

NONPRESCRIPTION DRUGS  
ADVISORY COMMITTEE AND  
ARTHRITIS ADVISORY  
COMMITTEE

JULY 20, 1999

NDA 21070 FLEXERIL OTC  
SWITCH

SAFETY REVIEW  
(MEDICAL OFFICER REVIEW  
HFD-560)

ATTACHMENT II

# **Attachment II**

**to**

**Safety Review**

Nonprescription Cyclobenzaprine  
 Clinical Documentation  
 D. Clinical Efficacy and Safety  
 1. Safety

Listing of Patients Discontinued Due To Clinical AE—Cyclobenzaprine 5 mg<sup>†</sup>

AN	Study Number	Gender/ Age	Dose (mg/Day) on Day of Onset	Study Day of Onset	Adverse Experience	Duration	Day of Drug Discontinuation	Severity	Drug Related	Serious	Outcome <sup>‡</sup>
0895	006/002	F/38	15	2	Blurred vision	2 days	3	Moderate	Possibly	No	Recovered
			15	2	Dizziness	23.5 hr		Moderate	Possibly	No	Recovered
			15	2	Somnolence	4 days		Moderate	Probably	No	Recovered
			15	2	Headache	2 days		Mild	Possibly	No	Recovered
			15	2	Confusion	2 days		Moderate	Possibly	No	Recovered
0149	006/005	M/58	10	1	Somnolence	3 days	4	Moderate	Probably	No	Recovered
			15	2	Nausea	4 days		Mild	Probably	No	Recovered
			15	3	Mental acuity decreased	3 days		Mild	Probably	No	Recovered
0220	006/007	F/33	10	2	Hypesthesia	4 days	2	Severe	Probably not	No	Still present
0333	006/010	M/37	5	1	Nausea	4 hr	1	Moderate	Probably	No	Recovered
0715	006/010	M/56	15	2	Somnolence	3 days	3	Moderate	Possibly	No	Recovered
			5	3	Dry mouth	3 days		Moderate	Possibly	No	Recovered
			5	3	Nausea	22 hr		Moderate	Possibly	No	Recovered
0717	006/010	M/60	5	2	Somnolence	12 hr	2	Severe	Possibly	No	Recovered
			5	2	Nausea	10 hr		Moderate	Possibly	No	Recovered

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Listing of Patients Discontinued Due To Clinical AE—Cyclobenzaprine 5 mg<sup>†</sup>

AN	Study Number	Gender/ Age	Dose (mg/Day) on Day of Onset	Study Day of Onset	Adverse Experience	Duration	Day of Drug Discontinuation	Severity	Drug Related	Serious	Outcome <sup>‡</sup>
0387	006/011	F/35	10	1	Dizziness	3 days	2	Moderate	Possibly	No	Recovered
0396	006/011	M/34	10	1	Asthenia/fatigue	4 days	3	Severe	Definitely	No	Recovered
0422	006/012	F/39	10	1	Somnolence	10 hr	1	Moderate	Possibly	No	Recovered
0449	006/013	M/39	15	2	Dizziness	3 days	2	Severe	Probably	No	Recovered
			15	2	Somnolence	3 days		Severe	Probably	No	Recovered
			15	2	Nausea	3 days		Severe	Probably	No	Recovered
0785	006/013	F/60	15	2	Perversion, toxic	3 days	2	Moderate	Possibly	No	Recovered
0578	006/017	M/57	10	1	Somnolence <sup>§</sup>	3 days	3	Mild	Definitely	No	Still present
			15	2	Dry mouth <sup>§</sup>	2 days		Mild	Definitely	No	Still present
			15	2	Neuritis	2 days		Severe	Definitely not	No	Still present
2028	008/001	M/46	15	2	Constipation	12 hr	2	Moderate	Possibly	No	Recovered

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Listing of Patients Discontinued Due To Clinical AE—Cyclobenzaprine 5 mg<sup>†</sup>

