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Diltiazem (Cardizem LA)

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Serious adverse reactions have been rare in studies carried out to date, but it should be recognized that patients with impaired ventricular function and cardiac conduction abnormalities have usually been excluded from these studies.

In the hypertension study, the following table presents adverse reactions more common on diltiazem than on placebo (but excluding events with no plausible -relationship to treatment), as reported in placebo-controlled hypertension trials in patients receiving a diltiazem hydrochloride extended-release formulation (once-a day dosing) up to 540 mg.

-Diltiazem hydrochloride extended release		Placebo	Adverse Reactions (MedDRA Term)
540 mg n= 123 # pts (%)	120-360 mg n= 501 # pts (%)	n= 120 # pts (%)	
10 (8)	24 (5)	4 (3)	Edema lower limb
2 (2)	2 (1)	0 (0)	Sinus congestion
2 (2)	3 (1)	0 (0)	Rash NOS

In the angina study, the adverse event profile of Cardizem LA (diltiazem) was consistent with what has been previously described for Cardizem LA and other formulations of diltiazem HCl. The most frequent adverse effects experienced by Cardizem LA-treated patients were edema lower-limb (6.8%), dizziness (6.4%), fatigue (4.8%), bradycardia (3.6%), first-degree atrioventricular block (3.2%), and cough (2%).

In clinical trials of other diltiazem formulations involving over 3200 patients, the most common events (i.e., greater than 1%) were edema (4.6%), headache (4.6%), dizziness (3.5%), asthenia (2.6%), first-degree AV block (2.4%), bradycardia (1.7%), flushing (1.4%), nausea (1.4%), and rash (1.2%).

In addition, the following events were reported infrequently (less than 1%) in angina or hypertension trials:

Angina, arrhythmia, AV block (second- or third-degree), bundle branch block, congestive heart failure, ECG abnormalities, hypotension, **Cardiovascular:** palpitations, syncope, tachycardia, ventricular extrasystoles.

Abnormal dreams, amnesia, depression, gait abnormality, hallucinations, insomnia, nervousness, paresthesia, personality change, somnolence, **Nervous System:** tinnitus, tremor.

Anorexia, constipation, diarrhea, dry mouth, dysgeusia, dyspepsia, mild elevations of SGOT, SGPT, LDH, and alkaline phosphatase (see **Gastrointestinal:**), thirst, vomiting, weight increase.**Acute Hepatic Injury** ,**WARNINGS**

Petechiae, photosensitivity, pruritus, urticaria. **Dermatological:**

Amblyopia, CPK increase, dyspnea, epistaxis, eye irritation, hyperglycemia, hyperuricemia, impotence, muscle cramps, nasal congestion, nocturia, **Other:** osteoarticular pain, polyuria, sexual difficulties.

The following postmarketing events have been reported infrequently in patients receiving Cardizem: acute generalized exanthematous pustulosis, allergic reactions, alopecia, angioedema (including facial or periorbital edema), asystole, erythema multiforme (including Stevens-Johnson syndrome, toxic epidermal necrolysis), exfoliative dermatitis, extrapyramidal symptoms, gingival hyperplasia, hemolytic anemia, increased bleeding time, leukopenia, photosensitivity (including lichenoid keratosis and hyperpigmentation at sun-exposed skin areas), purpura, retinopathy, myopathy, and thrombocytopenia. In addition, events such as myocardial infarction have been observed which are not readily distinguishable from the natural history of the disease in these patients. A number of well-documented cases of generalized rash, some characterized as leukocytoclastic vasculitis, have been reported. However, a definitive cause and effect relationship between these events and Cardizem therapy is yet to be established.