(For the use of a Registered Medical Practitioner or a Hospital or a Laboratory only) xxxxxxxx-5173

# DROXYL Instause

(Cefadroxil 125mg/5ml and 250mg/5ml oral suspension)

**Description:**

**DROXYL INSTAUSE** (Cefadroxil monohydrate ) is a semisynthetic cephalosporin antibiotic intended for oral administration. It is a white to yellowish-white crystalline powder. It is soluble in water and it is acid-stable. It is chemically designated as 5-Thia-1-azabicyclo[ 4.2.0] oct-2-ene-2-carboxylic acid, 7-[[amino (4-hydroxyphenyl) acetyl]amino]-3-methyl-8-oxo-, monohydrate,[6R[6a,7b(R*)]]-. It has the formula $C_{16}H_{17}N_3O_5S \cdot H_2O$ and the molecular weight of 381.40

**Clinical Pharmacology**

Cefadroxil is rapidly absorbed after oral administration. Following single doses of 500 and 1000 mg, average peak serum concentrations were approximately 16 and 28 μg/mL, respectively. Measurable levels were present 12 hours after administration. Over 90% of the drug is excreted unchanged in the urine within 24 hours. Peak urine concentrations are approximately 1800 μg/mL during the period following a single 500-mg oral dose. Increases in dosage generally produce a proportionate increase in Cefadroxil urinary concentration. The urine antibiotic concentration, following a 1-g dose, was maintained well above the MIC of susceptible urinary pathogens for 20 to 22 hours. Cefadroxil is widely distributed in body fluids and tissues. Tonsillar concentrations were found to be 10 times the MIC for hemolytic streptococci. Following a 1gm dose of Cefadroxil, lung tissue concentrations were found to be 7.4mcg/gm when corresponding serum concentrations were 11.4mg/L. This is more than the MIC for the common bacterial pathogens causing pneumonia. Similarly, concentrations in saliva and sputum were found to be well above the MIC for bacterial pathogens. Therapeutic concentrations are achieved in bone, muscle, synovial tissue/fluid and tendons. Other tissues where therapeutic concentrations are achieved are kidney, prostatic tissue, skin blisters, breast milk and fetus in utero. Therapeutic concentrations persists in urine for 20-22 hrs following a single 500mg to 1g dose. Cefadroxil is excreted virtually unchanged (93%) in urine over 24 hours both by glomerular filtration and tubular secretion. Probenecid interferes with tubular secretion and co-prescription with Cefadroxil increase the duration of action and enhance serum and tissue concentrations of Cefadroxil.

In vitro tests demonstrate that the cephalosporins are bactericidal because of their inhibition of cell-wall synthesis. Cefadroxil has been shown to be active against the following organisms both in vitro and in clinical infections

1. *Beta-hemolytic streptococci*
2. *Staphylococci, including penicillinase-producing strains*
3. *Streptococcus (Diplococcus) pneumoniae*
4. *Escherichia coli*
5. *Proteus mirabilis*
6. *Klebsiella species*
7. *Moraxella (Branhamella) catarrhalis*

Note: Most strains of Enterococcus faecalis (formerly Streptococcus faecalis) and Enterococcus faecium (formerly Streptococcus faecium) are resistant to Cefadroxil. It is not active against most strains of Enterobacter species, Morganella morganii (formerly Proteus morganii), and P. vulgaris. It has no activity against Pseudomonas species and Acinetobacter calcoaceticus (formerly Mima and Herellea species).

**Indications**

**DROXYL INSTAUSE** is indicated for the treatment of patients with infection caused by susceptible strains of the designated organisms in the following diseases:

Respiratory tract infections

Urinary tract infections

Skin and skin structure infections

***Note:*** Only penicillin by the intramuscular route of administration has been shown to be effective in the prophylaxis of rheumatic fever. Cefadroxil is generally effective in the eradication of streptococci from the oropharynx. However, data establishing the efficacy of Cefadroxil for the prophylaxis of subsequent rheumatic fever are not available.

**Dosage And Administration**

**DROXYL INSTAUSE** is acid-stable and may be administered orally without regard to meals. Administration with food may be helpful in diminishing potential gastrointestinal complaints occasionally associated with oral cephalosporin therapy.

**Children**

For urinary tract infections, the recommended daily dosage for children is 30 mg/kg/day in divided doses every 12 hours. For Pharyngitis, tonsillitis, and impetigo, the recommended daily dosage for children is 30 mg/kg/day in a single dose or in equally divided doses every 12 hours. For other skin and skin structure infections, the recommended daily dosage is 30 mg/kg/day in equally divided doses every 12 hours. In the treatment of beta hemolytic streptococcal infections, a therapeutic dosage of DROXYL INSTAUSE should be administered for at least 10 days. See chart for total daily dosage for children.