AN	Study Number	Gender/ Age	Dose (mg/Day) on Day of Onset	Study Day of Onset	Adverse Experience	Duration	Day of Drug Discontinuation	Severity	Drug Related	Serious	Outcome <sup>†</sup>
2058	008/002	F/48	5	3	Pain, neck	25 days	3	Severe	Definitely not	No	Recovered
			5	3	Paresthesia	25 days		Severe	Definitely not	No	Recovered
			5	3	Paresthesia	25 days		Severe	Definitely not	No	Recovered
			5	3	Trauma	1 min		Severe	Definitely not	No	Recovered
			5	3	Pain, back	25 days		Severe	Definitely not	No	Recovered
			5	3	Headache	25 days		Severe	Definitely not	No	Recovered
			Off drug	28	Pain, neck	5 days		Moderate	Definitely not	No	Still present
			Off drug	28	Pain, back	5 days		Moderate	Definitely not	No	Still present
2460	008/005	F/62	10	3	Somnolence	3 days	4	Moderate	Probably	No	Recovered
2303	008/006	F/29	15	3	Sinusitis	35 days	4	Moderate	Definitely not	No	Recovered
			15	3	Infection, upper respiratory	35 days		Mild	Definitely not	No	Recovered
2548	008/007	M/37	10	1	Dry mouth	4 days	3	Moderate	Probably	No	Recovered
			10	1	Somnolence	4 days		Moderate	Probably	No	Recovered
2553	008/007	F/28	15	2	Mental acuity decreased	6 days	5	Mild	Probably	No	Recovered
2155	008/012	F/30	5	1	Dizziness	7 hr	1	Severe	Probably	No	Recovered
2519	008/012	F/51	10	1	Somnolence	3 days	2	Severe	Probably	No	Recovered

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Listing of Patients Discontinued Due To Clinical AE—Cyclobenzaprine 5 mg<sup>†</sup>

AN	Study Number	Gender/ Age	Dose (mg/Day) on Day of Onset	Study Day of Onset	Adverse Experience	Duration	Day of Drug Discontinuation	Severity	Drug Related	Serious	Outcome <sup>†</sup>
2589	008/014	F/44	5	1	Somnolence	4 days	1	Severe	Probably	No	Recovered
			5	1	Dyspnea	4 days		Severe	Probably	No	Recovered
			5	1	Dry mouth	4 days		Severe	Probably	No	Recovered
4004	009/001	M/62	Off drug	2	Somnolence	2 days	1	Severe	Probably	No	Recovered
			Off drug	2	Dry lips <sup>§</sup>	2 days		Mild	Possibly	No	Recovered
			Off drug	2	Irritability <sup>§</sup>	2 days		Moderate	Possibly	No	Recovered
4008	009/001	M/31	15	2	Asthenia/fatigue <sup>§</sup>	5 days	5	Moderate	Probably	No	Recovered
			15	2	Headache	12 days		Mild	Definitely not	No	Recovered
			15	5	Nausea	5 days		Moderate	Possibly	No	Recovered
			15	5	Vomiting	5 days		Moderate	Possibly	No	Recovered
4425	009/001	M/24	15	2	Somnolence	4 days	4	Moderate	Probably	No	Recovered
			15	2	Headache <sup>§</sup>	4 days		Mild	Possibly	No	Recovered
4427	009/001	M/40	10	1	Somnolence	9 hr	2	Severe	Probably	No	Recovered
			5	2	Mental acuity decreased <sup>§</sup>	5.5 hr		Moderate	Possibly	No	Recovered
4038	009/002	F/36	Off drug	2	Somnolence	6 days	6	Moderate	Possibly	No	Recovered
4047	009/002	M/31	5	1	Somnolence	5 days	3	Mild	Possibly	No	Recovered

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Listing of Patients Discontinued Due To Clinical AE—Cyclobenzaprine 5 mg<sup>†</sup>

