8 (5; 43)	122 (23; 220)
Hill, 2006 ⁴⁴	7.5	15	25/108	43/107	0.58 (0.38; 0.87)	-0.17 (-0.29; -0.05)	-6 (-21; -3)	-170 (-293; -48)
Hill, 2006 ⁴⁴	7.5	30	25/108	68/115	0.39 (0.27; 0.57)	-0.36 (-0.48; -0.24)	-3 (-4; -2)	-360 (-480; -240)
Hill, 2006 ⁴⁴	15	30	43/107	68/115	0.68 (0.52; 0.90)	-0.19 (-0.32; -0.06)	-5 (-17; -3)	-189 (-319; -60)
Chapple, 2004 ⁴⁷³	15	60	7/53	36/115	0.42 (0.20; 0.89)	-0.18 (-0.31; -0.06)	-6 (-18; -3)	-181 (-305; -57)
Chapple, 2004 ⁴⁷³	30	60	43/229	36/115	0.60 (0.41; 0.88)	-0.13 (-0.22; -0.03)	-8 (-38; -4)	-125 (-224; -27)
Dyspepsia								
Chapple, 2004 ⁴⁷³	30	60	4/229	9/115	0.22 (0.07; 0.71)	-0.06 (-0.11; -0.01)	-16 (-113; -9)	-61 (-113; -9)
Headache								
Steers, 2005 ⁴⁵	7.5	15	13/108	5/160	3.85 (1.41; 10.49)	0.09 (0.02; 0.16)	11 (6; 45)	89 (22; 156)
Respiratory tract infection								
Hill, 2006 ⁴⁴	15	30	6/107	1/115	6.45 (0.79; 52.69)	0.05 (0.00; 0.09)	21 (11; 1665)	47 (1; 94)

Appendix Table F57. Significant dose response association with clinical outcomes after darifenacin (individual RCTs) (continued)

Studies, reference	Active dose, mg/day	Control 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 (95% CI)
Urinary tract disorder								
Hill, 2006 ⁴⁴	7.5	15	0/108	6/107	0.08 (0.00; 1.34)	-0.06 (-0.10; -0.01)	-18 (-106; -10)	-56 (-103; -9)