Ocefix®

Cefixime

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Composition:

Ocefix® 200 : Each film-coated tablet contains Cefixime USP as Trihydrate equivalent to Cefixime Anhydrous 200 mg.
Ocefix® 400 : Each film-coated tablet contains Cefixime USP as Trihydrate equivalent to Cefixime Anhydrous 400 mg.
Ocefix® 100 mg Powder for oral Suspension: Each 5 ml of reconstituted Suspension contains Cefixime USP as Trihydrate equivalent to Cefixime Anhydrous 100 mg.
Ocefix® Dispersible : Each uncoated Dispersible tablet contains Cefixime USP as Trihydrate equivalent to Cefixime anhydrous 100 mg.

Description:

Ocefix® (Cefixime) is a semi-synthetic antibiotic for oral administration.
Ocefix® is available in 200 mg and 400 mg tablets, 100 mg Dispersible tablets, and in powder form which when reconstituted provides 100 mg/5 ml oral suspension.

Properties:

As with other Cephalosporins, bactericidal action of cefixime results from inhibition of cell-wall synthesis. Cefixime is highly stable in the presence of beta-lactamase enzymes. As a result, many organisms resistant to penicillins and some cephalosporins due to the presence of beta-lactamase may be susceptible to cefixime. Cefixime has been shown to be active against most strains of the following organisms both in vitro and in clinical infections.

Susceptibility of pathogens is as follows:

Streptococcus pneumoniae, Streptococcus pyogenes, Haemophilus influenzae (beta-lactamase positive and negative strains), *Moraxella* (Branhamella) *catarrhalis* (most of which are beta-lactamase positive), *Escherichia coli, Proteus mirabilis, Neisseria gonorrhoeae* (including penicillinase and non-penicillinase producing strains).

Cefixime has been shown to be active in vitro against most strains of the following organisms; however, clinical efficacy has not been established.
Streptococcus agalactiae, Haemophilus parainfluenzae (beta-lactamase positive and negative strains), *Proteus vulgaris, Klebsiella Pneumoniae, Klebsiella oxytoca, Pasteurella multocida, Providencia species, Salmonella species, Shigella species, Citrobacter amalonaticus, Citrobacter diversus, Serratia marcescens.*

Note: *Pseudomonas species*, strains of group D *Streptococci* (including enterococci), *Listeria monocytogenes*, most strains of *Staphylococci* (including methicillin-resistant strains) and most strains of *Enterobacter* are resistant to cefixime. In addition, most strains of *Bacteroides fragilis* and *Clostridia* are resistant to cefixime.

Pharmacokinetics:

Ocefix® (Cefixime) given orally, is about 40% - 50% absorbed whether administered with or without food. However, time to maximal absorption is increased by approximately 8 hours when administered with food. Peak serum concentrations occur between 2 to 6 hours following a single 400 mg tablet or 400 mg suspension of cefixime.

Peak serum concentrations occur between 2 to 5 hours following a single administration of 200mg of suspension. Approximately 50% of the absorbed dose is excreted unchanged in the urine in 24 hours. In animal studies, it was noted that cefixime is also excreted unchanged in the urine in 24 hours. In animal studies, it was noted that cefixime is also excreted in the bile in excess of 10% of the administered dose. Serum protein binding is concentration independent with a bound fraction of approximately 65%.

In subjects with moderate impairment of renal function (20 to 40 ml/min creatinine clearance), the average serum half-life of cefixime is prolonged to 6.4 hours. In severe renal impairment (5 to 20 ml/min creatinine clearance), the half-life is increased to an average of 11.5 hours. The drug is not cleared significantly from the blood by hemodialysis or peritoneal dialysis. However, a study indicated that with doses of 400 mg, patients undergoing hemodialysis have similar blood profile as subjects with creatinine clearance of 21-60 ml/min. There is no evidence of metabolism of cefixime in vivo.
Adequate data on CSF levels of cefixime are not available.

Indications and Usage:

Ocefix® (Cefixime) is indicated in the treatment of the following infections when caused by susceptible strains of the designated microorganisms: Uncomplicated Urinary Tract Infections caused by *Eschericia coli* and *Proteus mirabilis*, Otitis Media caused by *Haemophilus influenzae* (beta-lactamase positive and negative strains), *Moraxella* (Branhamella) *catarrhalis*, (most of which are beta-lactamase positive) and *S. pyogenes*.
Acute Bronchitis and Acute Exacerbations of Chronic Bronchitis, caused by *Streptococcus pneumonia* and *Haemophilus influenza* (beta-lactamase positive and negative strains).
Uncomplicated gonorrhoea (cervical/urethral), caused by *Neisseria gonorrhoeae* (penicillinase and non penicillinase producing strains).
Appropriate cultures and susceptibility studies should be performed to determine the causative organism and its susceptibility to cefixime. However, therapy may be started while awaiting the results of these studies. Therapy should be adjusted, if necessary, once these results are known.
Ocefix® (Cefixime) may be used as empiric treatment for susceptible microorganisms but when culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.

