CEFOMIX
Instructions
by medical use medicinal facilities

Trade name drug: Cefomyx.
International generic name: Cefotaxime.
Medicinal form: powder for preparations solution for intravenous and intramuscular introduction.
Ingredients: *active substance:*
cefotaxime sodium V recalculation on cefotaxime 1.0 g.
Description: powder from white before yellow color.
Pharmacotherapeutic _ group: 3rd generation cephalosporin antibiotic.
Code ATX: [J 01 DD 01].
Pharmacological action:
Pharmacodynamics :
Cephalosporin antibiotic 3rd generations for parenteral administration. Valid bactericidal, violating cell synthesis walls microorganisms. Possesses wide spectrum actions. Active against gram-positive and gram-negative microorganisms, resistant to etc. antibiotics: Staphylococcus spp. (V incl. Staphylococcus aureus (including strains, forming penicillinase) and Staphylococcus epidermidis (behind except Staphylococcus epidermidis and Staphylococcus aureus, sustainable to methicillin)), Streptococcus pneumoniae, Streptococcus pyogenes, Streptococcus agalactiae, Enterococcus spp., Enthisbact g spp., Escherichia coli, Haemophilus influenzae (including penicillinase- producing strains), Haemophilus parainfluenzae, Moraxella catarrhalis, Klebsiella spp. (including Klebsiella pneumoniae), Morganella morganii, Neisseria gopoghoae (including penicillinase -producing strains), Acinetobacter spp., Coryne - bacterium diphtheriae, Erysipelothrix rhusiopathiae, Eubacter spp ., Propionibacterium spp ., Clostridium spp. (including Clostridium perfringens), Citrobacter spp., Proteus mirabilis, Proteus vulgaris, Providencia spp. (including Providencia rettgeri), Serratia spp., some strains Pseudomonas aeruginosa, Neisseria meningitis, Bacteroides spp. (V incl. some strains Bacteroides fragilis), Fusobacterium spp. (V incl. Fusobacterium nucleatum), Peptococcus spp., Peptostreptococcus spp.
Majority Clostridium strains difficile – stable.
Resistant to beta- lactamase gram-positive and gram-negative microorganisms.
Pharmacokinetics:
After one-time intravenous introduction V doses 1 - 2 g maximum concentration in blood plasma (Cmax) is determined In 5 min and is 39 μg/ml, 101.7 μg/ml and 214 μg/ml, respectively. After intramuscular injection of the drug into doses and 1 g Cmax is determined through 30 minutes and is 11 μg/ml and 21 μg/ml, respectively. Communication with blood plasma proteins is 30-50%. Bioavailability 90-95%.
Creates therapeutic concentrations V most fabrics (myocardium, bones, gall bubble, leather, soft fabrics) And body fluids (synovial, pericardial, pleural, spinal liquid, sputum, bile, urine). Volume distribution - 0.25-0.39 l/kg.
The half-life (T 1/2) is 1 hour with intravenous administration and 1-1.5 hours with intramuscular administration. Excreted by the kidneys 20-36% V unchanged form, rest quantity -V form metabolites (15 - 25% - V form pharmacologically active deacetyl - cefotaxime and 20-25% - in the form of 2 inactive metabolites.
For chronic renal failure (CRF) and in the elderly T 1/2 increases by 2 times. T1/2 in newborns is 0.75-1.5 hours, in premature newborns (body weight less than 1500 g) it increases to 4.6 hours; in children with body weight more than 1500 g – 3.4 hours. At repeated intravenous injections at a dose of 1 g every 6 hours for 14 days, no accumulation is observed. Penetrates into the chest milk passes through placental barrier.
Indications for use:
- respiratory tract infections (bacterial pneumonia);
- ENT infections;
- infections of the genitourinary system (including gonorrhea);
- septicemia, bacteremia;
- bacterial endocarditis;
- central nervous system infections (acute bacterial meningitis);
- infections of bones, joints;
- infected wounds and burns;
- salmonellosis;
- Lyme disease;
- infections due to immunodeficiency;
- skin and soft tissue infections;
- abdominal infections (including peritonitis);
- prevention of complications after surgical operations on the gastrointestinal tract, urological, obstetric and gynecological operations;
- sexually transmitted infections.

Contraindications:
- hypersensitivity to cefotaxime and other cephalosporins;
- intracardiac blockade without established driver rhythm;
- heavy cardiac insufficiency;
- pregnancy and lactation period.

Carefully. Newborn period; chronic renal failure; ulcerative colitis (including history); in patients with hypersensitivity to history of penicillins due to the possibility of developing cross-allergic reactions.
Use during pregnancy and breastfeeding: Application drug during pregnancy is possible in cases where the expected benefit for mother exceeds the potential risk to the fetus. If it is necessary to prescribe the drug during lactation, breastfeeding should be stopped during use drug.
Way applications and doses: The drug is administered intravenously (stream or drip) or intramuscularly. Dosage, route of administration and interval between administrations depend on the severity of the infection, the sensitivity of the microorganism that caused the disease and the condition of the patient.

