

Appendix Table F58. Clinical outcomes after solifenacin vs. placebo, pooled individual patient data from RCTs (high level of evidence)

Outcome	Reference	Dose, mg/day	Number of subjects	Relative risk (95% CI)	Absolute risk difference (95% CI)	Number needed to treat (95% CI)	Attributable events (95% CI)
Complete continence	Cardozo, 2006 ²⁵⁰	5.00	1,095	1.50 (1.29; 1.73)	0.17 (0.10; 0.23)	6 (4; 10)	169 (104; 233)
Complete continence	Cardozo, 2006 ²⁵⁰	10.00	1,559	1.53 (1.36; 1.72)	0.18 (0.13; 0.23)	6 (4; 8)	180 (132; 228)
Complete continence	Staskin, 2006 ³⁹	5.00	589	1.09 (0.82; 1.43)	0.02 (-0.06; 0.11)		
Complete continence	Staskin, 2006 ³⁹	10.00	882	1.43 (1.19; 1.73)	0.12 (0.06; 0.19)	8 (5; 16)	123 (61; 186)
Discontinued treatment due to adverse effects	Cardozo, 2006 ²⁵⁰	5.00	1,095	0.87 (0.48; 1.58)	-0.01 (-0.03; 0.02)		
Discontinued treatment due to adverse effects	Cardozo, 2006 ²⁵⁰	10.00	1,559	1.28 (0.86; 1.91)	0.01 (-0.01; 0.04)		
Discontinued treatment due to adverse effects	Staskin, 2006 ³⁹	5.00	589	0.57 (0.20; 1.65)	-0.02 (-0.05; 0.01)		
Discontinued treatment due to adverse effects	Staskin, 2006 ³⁹	10.00	882	1.55 (0.89; 2.71)	0.02 (-0.01; 0.06)		
Blurred vision	Staskin, 2006 ³⁹	5.00	1,794	2.10 (1.17; 3.77)	0.02 (0.00; 0.04)	50 (27; 375)	20 (3; 37)
Blurred vision	Staskin, 2006 ³⁹	10.00	2,449	2.64 (1.63; 4.29)	0.03 (0.02; 0.04)	34 (23; 64)	30 (16; 44)
Blurred vision	Cardozo, 2006 ²⁵⁰	5.00	1,095	2.31 (1.10; 4.86)	0.02 (0.00; 0.05)		
Blurred vision	Cardozo, 2006 ²⁵⁰	10.00	1,559	2.58 (1.40; 4.75)	0.03 (0.01; 0.05)	35 (22; 92)	28 (11; 46)
Mild blurred vision	Cardozo, 2006 ²⁵⁰	5.00	1,150	1.94 (0.86; 4.37)	0.02 (-0.01; 0.04)		
Mild blurred vision	Cardozo, 2006 ²⁵⁰	10.00	1,643	2.01 (1.04; 3.88)	0.02 (0.00; 0.03)	63 (33; 833)	16 (1; 31)
Moderate blurred vision	Cardozo, 2006 ²⁵⁰	5.00	1,150	2.52 (0.36; 17.79)	0.00 (-0.01; 0.01)		
Moderate blurred vision	Cardozo, 2006 ²⁵⁰	10.00	1,643	4.01 (0.86; 18.85)	0.01 (0.00; 0.02)		
Severe blurred vision	Cardozo, 2006 ²⁵⁰	5.00	1,150	7.54 (0.31; 184.53)	0.00 (-0.00; 0.01)		
Severe blurred vision	Cardozo, 2006 ²⁵⁰	10.00	1,643	9.03 (0.49; 167.51)	0.01 (0.00; 0.01)		
Constipation	Staskin, 2006 ³⁹	5.00	1,794	1.86 (1.16; 2.99)	0.03 (0.00; 0.05)	40 (22; 237)	25 (4; 45)
Constipation	Staskin, 2006 ³⁹	10.00	2,449	4.65 (3.26; 6.64)	0.11 (0.08; 0.13)	10 (8; 12)	105 (84; 126)
Constipation	Cardozo, 2006 ²⁵⁰	5.00	1,095	1.78 (1.02; 3.11)	0.03 (-0.00; 0.06)		
Constipation	Cardozo, 2006 ²⁵⁰	10.00	1,559	3.91 (2.61; 5.85)	0.10 (0.08; 0.13)	10 (8; 13)	104 (77; 132)
Mild constipation	Cardozo, 2006 ²⁵⁰	5.00	1,150	1.99 (1.02; 3.86)	0.02 (-0.00; 0.05)		
Mild constipation	Cardozo, 2006 ²⁵⁰	10.00	1,643	2.69 (1.61; 4.52)	0.039 (0.020; 0.059)	26 (17; 51)	39 (20; 59)
Moderate constipation	Cardozo, 2006 ²⁵⁰	5.00	1,150	1.14 (0.40; 3.27)	0.00 (-0.01; 0.02)		
Moderate constipation	Cardozo, 2006 ²⁵⁰	10.00	1,643	4.84 (2.54; 9.19)	0.05 (0.03; 0.07)	20 (14; 31)	51 (33; 70)
Severe constipation	Cardozo, 2006 ²⁵⁰	5.00	1,150	7.54 (0.31; 184.53)	0.00 (-0.00; 0.01)		
Severe constipation	Cardozo, 2006 ²⁵⁰	10.00	1,643	23.08 (1.36; 391.08)	0.01 (0.01; 0.02)	75 (46; 192)	13 (5; 22)
Dry mouth	Staskin, 2006 ³⁹	5.00	1,794	2.60 (1.82; 3.71)	0.07 (0.04; 0.10)	15 (11; 25)	67 (39; 95)
Dry mouth	Staskin, 2006 ³⁹	10.00	2,449	6.57 (4.95; 8.73)	0.23 (0.21; 0.26)	4 (4; 5)	234 (206; 261)
Dry mouth	Cardozo, 2006 ²⁵⁰	5.00	1,095	2.49 (1.59; 3.90)	0.07 (0.03; 0.10)	15 (10; 35)	67 (29; 104)