Dosage and Administration:

Adults:

The recommended dose of cefixime is 400 mg tablet daily. This may be given as a 400 mg tablet daily or as 200 mg tablet every 12hrs. For the treatment of uncomplicated cervical/urethral gonococcal infections, a single oral dose of 400mg tablet is recommended.

Children:

The recommended dosage is 8 mg/kg/day of the suspension or Dispersible tablet. This may be administered as a single daily dose or may be given in two divided doses, as 4 mg/kg every 12 hours.
Children weighing more than 50 kg or older than 12 years should be treated with the recommended adult dose. Efficacy and safety in infants aged less than six months have not been established. In the treatment of infections due to S. pyogenes, a therapeutic dosage of **Ocefix®** should be administered for at least 10 days.

Administration Instruction for Dispersible Tablet:

- To be dispersed in a small amount (5 to 10ml) of boiled and cooled water.
- Use of a clean and appropriate container is recommended to disperse the tablet.
- The dispersible tablet usually disintegrate within one minute when put in water.
- The water can be softly stirred to aid dispersion before swallowing.
- As a proportion of the active substance may remain in the container after swallowing, it is advisable to rinse it with a small amount of water and swallow again.
- Dispersible tablet must be used immediately after removal from the blister packaging.

Renal Impairment:
Ocefix® may be administered in the presence of impaired renal function. Normal dose and schedule may be employed in patients with creatinine clearances of 60 ml/min or greater. Patients whose clearance is between 21 and 60 ml/min or patients who are on renal hemodialysis may be given 75% of the standard dosage at the standard dosing interval (i.e., 300 mg daily). Patients whose clearance is < 20 ml/min or patients who are on continuous ambulatory peritoneal dialysis may be given half the standard dosage at the standard dosing interval (i.e., 200 mg daily). Neither hemodialysis nor peritoneal dialysis removes significant amounts of drug from the body.

Side Effects:
Most adverse reactions observed in clinical trials were of a mild and transient nature. The most commonly seen adverse reactions were gastrointestinal events. Clinically mild gastrointestinal side effects occurred in 20% of all patients, moderate events occurred in 9% of all patients and severe adverse reactions occurred in 2% of all patients. Individual event rates included diarrhea 16%, loose or frequent stools 6%, abdominal pain 3%, nausea 7%, dyspepsia 3%, and flatulence 4%. These symptoms usually responded to symptomatic therapy or ceased when Cefixime was discontinued. Several patients developed severe diarrhea and/or documented pseudomembranous colitis, and a few required hospitalization. Other adverse reactions (incidence rate < 2%) are Hypersensitivity Reactions, Hepatic; (Transient elevations in SGPT, SGOT, alkaline phosphatase, hepatitis, jaundice.), Renal; (Transient elevations in BUN or creatinine, acute renal failure.), Central Nervous system; **(**Headaches, dizziness, seizures.), Haemic and Lymphatic Systems; **(**Transient thrombocytopenia, leucopenia, neutropenia, and eosinophilia.) etc.

Drug Interactions:
Carbamazepine: Elevated carbamazepine levels have been reported in post marketing experience when Cefixime is administered concomitantly. Drug monitoring may be of assistance in detecting alterations in carbamazepine plasma concentrations.
Warfarin and Anticoagulants: Increased prothrombin time, with or without bleeding, has been reported when cefixime is administered concomitantly.

Precautions:
General:
The dose of cefixime should be adjusted in patients with renal impairment as well as those undergoing continuous ambulatory peritoneal dialysis (CAPD) and hemodialysis (HD). Patients on dialysis should be monitored carefully. Cephalosporins may be associated with a fall in prothrombin activity.
Usage in Pregnancy:
In the absence of adequate and well-controlled studies in pregnant woman, use of cefixime during pregnancy is not recommended unless benefits outweigh the risks.
Labour and Delivery:
Ocefix® (cefixime) has not been studied for use during labour and delivery. Treatment should only be given if clearly needed.
Nursing Mothers:
It is not known whether **Ocefix®** (cefixime) is excreted in human milk. Consideration should be given to discontinuing nursing temporarily during treatment with this drug.
Pediatric use:
Safety and effectiveness of **Ocefix®** (cefixime) in children aged less than six months old have not been established. The incidence of gastrointestinal adverse reactions, including diarrhea and loose stools, in the pediatric patients receiving the suspension, was comparable to the incidence seen in adult patients.
Overdose:
Gastric lavage may be indicated; otherwise, no specific antidote exists. **Ocefix®** (cefixime) is not removed in significant quantities from the circulation by hemodialysis or peritoneal dialysis. Adverse reactions in small numbers of healthy adult volunteers receiving single dose up to 2g of Cefixime did not differ from the profile seen in patients treated at the recommended doses.

Contraindications:
Ocefix® is contraindicated in patients with known allergy to the cephalosporin group of antibiotics.

Presentation:
Ocefix® is available in packs of 10 tablets for the 200 mg and 400 mg tablets and 100 mg dispersible tablet. The powder for suspension is available in 60 ml and 100 ml bottles for reconstitution.

Storage:
Tablets and powder for reconstitution should be stored below 30^{o}C.

KEEP OUT OF REACH OF CHILDREN: Parents and caregivers are advised to oversee treatment in children

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