Approved By:

Mary Grace Adora Marzan, RPh
Regulatory Pharmacist
Biocare Lifesciences, Inc.
23 May 2023

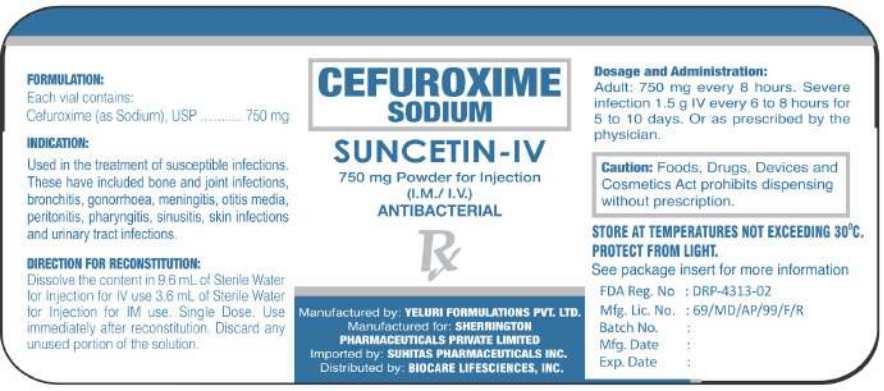
Design Size : 128 x 53 x 62 mm

Pantone Solid	
Coated	7683 C
UNCoated	2384 U
Cool Gray 4 C	
Cool Gray 4 U	
Coated	117-9 C
UNCoated	117-9 U

Approved By:

Mary Grace Adora Marzan, RPh
Regulatory Pharmacist
Biocare Lifesciences, Inc.
23 May 2023

Design Size 70 x 30 mm



PANTONE SOLID

COATED 7683 C
UNCOATED 2384 U

Cool Gray 4 C
Cool Gray 4 U

CEFUROXIME SODIUM

SUNCETIN-IV

750 mg Powder for Injection (I.M./ I.V.)

ANTIBACTERIAL

FORMULATION:

Each vial contains:

Cefuroxime (as Sodium), USP..... 750 mg

PHARMACOKINETICS:

Cefuroxime is widely distributed in the body including pleural fluid, sputum, bone, synovial fluid, and aqueous humour, but only achieves therapeutic concentrations in the CSF when the meninges are inflamed. It crosses the placenta and has been detected in breast milk. It is excreted unchanged, by glomerular filtration and renal tubular secretion, and high concentrations are achieved in the urine.

Following injection most of a dose of cefuroxime is excreted within 24 hours, the majority within 6 hours.

Probenecid competes for renal tubular secretion with cefuroxime resulting in higher and more prolonged plasma concentrations of cefuroxime. Small amounts of cefuroxime are excreted in bile. Plasma concentrations are reduced by dialysis.

INDICATIONS:

It is a second-generation cephalosporin antibiotic used in the treatment of susceptible infections. These have included bone and joint infections, bronchitis (and other lower respiratory-tract infections), gonorrhoea, meningitis, otitis media, peritonitis, pharyngitis, sinusitis, skin infections (including soft-tissue infections), and urinary tract infections. It is also used for surgical infection prophylaxis.

DRUG INTERACTION:

Probenecid reduces the renal clearance cefuroxime.

ADVERSE EFFECTS:

The most common are hypersensitivity reactions, including skin rashes, urticarial, eosinophilia, fever, reactions resembling serum sickness, and anaphylaxis.

There may be a positive response to the Coombs' test although haemolytic anaemia rarely occurs. Neutropenia and thrombocytopenia have occasionally been reported. Agranulocytosis has been associated rarely with some cephalosporins. Bleeding complications related to hypothrombinaemia and/or platelet dysfunction have occurred especially with cephalosporins and cephamycins having an N-methylthiotetrazole side-chain, including: cefamandole, cefbuperazone, cefmenoxime, cefmetazole, cefonicid, cefoperazone, ceforanide, cefotetan, cefpiramide, latamoxef.

The presence of am methylthiadiazolethiol side-chain, as in cefazolin, or an N-methylthiotriazine ring, as in ceftriaxone, might also be associated with such bleeding disorders. Hypoprothrombinaemia which is usually reversible with vitamin K, was once thought to be due to an alteration in intestinal flora but interference with prothrombin synthesis now seems more likely.

