

Appendix Table F55. Clinical outcomes after darifenacin vs. placebo in pooled analyses of individual patient data from RCTs (high level of evidence)

Studies, reference	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)
≥7 consecutive dry days							
Chapple, 2005 ²⁶²	7.5	19/337	15/388	1.46 (0.75; 2.82)	0.018 (-0.013; 0.049)		
Chapple, 2005 ²⁶²	15	24/334	16/388	1.74 (0.94; 3.22)	0.031 (-0.003; 0.065)		
≥3 dry days/week							
Chapple, 2005 ²⁶²	7.5	55/337	43/388	1.47 (1.02; 2.13)	0.052 (0.002; 0.103)	19 (10; 486)	52 (2; 103)
Chapple, 2005 ²⁶²	15	61/334	48/388	1.48 (1.04; 2.09)	0.059 (0.006; 0.112)	17 (9; 164)	59 (6; 112)
Reduction in incontinence episodes: ≥50%							
Chapple, 2005 ²⁶²	7.5	222/337	202/388	1.27 (1.12; 1.43)	0.138 (0.067; 0.209)	7 (5; 15)	138 (67; 209)
Chapple, 2005 ²⁶²	15	234/334	217/388	1.25 (1.12; 1.40)	0.141 (0.072; 0.211)	7 (5; 14)	141 (72; 211)
Reduction in incontinence episodes: ≥70%							
Chapple, 2005 ²⁶²	7.5	162/337	128/388	1.46 (1.22; 1.74)	0.151 (0.080; 0.222)	7 (5; 13)	151 (80; 222)
Chapple, 2005 ²⁶²	15	190/334	151/388	1.46 (1.25; 1.71)	0.180 (0.108; 0.252)	6 (4; 9)	180 (108; 252)
Reduction in incontinence episodes: ≥90%							
Chapple, 2005 ²⁶²	7.5	91/337	66/388	1.59 (1.20; 2.10)	0.100 (0.040; 0.160)	10 (6; 25)	100 (40; 160)
Chapple, 2005 ²⁶²	15	94/334	66/388	1.65 (1.25; 2.19)	0.111 (0.050; 0.172)	9 (6; 20)	111 (50; 172)
Incontinence impact							
Abrams, 2008 ⁵⁰	7.5	52/337	30/388	2.00 (1.30; 3.05)	0.077 (0.030; 0.124)	13 (8; 33)	77 (30; 124)
Abrams, 2008 ⁵⁰	15	46/334	30/388	1.78 (1.15; 2.75)	0.060 (0.015; 0.106)	17 (9; 67)	60 (15; 106)
Severity measures							
Abrams, 2008 ⁵⁰	7.5	47/337	27/388	2.00 (1.28; 3.14)	0.070 (0.025; 0.115)	14 (9; 40)	70 (25; 115)
Abrams, 2008 ⁵⁰	15	46/334	27/388	1.98 (1.26; 3.11)	0.068 (0.023; 0.113)	15 (9; 43)	68 (23; 113)
Role limitations							
Abrams, 2008 ⁵⁰	7.5	65/337	46/388	1.63 (1.15; 2.30)	0.074 (0.021; 0.127)	13 (8; 47)	74 (21; 127)
Abrams, 2008 ⁵⁰	15	59/334	46/388	1.49 (1.04; 2.13)	0.058 (0.006; 0.110)	17 (9; 165)	58 (6; 110)

Appendix Table F55. Clinical outcomes after darifenacin vs. placebo in pooled analyses of individual patient data from RCTs (high level of evidence) (continued)

