Cetafor®

ceftriaxone

BROAD SPECTRUM BACTERICIDAL ANTIBIOTIC
CETAFOR® 500 MG / CETAFOR® 1000 MG
Intramuscular / Intravenous

Do not waste time, rely on Cetafor®

Lower respiratory infections - Meningitis - Bacterial sepsis - Urinary tract infections - Intra-abdominal infections - Pelvic inflammatory disease - Uncomplicated gonorrhea - Cutaneous structure and skin infections - Bone and joint infections - Pre-operative prophylaxis

Age group	Normal Dosage	Frequency
Children 2 weeks - 12 years of age and weighing <50 kg	50 to 75 mg/kg Maximum: 4 g	Once a day
Adolescents more than 12 years and less than 17 years of age, weighing > 50 kg	1 to 2 g - maximum: 4 g	Once a day
Adolescents > 17 years	1 to 2 g - maximum: 4 g	Once a day
Adults	1 to 2 g - maximum: 4 g	Once a day

DAFRA PHARMA INTERNATIONAL

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Dafra PHARMA

Setting the Standard

www.dafrapharma.com

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EUROPEAN GMP

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PRESENTATION

Sterile powder and solvent for intravenous and intramuscular injectable preparation:

CETAFOR® 500 IV: Ceftriaxone 500mg + water for injection 5 ml
CETAFOR® 1000 IV: Ceftriaxone 1000mg + water for injection 10ml
CETAFOR® 1000 IM: Ceftriaxone 1000 mg + 4 ml lidocaine hydrochloride 1 %

INDICATIONS

CETAFOR® is suitable for treating severe infections caused by germs susceptible to ceftriaxone such as:

- ✓ Respiratory infections
- ✓ Abdominal infections (peritonitis and gastrointestinal tract infections)
- ✓ Renal and urinary tract infections
- ✓ Infections of the genitals, including gonorrhea
- ✓ Sepsis
- ✓ Infections of bones, joints and soft tissues
- ✓ Meningitis
- ✓ Pre-operative prophylaxis in the case of surgery of gastrointestinal tract, bile duct, genitourinary system

The recommendations for correct use of antibiotics should strictly be followed.

DOSAGE

The normal duration of treatment depends on the characteristics of the infection. Generally, administration of ceftriaxone must be continued for at least 48 to 72 hours after the body temperature drops down to normal and after obtaining a proof that the bacteria have been eradicated.

Age group	Normal Dosage	Frequency
Children 2 weeks - 12 years of age and weighing <50 kg	50 to 75 mg/kg maximum: 4 g	Once a day
Adolescents more than 12 years and less than 17 years of age, weighing ≥ 50 kg	1 to 2 g - maximum: 4 g	Once a day
Adolescents ≥ 17 years	1 to 2 g - maximum: 4 g	Once a day
Adults	1 à 2 g maximum : 4 g	Once a day

CONTRAINDICATIONS

- Known hypersensitivity to antibiotics of cephalosporin group.
- Not advised in newborns.
- In case of parenteral calcium treatment because of the risk of fatal lesions to the kidney and the lung following the precipitation of calcium salts of ceftriaxone.

WARNINGS AND PRECAUTIONS

Ceftriaxone may extend the thromboplastin time. During prolonged treatment, the complete blood count should be monitored at regular intervals. CETAFOR® should be used with caution in people with renal deficiencies treated simultaneously with aminosides or diuretics. Ceftriaxone should neither be mixed nor administered simultaneously with solutions containing calcium ions, nor when the solutions are administered at different injection or perfusion sites.

PREGNANCY AND LACTATION

There are no adequate and well-controlled studies in pregnant women. Therefore, Ceftriaxone should be used during pregnancy only if clearly needed. Ceftriaxone is excreted into breast milk in low concentrations. Caution should be exercised when CETAFOR® is administered to nursing women.

COMMON SIDE EFFECTS

CETAFOR® is generally well tolerated. The most common side effects are inflammation, pain or hardness, experienced at the site of intramuscular and intravenous injection immediately after administration; systemic adverse reactions include diarrhoea, nausea, vomiting, pruritus, rash, eosinophilia, leucopenia, and thrombocytosis. Other rarely observed adverse reactions include headache, dizziness, transient elevations in liver function tests, increase in serum creatinine and mycosis of the genital tract. These side effects usually disappear after discontinuing drug therapy. IN CASE OF AN UNEXPECTED SIDE EFFECT, CONSULT YOUR PHYSICIAN.

ACTION MECHANISM AND PHARMACODYNAMICS

The bactericidal ability of ceftriaxone is a result of inhibition of cell wall synthesis of the bacteria. Ceftriaxone possesses in vitro a broad spectrum of action against Gram-negative and Gram positive microorganisms. Ceftriaxone remains stable to a very large extent with respect to most of the lactamases - penicillinases as much as cephalosporinases - produced by Gram positive and Gram negative bacteria.

PHARMACOKINETICS

Ceftriaxone shows nonlinear kinetics. All pharmacokinetic parameters, with the exception of elimination half - life, are dose dependent when considering the total concentration (free ceftriaxone and ceftriaxone bound to proteins). The bioavailability of ceftriaxone administered intramuscularly or intravenously is 100%.

Metabolism

Ceftriaxone is not metabolized by the organism as such; it is only after it has been excreted with the bile in the intestinal lumen that it is transformed into inactive metabolites by the intestinal flora.

Elimination

The plasma clearance is 10-22 ml/min. The renal clearance is 5-12 ml/min. Ceftriaxone is excreted unchanged at the rate of 50-60 % through the kidneys and 40-50% with the bile. The plasma half -life in adults is about 8 hours.

INSTRUCTIONS FOR HANDLING

The reconstituted solutions should be used immediately after preparation. Depending on the concentration, the color of the solution varies from pale yellow to amber. This property of the active ingredient is not important from the point of view of efficacy or tolerance.

Intramuscular injection

For IM injection, dissolve the ceftriaxone powder in 1% lidocaine hydrochloride solution and inject deeply into a relatively large muscular area. It is recommended not to inject more than 1 g at the same site.

THE SOLUTION CONTAINING LIDOCAINE SHOULD NEVER BE INJECTED INTRAVENOUSLY.

Intravenous injection

For IV injection, dissolve the ceftriaxone powder in water for injection preparations. The intravenous injection should be administered over 2 to 4 minutes.

Intravenous infusion

Concentrations between 10 mg/ml and 40 mg/ml are recommended. Cetafor® g IV should be dissolved in one of the following solutions: 0.9 % sodium chloride; 5 % dextrose; 10 % dextrose; 5 % dextrose + 0.9 % sodium chloride; 5 % dextrose + 0.45 % sodium chloride. All these solutions should be administered immediately after reconstitution.

SHELF-LIFE

Shelf-life = 3 years

Store below 30°C, in the original package, protected from light. Keep out of reach and sight of children. Do not use after the expiry date, stated on the packaging (Exp.). The expiry date refers to the last day of that month.

For the full SMPC, please visit www.dafrapharma.com