# 82x170

# \*Cefuroxime Injection IP 1.5 gm

#### Composition:

Each vial contains : Cefuroxime Sodium (Sterile) I.P eq. to Anhydrous Cefuroxime 1.5 gm

#### DESCRIPTION

Cefuroxime is used in the treatment of infections caused by bacteria. It works by killing bacteria or preventing their growth. This medicine is available only with your doctor's prescription.

#### PHARMACOLOGICAL INFORMATION

Pharmacodynamics

#### Mechanism Of Action -

Cefuroxime is a well characterised and effective antibacterial agent which has bactericidal activity against a wide range of common pathogens, including -lactamase producing strains. Cefuroxime has good stability to bacterial -lactamase, and consequently is active against many ampicillin-resistant or amoxicillin-resistant strains.

The bactericidal action of cefuroxime results from inhibition of cell wall synthesis by binding to essential target proteins.

#### Pharmacokinetics

After intramuscular (IM) injection of a 750-mg dose of cefuroxime to normal volunteers, the mean peak serum concentration was 27 mcg/ml. The peak occurred at approximately 45 minutes (range, 15 to 60 minutes). Following IV doses of 750 mg and 1.5 g, serum concentrations were approximately 50 and 100 mcg/ml., respectively, at 15 minutes. Therapeutic serum concentrations of approximately 2 mcg/ml. or more were maintained for 5.3 hours and 8 hours or more, respectively. There was no evidence of accumulation of cefuroxime in the serum following IV administration of 1.5-g doses every 8 hours to normal volunteers. The serum half-life after either IM or IV injections is approximately 80 minutes.

Approximately 89% of a dose of cefuroxime is excreted by the kidneys over an 8-hour period, resulting in high urinary concentrations.

#### Microbiology

Cefuroxime has in vitro activity against a wide range of gram-positive and gram-negative organisms, and it is highly stable in the presence of beta-lactamases of certain gram-negative bacteria. The bactericidal action of cefuroxime results from inhibition of cell-wall synthesis.

# Indication And Usage

Moderate to severe infections, including those of skin, bone, joints, urinary or respiratory tract, gynecologic infections, and septicemia. It is prescribed in the treatment of lower respiratory tract, urinary tract, skin, and gonococcal infections; bacterial septicemia; and meningitis and for the prevention of postoperative infections.

# DOSAGE AND ADMINISTRATION

# Adult dose

The usual adult dosage range for Cefrox is 750 mg to 1.5 grams every 8 hours, usually for 5 to 10 days. In uncomplicated urinary tract infections, skin and skin-structure infections, disseminated gonococcal infections, and uncomplicated pneumonia, a 750-mg dose every 8 hours is recommended. In severe or complicated infections, a 1.5-gram dose every 8 hours is recommended.

For preventive use during open heart surgery, a 1.5-gram dose administered intravenously at the induction of anesthesia and every 12 hours thereafter for a total of 6 grams is recommended.

# ADMINISTRATION

#### Intramuscular

Add 1ml Water for Injections to Cefuroxime Sodium for Injection 250mg or 3ml Water for Injections to Cefuroxime Sodium for Injection 750mg. Shake gently to produce an opaque suspension.

#### Intravenous

Dissolve Cefuroxime Sodium for Injection in Water for Injections using at least 2ml for 750mg or 15ml for 1.5n

#### Intravenous infusion

For short intravenous infusion (e.g. up to 30 minutes). Cefuroxime Sodium for injection 1.5g may be dissolved in 50-100ml Water for Injections. These solutions may be given directly into the vein or introduced into the tubing of the giving set if the patient is receiving parenteral fluids.

Before you administer Cefuroxime, look at the solution closely. It should be clear and free of floating material. Gently squeeze the bag or observe the solution container to make sure there are no leaks. Do not use the solution if it is discolored, if it contains particles, or if the bag or container leaks. Use a new solution, but show the damaged one to your health care provider.

It is important that you use your medication exactly as directed. Do not stop your therapy on your own for any reason because your infection could worsen and result in hospitalization. Do not change your dosing schedule without talking to your health care provider. Your health care provider may tell you to stop your infusion if you have a mechanical problem (such as a blockage in the tubing, needle, or catheter); if you have to stop an infusion, call your health care provider immediately so your therapy can continue.

#### ISES

Cefuroxime is an antibiotic used to treat a wide variety of bacterial infections. It may also be used before and during certain surgeries to help prevent infection. This medication is known as a cephalosporin antibiotic. It works by stopping the growth of bacteria.

This antibiotic treats only bacterial infections. It will not work for viral infections (e.g., common cold, flu). Unnecessary use or misuse of any antibiotic can lead to its decreased effectiveness.

# CONTRAINDICATION

Cefuroxime Injection IP is contraindicated in patients with known allergy to the cephalosporin group of antibiotics.

#### PRECAUTIONS

Before administering Cefuroxime, tell your doctor and pharmacist -

- If you are allergic to Cefuroxime, any other cephalosporin [e.g., cefaclor (Ceclor), cefadroxil (Duricef), or cephalexin (Keflex)), penicillins, or any other drugs.
- What prescription and nonprescription medications you are taking, especially other probenecid (Benemid), and vitamins.
- If you have or have ever had kidney, liver, or gastrointestinal disease (especially colitis).
- If you are pregnant, plan to become pregnant, or are breast-feeding. If you become pregnant while taking Cefuroxime, call your doctor.
- If you have diabetes and regularly check your urine for sugar, use Clinistix or TesTape. Do not use Clinitest tablets because Cefuroxime may cause false positive results.

# ADVERSE REACTIONS

Swelling, redness, pain, or soreness at the injection site may occur. This medication may also infrequently cause loss of appetite, nausea, vomiting, upset stomach or diarrhea, irritability, or headache.

#### OVERDOSAGE

Overdosage of cephalosporins can cause cerebral irritation leading to convulsions. Serum levels of Cefuroxime can be reduced by hemodialysis and peritoneal dialysis.

Storage: Store below 30°C. Protect from moisture. Do not freeze.

Marketed by:

Windlas
Windlas Biotech Limited
(A WHO GMP Certified Company)
40/1, Mohabewala Industrial Area,

Manufactured by: Protech Telelinks (A WHO GMP Certified Co.) Mauza Ogli, Suketi Road, Kala Amb, Distt. Sirmour-173030 (H.P.) INDIA