EvoTaxime®

ایووٹیکزائم

(Cefotaxime 250, 500mg & lgm)

For IM/IV Use

Composition
EvoTaxime 250 mg: Each vial of dry powder contains; Cefotaxime U.S.P... 250 mg as Cefotaxime sodium.

EvoTaxime 500 mg: Each vial of dry powder contains; Cefotaxime U.S.P... 500 mg as Cefotaxime sodium.

EvoTaxime 1 g: Each vial of dry powder contains; Cefotaxime U.S.P... 1 g as Cefotaxime sodium.

Indications
Severe infections caused by cefotaxime susceptible pathogens:

Infections of:
- respiratory tract, including nose and throat,
- ear,
- kidneys and urinary tract,
- skin and soft tissues,
- bones and joints,
- genital organs, including gonorrhoea
- abdominal region.

Sepsis, endocardits, meningitis; for preoperative c„ophylaxis in patients who are at increased rik from infection, and for the prophylaxis of infections in patients with reduced resistance.

Cefotaxime is generally effective against the following pathogens: Staphylococci, aerobic and anaerobic streptococci, Streptococcus pneumoniae, Neisseria spp., Haemophilusinfluenzae, Escherichia coli, Citrobacter spp., Salmonella spp., KlebSiella spg....Enterobacter aerogenes, Serratia app., indole-positive and indole-negative Proteus spp., Yersinia enterocolitica, Clostridium spp., and Bacteroides spp.

Pathogens with varying susceptibility are: Streptococcus faecalis, Enterobacter cloacae, Pseudomonas aeruginosa, and t3acteroides fragilis.

There is not yet sufficient clinical experience with salmonella typhi and paratyphi A and B infections.

Cefotaxime is not effective against Treponema pallidum and Clostridium difficile.

Combination therapy: In severe, life-threatening infections, the combination of EvoTaxime with aminoglycosides is indicated without awaiting the results of sensitivity tests. The two preparations must be administered separately:

Infections with Pseudomonas aeruginosa may require concomitant treatment with other antibiotics effective against Pseudomonas.

Contraindications
Hypersensitivity to cephalosporins.

Special warnings and precautions
In patients hypersensitive to penicillins or other beta-lactam antibiotics, the possibility of cross-sensitivity exists.

Renal function must be monitored in patients treated concomitantly with aminoglycosides.

For courses of treatment lasting longer than 10 days, the blood count should be monitored and treatment with EvoTaxime be stopped in the event of neutropenia.

Administration of antibiotics, especially if prolonged, may lead to the proliferation of resistant microorganism. The patients condition must therefore be checked at regular intervals. If a secondary infection occurs appropriate measures must be taken,

The sodium content of EvoTaxime (2.09 mmol/g cefotaxime) should be t.iken into consideration.

Some adverse effects nay impair the ability to concentrate and react, and, therefore constitute a risk in situations where these abilities are of particular importance (e.g. operating a vehicle or machinery).

Use in pregnancy and lactation: Although animal experiments did not reveal any malformation or toxic effect on the fetus, EvoTaxim should not be used during pregnancy, especially in the first three months, unless strictly indicated.

As c'efotaxime is excreted in breast milk, either breast feeding or treatment of the mother with EvoTaxime shoud be discontinued.

Adverse effects
Effects on the blood picture: Thrombocytopenia, eosinophilia, and leucopenia.

As with other beta-lactam antibiotics granulocytopenia and morerarely agranulocytosis may develop during treatment with EvoTaxime, particularly if given over long periods. Rare cases of haemolyticanaemia have been reported.

Effects on the liver: Rise in serum liver enzymes (e.g.SGOT,SGPT, gamma-GT, alkaline phosphatase, LDH) and bilirubin.

Effects on the kidney: A transient increase in serum creatinineand urea and, in rare cases, interstitial nephritis may occur.

Effects on gastrointestinal tract: Nausea and vomiting, abdominal pain, diarrhoea. The possibility of pseudomembranous colitis (in most cases due to' Clostridium difficile) must be considered in patients in whom severe, persistent diarrhoea occurs during treatment or in the initial weeks thereafter. Even if pseudomembranous colitis is only suspected, administration of EvoTaxime must be halted immediately. Thistype of colitis requires immediate and appropriate treatment by a physician. Drugs that i;ihibit intestinal motility (peristalsis) must not be taken in such cases.

Local reactions: Inflammatory irritiation and pain at the site of injection.

Other reactions: Allergic skin reactions (e.g. urticaria, exanthema) and itching may occur.

As with other cephalosporins, isolated cases of bullous eruptions (erythema multiforme, Stevens-Johnson syndrome and toxic epidermal necrolysis) have been observed.

Drug fever and severe acute allergic reactions (anaphylaxis, sometimes progressing to shock) may occur and require emergency treatment.

Administration of high doses of beta-lactam antibiotics, particularly in patients with renal insufficiency, may result in encephalopathy (with, e.g., impairment of consciousness, abnormal movements and convulsions).

Administration of antibiotics, especially if prolonged, may lead to the proliferation of resistant microorganisms.

During treatment for spirochaetal infections, Herxheimer's reaction characterized by the occurrence or worsening of general symptoms such as fever, chills, headache, and joint pains. may develop.

The occurrence of one or more of the following symptoms has been reported after several weeks treatment of borreliosis: Skin rash, itching, leucopenia, increase in liver enzymes, difficulties in breathing, joint discomfort. To some extent, these manifestations are conistent with the symptoms of the underlying disease for which the patient is being treated.

