CEFORAN

Vials (For IV and IM injection)

Broad Spectrum Antibiotic

(Third-Generation Cephalosporin)

COMPOSITION :

Each vial contains :

Cefotaxime sodium equivalent to 0.5 or 1 g cefotaxime.

PROPERTIES

Ceforan (cefotaxime) is a broad spectrum antibiotic belonging to the third-generation cephalosporins. **Ceforan** possesses potent bactericidal activity against a wide range of Gram-positive and Gram-negative bacteria, including ß-lactamase-producing strains. **Ceforan** irreversibly inhibits bacterial cell wall synthesis resulting in rapid and complete eradication of sensitive bacteria. *In vitro* studies revealed that **Ceforan** has a broader spectrum and increased potency against Gram-negative bacteria compared to the first- and second-generation cephalosporins, most penicillins and aminoglycosides. Clinical experience has confirmed this extended spectrum of **Ceforan** and evidenced its marked curative effects on bacterial diseases particularly those caused by Gram-negative strains with multiple resistance to other antibiotics. This high clinical efficacy, besides documented safety and excellent tolerability make **Ceforan** the medication of choice whenever a parenteral antibiotic with broader spectrum of activity is indicated.

PHARMACOKINETICS

Peak plasma concentrations are achieved within 30 minutes after IM and 5 minutes of IV administration of **Ceforan**. About 40% of the drug is bound to plasma proteins. Cefotaxime is partially metabolized in the liver giving rise to the active metabolite, desacetylcefotaxime and some other inactive metabolites. Cefotaxime and its active metabolite are widely distributed into most body fluids and tissues reaching concentrations higher than the minimum inhibitory concentrations (MICs) of susceptible bacteria. Effective penetration into the CSF occurs with meningeal inflammation. Plasma half-life of cefotaxime is about 1 hour and that of desacetylcefotaxime is about 1.5 hours. Forty to sixty percent of the drug is excreted unchanged in the urine and 20 % as the desacetyl derivative. The remaining part is excreted in the feces.

ANTIMICROBIAL SPECTRUM

Ceforan is highly active against a wide range of pathogenic ß-lactamase- and non-ß-lactamase-producing organisms:

Gram-positive bacteria :

Aerobes: Staphylococcus aureus, Staph. epidermidis, Streptococcus pyogenes (group A beta-hemolytic streptococci), S. agalactiae (group B streptococci) and S. pneumoniae.

Anaerobes: Clostridium, Peptococcus and Peptostreptococcus species.

Gram-negative bacteria :

Aerobes: Haemophilus influenzae, H. parainfluenzae, Neisseria gonorrhoeae, N. meningitidis, Escherichia coli, Proteus mirabilis, P. vulgaris, Morganella morganii, Providencia rettgeri, Klebsiella, Citrobacter, Enterobacter, Serratia and Acinetobacter species and some Pseudomonas strains.

Anaerobes : Bacteroides and Fusobacterium species.

INDICATIONS

Ceforan is indicated for treatment of severe and moderately severe infections caused by cefotaxime-susceptible bacteria :

- **Lower respiratory tract infections :** severe bronchitis, pneumonia, bronchopneumonia, bronchiectasis, lung abscess and empyema.
- **CNS infections :** meningitis, ventriculitis and brain abscess.
- **Bone and joint infections :** osteomyelitis, bone abscess and septic arthritis.
- **Urinary tract infections:** pyelonephritis, cystitis and urethritis.
- **Gynecologic and obstetric infections :** oophoritis, salpingo-oophoritis, pelvic abscess and cellulitis, endometritis, puerperal sepsis and septic abortion .
- **Male genital tract infections :** prostatitis, orchitis and epididymo-orchitis.
- **Venereal diseases:** gonorrhea and chancroid.
- **Skin and soft tissue infections :** cellulitis , abscesses , pyoderma , infected burns , traumatic and postoperative wounds.
- **ENT infections :** otitis media, tonsillitis and sinusitis.

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- **Miscellaneous infections :** cholecystitis , cholangitis , bacteremia , septicemia , bacterial endocarditis and peritonitis.
- **Perioperative prophylaxis.**

CONTRAINDICATIONS

Hypersensitivity to cephalosporins.

SIDE EFFECTS

Ceforan is safe and well tolerated. Mild nausea, diarrhea, skin rash and urticaria may rarely occur. Transient elevation of serum transaminases and transient leucopenia may occur during therapy.

PRECAUTIONS

As with other antibiotics, the drug should not be used during the first trimester of pregnancy unless strictly indicated. Penicillin-hypersensitive patients may be also hypersensitive to cephalosporins (cross-sensitivity). Treatment should be stopped if allergic reaction occurs. Recommended doses should not be exceeded as convulsions might occur with very large doses.

Emergency measures in anaphylactic shock :

I - If anaphylaxis occurs, interrupt the injection immediately but leave the venous cannula in place or perform venous cannulation. In addition to the usual emergency measures, ensure that the patient is kept flat with the legs raised and airways patent. Artificial respiration and oxygen inhalation might be required.

II - Drug therapy :

A- Immediate IV epinephrine (adrenaline) : dilute 1 ml of commercially available epinephrine solution (1:1000) to 10 ml. In the first instance, slowly inject 1 ml of this diluted solution (equivalent to 0.1 mg epinephrine) while monitoring pulse and blood pressure (watch for disturbances of cardiac rhythm). The administration of epinephrine may be repeated.

B - Then IV glucocorticoid , e.g. 250 - 1000 mg methylprednisolone is given . The glucocorticoid administration may be repeated.

C - IV volume substitution by plasma expanders , human albumin or balanced electrolyte solution.

D - Calcium and antihistamincs.

INTERFERENCE WITH LABORATORY TESTS

False positive results may be obtained for urinary glucose if it is determined by reduction methods; this can be avoided by using enzymatic methods. The direct Coombs' test may give positive results in patients on cephalosporin treatment.

DOSAGE

The dose of **Ceforan** and route of administration (IV or IM) depend on the age of the patient , severity of infection and renal function. IV injection should be given slowly over 3-5 minutes. Unless otherwise prescribed by the physician the following doses are recommended :

- **Neonates (up to 7 days) :** 100 mg / kg / day , in equally divided doses every 12 hours.
- **Neonates (7 days to 1 month) :** 150 mg/kg/ day, in equally divided doses every 8 hours.
- **Infants and children (up to 12 years) :** 150 - 200 mg / kg/ day , in equally divided doses every 6 - 8 hours.
- **In bacterial meningitis (for neonates, infants and children):** 200 mg/kg/day, in equally divided doses every 6 hours.
- **Adults :** 2 g / day , in equally divided doses every 12 hours . **Severe infections :** up to 12 g / day in equally divided doses every 6-8 hours.
- **Uncomplicated gonorrhea :** a single dose of 1 g (IM).
- **For perioperative prophylaxis :** a single dose of 1 - 2 g , 1 hour before surgery , to be repeated, if necessary, 12 hours later.

N.B.

- In patients with renal impairment, the dose should be adjusted according to creatinine clearance.
- Reconstituted solutions should be used immediately or within 24 hours if kept at or below 22 °C.

PACKING :

A box containing 1 vial (powder equivalent to 0.5 or 1g cefotaxime)

STORAGE :

Keep at room temperature not exceeding 30°C away from light.
Keep out of the reach of children.

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