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Enalaprilat Injection (Enalaprilat Injection)

??? ??????: 30 ??????/?????? 2017

Enalaprilat has been found to be generally well tolerated in controlled clinical trials involving 349 patients (168 with hypertension, 153 with congestive heart failure and 28 with coronary artery disease). The most frequent clinically significant adverse experience was hypotension (3.4 percent), occurring in eight patients (5.2 percent) with congestive heart failure, three (1.8 percent) with hypertension and one with coronary artery disease. Other adverse experiences occurring in greater than one percent of patients were: headache (2.9 percent) and nausea (1.1 percent).

Adverse experiences occurring in 0.5 to 1.0 percent of patients in controlled clinical trials included: myocardial infarction, fatigue, dizziness, fever, rash and constipation.

Angioedema has been reported in patients receiving enalaprilat, with an incidence higher in black than in non-black patients. Angioedema associated **Angioedema:** with laryngeal edema may be fatal. If angioedema of the face, extremities, lips, tongue, glottis and/or larynx occurs, treatment with enalaprilat should be)**WARNINGS.**discontinued and appropriate therapy instituted immediately. (See

PRECAUTIONS, Cough. See**Cough:**

Enalapril Maleate

Since enalapril is converted to enalaprilat, those adverse experiences associated with enalapril might also be expected to occur with enalaprilat.

The following adverse experiences have been reported with enalapril and, within each category, are listed in order of decreasing severity.

) , chest pain, **WARNINGS, Anaphylactoid reactions during membrane exposure** Syncope, orthostatic effects, anaphylactoid reactions (see **Body As A Whole:** abdominal pain, asthenia.

Cardiac arrest; myocardial infarction or cerebrovascular accident, possibly secondary to excessive hypotension in high risk patients (see **Cardiovascular:**) ; pulmonary embolism and infarction; pulmonary edema; rhythm disturbances including atrial tachycardia and bradycardia; atrial **WARNINGS, Hypotension** fibrillation; orthostatic hypotension; angina pectoris; palpitation, Raynaud's phenomenon.

) , melena, **WARNINGS, Hepatic Failure** Ileus, pancreatitis, hepatic failure, hepatitis (hepatocellular [proven on rechallenge] or cholestatic jaundice) (see **Digestive:** diarrhea, vomiting, dyspepsia, anorexia, glossitis, stomatitis, dry mouth.

Rare cases of neutropenia, thrombocytopenia and bone marrow depression. **Hematologic:**

Muscle cramps. **Musculoskeletal:**

Depression, vertigo, confusion, ataxia, somnolence, insomnia, nervousness, peripheral neuropathy (e.g., paresthesia, dysesthesia), dream **Nervous/Psychiatric:** abnormality.

Bronchospasm, dyspnea, pneumonia, bronchitis, cough, rhinorrhea, sore throat and hoarseness, asthma, upper respiratory infection, pulmonary **Respiratory:** infiltrates, eosinophilic pneumonitis.

Exfoliative dermatitis, toxic epidermal necrolysis, Stevens-Johnson syndrome, pemphigus, herpes zoster, erythema multiforme, urticaria, pruritus, alopecia, **Skin:** flushing, diaphoresis, photosensitivity.

Blurred vision, taste alteration, anosmia, tinnitus, conjunctivitis, dry eyes, tearing.**Special Senses:**

), urinary tract infection, flank pain, gynecomastia, **DOSAGE AND ADMINISTRATION**and**PRECAUTIONS** Renal failure, oliguria, renal dysfunction (see **Urogenital:** impotence.

A symptom complex has been reported which may include some or all of the following: a positive ANA, an elevated erythrocyte sedimentation rate, **Miscellaneous:** arthralgia/arthritis, myalgia/myositis, fever, serositis, vasculitis, leukocytosis, eosinophilia, photosensitivity, rash and other dermatologic manifestations.

Combining the results of clinical trials in patients with hypertension or congestive heart failure, hypotension (including postural hypotension, and other **Hypotension:** orthostatic effects) was reported in 2.3 percent of patients following the initial dose of enalapril or during extended therapy. In the hypertensive patients, hypotension

occurred in 0.9 percent and syncope occurred in 0.5 percent of patients. Hypotension or syncope was a cause for discontinuation of therapy in 0.1 percent of)**WARNINGS.**hypertensive patients. (See

WARNINGS, Fetal/Neonatal Morbidity and Mortality.- See *Fetal/Neonatal Morbidity and Mortality*

Clinical Laboratory Test Findings

), hyponatremia.**PRECAUTIONS** Serum Electrolytes:Hyperkalemia (see

I n controlled clinical trials minor increases in blood urea nitrogen and serum creatinine, reversible upon discontinuation of **Creatinine, Blood Urea Nitrogen:** therapy, were observed in about 0.2 percent of patients with essential hypertension treated with enalapril alone. Increases are more likely to occur in patients)**PRECAUTIONS.**receiving concomitant diuretics or in patients with renal artery stenosis. (See

Small decreases in hemoglobin and hematocrit (mean decreases of approximately 0.3 g percent and 1.0 vol percent, respectively) occur frequently in **Hematology:** hypertensive patients treated with enalapril but are rarely of clinical importance unless another cause of anemia coexists. In clinical trials, less than 0.1 percent of patients discontinued therapy due to anemia. Hemolytic anemia, including cases of hemolysis in patients with G-6-PD deficiency, has been reported; a causal relationship to enalapril cannot be excluded.

) .**Hepatic Failure** ,**WARNINGS** Elevations of liver enzymes and/or serum bilirubin have occurred (see **Liver Function Tests:**