

**Appendix Table F56. Dose response association between clinical outcomes and darifenacin in pooled analyses of individual patient data from RCTs (high level of evidence)**

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)
<b>≥1 adverse effect</b>								
Chapple, 2005 <sup>262</sup>	7.5	15	182/337	219/334	0.82 (0.73; 0.93)	-0.116 (-0.189; -0.042)	-9 (-24; -5)	-116 (-189; -42)
<b>Adverse effects of any cause</b>								
Foote, 2005 <sup>288</sup>	7.5	15	52/97	76/110	0.78 (0.62; 0.97)	-0.155 (-0.286; -0.023)	-6 (-43; -3)	-155 (-286; -23)
<b>Discontinued</b>								
Chapple, 2005 <sup>262</sup>	7.5	15	19/337	43/334	0.44 (0.26; 0.74)	-0.072 (-0.116; -0.029)	-14 (-35; -9)	-72 (-116; -29)
<b>Adverse effects leading to discontinuation</b>								
Foote, 2005 <sup>288</sup>	7.5	15	1/97	10/110	0.11 (0.01; 0.87)	-0.081 (-0.138; -0.023)	-12 (-43; -7)	-81 (-138; -23)
<b>Adverse effects leading to discontinuation</b>								
Chapple, 2005 <sup>262</sup>	7.5	15	5/337	17/334	0.29 (0.11; 0.78)	-0.036 (- 0.063; -0.009)	-28 (-109; -16)	-36 (-63; -9)
<b>Incontinence impact</b>								
Abrams, 2008 <sup>50</sup>	7.5	15	52/337	46/334	1.12 (0.78; 1.62)	0.017 (-0.037; 0.070)		
<b>Severity measures</b>								
Abrams, 2008 <sup>50</sup>	7.5	15	47/337	46/334	1.01 (0.69; 1.48)	0.002 (-0.051; 0.054)		
<b>Role limitations</b>								
Abrams, 2008 <sup>50</sup>	7.5	15	65/337	59/334	1.09 (0.79; 1.50)	0.016 (-0.042; 0.075)		
<b>Social limitations</b>								
Abrams, 2008 <sup>50</sup>	7.5	15	57/337	54/334	1.05 (0.74; 1.47)	0.007 (-0.049; 0.064)		
<b>Physical limitations</b>								
Abrams, 2008 <sup>50</sup>	7.5	15	58/337	53/334	1.08 (0.77; 1.52)	0.013 (-0.043; 0.070)		
<b>Emotions</b>								
Abrams, 2008 <sup>50</sup>	7.5	15	56/337	53/334	1.05 (0.74; 1.48)	0.007 (-0.048; 0.063)		

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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)
<b>Personal relationships</b>								
Abrams, 2008 <sup>50</sup>	7.5	15	24/337	23/334	1.03 (0.60; 1.80)	0.002 (-0.036; 0.041)		
<b>Sleep/energy</b>								
Abrams, 2008 <sup>50</sup>	7.5	15	46/337	46/334	0.99 (0.68; 1.45)	-0.001 (-0.053; 0.051)		
<b>General health perception</b>								
Abrams, 2008 <sup>50</sup>	7.5	15	24/337	21/334	1.13 (0.64; 1.99)	0.008 (-0.029; 0.046)		
<b>Dry mouth</b>								
Chapple, 2005 <sup>262</sup>	7.5	15	68/337	118/334	0.57 (0.44; 0.74)	-0.152 (-0.218; -0.085)	-7 (-12; -5)	-152 (-218; -85)
Foote, 2005 <sup>288</sup>	7.5	15	20/97	34/110	0.67 (0.41; 1.08)	-0.103 (-0.221; 0.015)		
<b>Abdominal pain</b>								
Chapple, 2005 <sup>262</sup>	7.5	15	8/337	13/334	0.61 (0.26; 1.45)	-0.015 (-0.042; 0.011)		
<b>Back pain</b>								
Chapple, 2005 <sup>262</sup>	7.5	15	8/337	5/334	1.59 (0.52; 4.80)	0.009 (-0.012; 0.030)		
<b>Cardiovascular system (total)</b>								
Foote, 2005 <sup>288</sup>	7.5	15	3/97	1/110	3.40 (0.36; 32.17)	0.022 (-0.017; 0.061)		
<b>Constipation</b>								
Chapple, 2005 <sup>262</sup>	7.5	15	50/337	71/334	0.70 (0.50; 0.97)	-0.064 (-0.122; -0.006)	-16 (-161; -8)	-64 (-122; -6)
Foote, 2005 <sup>288</sup>	7.5	15	18/97	26/110	0.79 (0.46; 1.34)	-0.051 (-0.162; 0.060)		
<b>Dyspepsia</b>								
Chapple, 2005 <sup>262</sup>	7.5	15	9/337	28/334	0.32 (0.15; 0.66)	-0.057 (-0.091; -0.023)	-18 (-44; -11)	-57 (-91; -23)
Foote, 2005 <sup>288</sup>	7.5	15	2/97	8/110	0.28 (0.06; 1.30)	-0.052 (-0.108; 0.004)		
<b>Headache</b>								
Chapple, 2005 <sup>262</sup>	7.5	15	15/337	17/334	0.87 (0.44; 1.72)	-0.006 (-0.039; 0.026)		
Foote, 2005 <sup>288</sup>	7.5	15	0/97	0/110	0.00 (0.00; 0.00)	0.000 (-0.019; 0.019)		

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<b>Studies, reference</b>	<b>Active dose, mg/day</b>	<b>Control 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 (95% CI)</b>
<b>Nervous system (total)</b>								
Foote, 2005 <sup>288</sup>	7.5	15	2/97	2/110	1.13 (0.16; 7.90)	0.002 (-0.035; 0.040)		
<b>Respiratory tract information</b>								
Chapple, 2005 <sup>262</sup>	7.5	15	9/337	17/334	0.52 (0.24; 1.16)	-0.024 (-0.053; 0.005)		
<b>UTI</b>								
Chapple, 2005 <sup>262</sup>	7.5	15	16/337	15/334	1.06 (0.53; 2.10)	0.003 (-0.029; 0.034)		