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

XILCEF®

जिलिसेफ

Product Name
XILCEF® 500 Tablet
XILCEF® 250 Dispersible Tablet
XILCEF® 250 Dry Syrup

Name and Strength of Active Ingredient (s)
XILCEF® 500: Each film coated tablet contains: Cefadroxil Monohydrate USP equivalent to Anhydrous Cefadroxil 500 mg
XILCEF® 250 DT: Each dispersible tablet contains: Cefadroxil USP equivalent to Cefadroxil Anhydrous 250 mg
XILCEF® 250: Each 5ml of the reconstituted suspension contains: Cefadroxil USP equivalent to Cefadroxil Anhydrous 250 mg

Product Description
Cefadroxil is a semisynthetic cephalosporin antibiotic intended for oral administration.

Pharmacodynamics & Pharmacokinetics
Pharmacodynamics
It causes inhibition of cell wall synthesis by preferentially binding to specific penicillin-binding proteins (PBPs). Its action is bactericidal.

Pharmacokinetics
Cefadroxil is rapidly absorbed after oral administration. Following single doses of 500 and 1000 mg, average peak serum concentrations were approximately 16 and 28 mcg/mL, respectively. Over 90% of the drug is excreted unchanged in the urine within 24 hours. Peak urine concentrations are approximately 1800 mcg/mL during the period following a single 500 mg oral dose. Increases in dosage generally produce a proportionate increase in Cefadroxil urinary concentration.

Indications
- Urinary tract infections, including bladder infections caused by *E. coli*, *P. mirabilis*, and *Klebsiella* species
- Skin and skin structure infections caused by *Staphylococci* and/or *Streptococci*.
- Pharyngitis and/or tonsillitis caused by *Streptococcus pyogenes* (Group A beta-hemolytic *Streptococci*).

NOTE: Culture and Susceptibility tests should be initiated prior to and during therapy. Renal function studies should be performed when indicated.

Recommended Dose and Administration
Adults
Urinary Tract Infections: For uncomplicated lower urinary tract infections (i.e., cystitis) the usual dosage is 1 or 2 g per day in a single (o.d.) or divided doses (b.i.d.). For all other urinary tract infections the usual dosage is 2 g per day in divided doses (b.i.d.).
Skin and Skin Structure Infections: For skin and skin structure infections the usual dosage is 1 g per day in single (o.d.) or divided doses (b.i.d.).
Pharyngitis and Tonsillitis: Treatment of group A beta-hemolytic streptococcal pharyngitis and tonsillitis, 1 g per day in single (o.d.) or divided doses (b.i.d.) for 10 days.
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 cefadroxil should be administered for at least 10 days.

Contraindications
Contraindicated in patients with known allergy to the cephalosporin/penicillin group of antibiotics.

Warning and Precautions
- Careful inquiry should be made to determine whether the patient has had previous hypersensitivity reactions to cefadroxil, cephalosporins, penicillins, or other drugs.
- Cefadroxil should be used with caution in the presence of markedly impaired renal function.
- Cefadroxil in the absence of a proven or strongly suspected bacterial infection or a prophylactic indication is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria.
- Cefadroxil should be prescribed with caution in individuals with history of gastrointestinal disease particularly colitis.

Drug Interactions
Positive direct Coombs' tests have been reported during treatment with the cephalosporin antibiotics. In hematologic studies or in transfusion cross-matching procedures when antiglobulin 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.

Special Populations
Pregnancy: Pregnancy Category B
Reproduction studies have been performed in mice and rats at doses up to 11 times the human dose and have revealed no evidence of impaired fertility or harm to the fetus due to cefadroxil monohydrate. There are, however, no adequate and well controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.
Labor and Delivery
Cefadroxil has not been studied for use during labor and delivery. Treatment should only be given if clearly needed.
Nursing Mothers
Caution should be exercised when cefadroxil monohydrate is administered to a nursing mother.
Geriatric Use
Cefadroxil is substantially excreted by the kidney, and dosage adjustment is indicated for patients with renal impairment. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

Side effects
The most common side effects of cefadroxil are diarrhea (which, less commonly, may be bloody), nausea, upset stomach, and vomiting. Other side effects include rashes, hives, and itching.

Storage
Protect from direct sunlight and moisture. Store XILCEF below 30 ºC at cool and dry place but not in refrigerator. Keep the medication away from children.

Presentation
XILCEF® 500: Each film coated tablet contains: Cefadroxil Monohydrate USP equivalent to Anhydrous Cefadroxil 500 mg supplied in a blister pack of 10 Tablets x 10 Blisters

XILCEF® 250 DT: Each dispersible tablet contains: Cefadroxil USP equivalent to Cefadroxil Anhydrous 250 mg supplied in a blister pack of 10 Tablets x 10 Blisters

XILCEF® 250: Each 5ml of the reconstituted suspension contains: Cefadroxil USP equivalent to Cefadroxil Anhydrous 250 mg supplied in 30ml bottle

Manufactured by:
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