**DAILY DOSAGE OF DROXYL INSTAUSE ® SUSPENSION**

| Child's Weight | | | |
|---|---|---|---|
| **lbs** | **kg** | **125 mg/5 mL** | **250 mg/5 mL** |
| 10 | 4.5 | 1 tsp | — |
| 20 | 9.1 | 2 tsp | 1 tsp |
| 30 | 13.6 | 3 tsp | 1 1/2 tsp |
| 40 | 18.2 | 4 tsp | 2 tsp |
| 50 | 22.7 | 5 tsp | 2 1/2 tsp |
| 60 | 27.3 | 6 tsp | 3 tsp |
| 70 & above | 31.8+ | — | — |

In patients with renal impairment, the dosage of Cefadroxil should be adjusted according to creatinine clearance rates to prevent drug accumulation. The following schedule is suggested. In adults, the initial dose is 1000 mg of Cefadroxil and the maintenance dose (based on the creatinine clearance rate [mL/min/1.73 M 2]) is 500 mg at the time intervals listed below.

| Creatinine Clearances | Dosage Interval |
|---|---|
| 0-10 mL/min | 36 hours |
| 10-25 mL/min | 24 hours |
| 25-50 mL/min | 12 hours |

Patients with creatinine clearance rates over 50 mL/min may be treated as if they were patients having normal renal function.

**Overdosage**

A study of children under six years of age suggested that ingestion of less than 250 mg/kg of cephalosporins is not associated with significant outcomes. No action is required other than general support and observation. For amounts greater than 250 mg/kg, induce gastric emptying.

In five anuric patients, it was demonstrated that an average of 63% of a 1 g oral dose is extracted from the body during a 6-8 hour hemodialysis session.

**Contraindications**

DROXYL INSTAUSE is contraindicated in patients with known allergy to the cephalosporin group of antibiotics.

**Precautions**

As experience in premature infants and neonates is limited, Cefadroxil should be used taken with caution in such patients.

Cefadroxil should be used with caution in the presence of markedly impaired renal function (creatinine clearance rate of less than 50ml/min/1.73m2). In patients with known or suspected renal impairment, careful clinical observation and appropriate laboratory studies should be made prior to and during therapy.

Cefadroxil should be prescribed with caution in individuals with history of gastrointestinal disease, particularly colitis.

During treatment with Cefadroxil, false positive reaction for direct coombs test and glucose in urine may occur with Benedict's or Fehling's solution, but not enzyme based tests. As with all antibiotics, prolonged use may result in over-growth of non-susceptible organisms.

**Use In Pregnancy And Lactation:**

There is no evidence of risk with the use of Cefadroxil in pregnant animals; however, Cefadroxil should be used in pregnancy hen the benefits outweigh the potential risk. As Cefadroxil is excreted in the breast milk, Cefadroxil should be used with caution in nursing mothers.

**Adverse Reactions**

**Gastrointestinal**

Onset of pseudomembranous colitis symptoms may occur during or after antibiotic treatment. Dyspepsia, nausea and vomiting have been reported rarely. Diarrhea has also occurred.

**Hypersensitivity**

Allergies (in the form of rash, urticaria, angioedema, and pruritis) have been observed. These reactions usually subsided upon discontinuation of the drug. Anaphylaxis has also been reported.

**Other**

Other reactions have included hepatic dysfunction including cholestasis and elevations in serum transaminase, genital pruritus, genital moniliasis, vaginitis, moderate transient neutropenia, fever. Agranulocytosis, thrombocytopenia, idiosyncratic hepatic failure, erythema multiforme, Stevens-Johnson syndrome, serum sickness, and arthralgia have been rarely reported.

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

Aminotransferase (AST), elevated alanine aminotransferase (ALT), elevated bilirubin, elevated LDH, eosinophilia, pancytopenia, neutropenia.

Several cephalosporins have been implicated in triggering seizures, particularly in patients with renal impairment, when the dosage was not reduced. If seizures associated with drug therapy occur, the drug should be discontinued. Anticonvulsant therapy can be given if clinically indicated.

**DRUG INTERACTIONS**

**Drug/Laboratory Test Interactions**

Positive direct Coombs' tests have been reported during treatment with the cephalosporin antibiotics. In hematologic studies or in transfusion cross-matching procedures when anti-globulin tests are performed on the minor side or in Coombs' testing of newborns whose mothers have received cephalosporin antibiotics before parturition, it should be recognized that a positive Coombs' test may be due to the drug.

**Instruction for administration: Droxyl instause** to be administered as such and it should not be mixed with water, fruit juice or any other liquid before administration. **Droxyl instause** Should be shaken well before use.

**Presentation:**

**DROXYL INSTAUSE** is orange flavored, and is supplied as follows:

| | |
|---|---|
| 125 mg/5 mL | 30 mL Bottle |
| 250 mg/5 mL | 30 mL Bottle |

**Storage:** STORE BELOW 30°C, PROTECTED FROM MOISTURE

FOR PAEDIATRIC USE ONLY.

SHAKE WELL BEFORE USE

torrent PHARMA

Manufactured by :
TORRENT PHARMACEUTICALS LTD.
Indrad-382 721, Dist. Mehsana, INDIA.
At : Vill. Manakpur, Teh. Nalagarh, Dist. Solan (H.P.)