Studies, reference	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)
Social limitations							
Abrams, 2008 ⁵⁰	7.5	57/337	42/388	1.56 (1.08; 2.26)	0.061 (0.010; 0.111)	16 (9; 97)	61 (10; 111)
Abrams, 2008 ⁵⁰	15	54/334	42/388	1.49 (1.03; 2.17)	0.053 (0.003; 0.104)	19 (10; 305)	53 (3; 104)
Physical limitations							
Abrams, 2008 ⁵⁰	7.5	58/337	49/388	1.36 (0.96; 1.94)	0.046 (-0.006; 0.098)		
Abrams, 2008 ⁵⁰	15	53/334	49/388	1.26 (0.88; 1.80)	0.032 (-0.019; 0.084)		
Emotions							
Abrams, 2008 ⁵⁰	7.5	56/337	44/388	1.47 (1.02; 2.11)	0.053 (0.002; 0.104)	19 (10; 493)	53 (2; 104)
Abrams, 2008 ⁵⁰	15	53/334	44/388	1.40 (0.96; 2.03)	0.045 (-0.005; 0.096)		
Personal relationships							
Abrams, 2008 ⁵⁰	7.5	24/337	20/388	1.38 (0.78; 2.46)	0.020 (-0.016; 0.055)		
Abrams, 2008 ⁵⁰	15	23/334	20/388	1.34 (0.75; 2.39)	0.017 (-0.018; 0.052)		
Sleep/energy							
Abrams, 2008 ⁵⁰	7.5	46/337	37/388	1.43 (0.95; 2.15)	0.041 (-0.006; 0.088)		
Abrams, 2008 ⁵⁰	15	46/334	37/388	1.44 (0.96; 2.17)	0.042 (-0.005; 0.089)		
General health perception							
Abrams, 2008 ⁵⁰	7.5	24/337	19/388	1.45 (0.81; 2.61)	0.022 (-0.013; 0.057)		
Abrams, 2008 ⁵⁰	15	21/334	19/388	1.28 (0.70; 2.35)	0.014 (-0.020; 0.048)		
≥1 adverse effect							
Chapple, 2005 ²⁶²	7.5	182/337	189/388	1.11 (0.96; 1.28)	0.053 (-0.020; 0.126)		
Chapple, 2005 ²⁶²	15	219/334	189/388	1.35 (1.18; 1.53)	0.169 (0.097; 0.240)	6 (4; 10)	169 (97; 240)
Adverse effects of any cause							
Foote, 2005 ²⁸⁸	15	76/110	56/110	1.36 (1.09; 1.69)	0.182 (0.055; 0.309)	5 (3; 18)	182 (55; 309)
Foote, 2005 ²⁸⁸	7.5	52/97	56/110	1.05 (0.81; 1.37)	0.027 (-0.109; 0.163)		
Discontinued							
Chapple, 2005 ²⁶²	7.5	19/337	31/388	0.71 (0.41; 1.23)	-0.024 (-0.060; 0.013)		
Chapple, 2005 ²⁶²	15	43/334	31/388	1.61 (1.04; 2.50)	0.049 (0.004; 0.094)	20 (11; 255)	49 (4; 94)

Appendix Table F55. Clinical outcomes after darifenacin vs. placebo in pooled analyses of individual patient data from RCTs (high level of evidence) (continued)

