CLAVOCEF

Instructions

on medical use of medicinalfacilities

Tradename: ClavoCef.
International nonproprietary name: Cefixime + lactobacilli.
Dosage form: Dispersible tablets, for oral administration.
Composition: *Each dispersible tablet contains:*
Active substances:
Cefixima trihydrate equivalent to cefixime ……. ……..…400 mg;
Lactobacilli (Lactic Acid Bacillus) …….……2.5 billion spores;
Excipients: microcrystalline cellulose, magnesium stearate, purified talc, anhydrous colloidal silicon dioxide, crospovidone, aspartame, sodium lauryl sulfate, orange flavor.
Pharmaco -therapeutic group: Third generation cephalosporin antibiotic.
ATX code: J 01 DA 23.
Pharmacological properties:
Pharmacodynamics:
Cefixime is a semisynthetic antibiotic of the third generation cephalosporin group. The drug has a wide spectrum of bactericidal action, effective against most gram-positive and gram-negative microorganisms that are resistant to other cephalosporins, penicillins and other chemotherapeutic agents, as well as Pseudomonas aeruginosa. Resistant to beta- lactamases of gram-positive and gram-negative microorganisms. The drug is highly active against Streptococcus pneumoniae, Streptococcus pyogenes , Streptococcus agalactiae, Haemophilus influenzae, Haemophilus parainfluenzae, Moraxella catarrhalis (also known as strains producing beta a- lactamase), Escherichia coli, Proteus mirabilis , Proteus vulgaris, Neisseria gonorrhoeae, Klebsiella pneumoniae, Klebsiella oxytoca, Pasteurella multocida , Providencia spp ., Salmonella spp ., Shigella spp ., Citrobacter spp. (including Citrobacter diversus), Serratia marcescens.
Pseudomonas spp., Acinetobacter spp , some strains of Streptococcus, Enterococcus spp. (methicillin-resistant strains), Listeria monocytogenes , Bacteroides fragilis, majority strains of Staphylococcus, Enterobacter and Clostridium are resistant to cefixime.
Lactobacilli - lactic acid bacteria are mainly known as probiotics. They are living microorganisms that help stabilize and balance the intestinal microflora. Lactic acid bacteria are beneficial bacteria normally present in the intestinal microflora. They are able to transform into spores that can multiply in the small intestine. Taking lactobacilli helps restore the balance of normal intestinal microflora and reduces the chances of re-infection. They are responsible for the synthesis of certain digestive enzymes that are involved in the absorption of vitamins. They also play a significant role in maintaining tone by synthesizing lactic acid and antimicrobial substances that deactivate pathogenic microorganisms in the intestines. Adding lactobacilli to your diet prevents diarrhea and helps you recover faster. Probiotics (life-protecting) strengthen the immune system, block pathogens, reduce the recovery period after illness, and promote overall health of the body.
Pharmacokinetics:
Cefixime
Absorption: After oral administration, the absorption of cefixime is 40-50%, regardless of food intake; however, it was noted that maximum concentrations (C m ax) in the blood serum are achieved 0.8 hours faster when taking the drug with food. Maximum plasma concentrations are reached after 2 to 6 hours. Approximately 50% of the absorbed dose is excreted unchanged in the urine within 24 hours.
Distribution: Plasma protein binding is 50-60%. The volume of distribution is 0.6-1.1 l/kg. High concentrations of the drug remain for a long time in blood serum, bile, and urine.
Metabolism: There are no data on metabolites of cefixime.
Excretion: Cefixime is excreted mainly by the kidneys unchanged 50%, with bile -10%. The half-life in healthy volunteers averages 3-4 hours, in some cases up to
9 hours. Long half-life makes single dosing possible. If renal function is impaired with a creatinine clearance (CL) of 20-40 ml/min, the half-life increases and averages 6.4 hours, with a CL of 5-20 ml/min - 11.5 hours.
Lactobacilli
After oral administration, lactobacilli have a local effect in the digestive tract.
Suction: No.
Distribution: Local mainly in the large intestine.
Elimination: Feces.

Indications for use:
- infections of the ENT organs (pharyngitis, tonsillitis, sinusitis, otitis media);
- respiratory tract infections (acute and chronic bronchitis, pneumonia);
- infections of the genitourinary system (acute and chronic pyelonephritis, cystitis, urethritis, asymptomatic bacteriuria, gonococcal infection of the urinary tract and cervix);
- typhoid fever.

Directions for use and dosage:
Consult a doctor before starting to take the drug. Adults and children over 12 years of age (weighing more than 50 kg) are prescribed 400 mg 1 time / day or 200 mg 2 times / day. For gonorrhea of the urethra and cervix, 400 mg is prescribed once a day.
For diseases caused by S. pyogenes, the course of treatment should be at least 10 days.
In case of impaired renal function, it is prescribed taking into account creatinine clearance: if it is > 60 ml/min, no dose adjustment is required, if the clearance is 21-60 ml/min, 75% of the standard dose is prescribed, and when clearance is < 20 ml/min, half is prescribed standard dose.

Side effects:
From the nervous system and sensory organs: headache, dizziness.
From the hematopoietic system: eosinophilia, leukopenia, thrombocytopenia, neutropenia, hemolytic anemia.
From the gastrointestinal tract: stomatitis, diarrhea, nausea, vomiting, abdominal pain, pseudomembranous colitis, transient increase in the activity of liver transaminases and alkaline phosphatase.
From the genitourinary system: increased urea nitrogen or creatinine in the blood serum, cases of interstitial nephritis have been described.
Allergic reactions: skin rash, itching, urticaria, erythema multiforme, Stevens Johnson syndrome.
Other: genital mycosis, vaginitis, candidiasis.

Contraindications:
- hypersensitivity to cephalosporins and penicillins;

- history of bleeding;

- pregnancy and lactation period;

- children under 12 years of age;

- severe gastrointestinal diseases accompanied by vomiting and diarrhea.

Use during pregnancy and lactation:
The use of cefixime 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 during lactation, breastfeeding should be stopped.

Special instructions:
Patients with a history of allergic reactions to penicillins may have increased sensitivity to cephalosporin antibiotics. If an allergic reaction occurs, you must stop using the drug and, if necessary, take appropriate measures.
As with other antibacterial drugs, long-term use of cefixime may lead to the growth of Clostridium difficile, which is manifested by the development of severe diarrhea. In this case, it is especially important to consider the possibility of developing pseudomembranous colitis. During treatment, a false-positive direct Coombs reaction and a false-positive urine reaction to glucose and ketonuria are possible. Although lactobacilli are considered safe and have few side effects, they should be avoided by those with weakened immune systems.

Features of the influence on the ability to drive a car and other types of potentially dangerous mechanisms:
The use of the drug does not affect the ability to drive vehicles or operate potentially dangerous mechanisms.

Release form and packaging:
10 tablets in a blister pack made of aluminum foil, together with instructions for use, are placed in a pack of cardboard.

Storage conditions:
Store in a dry place, protected from light, at a temperature not exceeding 25 °C.
Keep the drug out of the reach of children.
Do not use the drug after the expiration date indicated on the blister and cardboard box.

Conditions for dispensing from pharmacies:
By doctor's prescription.

Made for:
MAXX PHARM LTD.
London, Great Britain