

NONPRESCRIPTION DRUGS
ADVISORY COMMITTEE AND
ARTHRITIS ADVISORY
COMMITTEE

JULY 20, 1999

NDA 21070 FLEXERIL OTC
SWITCH

SAFETY REVIEW
(MEDICAL OFFICER REVIEW
HFD-560)

ATTACHMENT 1

Attachment I

to

Safety Review

5. Safety (Cont.)

Table 37

Patients Discontinued Due to Adverse Experiences

Investigator/ Study No.	AN	Sex/Age	Onset Day	Adverse Experience	Discon. Study	Duration	Serious	Intensity	Drug Relation	Outcome	Discon. Day
Dr. Adams/009-001	4004	M/62	2	Somnolence	Yes	2 days	No	Severe	Probably	Recovered	11
			2	Dry Lips	No	2 days	No	Mild	Possibly	Recovered	
			2	Irritability	No	2 days	No	Moderate	Possibly	Recovered	
Dr. Adams/009-001	4008	M/31	2	Headache	Yes	12 days	No	Mild	Definitely Not	Recovered	13
			2	Asthenia/Fatigue	No	5 days	No	Moderate	Probably	Recovered	
			5	Nausea	Yes	5 days	No	Moderate	Possibly	Recovered	
			5	Vomiting	Yes	5 days	No	Moderate	Possibly	Recovered	
Dr. Blanchard/009-002	4038	F/36	2	Somnolence	Yes	6 days	No	Moderate	Possibly	Recovered	9
Dr. Blanchard/009-002	4047	M/31	1	Somnolence	Yes	5 days	No	Mild	Possibly	Recovered	42
Dr. Blanchard/009-002	4052	F/61	2	Asthenia/Fatigue	Yes	4 days	No	Moderate	Possibly	Recovered	8
			2	Dizziness	Yes	3 days	No	Mild	Possibly	Recovered	
Dr. Dawson/009-004	4096	M/37	1	Infection, Fungal	No	10 days	No	Mild	Definitely Not	Recovered	10
			2	Somnolence	No	5.2 hrs	No	Mild	Possibly	Recovered	
			2	Depression	No	5.2 hrs	No	Mild	Probably Not	Recovered	
			2	Dyspnea	No	50 mins	No	Mild	Probably Not	Recovered	
			2	Pain, Abdominal	No	5 hrs	No	Mild	Possibly	Recovered	
			3	Anxiety	No	42 mins	No	Mild	Probably Not	Recovered	
			3	Anxiety	No	1.8 hrs	No	Mild	Probably Not	Recovered	
			3	Dry Mouth	No	3.2 hrs	No	Mild	Probably Not	Recovered	
			3	Tremor	No	1.8 hrs	No	Mild	Probably Not	Recovered	
			3	Spasm	No	1.9 hrs	No	Mild	Probably Not	Recovered	
3	Dry Mouth	No	3.2 hrs	No	Mild	Probably Not	Recovered				

Data Source: [4.4]

5. Safety (Cont.)

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Patients Discontinued Due to Adverse Experiences

Investigator/ Study No.	AN	Sex/Age	Onset Day	Adverse Experience	Discon. Study	Duration	Serious	Intensity	Drug Relation	Outcome	Discon. Day
Dr. Dietz/009-005	4123	M/40	3	Tachycardia	No	42 mins	No	Mild	Probably Not	Recovered	
			3	Pain, Abdominal	No	42 mins	No	Mild	Probably Not	Recovered	
			3	Infection, Resp. Upper	No	3 days	No	Mild	Definitely Not	Recovered	
			3	Panic Disorder	No	6 days	No	Moderate	Probably Not	Recovered	
			4	Spasm	No	9 hrs	No	Mild	Probably Not	Recovered	
			4	Nervousness	No	9 hrs	No	Mild	Probably Not	Recovered	
			7	Hyperventilation	No	3 days	No	Mild	Probably Not	Recovered	
			7	Spasm	No	3 days	No	Mild	Probably Not	Recovered	
			7	Nervousness	No	3 days	No	Mild	Probably Not	Recovered	
			8	Headache	No	7 hrs	No	Mild	Probably Not	Recovered	
9	Rash	Yes	2 days	No	Mild	Possibly	Still Present				
Dr. Dietz/009-005	4134	F/25	1	Somnolence	No	5 hrs	No	Moderate	Definitely	Recovered	6
			2	Somnolence	No	14.5 hrs	No	Moderate	Definitely	Recovered	
			3	Somnolence	No	15 hrs	No	Moderate	Definitely	Recovered	
			3	Dizziness	No	2.5 hrs	No	Moderate	Definitely	Recovered	
			4	Somnolence	Yes	5 hrs	No	Moderate	Definitely	Recovered	
Dr. Dietz/009-005	4135	F/51	2	Asthenia/Fatigue	Yes	4.5 hrs	No	Severe	Definitely	Recovered	9
			1	Somnolence	No	11 hrs	No	Moderate	Probably	Recovered	
			1	Headache	No	6 hrs	No	Mild	Definitely Not	Recovered	
			2	Somnolence	No	7.5 hrs	No	Moderate	Probably	Recovered	
			3	Somnolence	No	9 hrs	No	Mild	Probably	Recovered	
			3	Headache	No	12 hrs	No	Moderate	Definitely Not	Recovered	
			6	Headache	No	9.5 hrs	No	Moderate	Definitely Not	Recovered	
			8	Somnolence	Yes	8 hrs	No	Moderate	Probably	Recovered	

