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Ceftriaxone (Rocephin)

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Rocephin (ceftriaxone) is generally well tolerated. In clinical trials, the following adverse reactions, which were considered to be related to Rocephin (ceftriaxone) therapy or of uncertain etiology, were observed:

pain, induration and tenderness was 1% overall. Phlebitis was reported in < 1% after IV administration. The incidence of warmth, tightness or**LOCAL REACTIONS -** induration was 17% (3/17) after IM administration of 350 mg/mL and 5% (1/20) after IM administration of 250 mg/mL.

rash (1.7%). Less frequently reported (< 1%) were pruritus, fever or chills.**HYPERSENSITIVITY -**

eosinophilia (6%), thrombocytosis (5.1%) and leukopenia (2.1%). Less frequently reported (< 1%) were anemia, hemolytic anemia, neutropenia, **HEMATOLOGIC -** lymphopenia, thrombocytopenia and prolongation of the prothrombin time.

diarrhea (2.7%). Less frequently reported (< 1%) were nausea or vomiting, and dysgeusia. The onset of pseudomembranous colitis **GASTROINTESTINAL -**).**WARNINGS**symptoms may occur during or after antibacterial treatment (see

elevations of SGOT (3.1%) or SGPT (3.3%). Less frequently reported (< 1%) were elevations of alkaline phosphatase and bilirubin.**HEPATIC -**

elevations of the BUN (1.2%). Less frequently reported (< 1%) were elevations of creatinine and the presence of casts in the urine.**RENAL -**

headache or dizziness were reported occasionally (< 1%).**CENTRAL NERVOUS SYSTEM -**

moniliasis or vaginitis were reported occasionally (< 1%).**GENITOURINARY -**

diaphoresis and flushing were reported occasionally (< 1%).**MISCELLANEOUS -**

Other rarely observed adverse reactions (< 0.1%) include abdominal pain, agranulocytosis, allergic pneumonitis, anaphylaxis, basophilia, biliary lithiasis, bronchospasm, colitis, dyspepsia, epistaxis, flatulence, gallbladder sludge, glycosuria, hematuria, jaundice, leukocytosis, lymphocytosis, monocytosis, nephrolithiasis, palpitations, a decrease in the prothrombin time, renal precipitations, seizures, and serum sickness.

Postmarketing Experience

In addition to the adverse reactions reported during clinical trials, the following adverse experiences have been reported during clinical practice in patients treated with Rocephin (ceftriaxone) . Data are generally insufficient to allow an estimate of incidence or to establish causation.

A small number of cases of fatal outcomes in which a crystalline material was observed in the lungs and kidneys at autopsy have been reported in neonates receiving Rocephin (ceftriaxone) and calcium-containing fluids. In some of these cases, the same intravenous infusion line was used for both Rocephin (ceftriaxone) and calcium-containing fluids and in some a precipitate was observed in the intravenous infusion line. At least one fatality has been reported in a neonate in whom Rocephin (ceftriaxone) and calcium-containing fluids were administered at different time points via different intravenous lines; no crystalline material was observed at autopsy in this neonate. There have been no similar reports in patients other than neonates.

stomatitis and glossitis. **GASTROINTESTINAL –**

oliguria. **GENITOURINARY –**

exanthema, allergic dermatitis, urticaria, edema. As with many medications, isolated cases of severe cutaneous adverse reactions (erythema **DERMATOLOGIC –** multiforme, Stevens-Johnson syndrome or Lyell's syndrome/toxic epidermal necrolysis) have been reported.

Cephalosporin Class Adverse Reactions

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

Adverse Reactions

Allergic reactions, drug fever, serum sickness-like reaction, renal dysfunction, toxic nephropathy, reversible hyperactivity, hypertonia, hepatic dysfunction including cholestasis, aplastic anemia, hemorrhage, and superinfection.

Altered Laboratory Tests

Positive direct Coombs' test, false-positive test for urinary glucose, and elevated LDH.

DOSAGE AND ADMINISTRATION 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 given if clinically indicated.