AN	Study Number	Gender/ Age	Dose (mg/Day) on Day of Onset	Study Day of Onset	Adverse Experience	Duration	Day of Drug Discontinuation	Severity	Drug Related	Serious	Outcome <sup>‡</sup>
4052	009/002	F/61	5	2	Dizziness	3 days	3	Mild	Possibly	No	Recovered
			5	2	Asthenia/fatigue	4 days		Moderate	Possibly	No	Recovered
4515	009/003	F/22	10	2	Somnolence	24 hr	2	Severe	Definitely	No	Recovered
4096	009/004	M/37	0	1	Infection, fungal <sup>§</sup>	10 days	9	Mild	Definitely not	No	Recovered
			5	2	Somnolence <sup>§</sup>	5.2 hr		Mild	Possibly	No	Recovered
			5	2	Dyspnea <sup>§</sup>	50 min		Mild	Probably not	No	Recovered
			5	2	Depression <sup>§</sup>	5.2 hr		Mild	Probably not	No	Recovered
			5	2	Pain, abdominal <sup>§</sup>	5 hr		Mild	Possibly	No	Recovered
			15	3	Anxiety <sup>§</sup>	42 min		Mild	Probably not	No	Recovered
			15	3	Anxiety <sup>§</sup>	1.8 hr		Mild	Probably not	No	Recovered
			15	3	Dry mouth <sup>§</sup>	3.2 hr		Mild	Probably not	No	Recovered
			15	3	Dry mouth <sup>§</sup>	3.2 hr		Mild	Probably not	No	Recovered
			15	3	Infection, respiratory, upper <sup>§</sup>	3 days		Mild	Definitely not	No	Recovered
			15	3	Pain, abdominal <sup>§</sup>	42 min		Mild	Probably not	No	Recovered
			15	3	Panic disorder <sup>§</sup>	6 days		Moderate	Probably not	No	Recovered
			15	3	Tremor <sup>§</sup>	1.8 hr		Mild	Probably not	No	Recovered
			15	3	Tachycardia <sup>§</sup>	42 min		Mild	Probably not	No	Recovered
			15	3	Spasm <sup>§</sup>	1.9 hr		Mild	Probably not	No	Recovered
10	4	Nervousness <sup>§</sup>	9 hr	Mild	Probably not	No	Recovered				
10	4	Spasm <sup>§</sup>	9 hr	Mild	Probably not	No	Recovered				
5	7	Hyperventilation <sup>§</sup>	3 days	Mild	Probably not	No	Recovered				

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Listing of Patients Discontinued Due To Clinical AE—Cyclobenzaprine 5 mg<sup>†</sup>

AN	Study Number	Gender/ Age	Dose (mg/Day) on Day of Onset	Study Day of Onset	Adverse Experience	Duration	Day of Drug Discontinuation	Severity	Drug Related	Serious	Outcome <sup>‡</sup>
4123	009/005	M/40	5	7	Nervousness <sup>§</sup>	3 days	4	Mild	Probably not	No	Recovered
			5	7	Spasm <sup>§</sup>	3 days		Mild	Probably not	No	Recovered
			10	8	Headache <sup>§</sup>	7 hr		Mild	Probably not	No	Recovered
			5	9	Rash	2 days		Mild	Possibly	No	Still present
			10	1	Somnolence <sup>§</sup>	5 hr		Moderate	Definitely	No	Recovered
			15	2	Somnolence <sup>§</sup>	14.5 hr		Moderate	Definitely	No	Recovered
			15	3	Somnolence <sup>§</sup>	15 hr		Moderate	Definitely	No	Recovered
			15	3	Dizziness <sup>§</sup>	2.5 hr		Moderate	Definitely	No	Recovered
			5	4	Somnolence	5 hr		Moderate	Definitely	No	Recovered
			4134	009/005	F/25	5		2	Asthenia/fatigue	4.5 hr	2
4135	009/005	F/51	5	1	Somnolence <sup>§</sup>	11 hr	8	Moderate	Probably	No	Recovered
			5	1	Headache <sup>§</sup>	6 hr		Mild	Definitely not	No	Recovered
			5	2	Somnolence <sup>§</sup>	7.5 hr		Moderate	Probably	No	Recovered
			5	3	Somnolence <sup>§</sup>	9 hr		Mild	Probably	No	Recovered
			5	3	Headache <sup>§</sup>	12 hr		Moderate	Definitely not	No	Recovered
			Off drug	6	Headache <sup>§</sup>	9.5 hr		Moderate	Definitely not	No	Recovered
			5	8	Somnolence	8 hr		Moderate	Probably	No	Recovered

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Listing of Patients Discontinued Due To Clinical AE—Cyclobenzaprine 5 mg<sup>1</sup>

