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Cefprozil (Cefzil)

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The adverse reactions to cefprozil are similar to those observed with other orally administered cephalosporins. Cefprozil was usually well tolerated in controlled clinical trials. Approximately 2% of patients discontinued cefprozil therapy due to adverse events.

The most common adverse effects observed in patients treated with cefprozil are:

Diarrhea (2.9%), nausea (3.5%), vomiting (1%), and abdominal pain (1%). **Gastrointestinal:**

Hepatobiliary: Elevations of AST (SGOT) (2%), ALT (SGPT) (2%), alkaline phosphatase (0.2%), and bilirubin values (< 0.1%). As with some penicillins and some other cephalosporin antibiotics, cholestatic jaundice has been reported rarely.

Rash (0.9%), urticaria (0.1%). Such reactions have been reported more frequently in children than in adults. Signs and symptoms usually occur a **Hypersensitivity:** few days after initiation of therapy and subside within a few days after cessation of therapy.

Dizziness (1%), hyperactivity, headache, nervousness, insomnia, confusion, and somnolence have been reported rarely (< 1%). All were reversible.**CNS:**

Decreased leukocyte count (0.2%), eosinophilia (2.3%). **Hematopoietic:**

Elevated BUN (0.1%), serum creatinine (0.1%). **Renal:**

Diaper rash and superinfection (1.5%), genital pruritus and vaginitis (1.6%). **Other:**

The following adverse events, regardless of established causal relationship to CEFZIL (cefprozil) , have been rarely reported during postmarketing surveillance: anaphylaxis, angioedema, colitis (including pseudomembranous colitis), erythema multiforme, fever, serum-sickness like reactions, Stevens-Johnson syndrome, and thrombocytopenia.

Cephalosporin class paragraph

In addition to the adverse reactions listed above which have been observed in patients treated with cefprozil, the following adverse reactions and altered laboratory tests have been reported for cephalosporin-class antibiotics:

Aplastic anemia, hemolytic anemia, hemorrhage, renal dysfunction, toxic epidermal necrolysis, toxic nephropathy, prolonged prothrombin time, positive Coombs' test, elevated LDH, pancytopenia, neutropenia, agranulocytosis.

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