CEFOMAXX
Instructions
on medical use of the drug

Tradename: Cefomaxx.
INN: Ceftriaxone + sulbactam.
Dosage form: Powder for the preparation of a solution for intravenous and intramuscular administration.
Compound: *One bottle contains:*
Sterile Ceftriaxone sodium USP eq. ceftriaxone 1000 mg;
Sterile Sulbactam Sodium USP eq. sulbactam 500 mg.
Pharmacotherapeutic group: Antibiotic, third generation cephalosporin with beta- lactamase inhibitor.

Pharmacological properties:

Pharmacodynamics:

The drug is a combination of sulbactam sodium and ceftriaxone sodium.
Ceftriaxone is a semisynthetic broad-spectrum cephalosporin antibiotic for intravenous (IV) and intramuscular (IM) administration.
Ceftriaxone has a wide spectrum of action: it is active against aerobic gram-positive microorganisms: facultative anaerobes - Staphylococcus aureus (including penicillinase-forming strains), Staphylococcus epidermidis, Streptococcus pneumoniae , group A b-hemolytic streptococci (S.pyogenes), group B streptococci (S.agalactiae), Streptococcus viridans , Streptococcus bovis , non-enterococcal group D streptococci; gram-negative microorganisms: Escherichia coli, Haemophilus influenzae, H. p arainfluenzae, Klebsiella species (including Kb . pneumoniae), Morganella morganii, Proteus mirabilis , Proteus vulgaris, Providencia , Salmonella (including S.typhy), Serratia spp . (including S.marcescens), Shigella, Versinia (including Y.enterocolitica); microaerophiles – Treponema pallidum; Aerobes - Neisseria gonorrheae (including penicillinase-producing strain), Neisseria meningitides, Pseudomonas aeruginosa; obligate anaerobes - varieties of bacteroides (including some strains of B. Fragilis), Clostridium (but most strains of C. difficile are resistant), Peptococcus, Peptostreptococcus, Fusobacterium (including F. mortiferum and F. varium).

Sulbactam is a derivative of the main penicillin core.
Sulbactam does not have clinically significant antibacterial activity. Studies have shown that it is an irreversible inhibitor of most major β- lactamases, which are produced by microorganisms resistant to β- lactam antibiotics.
Sulbactam binds to certain penicillin-binding proteins, so the ceftriaxone / sulbactam combination often has a greater effect on susceptible strains than ceftriaxone alone.

Pharmacokinetics :
After intramuscular administration of the drug, the maximum concentration (Cmax) of ceftriaxone and sulbactam in plasma is determined between 15 minutes and 2 hours. Cmax in plasma of ceftriaxone after a single IM dose of 1.0 g is approximately 81 mg/l and is determined within 2-3 hours after dosing, while the concentration of sulbactam sodium is 6-24 mg/ml and is determined within 1 hour after dosing.
When administered intravenously at the recommended dose, ceftriaxone distributes well into the tissues of the body's organs. Bactericidal concentrations are maintained for 24 hours. Ceftriaxone binds reversibly to albumin, and binding decreases with increasing concentration, for example, from 95% binding at plasma concentrations <100 mg/L to 85% binding at 300 mg/L. Due to the low albumin content, the proportion of free ceftriaxone in tissue fluid is correspondingly higher than in plasma. The volume of distribution (Vd) of ceftriaxone sodium is 7-12 L and that of sulbactam is -18-27.6 L. Both are widely distributed in the amniotic fluid. It is also detected in milk. In young and healthy adult volunteers, the plasma clearance rate is 10-22 ml/min. Hepatic clearance is 5-12 ml/min. Approximately 75-85% sulbactam and 50-80% of ceftriaxone are excreted unchanged by the kidneys, while the remainder of the dose is excreted in the bile.
The mean plasma half-life of ceftriaxone is 8 hours in healthy, young, adult volunteers. In neonates, urinary recovery is estimated to be approximately 70% of the dose. In children and elderly people over 75 years of age, the average half-life usually increases 2-3 times more than in a group of young healthy people. The average plasma half-life of sulbactam is approximately 1 hour.

Hemodialysis alters half-life, total body excretion and Vd sulbactam.
Studies conducted in pediatrics did not show significant changes in the pharmacokinetics of the components of ceftriaxone when administered in combination form.

Indications for use:

- infections of the upper and lower respiratory tract;
- acute bacterial otitis; - skin and soft tissue infections; - urinary tract infections (complicated and uncomplicated); - pelvic organ infections; - bacterial sepsis; - bone and joint infections; - gastrointestinal tract infections; - meningitis;
- Lyme disease;
- sexually transmitted infections;
- secondary infections in cancer patients and patients with reduced immunity;
- prevention of postoperative infections.

Preoperative use of the drug may reduce the incidence of postoperative infections in patients undergoing surgical procedures.

Mode of application:

Ceftriaxone + sulbactam can be administered intravenously or intramuscularly after dissolution in sterile water for injection. It is recommended to use the solution immediately after dissolution. The duration of treatment depends on the severity of the disease and is determined by the doctor individually.

Adults and children over 12 years old - 1-2 g (calculated as ceftriaxone) 1 time per day or 0.5 - 1 g every 12 hours, the daily dose should not exceed 4 g.

For gonorrhea – intramuscularly , once, 250 mg.

For the prevention of postoperative complications - once, 1-2 g 30 - 90 minutes before the start of surgery.

For newborns (up to 2 weeks) - 20-50 mg/kg per day.

For infants and children under 12 years of age, the daily dose is 20-80 mg/kg. In children weighing 50 kg and above, adult doses are used.

For bacterial meningitis in infants and young children - 100 mg/kg (but not more than 4 g) 1 time per day. The duration of treatment depends on the pathogen and can range from 4 days for Neisseria meningitidis, up to 10-14 days for susceptible Enterobacteriaceae strains.

For children with skin and soft tissue infections - a daily dose of 50-75 mg/kg once a day or 25-37.5 mg/kg every 12 hours, not more than 2 g per day.

For severe infections of other localizations - 25-37.5 mg/kg every 12 hours, no more than 2 g per day.

For otitis media - intramuscularly, once, 50 mg/kg, no more than 1 g.

In patients with chronic renal failure, dose adjustment is required only when CC is below 10 ml/min. In this case, the daily dose should not exceed 2 g.

Contraindications:

- patients with allergic reactions to sulbactam and ceftriaxone , as well as to cephalosporins and penicillins;
- for hyperbilirubinemia in newborns and premature infants;
- renal and/or liver failure;
- nonspecific ulcerative colitis, enteritis or colitis associated with the use of antibacterial drugs;
- pregnancy and lactation period;

Pregnancy and lactation:

The use of the drug during pregnancy is possible only if the expected benefit to the mother outweighs the potential risk to the fetus. If it is necessary to prescribe the drug during lactation, breastfeeding should be stopped.

Release form:

Powder for intravenous and intramuscular administration, 1.5 g in bottles. One bottle along with instructions for use in a cardboard box.

Special storage conditions:

See the expiration date on the packaging.
Do not use after expiration date.

Vacation conditions:

On prescription.

Made for:
MAXX-PHARM LTD.
London, Great Britain