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

TORODROXYL-500

(Cefadroxil Tablets U.S.P., 500 mg)

DESCRIPTION

Cefadroxil is a semi-synthetic cephalosporin antibiotic intended for oral administration. Its unique pharmacodynamic profile allows excellent absorption and tissue penetration in addition to sustained therapeutic concentration of the drug at the site of infection. This accounts for the fact that clinical efficacy is often better than can be summarized from in vitro respiratory tract infections, urinary tract infections, skin and soft tissue infections, acute otitis media and sinusitis. Since tissue levels are higher and more sustained, Torodroxyl is considered to be the agent of choice in preoperative prophylaxis.

COMPOSITION

Each uncoated tablet contains:
Cefadroxil U.S.P. equivalent to Cefadroxil Anhydrous 500 mg
Microcrystalline Cellulose (Rancel RQ-102)
Colloidal Silicon Dioxide (Aerosil)
Sodium Starch Glycolate
Magnesium Stearate
Talc

CLINICAL PHARMACOLOGY

Anti microbial activity

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

1. Urinary tract infections
2. Skin and skin structure infections
3. Pharyngitis and tonsillitis
4. Respiratory tract infections

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.

USE IN PREGNANCY AND LACTATING MOTHER

There is no evidence of risk when Cefadroxil is used in pregnant and lactating animals, however, Torodroxyl should be used in pregnant and lactating women when the benefits outweigh the potential risk.

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.

Inform your doctor in case of any adverse reactions related to drug use.

DOSAGE AND ADMINISTRATION

Torodroxyl may be administered with food to diminish gastrointestinal complaints. The recommended doses of Cefadroxil in adults and children for treatment of various infections are as follows.

Adults : 2gm in a single or 2 divided doses

Children: 25-50mg/kg/day in a single or 2 divided doses
Torodroxyl dispersible tablet should be dissolved in a spoon with little water which may be administered with food to diminish gastrointestinal complaints.

Elderly : Cefadroxil is excreted by renal route; renal function should be assessed whenever possible and dosage adjusted as below:

DOSE MODIFICATION IN RENAL FAILURE

140-age x wt. in kg.

Creatinine clearance = $\frac{140 - \text{age} \times \text{wt. in kg.}}{72 \times \text{serum creatinine}}$ ml/min

Creatinine clearance [ml/min]	Dosage interval
50ml/min	No adjustment
25-30ml/min	12 hours
10-25ml/min	24 hours
0-10ml/min	36 hours

OVERDOSAGE

There is no specific antidote known for Torodroxyl overdose, therefore symptomatic treatment should be advocated.

STORAGE

Store below 30°C, protected from light.

PRESENTATION

TORODROXYL-500 is packed in Strip of Printed Aluminium foil sealed with Plain Aluminium foil. Each strip contains 10 tablets.



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