Rx CEFOXITIN

Cefoxid
1g Powder for Injection (IM/IV)
Antibacterial (Cephalosporin)

FORMULATION:
Each vial contains:
Cefoxitin (as sodium).....1g

PRODUCT DESCRIPTION:
Cefoxitin (CEFOXID) is a white or almost white powder.

ANTIMICROBIAL ACTIONS:
Cefoxitin is a cephamycin antibacterial which, like the other beta lactams, is bactericidal and is considered to act through the inhibition of bacterial cell wall synthesis. It has a similar spectrum of activity to cefamandole but is more active against anaerobic bacteria, especially *Bacteroides fragilis*. Cefoxitin can induce the production of beta-lactamases by some bacteria, and use of cefoxitin with other beta lactams has been shown to be antagonistic in vitro. Cefoxitin itself is considered to be resistant to a wide range of beta-lactamases, including those produced by *Bacteroides spp.* However, acquired resistance to cefoxitin has been reported in *B. fragilis* and has been attributed to beta-lactamase as well as to alterations in penicillin-binding proteins or to outer membrane proteins; there may be cross-resistance to other antibacterials.

PHARMACOKINETICS:
Cefoxitin is not absorbed from the gastrointestinal tract; it is given parenterally as the sodium salt. After 1 g by intramuscular injection a peak plasma concentration of up to 30 micrograms/mL at 20 to 30 minutes has been reported whereas concentrations of 125, 72, and 25 micrograms/mL have been achieved after intravenous doses of 1 g over 3, 30, and 120 minutes respectively. Cefoxitin is about 70% bound to plasma proteins. It has a plasma half-life of 45 to 60 minutes which is prolonged in renal impairment. Cefoxitin is widely distributed in the body but there is normally little penetration into the CSF, even when the meninges are inflamed. It crosses the placenta and has been detected in breast milk. Relatively high concentrations are achieved in bile. The majority of a dose is excreted unchanged by the kidneys, up to about 2% being metabolised to descarbamylcefoxitin which is virtually inactive. Cefoxitin is excreted in the urine by glomerular filtration and tubular secretion and about 85% of a dose is recovered within 6 hours; probenecid slows this excretion. After an intramuscular dose of 1 g, peak concentrations in the urine are usually greater than 3 mg/mL. Cefoxitin is removed to some extent by haemodialysis.

INDICATION:
It is used principally in the treatment and prophylaxis of anaerobic and mixed bacterial infections, especially intra-abdominal and pelvic infections. Indications include endometritis (prophylaxis at caesarean section), pelvic inflammatory disease, and surgical infection (prophylaxis). It may also be used in the treatment of gonorrhoea and urinary tract infections.

DOSAGE & ADMINISTRATION:
Patients with Normal Kidney Function: Adults: 1-2 g IM/IV every 8 hrs; up to 12 g daily in severe infections.

Children and Older Infants: 20-40 mg/kg body weight every 6-8hrs.
Neonates 1-4 weeks: 20-40 mg/kg body weight every 8 hrs; Neonates up to 1 week: 20-40 mg/kg body weight every 12 hrs.
In severe infections up to 200 mg/kg daily to maximum of 12 g daily.
Prophylaxis: Postoperative Surgical Infections:
Adults: 2 g per IV route when inducing anesthesia, followed by injections of 1-2g every 2 hrs until the skin has closed up.
Antibioprophylaxis must be short; mostly limited to postoperation period, sometimes up to 24 hrs, but never exceeds 48 hrs.
Children and Infants: 30-40 mg/kg body weight every 6 hrs.
Neonates: 30-40mg/kg interval of 8-12hrs.
Appendectomy: A single dose is sufficient.
Uncomplicated UTI: 1 g 2 times daily for IM.
Uncomplicated Gonorrhea: Single dose of 2 g IM with probenecid 1 g by mouth.
Caesarian Section: A single 2g dose may be given IV to the mother as soon as the umbilical cord is clamped.
IV route is recommended for children.
Patients with Renal Impairment: Adults: Initial Dose: 1-2 g.

CONTRAINDICATIONS:
Patients who are hypersensitive to cefoxitin sodium or to other cephalosporins.
And patients who are allergic to penicillins.

PRECAUTIONS:
Care is also necessary in patients with known histories of allergy. Cefoxitin sodium should be given with caution to patients with renal impairment. Renal and haematological status should be monitored especially during prolonged and high dose therapy.

INTERACTIONS:

Drug

Increased nephrotoxicity has been reported following concomitant administration of cephalosporins and aminoglycoside antibiotics.

Laboratory Test

High concentrations of cefoxitin (>100 micrograms/mL) may interfere with measurement of serum and urine creatinine levels by the Jaffé reaction, and produce false increases of modest degree in the levels of creatinine reported. Serum samples from patients treated with cefoxitin should not be analyzed for creatinine if withdrawn within 2 hours of drug administration.

High concentrations of cefoxitin in the urine may interfere with measurement of urinary 17–hydroxy-corticosteroids by the Porter-Silber reaction, and produce false increases of modest degree in the levels reported.

ADVERSE REACTIONS:

Hypersensitivity reactions, including skin rashes, urticaria, eosinophilia, fever, reactions resembling serum sickness, and anaphylaxis. Acute renal tubular necrosis has followed excessive dosage and has also been associated with its use in old patients or those with preexisting renal impairment or with the concomitant administration of nephrotoxic drugs e.g., aminoglycoside antibiotics. Acute interstitial nephritis is also a possible manifestation of hypersensitivity. Convulsions and other signs of central nervous system toxicity have been associated with high doses, especially in patients with renal failure. There may be pain at the site of injection site following IM injection and thrombophlebitis has occurred following IV infusion usually of >6 g daily for >3 days.

REPORTING OF SUSPECTED ADVERSE REACTION

To allow continued monitoring of the benefit/risk balance of the medicinal product, reporting of suspected adverse reaction is necessary.

Healthcare professionals are encouraged to report any suspected adverse reactions directly to the importer/distributor and/or report to FDA: www.fda.gov.ph.

Patients are advised to seek immediate medical attention at first sign/s of adverse reactions.

OVERDOSE AND TREATMENT

In the case of overdose/aggravated symptoms; appropriate monitoring and management of the patient should be implemented.

DIRECTION FOR RECONSTITUTION:

IM: Reconstitute the solution in 2 mL of water for injection.

IV: Add 10 mL of water for injection. The solution can be administered by slow direct IV injection or through intermittent or continuous infusion.

IV Infusion: Add 10 mL of 0.9% sodium chloride for injection. The solution can be administered by slow direct IV injection or through intermittent or continuous infusion.

CAUTION:

Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.

AVAILABILITY:

USP Type II Modular Vial x 10mL (Box of 1's).

STORAGE CONDITION:

Store at temperatures not exceeding 30 °C . The dry material as well as solutions tend to darken, depending on storage conditions; product potency, however, is not adversely affected.

Manufactured by:
CSPC ZHONGNUO PHARMACEUTICAL (SHIJIAZHUANG) CO., LTD.
No. 88 Yangzi Road, Shijiazhuang Economic and Technological Development Zone, Hebei Province, China

Imported by:
SAHAR INTERNATIONAL TRADING INC.
354 Aguirre Ave., Phase III, BF Homes, Parañaque City

Distributed by:
Dynasty Pharmaceuticals
2432 Legarda Street, Sampaloc, Manila City, Metro Manila

FDA REGISTRATION NUMBER: DRP-6501

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