Nephrotoxicity has been reported with cefalotin although it is less toxic than cefaloridine. Acute renal tubular necrosis has followed excessive dosage and has also been associated with its use in older patients or those with pre-existing renal impairment, or when used with nephrotoxic drugs such as aminoglycosides. Acute interstitial nephritis is also a possibility as a manifestation of hypersensitivity.

Transient increases in liver enzyme values have been reported. Hepatitis and cholestatic jaundice have occurred rarely with some cephalosporins.

Convulsions and other signs of CNS toxicity have been associated with high doses, especially in patients with severe renal impairment.

Gastrointestinal adverse effects such as nausea, vomiting, and diarrhea have been reported rarely. Prolonged use may result in overgrowth of non-susceptible organisms and, as with other broad-spectrum antibiotics, pseudomembranous colitis may develop.

There may be pain at the injection site after intramuscular use, and thrombophlebitis has occurred on intravenous infusion of cephalosporins. Cefuroxime appears to be more likely to cause such local reactions than other cephalosporins.

PRECAUTIONS:
Immunological studies have suggested that up to 20% of penicillin-sensitive patients may also be allergic to cephalosporins although clinical studies indicate a lower frequency and the true incidence is uncertain;great care should be taken if cefalotin is to be given to such patients. Care is also necessary in patients with a history of allergy.
Cefuroxime should be given with caution to patients with renal impairment, dosage reduction may be necessary. Renal and haematological status should be monitored especially during prolonged and high-dose therapy. Cefuroxime and some other cephalosporins and cephamycins (ceforanide, cefotetan, cefoxitin, and cefpirome) may interfere with the Jaffe method of measuring creatinine concentrations and may produce falsely high values; this should be borne in mind when measuring renal function. Positive results to the direct Coombs' test have been found during treatment with cefuroxime and these can interfere with blood cross matching. The urine of patients being treated with cefuroxime may give false-positive reactions for glucose using copper-reduction reactions.

CONTRAINDICATIONS:
Cefuroxime should not be given to patients who are hypersensitive to it or to other cephalosporins.

DOSAGE AND ADMINISTRATION:
Cefuroxime sodium may be given by deep intramuscular injection, by slow intravenous injection over 3 to 5 minutes, or by intravenous infusion.
By injection the usual adult dose is 750 mg of cefuroxime every 8 hours but in more severe infections 1.5 g may be given intravenously every 8, or in some cases every 6 hours. Infants and children can be given to 30 to 60 mg/kg daily, increased to 100 mg/kg daily if necessary, given in 3 or 4 divided doses. Neonates may be given similar total daily doses but in 2 or 3 divided doses.
Adults with pneumonia or with acute exacerbations of chronic bronchitis may respond to sequential therapy with parenteral cefuroxime 1.5 g twice daily or 750 mg twice daily respectively, followed by oral cefuroxime 500 mg twice daily in each case.
For the treatment of meningitis due to sensitive strains of bacteria, cefuroxime is given intravenously in adult doses of 3 g every 8 hours. Infants and children are given 200 to 240 mg/kg daily intravenously in 3 or 4 divided doses, which may be decreased to 100 mg/kg daily after 3 days or when there is clinical improvement. For neonates, a dose of 100 mg/kg daily, decreased to 50 mg/kg daily when indicated, may be used.
In the treatment of gonorrhea, a single dose of 1.5 g by intramuscular injection, divided between 2 injection sites, has been used.
For surgical infection prophylaxis, the usual dose is 1.5 g of cefuroxime intravenously before the procedure; this may be supplemented by 750 mg intramuscularly every 8 hours for up to 24 to 48 hours depending upon the procedure. For total joint replacement, 1.5 g of cefuroxime powder may be mixed with the methylmethacrylate cement.

DIRECTION FOR RECONSTITUTION:
Dissolve the content in 9.6 mL of Sterile Water for Injection IV use. 3.6 mL of Sterile Water for Injection for IM use. Single Dose. Use immediately after preparation. Discard any unused portion of the solution.

AVAILABILITY:
10 mL USP Type III clear and colorless glass vial (Box of 10's)

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

STORE AT TEMPERATURES NOT EXCEEDING 30°C.

DATE OF FIRST AUTHORIZATION : OCTOBER 2019

Manufactured by:
YELURI FORMULATIONS PVT. LTD.
Sy. No. 296/7/6, I.D.A. Bollaram,
Medak District, Telangana, India

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