Opixeme

Cefuroxime Dry Powder For Oral Suspension

Composition:
Each 5ml of the reconstituted suspension contains:
Cefuroxime Axetil (Amorphous) USP
Eq. To Cefuroxime 125mg
Excipients.....q.s.
Approved Colour used.

Therapeutic indications:
Cefuroxime Axetil is indicated for the treatment of the infections listed below in adults and children from the age of 3 months.
Acute streptococcal tonsillitis and pharyngitis.
Acute bacterial sinusitis.
Acute otitis media.
Acute exacerbations of chronic bronchitis.
Cystitis.
Pyelonephritis.
Uncomplicated skin and soft tissue infections.
Treatment of early Lyme disease.
Consideration should be given to official guidance on the appropriate use of antibacterial agents.

Contraindications:
Hypersensitivity to cefuroxime.
Patients with known hypersensitivity to cephalosporin antibiotics.
History of severe hypersensitivity (e.g. anaphylactic reaction) to any other type of betalactam antibacterial agent (penicillins, monobactams and carbapenems).

Special warnings and precautions for use:
Hypersensitivity reactions
Special care is indicated in patients who have experienced an allergic reaction to penicillins or other beta-lactam antibiotics because there is a risk of cross-sensitivity. As with all beta-lactam antibacterial agents, serious and occasionally fatal hypersensitivity reactions have been reported. In case of severe hypersensitivity reactions, treatment with cefuroxime must be discontinued immediately and adequate emergency measures must be initiated.
Jarisch-Herxheimer reaction
The Jarisch-Herxheimer reaction has been seen following cefuroxime axetil treatment of Lyme disease. It results directly from the bactericidal activity of cefuroxime axetil on the causative bacteria of Lyme disease, the spirochaete Borrelia burgdorferi. Patients should be reassured that this is a common and usually self-limiting consequence of antibiotic treatment of Lyme disease.
Overgrowth of non-susceptible microorganisms
As with other antibiotics, use of cefuroxime axetil may result in the overgrowth of Candida. Prolonged use may also result in the overgrowth of other non-susceptible microorganisms (e.g. enterococci and Clostridium difficile), which may require interruption of treatment.
Interference with diagnostic tests
The development of a positive Coombs Test associated with the use of cefuroxime may interfere with cross matching of blood.
As a false negative result may occur in the ferricyanide test, it is recommended that either the glucose oxidase or hexokinase methods are used to determine blood/plasma glucose levels in patients receiving cefuroxime axetil.
Important information about excipients
The sucrose content of cefuroxime axetil suspension should be taken into account when treating diabetic patients and appropriate advice provided.
Contains 3 g of sucrose per 5 ml dose
Contains 6 mg of propylene glycol (E1520) per 5 ml dose.
Contains 4.5 mg benzyl alcohol (E1519) per 5 ml dose. Benzyl alcohol may cause allergic reactions
Cefuroxime axetil suspension contains aspartame, which is a source of phenylalanine and so should be used with caution in patients with phenylketonuria. Neither non-clinical nor clinical data are available to assess aspartame use in infants below 12 weeks of age.

Fertility, pregnancy and lactation:
Pregnancy
There are limited data from the use of cefuroxime in pregnant women. Studies in animals have shown no harmful effects on pregnancy, embryonal or foetal development, parturition or postnatal development. Cefuroxime Axetil should be prescribed to pregnant women only if the benefit outweighs the risk.
Breastfeeding
Cefuroxime is excreted in human milk in small quantities. Adverse effects at therapeutic doses are not expected, although a risk of diarrhoea and fungus infection of the mucous membranes cannot be excluded. Breastfeeding might have to be discontinued due to these effects. The possibility of sensitisation should be taken into account. Cefuroxime should only be used during breastfeeding after benefit/risk assessment by the physician in charge.
Fertility
There are no data on the effects of cefuroxime axetil on fertility in humans. Reproductive studies in animals have shown no effects on fertility.

Undesirable effects:
The most common adverse reactions are Candida overgrowth, eosinophilia, headache, dizziness, gastrointestinal disturbances and transient rise in liver enzymes.
The frequency categories assigned to the adverse reactions below are estimates, as for most reactions suitable data (for example from placebo-controlled studies) for calculating incidence were not available. In addition the incidence of adverse reactions associated with cefuroxime axetil may vary according to the indication.

Overdose:
Overdose can lead to neurological sequelae including encephalopathy, convulsions and coma. Symptoms of overdose can occur if the dose is not reduced appropriately in patients with renal impairment.
Serum levels of cefuroxime can be reduced by haemodialysis and peritoneal dialysis.

Dosage: As directed by the physician.

To make the reconstitution:
Shake the bottle to loosen the powder and add 40ml boiled and cooled water.
The reconstituted suspension, when refrigerated between 2 and 8°C can be kept for up to 10 days.

Storage:
Store in a cool, dry place. Protect from light. Do not store above 30°C.

Keep all medicines out of the reach of children.

Presentation: 50 ml

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