AN	Study Number	Gender/ Age	Dose (mg/Day) on Day of Onset	Study Day of Onset	Adverse Experience	Duration	Day of Drug Discontinuation	Severity	Drug Related	Serious	Outcome†
4154	009/006	F/24	15	2	Somnolence	4.5 hr	2	Moderate	Probably	No	Recovered
4161	009/006	F/24	5	2	Somnolence	2 hr	2	Moderate	Probably	No	Recovered
4182	009/007	F/32	5	1	Menstrual disorder	2 hr	1	Severe	Possibly Definitely not	No	Recovered
			5	1	Pneumonia <sup>§</sup>	22 days		Severe		No	Recovered
4223	009/008	M/40	10	1	Pain, flank	2 days	1	Moderate	Probably not	No	Recovered
4224	009/008	F/49	10	2	Pain, abdominal	2 days	2	Moderate	Probably not	No	Recovered
4230	009/008	M/47	5	3	Headache	4 days	4	Moderate	Definitely not	No	Recovered
4231	009/008	M/37	10	1	Anxiety	2 hr	1	Moderate	Probably not Probably Definitely not	No	Recovered
			10	1	Somnolence	2 hr		Severe		No	Recovered
			10	1	Pain, back <sup>§</sup>	16 hr		Moderate		No	Recovered
4248	009/009	M/39	15	2	Somnolence	3 days	3	Mild	Possibly Possibly Possibly	No	Recovered
			15	2	Ataxia	3 days		Mild		No	Recovered
			15	2	Psychic disturbance	3 days		Mild		No	Recovered

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Listing of Patients Discontinued Due To Clinical AE—Cyclobenzaprine 5 mg<sup>†</sup>

AN	Study Number	Gender/ Age	Dose (mg/Day) on Day of Onset	Study Day of Onset	Adverse Experience	Duration	Day of Drug Discontinuation	Severity	Drug Related	Serious	Outcome <sup>‡</sup>
4273	009/010	F/65	5	3	Urticaria	3 days	3	Mild	Possibly	No	Recovered
4323	009/011	F/26	5 Off drug	1 5	Somnolence Headache <sup>§</sup>	3 days 2 hr	2	Severe Mild	Definitely Definitely not	No No	Recovered Recovered
4453	009/012	F/41	10	1	Somnolence	5 days	4	Moderate	Probably	No	Recovered
4402	009/014	F/22	5 5	1 1	Somnolence Dry mouth <sup>§</sup>	7 days 7 days	6	Mild Mild	Probably Probably	No No	Recovered Recovered
4464	009/015	F/23	10	1	Somnolence	3 days	3	Moderate	Probably	No	Recovered
0013	003/001	F/67	15 5 5	2 3 3	Dry mouth <sup>§</sup> Headache <sup>§</sup> Myalgia	110 min 55 min 4 days	3	Mild Mild Moderate	Possibly Possibly Probably not	No No No	Recovered Recovered Recovered

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<sup>†</sup> One patient (AN 2489) from disqualified Site 008/21 also discontinued the study on Day 5 due to cardiac arrest, diabetes mellitus, myocardial infarction, followed by death.  
<sup>‡</sup> Outcome of "still present" indicates that adverse experience was still present at the final contact with the patient.  
<sup>§</sup> This adverse experience did not prompt discontinuation of study medication.

{3; 8; 9; 10; 90; 113}

Listing of Patients Discontinued Due To Clinical AE—Cyclobenzaprine 2.5 mg<sup>†</sup>

AN	Study Number	Gender/ Age	Dose (mg/Day) on Day of Onset	Study Day of Onset	Adverse Experience	Duration	Day of Drug Discon- tinuation	Severity	Drug Related	Serious	Outcome
2558	008/007	M/42	5	1	Asthenia/fatigue	3 days	2	Moderate	Probably	No	Recovered
2605	008/014	M/62	7.5	2	Somnolence	4 days	3	Moderate	Probably	No	Recovered
2187	008/015	F/63	5	1	Somnolence	3 days	2	Moderate	Probably	No	Recovered
			5	1	Dry mouth	3 days		Mild	Probably	No	Recovered
2694	008/017	F/43	7.5	2	Somnolence	45 days	3	Severe	Probably	No	Recovered
2721	008/022	M/54	7.5	3	Dizziness	6 days	4	Mild	Possibly	No	Recovered
			7.5	3	Nausea	6 days		Mild	Possibly	No	Recovered
			7.5	3	Fasciculation	6 days		Moderate	Possibly	No	Recovered

† One patient (AN 2502) from the excluded Site 008/021 also discontinued the study on due to mild dizziness and mild asthenia/fatigue beginning on Day 1 (after 5 mg) and lasting a total of 2 days. The adverse experiences were both determined to be possibly drug related, not serious, and the patient recovered.