Data Source: [4,4]

5. Safety (Cont.)

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Patients Discontinued Due to Adverse Experiences

Investigator/ Study No.	AN	Sex/Age	Onset Day	Adverse Experience	Discon. Study	Duration	Serious	Intensity	Drug Relation	Outcome	Discon. Day
Dr. Dockhorn/009-006	4154	F/24	2	Somnolence	Yes	4.5 hrs	No	Moderate	Probably	Recovered	11
Dr. Dockhorn/009-006	4161	F/24	2	Somnolence	Yes	2 hrs	No	Moderate	Probably	Recovered	11
Dr. Hu/009-007	4192	F/32	1	Menstruation Disorder	Yes	2 hrs	No	Severe	Possibly	Recovered	46
			1	Pneumonia	No	22 days	Yes	Severe	Definitely Not	Recovered	
			1	Pneumonia	No	15 days	Yes	Severe	Definitely Not	Recovered	
Dr. Johnson/009-008	4223	M/40	1	Pain, Flank	Yes	2 days	No	Moderate	Probably Not	Recovered	12
Dr. Johnson/009-008	4224	F/49	2	Pain, Abdominal	Yes	2 days	No	Moderate	Probably Not	Recovered	7
Dr. Johnson/009-008	4230	M/47	3	Headache	Yes	4 days	No	Moderate	Definitely Not	Recovered	14
Dr. Johnson/009-008	4231	M/37	1	Anxiety	Yes	2 hrs	No	Moderate	Probably Not	Recovered	2
			1	Somnolence	Yes	2 hrs	No	Severe	Probably	Recovered	
			1	Pain, Back	No	16 hrs	No	Moderate	Definitely Not	Recovered	
Dr. Marbury/009-009	4248	M/39	2	Psychic Disturbance	Yes	3 days	No	Mild	Possibly	Recovered	15
			2	Somnolence	Yes	3 days	No	Mild	Possibly	Recovered	
			2	Ataxia	Yes	3 days	No	Mild	Possibly	Recovered	
Dr. Napier/009-010	4273	F/65	3	Urticaria	Yes	3 days	No	Mild	Possibly	Still Present	11
Dr. Sack/009-011	4323	F/26	1	Somnolence	Yes	3 days	No	Severe	Definitely	Recovered	8
			5	Headache	No	2 hrs	No	Mild	Definitely Not	Recovered	
Dr. Ross/009-014	4402	F/22	1	Somnolence	Yes	7 days	No	Mild	Probably	Recovered	8

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5. Safety (Cont.)

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Investigator/ Study No.	AN	Sex/Age	Onset Day	Adverse Experience	Discon. Study	Duration	Serious	Intensity	Drug Relation	Outcome	Discon. Day
Dr. Adams/009-001	4425	M/24	1	Dry Mouths	No	7 days	No	Mild	Probably	Recovered	10
			2	Headache	No	4 days	No	Mild	Possibly	Recovered	
Dr. Adams/009-001	4427	M/40	2	Somnolence	Yes	4 days	No	Moderate	Probably	Recovered	8
			1	Somnolence	Yes	9 hrs	No	Severe	Probably	Recovered	
Dr. Tilker/009-012	4453	F/41	2	Mental Acuity Decreased	No	5.5 hrs	No	Moderate	Possibly	Recovered	10
			1	Somnolence	Yes	5 days	No	Moderate	Probably	Recovered	
Dr. McCluskey/009-015	4464	F/23	1	Somnolence	Yes	3 days	No	Moderate	Probably	Recovered	10
Dr. Brodie/009-003	4515	F/22	2	Somnolence	Yes	24 hrs	No	Severe	Definitely	Recovered	7

Data Source: [4.4]

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