



Memantine Clinical Data Quick Reference

Trial	Treatment Duration/Groups/Dosage	Patient Population Inclusion Criteria	Efficacy Outcome Measures								Other Efficacy Outcome Measures	Safety Assessments					
			Function		Cognition		Global										
Key Randomized, Double-Blind, Placebo-Controlled Dementia Trials																	
9605 N = 252 Total Outpatients	28-week Placebo (n=126) Memantine (n=126) 10 mg BID	Moderate to severe AD • Diagnosis criteria: DSM-IV and NINCDS-ADRDA • MMSE 3-14 • GDS 5-6 • FAST ≥ 6a • HIS ≤ 4 • ≥ 50 years of age	ADCS-ADL ₁₉ : Mean Change from Baseline (Primary Efficacy Parameter)				SIB: Mean Change from Baseline				CIBIC+: Mean Score (Primary Efficacy Parameter)						
			LOCF at Endpoint		OC at Week 28		LOCF at Endpoint		OC at Week 28		LOCF at Endpoint						
			PBO	MEM	PBO	MEM	PBO	MEM	PBO	MEM	PBO	MEM					
			-5.1	-3.0	-5.9	-2.5	-9.8	-3.9	-10.2	-4.5	4.73	4.48					
			p-value = 0.022	p-value = 0.003	p-value <0.001		p-value = 0.002		p-value = 0.064		p-value = 0.025						
	24-week open-label extension (optional) Memantine (n=175) 10 mg BID		p-value = 0.022				p-value <0.001				p-value = 0.002						
			p-value = 0.003				p-value = 0.002				p-value = 0.064						
			p-value = 0.003				p-value <0.001				p-value = 0.025						
			p-value = 0.002				p-value = 0.002				p-value = 0.064						
			p-value = 0.002				p-value = 0.002				p-value = 0.025						
MD-02 N = 404 Total Outpatients	24-week Placebo (n=201) Memantine (n=203) 10 mg BID	Moderate to severe AD • Diagnosis criteria: NINCDS-ADRDA • MMSE 5-14 • ≥ 50 years of age • Ongoing daily donepezil therapy for ≥ 6 months prior to trial and stable dose (5-10 mg/day) for the past 3 months	ADCS-ADL ₁₉ : Mean Change from Baseline (Primary Efficacy Parameter)				SIB: Mean Change from Baseline (Primary Efficacy Parameter)				CIBIC+: Mean Score						
			LOCF at Endpoint		OC at Week 24		LOCF at Endpoint		OC at Week 24		LOCF at Endpoint						
			PBO	MEM	PBO	MEM	PBO	MEM	PBO	MEM	PBO	MEM					
			-3.2	-1.8	-3.0	-1.5	-2.3	1.1	-2.1	1.2	4.66	4.41					
			p-value = 0.028	p-value = 0.020	p-value <0.001		p-value <0.001		p-value = 0.027		p-value = 0.028						
	12-week Placebo (n=84) Memantine (n=82) 10 mg QD	Severe dementia (AD and VaD) • Diagnosis criteria: DSM-III-R • MMSE <10 • GDS 5-7 • CGI-S 5-7 • HIS ≤ 4 for AD Patients • 60-80 years of age	BGP-Care Dependency: Mean Change from Baseline (Primary Efficacy Parameter)				BGP-Cognitive: Mean Change from Baseline				CGI-C: Mean Score (Primary Efficacy Parameter)						
			LOCF at Endpoint		OC at Week 12		LOCF at Endpoint		OC at Week 12		LOCF at Endpoint						
			PBO	MEM	PBO	MEM	PBO	MEM	PBO	MEM	PBO	MEM					
			-3.3	-5.3	-3.5	-5.6	-1.1	-1.9	-1.2	-1.9	3.5	3.1					
			p-value = 0.012	p-value = 0.010	p-value = 0.001		p-value = 0.001		p-value <0.001		p-value <0.001						

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