Studies, reference	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 leading to discontinuation							
Chapple, 2005 ²⁶²	7.5	5/337	10/388	0.58 (0.20; 1.67)	-0.011 (-0.031; 0.009)		
Chapple, 2005 ²⁶²	15	17/334	10/388	1.97 (0.92; 4.25)	0.025 (-0.003; 0.053)		
Foote, 2005 ²⁸⁸	15	10/110	6/110	1.67 (0.63; 4.43)	0.036 (-0.032; 0.105)		
Foote, 2005 ²⁸⁸	7.5	1/97	6/110	0.19 (0.02; 1.54)	-0.044 (-0.091; 0.003)		
Reduction in incontinence episodes: ≥30%							
Chapple, 2005 ²⁶²	7.5	259/337	248/388	1.20 (1.09; 1.32)	0.129 (0.064; 0.195)	8 (5; 16)	129 (64; 195)
Chapple, 2005 ²⁶²	15	274/334	264/388	1.21 (1.11; 1.31)	0.140 (0.078; 0.202)	7 (5; 13)	140 (78; 202)
Abdominal pain							
Chapple, 2005 ²⁶²	7.5	8/337	2/388	4.61 (0.98; 21.54)	0.019 (0.001; 0.036)	54 (28; 1194)	19 (1; 36)
Chapple, 2005 ²⁶²	15	13/334	2/388	7.55 (1.72; 33.22)	0.034 (0.012; 0.056)	30 (18; 84)	34 (12; 56)
Back pain							
Chapple, 2005 ²⁶²	7.5	8/337	12/388	0.77 (0.32; 1.86)	-0.007 (-0.031; 0.016)		
Chapple, 2005 ²⁶²	15	5/334	12/388	0.48 (0.17; 1.36)	-0.016 (-0.038; 0.006)		
Cardiovascular system (total)							
Foote, 2005 ²⁸⁸	7.5	3/97	0/110	7.93 (0.41; 151.59)	0.031 (-0.008; 0.070)		
Foote, 2005 ²⁸⁸	15	1/110	0/110	3.00 (0.12; 72.85)	0.009 (-0.016; 0.034)		
Constipation							
Chapple, 2005 ²⁶²	7.5	50/337	24/388	2.40 (1.51; 3.82)	0.087 (0.042; 0.131)	12 (8; 24)	87 (42; 131)
Chapple, 2005 ²⁶²	15	71/334	24/388	3.44 (2.22; 5.33)	0.151 (0.101; 0.201)	7 (5; 10)	151 (101; 201)
Foote, 2005 ²⁸⁸	7.5	18/97	7/110	2.92 (1.27; 6.68)	0.122 (0.032; 0.212)	8 (5; 31)	122 (32; 212)
Foote, 2005 ²⁸⁸	15	26/110	7/110	3.71 (1.68; 8.20)	0.173 (0.081; 0.264)	6 (4; 12)	173 (81; 264)
Dry mouth							
Chapple, 2005 ²⁶²	7.5	68/337	32/388	2.45 (1.65; 3.63)	0.119 (0.068; 0.170)	8 (6; 15)	119 (68; 170)
Chapple, 2005 ²⁶²	15	118/334	32/388	4.28 (2.98; 6.15)	0.271 (0.213; 0.329)	4 (3; 5)	271 (213; 329)
Foote, 2005 ²⁸⁸	7.5	20/97	5/110	4.54 (1.77; 11.63)	0.161 (0.071; 0.250)	6 (4; 14)	161 (71; 250)
Foote, 2005 ²⁸⁸	15	34/110	5/110	6.80 (2.76; 16.74)	0.264 (0.169; 0.358)	4 (3; 6)	264 (169; 358)
Dyspepsia							
Chapple, 2005 ²⁶²	7.5	9/337	10/388	1.04 (0.43; 2.52)	0.001 (-0.022; 0.024)		

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Studies, reference	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)
Chapple, 2005 ²⁶²	15	28/334	10/388	3.25 (1.60; 6.60)	0.058 (0.024; 0.092)	17 (11; 41)	58 (24; 92)
Foote, 2005 ²⁸⁸	7.5	2/97	1/110	2.27 (0.21; 24.63)	0.012 (-0.022; 0.045)		
Foote, 2005 ²⁸⁸	15	8/110	1/110	8.00 (1.02; 62.89)	0.064 (0.012; 0.115)	16 (9; 84)	64 (12; 115)
Headache							
Chapple, 2005 ²⁶²	7.5	15/337	21/388	0.82 (0.43; 1.57)	-0.010 (-0.041; 0.022)		
Chapple, 2005 ²⁶²	15	17/334	21/388	0.94 (0.50; 1.75)	-0.003 (-0.036; 0.029)		
Foote, 2005 ²⁸⁸	7.5	0/97	2/110	0.23 (0.01; 4.66)	-0.018 (-0.049; 0.013)		
Foote, 2005 ²⁸⁸	15	0/110	2/110	0.20 (0.01; 4.12)	-0.018 (-0.048; 0.012)		
Nervous system (total)							
Foote, 2005 ²⁸⁸	7.5	2/97	2/110	1.13 (0.16; 7.90)	0.002 (-0.035; 0.040)		
Foote, 2005 ²⁸⁸	15	2/110	2/110	1.00 (0.14; 6.97)	0.000 (-0.035; 0.035)		
Respiratory tract information							
Chapple, 2005 ²⁶²	7.5	9/337	26/388	0.40 (0.19; 0.84)	-0.040 (-0.071; -0.010)	-25 (-99; -14)	-40 (-71; -10)
Chapple, 2005 ²⁶²	15	17/334	26/388	0.76 (0.42; 1.38)	-0.016 (-0.050; 0.018)		
UTI							
Chapple, 2005 ²⁶²	7.5	16/337	10/388	1.84 (0.85; 4.00)	0.022 (-0.006; 0.049)		
Chapple, 2005 ²⁶²	15	15/334	10/388	1.74 (0.79; 3.83)	0.019 (-0.008; 0.046)		