

Table 14.3.8
Summary of Treatment Duration
Safety Population

	Lead-in Treatment Group				Total	
	Donepezil SR 23 mg		Donepezil IR 10 mg			
	From the First Dose Date of 326	From the First Dose Date of 328	From the First Dose Date of 326	From the First Dose Date of 328	From the First Dose Date of 326	From the First Dose Date of 328
Number of subjects	570	570	332	332	902	902
Treatment Duration (Months)						
n	569	569	332	332	901	901
Mean (SD)	16.21 (3.18)	10.59 (3.17)	15.41 (3.81)	9.79 (3.82)	15.92 (3.44)	10.30 (3.45)
Median	17.67	12.07	17.57	12.00	17.63	12.03
Min, Max	5.9, 18.9	0.3, 13.3	5.5, 18.9	0.0, 13.4	5.5, 18.9	0.0, 13.4
Duration in Months: n (%)						
< 3	0 (0.0)	34 (6.0)	0 (0.0)	38 (11.4)	0 (0.0)	72 (8.0)
3 to <6	1 (0.2)	32 (5.6)	7 (2.1)	23 (6.9)	8 (0.9)	55 (6.1)
6 to <9	44 (7.7)	33 (5.8)	35 (10.5)	29 (8.7)	79 (8.8)	62 (6.9)
9 to <12	37 (6.5)	146 (25.6)	28 (8.4)	73 (22.0)	65 (7.2)	219 (24.3)
12 to <15	32 (5.6)	324 (56.8)	26 (7.8)	169 (50.9)	58 (6.4)	493 (54.7)
15 to <18	408 (71.6)	0 (0.0)	216 (65.1)	0 (0.0)	624 (69.2)	0 (0.0)
>=18	47 (8.2)	0 (0.0)	20 (6.0)	0 (0.0)	67 (7.4)	0 (0.0)
Missing	1 (0.2)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.1)	1 (0.1)

Data Source: Listing 16.2.5.1

The treatment duration is defined as the total number of dosing days from first to last day (inclusive) of study treatment.

The duration in months is calculated as the treatment duration in days / 30 days.

Number of subjects in the Safety Population is used as the denominator for computing percentages.

SD = standard deviation.

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Ad hoc Table 14.3.8
Summary of Treatment Duration
Safety Population
Excluding Site 7139

	Lead-in Treatment Group				Total	
	Donepezil SR 23 mg		Donepezil IR 10 mg			
	From the First Dose Date of 326	From the First Dose Date of 328	From the First Dose Date of 326	From the First Dose Date of 328	From the First Dose Date of 326	From the First Dose Date of 328
Number of subjects	569	569	330	330	899	899
Treatment Duration (Months)						
n	569	569	330	330	899	899
Mean (SD)	16.21 (3.18)	10.59 (3.17)	15.47 (3.75)	9.85 (3.76)	15.94 (3.42)	10.32 (3.42)
Median	17.67	12.07	17.57	12.00	17.63	12.03
Min, Max	5.9, 18.9	0.3, 13.3	5.5, 18.9	0.0, 13.4	5.5, 18.9	0.0, 13.4
Duration in Months: n (%)						
< 3	0 (0.0)	34 (6.0)	0 (0.0)	36 (10.9)	0 (0.0)	70 (7.8)
3 to <6	1 (0.2)	32 (5.6)	5 (1.5)	23 (7.0)	6 (0.7)	55 (6.1)
6 to <9	44 (7.7)	33 (5.8)	35 (10.6)	29 (8.8)	79 (8.8)	62 (6.9)
9 to <12	37 (6.5)	146 (25.7)	28 (8.5)	73 (22.1)	65 (7.2)	219 (24.4)
12 to <15	32 (5.6)	324 (56.9)	26 (7.9)	169 (51.2)	58 (6.5)	493 (54.8)
15 to <18	408 (71.7)	0 (0.0)	216 (65.5)	0 (0.0)	624 (69.4)	0 (0.0)
>=18	47 (8.3)	0 (0.0)	20 (6.1)	0 (0.0)	67 (7.5)	0 (0.0)

Data Source: Listing 16.2.5.1

The treatment duration is defined as the total number of dosing days from first to last day (inclusive) of study treatment.

The duration in months is calculated as the treatment duration in days / 30 days.

Number of subjects in the Safety Population is used as the denominator for computing percentages.

SD = standard deviation.

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