{9; 90; 113}

Attachment II

Listing of Patients Discontinued Due To Clinical AE—Cyclobenzaprine 10 mg

AN	Study Number	Gender/ Age	Dose (mg/Day) on Day of Onset	Study Day of Onset	Adverse Experience	Duration	Day of Drug Discon- tinuation	Severity	Drug Related	Serious	Outcome <sup>†</sup>
0145	006/005	F/44	10	1	Somnolence	14 hr	1	Severe	Definitely	No	Recovered
0146	006/005	F/35	20	1	Somnolence	5 days	4	Severe	Definitely	No	Recovered
			20	1	Dry mouth	5 days		Moderate	Definitely	No	Recovered
0233	006/007	M/56	20	1	Somnolence	4 days	3	Severe	Definitely	No	Recovered
0252	006/007	M/42	20	1	Somnolence	5 days	4	Moderate	Probably	No	Recovered
			20	1	Apprehension	5 days		Moderate	Probably	No	Recovered
0329	006/010	F/57	30	2	Herpes zoster	50 days	3	Severe	Definitely not	No	Recovered
0353	006/010	F/39	30	4	Blurred vision	12 days	7	Moderate	Probably	No	Recovered
			30	4	Confusion	12 days		Moderate	Probably	No	Recovered
0360	006/010	F/53	10	1	Blurred vision	13.5 hr	1	Moderate	Possibly	No	Recovered
			10	1	Vertigo	13.5 hr		Moderate	Possibly	No	Recovered
			10	1	Asthenia/fatigue	13.5 hr		Moderate	Possibly	No	Recovered
0838	006/010	F/50	30	1	Somnolence	7 days	4	Moderate	Probably	No	Recovered
			30	1	Dry mouth	7 days		Severe	Probably	No	Recovered
			30	2	Anxiety	6 days		Severe	Probably	No	Recovered

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Listing of Patients Discontinued Due To Clinical AE—Cyclobenzaprine 10 mg

AN	Study Number	Gender/ Age	Dose (mg/Day) on Day of Onset	Study Day of Onset	Adverse Experience	Duration	Day of Drug Discon- tinuation	Severity	Drug Related	Serious	Outcome <sup>†</sup>
0840	006/010	F/32	10	2	Somnolence	9.1 hr	2	Mild	Possibly	No	Recovered
			10	2	Nervousness	13 hr		Mild	Possibly	No	Recovered
			10	2	Disorientation	8.5 hr		Mild	Possibly	No	Recovered
0374	006/011	M/42	10	1	Asthenia/fatigue	22 hr	1	Severe	Probably	No	Recovered
0455	006/013	F/29	30	2	Somnolence	19 hr	2	Moderate	Probably	No	Recovered
			30	2	Irritability	16 hr		Moderate	Possibly	No	Recovered
0461	006/013	F/58	20	1	Somnolence	3 days	2	Moderate	Probably	No	Recovered
			20	1	Nervousness	4 days		Moderate	Probably	No	Recovered
			20	1	Dysarthria	7 days		Mild	Probably	No	Recovered
			Off drug	3	Pain, abdominal	8 hr		Mild	Possibly	No	Recovered
0776	006/013	F/20	30	2	Dizziness	0.5 hr	3	Mild	Definitely	No	Recovered
			30	2	Asthenia/fatigue	2 days		Severe	Definitely	No	Recovered
			30	2	Nausea	1 hr		Mild	Definitely	No	Recovered
0535	006/015	F/47	10	2	Somnolence	5.5 hr	2	Severe	Probably	No	Recovered
			10	2	Headache	5.5 hr		Mild	Probably	No	Recovered
			10	2	Blurred vision	5.5 hr		Moderate	Probably	No	Recovered

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Listing of Patients Discontinued Due To Clinical AE—Cyclobenzaprine 10 mg

