



CODAL-SYNTO



Your choice in complicated infections

Ceftriax[®]

Ceftriaxone

CEFTRIX[®] 500mg vials • CEFTRIX[®] 1g vials



Summary of SPC for Ceftriax[®]

Trade Name of the Medicinal Product:	Ceftriax [®]
Qualitative and Quantitative Composition:	Each vial contains 250mg, 500mg, 1g, 2g ceftriaxone as hydrated ceftriaxone disodium.
Therapeutic indications:	Bone, skin and soft tissue infection. Gonorrhoea. Infections in neutropenic patients. Meningitis (bacterial). Pneumonia. Septicaemia. Prophylaxis of infection associated with surgical procedures.
Posology and Method of Administration:	Adults and children aged 12 years and older: 1g administered as a single daily dose. In severe infections, the dosage may be increased to 2g to 4g usually administered as a single dose every 24 hours. Gonorrhoea (acute, uncomplicated): Intramuscular administration of a single 250mg dose. Peri-operative prophylaxis: 1g administered as a single intramuscular or slow intravenous dose. Neonates: A daily dose from 20mg – 50mg/kg bodyweight, the daily dosage must not exceed 50mg/kg bodyweight. If the intravenous route of administration is used the dose must be administered over a 60 minute period to reduce the displacement of bilirubin from albumin, hence reducing the risk of potential bilirubin encephalopathy. Children aged over 6 weeks to 12 years: 25mg – 50mg/kg bodyweight/day administered as a single daily dose. In severe infections a dose of up to 80 mg/kg bodyweight/day may be administered as a single daily dose. Doses of 50mg/kg or greater must be administered by slow intravenous infusion with a minimum duration of 30 minutes. Dosage greater than 80mg/kg bodyweight should not be used as there is an increased risk of biliary precipitation.
Contra-indications:	Previous immediate and/or severe hypersensitivity reactions to a penicillin or to any other type of beta-lactam drug. History of hypersensitivity to the cephalosporins. Premature newborns up to a correct age of 41 weeks (weeks of gestation + weeks of life); Full-term newborns (up to 28 days of age) with jaundice, or who are hypoalbuminaemic or acidotic or if they require (or are expected to require) IV calcium treatment, or calcium-containing infusions because of the risk of precipitation of ceftriaxone-calcium.
Special Warnings and Precautions for Use:	The recommended daily dosages should not be exceeded; Antibiotic associated diarrhoea, colitis and pseudomembranous colitis; History of gastro-intestinal disease, colitis; Prolonged used; Severe renal impairment; Hepatic impairment; Neonates; Premature infants; Increased risk of biliary precipitation; Cross reactivity with penicillins; Interactions with Calcium-Containing Products.
Interactions with other Medicaments and other forms of Interaction:	Aminoglycoside antibiotics; Chloramphenicol; Hormonal Contraceptives; Laboratory tests (Coombs test, Galactosaemia, Glucose in urine), Alcohol.
Pregnancy and Lactation:	Use in pregnancy is not recommended unless such use is essential. Caution is advised in breast feeding and it is suggested that breast feeding be discontinued during therapy.
Undesirable Effects:	Headache, dizziness, allergic dermatitis, erythema multiforme, oedema, pruritus, urticaria, maculopapular rash, exanthema, erythema multiforme, toxic epidermal necrolysis, Stevens Johnson syndrome; Loose stools or diarrhoea, nausea, vomiting, stomatitis, glossitis, pseudomembranous colitis, pancreatitis; Increase in serum creatinine, glycosuria, haematuria, oliguria, urinary precipitates of calcium ceftriaxone, anuria and renal impairment; Haemolytic anaemia, eosinophilia, leucopenia, neutropenia, thrombocytopenia, prolongation of prothrombin time, positive Coomb's test, agranulocytosis, coagulation disorders; Elevations in liver function tests; Precipitates of calcium ceftriaxone; Anaphylactic type reactions, drug fever and shivering; Pain or discomfort at the injection site, local phlebitis; Fungal super-infection of the genital tract.