CUT25e MYS-003
R.O.C. Reg. No.:045671

Ceflour ®
Film Coated Tablet 250mg

Ingredient(s):
Each tablet contains:
Cefuroxime …… 250mg
(as Cefuroxime Axetil)

Pharmacodynamics:
Cefuroxime axetil is an oral prodrug of the bactericidal cephalosporin antibiotic cefuroxime. Cefuroxime is a well-characterized and effective antibacterial agent which has broad-spectrum bactericidal activity against a wide range of common pathogens, including beta-lactamase-producing strains.
Cefuroxime has good stability to bacterial beta-lactamase and consequently, is active against many ampicillin-resistant and amoxicillin-resistant strains. The bactericidal action of cefuroxime results from inhibition of cell-wall synthesis by binding to essential target proteins.

Pharmacokinetics:
After oral administration, cefuroxime axetil is absorbed from the gastro-intestinal tract and rapidly hydrolyzed in the intestinal mucosa and blood to release cefuroxime into the circulation. Optimum absorption occurs when it is administered after a meal. Peak serum cefuroxime levels occur approximately two to three hours after oral dosing. The serum half life is about 1.2 hours. Approximately 50% of serum cefuroxime is protein bound. Cefuroxime is not metabolised and is excreted by glomerular filtration and tubular secretion. Concurrent administration of probenecid increases the area under the mean serum concentration time curve by 50%. Serum levels of cefuroxime are reduced by dialysis.

Indication(s):
For the treatment of the following infections due to susceptible gram-positive and gram-negative microorganisms:
upper and lower respiratory tract infections, genitourinary tract infections, gonorrhoea, skin and soft tissue infections.

Dosage and Administration:
The usual course of therapy is 7 days (range 5 to 10 days).
Ceflour should be taken after food for optimum absorption.

Adults and Adolescents over 13 years of age:
Most infections will respond to 250mg twice daily.
Mild to moderate lower tract infection, eg. Bronchitis: 250mg twice daily.
More severe lower tract infection if pneumonia is suspected: 500mg twice daily.
Urinary tract infection: 250mg twice daily.
Pyelonephritis: 250mg twice daily.
Uncomplicated gonorrhoea: 1g as a single dose.

Children:
The usual dose is 125mg twice daily.
For acute otitis media, children more than 2 years old: 250mg twice daily.

Ceflour tablets should not be crushed and are therefore unsuitable for treatment of patients eg. younger children, who cannot swallow tablets. There is no experience of using Ceflour in children <3 years.

Route of Administration
For oral use.

Contraindication(s):
Hypersensitivity to cephalosporin antibiotics.

Side Effect(s) / Adverse Reaction(s):
Gastrointestinal: Diarrhea, nausea and vomiting. Reports of pseudomembranous colitis have occurred.
Hypersensitivity: Erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis (exanthematic necrolysis) and hypersensitivity reactions including rashes, urticaria, pruritus, drug fever, serum sickness and very rarely anaphylaxis.
Haematological: Thrombocytopenia and leukopenia (sometimes profound), positive Coombs' test, pancytopenia, eosinophilia, increased prothrombin time and very rarely hemolytic anemia.
Hepatic: Transient elevations in AST, ALT and LDH. Hepatic impairment including hepatitis and cholestasis, jaundice.
Central nervous system: Headache and dizziness.

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Precaution(s) / Warning(s):
1. If a clinically significant allergic reaction to cefuroxime axetil occurs, the drug should be discontinued and the patient treated appropriately.
2. Pseudomembranous colitis has been reported with nearly all antibacterial agents, including cefuroxime, and may range from mild to life-threatening. Therefore, it is important to consider this diagnosis in patients who present with diarrhoea in association with the use of antibacterial agents. Mild cases usually respond to drug discontinuation alone. In moderate to severe cases, consideration should be given to management with fluids and electrolytes, protein supplementation, and treatment with an antibacterial drug effective against Clostridium difficile.
3. Cefuroxime axetil should be prescribed with caution in individuals with a history of gastrointestinal disease, particularly colitis.
4. Prolonged use of cefuroxime axetil may result in the overgrowth of nonsusceptible organisms. If superinfection occurs during therapy, appropriate measures should be taken.
5. Serious and occasionally fatal hypersensitivity reactions (including anaphylactoid and severe cutaneous adverse reactions) have been reported in patients receiving therapy with beta-lactams. Before initiating therapy with cefuroxime axetil, careful inquiry should be made concerning previous hypersensitivity reactions to penicillins, cephalosporins, carbapenems or other beta-lactam agents. If an allergic reaction occurs, cefuroxime axetil must be discontinued immediately and appropriate alternative therapy instituted.

Interaction with Other Medicaments:
Concomitant administration of oral probenecid competitively inhibits tubular secretion resulting in higher and more prolonged serum concentration of cefuroxime.
Drugs that reduce gastric acidity may result in a lower bioavailability of cefuroxime compared with that of fasting state and tend to cancel the effect of postprandial absorption.

Pregnancy and Lactation:
Pregnancy: Animal studies have shown no evidence of impaired fertility or teratogenicity. However, since there are no adequate or well-controlled studies in pregnant women, this drug should be used during pregnancy only if clearly needed.
Nursing mothers: Because cefuroxime is excreted in human milk, consideration should be given to discontinuing nursing temporarily during treatment with cefuroxime axetil.

Effects on Ability to Drive and Use Machine:
As this medicine may cause dizziness, patients should be warned to be cautious when driving or operating machinery.

Symptoms and Treatment for Overdosage, and Antidote(s):
Overdosage of cephalosporins can cause cerebral irritation leading to convulsions. Serum levels of cefuroxime can be reduced by haemodialysis or peritoneal dialysis.

Shelf-Life:
2 years from the date of manufacture.

Storage conditions:
Store at temperature below 30°C. Protect from light and moisture. Keep medicine out of reach of children.

Product Description & Packing(s):
An elliptical white to off-white film coated tablet, one side embossed with "YSP39".

Blister packing of 10's x 10, 10's x 50 and 10's x 100.

Y. S. P. ®

Manufacturer:
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Importer and Product Registration Holder:
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