Please consult a physicin if you notice any of the adverse effects mentioned in this leaflet or any other undesired effects or unexpected changes.

Since some adverse effects (for example, pseudomembranous colitis, anaphylaxis, some changes in blood picture) may under certain circumstances become life-threatening, it is essential that, if sudden or severe reactions do occur, you inform a physician at once.

Interactions
By delaying renal excretions, the concurrent administration of probenecid increases the concentration of cefotaxime in serum and prolongs its duration of action.

Patients under concurrent or subsequent medication with potentially nephrotoxic drugs (e.g. aminoglycosides) should be Closely monitored for renal function.

Administration of cephalosporins including EvoTaxime maycause a transient reduction in plasma concentrations of oestrogens and gestagens. The effectiveness of oral contraceptives is therfore uncertain.

Interference with laboratory tests: A false positive result for the Coombs' test may be obtained in rare cases during treatment with EvoTaxime. Non-enzymatic methods for the determination of glycosuria may also give a false positive result. Glycosuria should therefore be determined by enzymatic methods during EvoTaxime treatment.

Dosage
Dosage, (node, and frequency of administration depend oil the severity of the infection, susceptibility of the pathogen, and condition of the patient.

Unless otherwise prescribed, infants and children up to 12 years old are given daily doses of 50-100 mg/kg body weight, divided into equal doses at intervals of 12-6 hours. In individual cases, patients with life threatening infections were treated with daily amounts of 150-200 mg/kg body weight; these doses were well tolerated.

Since renal clearance is not yet fully developed in premature infants, daily doses of 50 mg/kg body weight should not be exceeded.

For the preoperative prophylaxis of infections, one of the above single doses is administered 30-60 minutes before the start of surgery. Depending on the risk of infection, the same dose may be repeated.

Dosage in patients with impaired renal function: In patients with a creatinine clearance of 5 ml/min or below, the maintenance dose should be reduced to half the normal dose. The initial does depends on the susceptibility of the pathogen and the severity of the infection. These dosage recommendations are based on experience in adults.

Duration of treatment: The duration of treatment depends on the patient's response. It should be continued for at least three days after the body temperature has returned to normal.

Administration
EvoTaxime is injected preferably by the intravenous route. The required dose of 250 mg and 500 mg are dissolved in at least 2 ml water for injection while 1 g is dissolved in at least 4 ml water for injection; the solution is then injected over a period of 3 to 5 minutes. Sodium bicarbonate solutions must not be mixed with EvoTaxime.

EvoTaxime may also be injected intramuscularly. For this purpose. the contents of one vial are dissolved in,2 ml water for injection; the solution is then injected deep into the gluteus muscle.

Pain resulting from the i.m. injection cap be prevented by dissolving EvoTaxime 500 mg in the corresponding amount of 1% lidocaine solution, but in this case intravascular injection must be strictly avoided.

Reconstitution: To avoid septic complications on injection, care should be taken during reconstitution to ensure aseptic handling. The solution should be used immediately after reconstitution. Aseptic handling is particularly important if the solution is not intended for immediate use. After reconstitution, EvoTaxime can be stored for up to 24 hours at temperatures below 25°C without undergoing any significant physical or chemical changers. A pale yellowish colour of the solution does not indicate change in potency.

Emergency measures to be taken in the event of anaphylactic shock
Generally, the following emergency procedure is recommended: At the first signs (sweating, nausea, cyanosis), interrupt the injection immediately, but leave the venous cannula in place or perform venous cannulation. In addition to the usual emergency measures, ensure that the patient remains lying down, with the legs raised and airways patent.

Emergency- drug therapy
Immediately epinephrine (adrenaline) i.v.: In the first instance, slowly inject 1 ml of a solution containing 0.1 mg epinephrine per ml while monitoring pulse and blood pressure (watch for disturbances in cardiac rhythm). Repeat as required.

Then volume substitution i.v., e.g. plasma expanders, human albumin, balanced electrolyte solution subsequently glucocorticoids i.v., e.g. 250-1000 mg methylprednisolone. Repeat as required.

The dosage recommendations refer to adults of normal weight. In children, the reduction of dose should be in relation to body weight. Other therapeutic measures, e.g. artificial respiration, oxygen inhalation, antihistamirlics.

Storage
Store below 25°C. Protect from light.

Keep all medicines out of the reach of children.

Presentation
EvoTaxime 250 mg: 1 vial of 250 mg dry powder, with 1 ampoule of 5 ml water for injection.

EvoTaxime 500 mg: 1 vial of 500 mg dry powder, with 1 ampoule of 5 ml water for injection.

EvoTaxime 1 g: 1 vial of 1 g dry powder, with 1 ampoule of 5 ml water for injection.

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انجکشن کے لئے صرف تازہ تیار کردہ محلول استعمال کریں۔
اس محلول کو بنانے کے بعد ایوٹیکزائم کو ۲۵ سینٹی گریڈ سے کم
درجہ حرارت پر ۲۴ گھنٹے تک رکھا جا سکتا ہے۔
وریدی انجکشن کے لئے وقت ۳ تا ۵ منٹ ہے۔
ڈاکٹر کی ہدایات کے مطابق استعمال کریں۔
صرف رجسٹرڈ ڈاکٹر کے نسخہ پر فروخت کی جائے۔