No	Age and disease	Dose
1	Adults with normal kidney function with uncomplicated acute gonorrhea	0.5 – 1 g once
2	For uncomplicated moderate infections	In a single dose of 1-2 g with an interval of 8-12 hours; daily dose is 2-6 g
3	For severe infections	In a single dose of 2 g, the interval between administrations is 6-8 hours; daily dose 6-8 g
4	Adults with severe renal impairment (creatinine clearance 10 ml/min or less)	The single dose is reduced by 2 times, the interval between administrations is not changed, while the daily dose is also reduced by 2 times
5	Premature babies up to 1 week of life	50 – 100 mg/kg, (every 12 hours) divided into 2 injections
6	Premature babies 1-4 weeks of life	75 - 150 mg/kg, administered in single doses at intervals of 6-8 hours
7	Children weighing up to 50 kg	50-100 mg/kg, administered in single doses at intervals of 6-8 hours
8	Children weighing more than 50 kg	The drug is prescribed in the same dose as for adults

Duration treatment install individually.
WITH purpose prevention development infections before surgical operation introduce during induction of general anesthesia, 1 g once. If necessary, the administration is repeated after 6-12 hours.
For caesarean section - at the moment of applying clamps to the umbilical vein - 1 g intravenously, then 6 and 12 hours after the first dose - an additional 1 g.
When creatinine clearance (CC) is 20 ml/min/1.73 m2 or less, the daily dose is reduced by 2 times.
Rules for preparing injection solutions: for intravenous injections use water for injection as a solvent (0.5 - 1 g diluted in 4 ml of solvent, 2 g - in 10 ml), the drug is administered slowly over 3 - 5 minutes; for intravenous infusion, 0.9% sodium chloride solution or 5% dextrose solution is used as a solvent (1 - 2 g diluted in 50 - 100 ml of solvent;) infusion duration - 50 - 60 minutes; for intramuscular administration, use water for injection or 1% lidocaine solution (for a dose of the drug - 2 ml, for a dose of 1 g - 4 ml).

Side effect:

Allergic reactions: urticaria, chills or fever, rash, itching, rarely - bronchospasm, eosinophilia, erythema malignant exudative (Stevens -Johnson syndrome), toxic epidermal necrolysis (Lyell's syndrome), angioedema, rarely anaphylactic shock.
From the cardiovascular system: potentially life-threatening arrhythmias after rapid bolus administration into the central vein.
From the central nervous system: headache, dizziness.
From the gastrointestinal tract: nausea, vomiting, diarrhea or constipation, flatulence, abdominal pain, dysbiosis, liver dysfunction, rarely - stomatitis, glossitis, pseudomembranous enterocolitis.
From the urinary system: impaired renal function, oliguria, interstitial nephritis.
From the hematopoietic organs: hemolytic anemia, leukopenia, neutropenia, granulocytopenia, thrombocytopenia, hypocoagulation.
Laboratory indicators: azotemia, increased urea concentration in the blood, increased activity of "liver" transaminases and alkaline phosphatase, hypercreatininemia, hyperbilirubinemia, positive Coombs test .
Local reactions: phlebitis, pain along the vein, pain and infiltration at the site of intramuscular injection.
Other: superinfection (in particular, candidal vaginitis).

Overdose:

Symptoms: convulsions, encephalopathy (in case of large doses, especially in patients with renal failure), tremor, neuromuscular irritability.
Treatment: symptomatic, there is no specific antidote.

Interaction with other drugs:

Increases the risk of bleeding when combined with antiplatelet agents and non-steroidal anti-inflammatory drugs.
The likelihood of kidney damage increases when taken simultaneously with amino glycosides, polymyxin B and loop diuretics.
Drugs that block tubular secretion increase plasma concentrations of cefotaxime and slow down its elimination.
Pharmaceutically incompatible with solutions of other antibiotics in the same syringe.

Special instructions:

In the first weeks of treatment, pseudomembranous colitis may occur, manifested by severe, prolonged diarrhea. In this case, stop taking the drug and prescribe adequate therapy, including vancomycin or metronidazole.
Patients with a history of allergic reactions to penicillins may have increased sensitivity to cephalosporin antibiotics.
When treating with the drug for more than 10 days, monitoring of the peripheral blood picture is necessary.

During treatment with cefotaxime, it is possible to obtain a false-positive Coombs test and a false-positive urine test for glucose.
During treatment, ethanol should not be consumed due to the possibility of disulfiram-like reactions (facial hyperemia, spasms in the abdomen and stomach, nausea, vomiting, headache, decreased blood pressure, tachycardia, shortness of breath).

Release form:
Powder for the preparation of a solution for intravenous and intramuscular administration 1.0 g.
The package contains bottle No 1.
Storage conditions:
In a place protected from light at a temperature not exceeding 25 ° C.
Keep out of the reach of children.
Best before date:
3 years.
Do not use after expiration date.
Conditions for dispensing from pharmacies:
On prescription.

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