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Cefaclor (Ceclor)

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

Adverse effects considered to be related to therapy with Ceclor (cefaclor) are listed below:

reactions have been reported in about 1,5% of patients and include morbilliform eruptions (1 in 100). Pruritus, urticaria, and positive Coombs' tests *Hypersensitivity* each occur in less than 1 in 200 patients.

reactions have been reported with the use of Ceclor (cefaclor) . These are characterized by findings of erythema multiforme, rashes, **serum-sickness-like** Cases of and other skin manifestations accompanied by arthritis/arthralgia, with or without fever, and differ from classic serum sickness in that there is infrequently associated lymphadenopathy and proteinuria, no circulating immune complexes, and no evidence to date of sequelae of the reaction. Occasionally, solitary symptoms may reactions appear to be due to **serum-sickness-like** reaction. While further investigation is ongoing, **serum-sickness-like**occur, but do not represent a hypersensitivity and more often occur during or following a second (or subsequent) course of therapy with Ceclor (cefaclor) . Such reactions have been reported more frequently in pediatric patients than in adults with an overall occurrence ranging from 1 in 200 (0.5%) in one focused trial to 2 in 8346 (0.024%) in overall clinical trials (with an incidence in pediatric patients in clinical trials of 0.055%) to 1 in 38,000 (0.003%) in spontaneous event reports. Signs and symptoms usually occur a few days after initiation of therapy and subside within a few days after cessation of therapy; occasionally these reactions have resulted in hospitalization, usually of short duration ' (median hospitalization = 2 to 3 days, based on postmarketing surveillance studies). In those requiring hospitalization, the symptoms have ranged from mild to severe at the time of admission with more of the severe reactions occurring in pediatric patients. Antihistamines and glucocorticoids appear to enhance resolution of the signs and symptoms. No serious sequelae have been reported.

More severe hypersensitivity reactions, including Stevens-Johnson syndrome, toxic epidermal necrolysis, and anaphylaxis have been reported rarely. Anaphylactoid events may be manifested by solitary symptoms, including angioedema, asthenia, edema (including face and limbs), dyspnea, paresthesias, syncope, hypotension, or vasodilatation. Anaphylaxis may be more common in patients with a history of penicillin allergy. Rarely, hypersensitivity symptoms may persist for several months.

symptoms occur in about 2.5% of patients and include diarrhea (1 in 70). Onset of pseudomembranous colitis symptoms may occur during or after *Gastrointestinal*). Nausea and vomiting have been reported rarely. As with some penicillins and some other cephalosporins, transient hepatitis **WARNINGS** antibiotic treatment {see and cholestatic jaundice have been reported rarely.

effects considered related to therapy included eosinophilia (1 in 50 patients), genital pruritus, moniliasis or vaginitis (about 1 in 50 patients), and, rarely, *Other* thrombocytopenia or reversible interstitial nephritis.

- ***Causal Relationship Uncertain***

- Rarely, reversible hyperactivity, agitation, nervousness, insomnia, confusion, hypertonia, dizziness, hallucinations, and somnolence have been reported. ***CNS***

Transitory abnormalities in clinical laboratory test results have been reported. Although they were of uncertain etiology, they are listed below to serve as alerting information for the physician.

- Slight elevations of AST, ALT, or alkaline phosphatase values (1 in 40). ***Hepatic***

- As has also been reported with other p-lactam antibiotics, transient lymphocytosis, leukopenia, and, rarely, hemolytic anemia, aplastic anemia, ***Hematopoietic*** agranulocytosis, and reversible neutropenia of possible clinical significance.

There have been rare reports of increased prothrombin time with or without clinical bleeding in patients receiving Ceclor (cefaclor) and Coumadin® concomitantly.

- Slight elevations in BUN or serum creatinine (less than 1 in 500) or abnormal urinalysis (less than 1 in 200). ***Renal***

Cephalosporin-class Adverse Reactions

In addition to the adverse reactions listed above that have been observed in patients treated with cefaclor, the following adverse reactions and altered laboratory tests have been reported for cephalosporin-class antibiotics: fever, abdominal pain, superinfection, renal dysfunction, toxic nephropathy, hemorrhage, false positive test for urinary glucose, elevated bilirubin, elevated LDH, and pancytopenia.

Several cephalosporins have been implicated in triggering seizures, particularly in patients with renal impairment when the dosage was not reduced. If seizures **DOSAGE AND** associated with drug therapy occur, the drug should be discontinued. Anticonvulsant therapy can be given if clinically indicated (see). **OVERDOSAGE sections**and**ADMINISTRATION**