Important Information. Please read carefully.

Sofidrox™

Cefadroxil Monohydrate Equivalent to Cefadroxil

Capsules

Composition

Each Sofidrox Capsule 500mg contains Cefadroxil Monohydrate equivalent to 500mg Cefadroxil.

Pharmacodynamics

Cefadroxil is a beta-lactam antibiotic. It is bactericidal and acts similarly to benzylpenicillin by inhibiting synthesis of the bacterial cell wall. It is most active against Gram-positive cocci, and has moderate activity against some Gram-negative bacilli. Sensitive Gram-positive cocci include both penicillinase-producing staphylococci, although methicillin-resistant staphylococci are usually resistant; most streptococci are also sensitive, but not penicillin-resistant *Streptococcus pneumoniae;* enterococci are usually resistant. Some Gram-positive anaerobes are also sensitive. Among Gram-negative bacteria, cefadroxil has activity against some Enterobactericeae including strains of *Escherichia coli, Klebsiella pneumoniae, Proteus mirabilis,* Salmonella and Shigella *spp.,* but not against Enterobacter, indole-positive Proteus, *or Serratia marcescens*. It is also active against *Haemophilus influenzea*, *Moraxella (Branhamella) catarrhalis*, and Neisseria *spp, Bacteroides fragilis* and *Pseudomonas aeruginosa* are not sensitive, neither are mycobacteria, mycoplasma and fungi.

Pharmacokinetics

Cefadroxil is almost completely absorbed from the gastrointestinal tract. After oral doses of 500 mg and 1 g, peak plasma concentrations of about 16 and 30 micrograms/ mL respectively are obtained after 1.5 to 2 hours. Although peak concentrations are similar to those of cefalexin, plasma concentrations are more sustained. Dosage with food does not appear to affect the absorption of cefadroxil. About 20% of cefadroxil is reported to be bound to plasma proteins. The plasma half-life of cefadroxil is about 1.5 hours and is prolonged in patients with renal impairment. Cefadroxil is widely distributed to body tissues and fluids. It crosses the placenta and appears in breast milk. More than 90% of a dose of cefadroxil may be excreted unchanged in the urine within 24 hours by glomerular filtration and tubular secretion; peak urinary concentrations of 1.8 mg/mL have been reported after a dose of 500 mg. Cefadroxil is removed by haemodialysis.

Indications

Infections due to sensitive Gram-positive and Gram-negative bacteria, including those of the biliary, respiratory, urinary tracts and of the skin.

Dosage and Administration

To be administered orally. Adult and children (over 6 years), body weight more than 40 kg:

Urinary Tract Infections:
For acute uncomplicated lower urinary tract infections (e.g. cystitis), the usual daily dosage is 1 or 2 grams per day in a single dose. In complicated or chronic urinary tract infections, the usual dose is 1 g every 12 hours for a minimum of 7 - 10 days.

Skin and Skin Structure Infections:
The usual dosage is 1 gram per day in a single dose.

Upper Respiratory Tract Infections:
The usual dosage is 500 mg every 12 hours. For group A β-haemolytic streptococcal pharyngitis and tonsillitis, 1 gram may be given as a single, daily dose. For any infections caused by Group A β-haemolytic streptococcus, treatment should be administered for 10 days.

Lower Respiratory Tract Infections:
The recommended dosage is 500 mg to 1 gram every 12 hours.

Doses should be reduced in patients with impaired renal function.

Contraindications

Cefadroxil is contraindicated in patients who are sensitive to cephalosporin and in patients with acute porphyria.

Side-Effects

Side-effects include diarrhoea and rarely reported pseudomembranous colitis, nausea and vomiting; allergic reactions including rashes, pruritis, urticaria, serum sickness-like reactions with rashes and anaphylaxis; erythema multiforme, toxic epidermal necrolysis reported; eosinophilia and rarely thrombocytopenia or neutropenia; disturbances in liver enzymes, transient hepatitis and cholestatic jaundice; other side-effects reported include reversible interstitial nephritis, hyperactivity, nervousness, sleep disturbances, confusion, hypertonia and dizziness.

Precautions / Warnings

Cefadroxil should not be given to patients who are hypersensitive to it or to other cephalosporins. Cefadroxil should be given with caution to patients with renal impairment; a dosage reduction may be necessary. Prolonged use may result in overgrowth of non-susceptible organisms. Positive Coomb's tests have been reported. Caution in individuals with history of GIT disease, particularly colitis. Pseudomembranous colitis has been reported.

Serious and occasionally fatal hypersensitivity reactions (including anaphylactoid and severe cutaneous adverse reactions) have been reported in patients receiving therapy with beta-lactams. Before initiating therapy with Sofidrox, careful inquiry should be made concerning previous hypersensitivity reactions to penicillins, cephalosporins, carbapenems or other beta-lactam agents. If an allergic reaction occurs, Sofidrox must be discontinued immediately and appropriate alternative therapy instituted.

Pregnancy and Lactation

To be used with caution in nursing mother. Reproduction studies have been done in mice, but not in human. Thus, this drug should be used with caution in pregnant women.

Drug Interactions

Probenecid reduces the excretion of cephalosporins. Positive Coomb's tests have been reported during treatment with cephalosporin antibiotics. False positive results in urine glucose test.

Symptoms and Treatment of Overdose

No clinical reports are as yet available on cefadroxil in this respect. However in view of experience gained with other cephalosporins the following symptoms are possible: nausea, hallucinations, hyperreflexia, extrapyramidal symptoms, clouded consciousness, or even coma and renal functional impairment. First aid after intake of toxic doses: induce vomiting at once or gastric lavage, if necessary haemodialysis. Monitor and if necessary correct the water and electrolyte balance, monitor renal function.

Shelf-life

The expiry date is indicated on the packaging.

Presentation

Size 0, maroon/white hard gelatin capsule, printed with 'XSP'.

Packing

100's in blister pack of 10's.

Storage

Store below 30ºC. Protect from light.

KEEP OUT OF REACH OF CHILDREN
JAUHI DARI KANAK-KANAK

For further information, please consult your pharmacist or physician.

Revision Date : 17-Apr-2020

Xepa sp

Manufacturer and Product Registration Holder
Xepa-Soul Pattinson (Malaysia) Sdn Bhd
1-5 Cheng Industrial Estate, 75250 Melaka, Malaysia.