AN	Study Number	Gender/ Age	Dose (mg/Day) on Day of Onset	Study Day of Onset	Adverse Experience	Duration	Day of Drug Discon- tinuation	Severity	Drug Related	Serious	Outcome <sup>†</sup>
0538	006/015	M/75	30	1	Dizziness	3 days	2	Severe	Probably	No	Recovered
			30	1	Dry mouth	3 days		Moderate	Probably	No	Recovered
			30	1	Dyspepsia	3 days		Mild	Probably	No	Recovered
			30	1	Nervousness	3 days		Moderate	Probably	No	Recovered
0607	006/017	M/68	10	1	Somnolence	8 days	2	Moderate	Probably	No	Still present
			10	1	Disorientation <sup>‡</sup>	1 hr		Mild	Possibly	No	Recovered
0644	006/018	M/58	30	2	Somnolence	3 days	2	Severe	Probably	No	Recovered
			30	2	Urinary frequency	8 days		Moderate	Possibly	No	Recovered
0696	006/019	M/47	30	2	Influenza	4 days	4	Moderate	Probably not	No	Recovered
0264	006/020	F/51	20	1	Somnolence	4 days	1	Severe	Probably	No	Recovered
			20	1	Ataxia	4 days		Severe	Probably	No	Recovered
			20	1	Ataxia	4 days		Severe	Probably	No	Recovered
0500	006/022	F/54	20	1	Somnolence	4 days	3	Severe	Definitely	No	Recovered

<sup>†</sup> Outcome of "still present" indicates that adverse experience was still present at the final contact with the patient.

<sup>‡</sup> This adverse experience did not prompt discontinuation of study medication.

{8; 113}

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Listing of Patients Discontinued Due To Clinical AE—Placebo<sup>†</sup>

AN	Study Number	Gender/ Age	Dose (tab/Day) on Day of Onset	Study Day of Onset	Adverse Experience	Duration	Day of Drug Discon- tinuation	Severity	Drug Related	Serious	Outcome
0238	006/007	F/29	1 tablet	2	Headache	24 days	2	Severe	Probably not	No	Recovered
			1 tablet	2	Pain, back	24 days		Severe	Probably not	No	Recovered
0300	006/009	M/45	1 tablet	4	Somnolence	1.5 hr	4	Moderate	Possibly	No	Recovered
0348	006/010	M/50	3 tablets	2	Pain, abdominal	4 days	3	Mild	Probably	No	Recovered
			3 tablets	2	Diarrhea	4 days		Mild	Probably	No	Recovered
0381	006/011	F/68	2 tablets	3	Hypesthesia	5 days	3	Mild	Probably	No	Recovered
0609	006/017	M/31	3 tablets	3	Somnolence	3 days	5	Severe	Definitely	No	Recovered
0487	006/022	F/28	3 tablets	2	Emotional changes	3 days	3	Moderate	Possibly	No	Recovered
2006	008/001	F/46	2 tablets	6	Nausea	2 days	6	Moderate	Possibly	No	Recovered
2298	008/006	F/27	3 tablets	2	Asthenia/fatigue	3 days	2	Moderate	Probably	No	Recovered
2146	008/012	F/43	2 tablets	1	Somnolence	22.8 hr	2	Severe	Probably	No	Recovered
2401	008/013	F/35	3 tablets	4	Headache	4 days	6	moderate	Probably not	No	Recovered

<sup>†</sup> One patient (AN 2471) from disqualified Site 008/021 also discontinued the study on Day 1 due to moderate vomiting after 1 dose, which lasted for 90 minutes and was considered to be possibly related to study drug. The patient recovered.

{8; 9; 90; 113}

Listing of Patients Discontinued Due To Clinical AE—Diphenhydramine 50 mg

AN	Study Number	Gender/ Age	Dose (mg/Day) on Day of Onset	Study Day of Onset	Adverse Experience	Duration	Day of Drug Discon- tinuation	Severity	Drug Related	Serious	Outcome
0001	003/001	F/74	150	3	Dizziness†	2 hr	3	Mild	Possibly	No	Recovered
			0	20	Diarrhea	4 days		Mild	Probably not	No	Recovered
			0	20	Headache	4 days		Mild	Probably not	No	Recovered
			0	20	Vomiting	15 hr		Moderate	Probably not	No	Recovered
			0	20	Pain, abdominal	4 days		Mild	Probably not	No	Recovered
			0	27	Diarrhea	4 days		Mild	Possibly	No	Recovered

† This adverse experience did not prompt discontinuation of study medication.

[3; 113]

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