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For the use only of a Registered Medical Practitioner or a Hospital or a Laboratory

TORODROXYL-250 DT

(Cefadroxil Dispersible Tablets, 250 mg)

Torodroxyl DT (Cefadroxil) is a semisynthetic cephalosporin antibiotic in dispersible form intended for paediatric patients. It is indicated in the treatment of urinary tract infections, skin and skin structure infections caused by staphylococci or streptococci, pharyngitis, tonsillitis and respiratory tract infections in children.

CLINICAL PHARMACOLOGY

Cefadroxil is bactericidal in vitro against a wide range of Gram-positive and Gram-negative microorganisms. Sensitive organisms include Penicillinase and Non-penicillinase producing Staphylococci, Beta-haemolytic Streptococci, Streptococcus pneumoniae, Streptococcus pyogenes, E.coli, Klebsiella pneumoniae, Proteus mirabilis, Haemophilus influenzae, Salmonella spp and Shigella spp. Cefadroxil acts by virtue of interfering with stable bacterial cell wall synthesis and with the activity of the inhibitory enzymes that normally curb autolysis. It is more stable against Beta-lactamases produced by many Gram-negative bacteria and Staphylococci and hence have a broader spectrum of efficacy. Cefadroxil is rapidly and completely absorbed after oral administration. The presence of food has no effect on extent of absorption. It is 20% protein bound and widely distributed in body fluids and tissues.

The concentration of Cefadroxil in tonsil, lung, saliva and sputum were found to be well above the MIC for bacterial pathogens. Therapeutic concentrations of Cefadroxil are achieved in bone, muscle, synovial tissue/fluid, tendons, kidney, skin blisters etc. Cefadroxil is excreted unchanged (93%) in urine over 24 hours.

INDICATIONS

Torodroxyl DT is indicated in the treatment of urinary tract infections, skin and skin structure infections caused by staphylococci or streptococci, pharyngitis, tonsillitis and respiratory tract infections in children only.

CONTRAINDICATIONS

Cefadroxil is contraindicated in patients with known hypersensitivity to Cephalosporins. In patients with a history of Penicillin allergy, Cefadroxil should be used with extreme caution.

PRECAUTIONS

As experience in premature infants and neonates is limited, the use of Cefadroxil in these patients should be undertaken with caution. A false positive Coombs reaction may occur in some patients. Urine from patients treated with Cefadroxil may give false positive glycosuria reaction when tested with Benedict's or Fehling's solutions. Renal function should be assessed whenever possible and dosage of Cefadroxil should be adjusted in impaired renal function.

ADVERSE REACTIONS

Cefadroxil is well tolerated. Some adverse reactions, including nausea, vomiting, diarrhoea, dyspepsia, dizziness, headache may occur. Rash pruritus, urticaria and angioneurotic oedema may be observed infrequently.

DOSAGE AND ADMINISTRATION

Torodroxyl DT should be dissolved in a spoon with little water which may be administered with food to diminish gastrointestinal complaints. The recommended dosage of Cefadroxil in children for treatment of various infections are

as follows:

Children weighing (less than 40kgs)

Under 1 year : 25 mg/kg daily in two or three divided doses.

1-6 years : 250mg twice a day.

Over 6 years : 500mg (250mg 2 tablets) twice a day

Children weighing (more than 40kgs.)

500mg - 1gm twice a day, depending upon the severity of infection.

In patients with renal impairment the dosage of Cefadroxil should be adjusted according to creatinine clearance rates to prevent drug accumulation as follows:

50ml/min : No adjustment

25-50ml/min : Dosage interval 12 hours

10-25ml/min : Dosage interval 24 hours

0-10ml/min : Dosage interval 36 hours

DIRECTIONS FOR USE

Disperse the tablet in a teaspoonful of water before administration.

STORAGE

Store below 30°C, Protected from light.

PRESENTATION

Torodroxyl-250 DT is available in strip of 10 tablets, each dispersible tablet containing Cefadroxil U.S.P. equivalent of Cefadroxil anhydrous 250 mg.



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