Appendix Table F58. Clinical outcomes after solifenacin vs. placebo, pooled individual patient data from RCTs (high level of evidence) (continued)

Outcome	Reference	Dose, mg/day	Number of subjects	Relative risk (95% CI)	Absolute risk difference (95% CI)	Number needed to treat (95% CI)	Attributable events (95% CI)
Dry mouth	Cardozo, 2006 ²⁵⁰	10.00	1,559	6.48 (4.60; 9.12)	0.25 (0.21; 0.28)	4 (4; 5)	246 (211; 281)
Mild dry mouth	Cardozo, 2006 ²⁵⁰	5.00	1,150	2.92 (1.74; 4.91)	0.06 (0.03; 0.09)	17 (11; 39)	58 (25; 91)
Mild dry mouth	Cardozo, 2006 ²⁵⁰	10.00	1,643	6.18 (4.10; 9.33)	0.16 (0.13; 0.19)	6 (5; 8)	157 (128; 187)
Moderate dry mouth	Cardozo, 2006 ²⁵⁰	5.00	1,150	1.60 (0.63; 4.10)	0.01 (-0.01; 0.03)		
Moderate dry mouth	Cardozo, 2006 ²⁵⁰	10.00	1,643	6.30 (3.36; 11.81)	0.07 (0.05; 0.09)	14 (11; 20)	71 (50; 91)
Severe dry mouth	Cardozo, 2006 ²⁵⁰	5.00	1,150	0.84 (0.03; 20.50)	-0.00 (-0.01; 0.00)		
Severe dry mouth	Cardozo, 2006 ²⁵⁰	10.00	1,643	16.06 (2.13; 120.81)	0.02 (0.01; 0.03)	55 (36; 117)	18 (9; 28)