Skip to main content

Capoten (Captopril)

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

Reported incidences are based on clinical trials involving approximately 7000 patients.

).**WARNINGS** About one of 100 patients developed proteinuria (see **Renal:**

Each of the following has been reported in approximately 1 to 2 of 1000 patients and are of uncertain relationship to drug use: renal insufficiency, renal failure, nephrotic syndrome, polyuria, oliguria, and urinary frequency.

). Cases of anemia, thrombocytopenia, and pancytopenia have been reported.**WARNINGS** Neutropenia/agranulocytosis has occurred (see **Hematologic:**

Rash, often with pruritus, and sometimes with fever, arthralgia, and eosinophilia, occurred in about 4 to 7 (depending on renal status and dose) of 100**Dermatologic:** patients, usually during the first four weeks of therapy. It is usually maculopapular, and rarely urticarial. The rash is usually mild and disappears within a few days of dosage reduction, short-term treatment with an antihistaminic agent, and/or discontinuing therapy; remission may occur even if captopril is continued. Pruritus, without rash, occurs in about 2 of 100 patients. Between 7 and 10 percent of patients with skin rash have shown an eosinophilia and/or positive ANA titers. A reversible associated pemphigoid-like lesion, and photosensitivity, have also been reported.

Flushing or pallor has been reported in 2 to 5 of 1000 patients.

for discussion of hypotension with captopril therapy. **PRECAUTIONS: DRUG INTERACTIONS**and**WARNINGS** Hypotension may occur; see **Cardiovascular:**

Tachycardia, chest pain, and palpitations have each been observed in approximately 1 of 100 patients.

Angina pectoris, myocardial infarction, Raynaud's syndrome, and congestive heart failure have each occurred in 2 to 3 of 1000 patients.

Approximately 2 to 4 (depending on renal status and dose) of 100 patients developed a diminution or loss of taste perception. Taste impairment is **Dysgeusia:** reversible and usually self-limited (2 to 3 months) even with continued drug administration. Weight loss may be associated with the loss of taste.

Angioedema involving the extremities, face, lips, mucous membranes, tongue, glottis or larynx has been reported in approximately one in 1000 **Angioedema:** **Intestinal Angioedema** ,**Head and Neck Angioedema** :**WARNINGS** patients. Angioedema involving the upper airways has caused fatal airway obstruction. (See .)**PATIENT INFORMATION** and

).**Cough** ,**General** :**PRECAUTIONS** Cough has been reported in 0.5 to 2% of patients treated with captopril in clinical trials (see **Cough:**

The following have been reported in about 0.5 to 2 percent of patients but did not appear at increased frequency compared to placebo or other treatments used in controlled trials: gastric irritation, abdominal pain, nausea, vomiting, diarrhea, anorexia, constipation, aphthous ulcers, peptic ulcer, dizziness, headache, malaise, fatigue, insomnia, dry mouth, dyspnea, alopecia, paresthesias.

Other clinical adverse effects reported since the drug was marketed are listed below by body system. In this setting, an incidence or causal relationship cannot be accurately determined.

).**Hemodialysis** :**PRECAUTIONS** and **Anaphylactoid and possible related reactions** :**WARNINGS** Anaphylactoid reactions (see **Body as a whole:**

Asthenia, gynecomastia. **General:**

Cardiac arrest, cerebrovascular accident/insufficiency, rhythm disturbances, orthostatic hypotension, syncope. **Cardiovascular:**

Bullous pemphigus, erythema multiforme (including Stevens-Johnson syndrome), exfoliative dermatitis. **Dermatologic:**

Pancreatitis, glossitis, dyspepsia. **Gastrointestinal:**

Anemia, including aplastic and hemolytic. **Hematologic:**

Jaundice, hepatitis, including rare cases of necrosis, cholestasis. **Hepatobiliary:**

Symptomatic hyponatremia. **Metabolic:**

Myalgia, myasthenia. **Musculoskeletal:**

Ataxia, confusion, depression, nervousness, somnolence. **Nervous/Psychiatric:**

Bronchospasm, eosinophilic pneumonitis, rhinitis. **Respiratory:**

Blurred vision. **Special Senses:**

Impotence. **Urogenital:**

As with other ACE inhibitors, a syndrome has been reported which may include: fever, myalgia, arthralgia, interstitial nephritis, vasculitis, rash or other dermatologic manifestations, eosinophilia and an elevated ESR.

Altered Laboratory Findings

).**PRECAUTIONS** small increases in serum potassium,especially in patients with renal impairment (see ***:Serum Electrolytes: Hyperkalemia***

particularly in patients receiving a low sodium diet or concomitant diuretics. ***:Hyponatremia***

Transient elevations of BUN or serum creatinine especially in volume or salt depleted patients or those with renovascular hypertension may ***:BUN/Serum Creatinine*** occur. Rapid reduction of longstanding or markedly elevated blood pressure can result in decreases in the glomerular filtration rate and, in turn, lead to increases in BUN or serum creatinine.

A positive ANA has been reported. ***:Hematologic***

Elevations of liver transaminases, alkaline phosphatase, and serum bilirubin have occurred. ***:Liver Function Tests***