CLAVOCEF

Instructions

on medical use of medicinalfacilities

Tradename: ClavoCef.
International nonproprietary name: Cefixime + lactobacilli.
Dosage form: Powder for the preparation of suspension for oral administration.
Composition: *Every 5 ml of the finished suspension contains:*
Active substances:
Cefixima trihydrate , equivalent to cefixime …….100 mg;
Lactobacilli (Lactic Acid Bacillus) …….60 million spores;
Excipients: xanthan gum, sucrose, colloidal silicon dioxide, sodium metabisulfite edetate, sodium saccharin, sodium citrate, sodium benzoate, banana flavor, quinoline yellow.
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 (including 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. (V T. h. Citrobacter diversus), Serratia marcescens.
Pseudomonas spp ., Acinetobacter spp, some strains 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.
Toxicological characteristics:
Cefixime: Long-term animal experiments to assess the carcinogenic effect of cefixime have not been conducted. Mutagenic effect in tests in vitro and in vivo not detected. There was no effect on fertility and reproductive behavior in rats when administered doses up to 125 times higher than the therapeutic dose for humans.
Lactobacilli:
Carcinogenicity, mutagenicity and effects on fertility: No data available.
Pharmacokinetics
Cefixime
Absorption: After oral administration, the absorption of cefixime is 40-50%, regardless of food intake; however, it was noted that maximum concentrations (Cmax) in the blood serum are achieved faster by 0.8 hours 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. The 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.
Absorption: inside – no.
Distribution: local, mainly in the large intestine.
Elimination: feces.

Indications for use:

- hypersensitivity to cephalosporins and penicillins;
- history of bleeding;
- children up to 6 months;
- severe gastrointestinal diseases accompanied by vomiting and diarrhea.

Directions for use and dosage:
Consult a doctor before starting to take the drug orally. The suspension is intended for use in pediatrics. For children weighing 50 kg or over the age of 12 years, the drug is prescribed in adult doses. For children under 12 years of age, the drug is prescribed at a dose of 8 mg/kg 1 time/day or 4 mg/kg every 12 hours. For diseases caused by S. pyogene, the course of treatment should be at least 10 days.
If renal function is impaired, 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.

Rules for preparing the suspension:
Turn the bottle over and shake the powder. Approximately half the required volume of boiled water cooled to room temperature is added to the bottle with the drug, closed with a lid, and thoroughly shaken until a homogeneous suspension is formed. Next, add cooled boiled water to the mark (arrow) indicated on the label, close the lid, and shake thoroughly until a homogeneous suspension is formed. Let stand for 5 minutes.

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, incl. to penicillins, penicillamine .
With caution: renal failure, colitis (history).

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 and control
potentially dangerous mechanisms.

Interaction with other drugs:
Cefixime
Blockers of tubular secretion (including allopurinol, diuretics) delay the excretion of cefixime by the kidneys, which can lead to increased toxicity. Cefixime reduces the prothrombin index and enhances the effect of indirect anticoagulants. Antacids containing magnesium or aluminum hydroxide slow down the absorption of the drug.
Lactobacilli
No undesirable interactions with other drugs were noted.

Overdose:
Symptom : increased manifestations of the described side effects.

Treatment: gastric lavage, symptomatic and supportive therapy, incl. prescription of antihistamines and glucocorticoids > oxygen therapy, mechanical ventilation. Hemodialysis and peritoneal dialysis are ineffective. A specific antidote is unknown.

Release form and packaging:

Powder for the preparation of suspension for oral administration. 1 bottle along with instructions for use is placed in a cardboard box.

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.

Vacation conditions:

By doctor's prescription.

Made for:
MAXX PHARM LTD .
London, Great Britain