Ceftem®

Cefixime

COMPOSITION :

Ceftem ® 200 Capsule: Each capsule contains Cefixime Trihydrate USP equivalent to Cefixime 200 mg.
Ceftem ® 400 Capsule: Each capsule contains Cefixime Trihydrate USP equivalent to Cefixime 400 mg.
Ceftem ® Powder for Suspension: Each 5 ml reconstituted suspension contains Cefixime Trihydrate USP equivalent to Cefixime 100 mg.
Ceftem-DS ® Powder for Suspension: Each 5 ml reconstituted suspension contains Cefixime Trihydrate USP equivalent to Cefixime 200 mg.

PHARMACOLOGY :

Ceftem ® is a broad spectrum cephalosporin antibiotic of third generation for oral administration. It is a bactericidal antibiotic and is stable to hydrolysis by many beta-lactamases. Ceftem ® kills bacteria by interfering in the synthesis of the bacterial cell wall. Ceftem ® is highly active against Neisseria gonorrhoeae, Haemophilus influenzae, Moraxella catarrhalis including beta-lactamase producers, most of the Enterobacteriaceae, beta-haemolytic Streptococcus (group A & B) and Streptococcus pneumoniae. Ceftem ® is more active than other oral cephalosporins against Escherichia coli, Klebsiella spp, Proteus mirabiltis and Serratia marcescens. Ceftem ® is also active against Streptococcus pyogenes. 40-50% of an oral dose is absorbed from gastro-intestinal tract, whether taken with meals or not. The plasma half life is usually about 3 to 4 hours and may be prolonged when there is renal impairment. About 65% of Ceftem ® in the circulation is bound to plasma protein. Ceftem ® is mainly excreted unchanged in bile and urine.

INDICATION :

Upper and lower respiratory tract infections, Urinary tract infections, Gonococcal urethritis, Acute otitis media.

DOSE & ADMINISTRATION :

Ceftem ® Capsule: 200 mg - 400 mg, as a single dose or in 2 divided doses daily for 7-14 days, according to the severity of infection.
Ceftem ® / Ceftem ® DS Powder for Suspension :
Child dose: 8 mg/kg daily as a single dose or in two divided doses for 7-14 days according to the severity of infection or for children of age 1/2-1 year: 75 mg; 1-4 years: 100 mg; 5-10 years: 200 mg; 11-12 years: 300 mg; above 12 years: adult dose.

CONTRA-INDICATION :

Patients with known hypersensitivity to cephalosporin group of drugs.

WARNING AND PRECAUTION :

Ceftem ® should be prescribed with caution in individuals with a history of gastrointestinal diseases, particularly colitis. Dosage adjustment is only necessary in severe renal failure (creatinine clearance < 20 ml. min-1).

SIDE EFFECTS :

Ceftem ® is generally well tolerated. The majority of adverse reactions observed in clinical trials were mild and self-limiting in nature.
Gastro-intestinal disturbances : Diarrhoea (if severe diarrhoea occurs, Ceftem ® should be discontinued), changes in the colour of stool, nausea, abdominal pain, dyspepsia, vomiting, flatulence have been reported.
Central nervous system disturbances: Headache, dizziness.
Others: Hypersensitivity reactions which usually subside upon discontinuation of therapy; infrequent and reversible haematological changes; elevation of serum amylase.

USE IN PREGNANCY & LACTATION :

Cefixime should be used during pregnancy only if clearly needed.

USE IN CHILDREN & ADOLESCENTS :

For children younger than 12 years or weighing less than 50 kg, the usual dose is 8 mg/kg/day.
No special precautions are necessary. Old age is not an indication for dose adjustment.

DRUG INTERACTION :

In common with other Cephalosporins, increases in prothrombin times have been noted in few patients. Care should therefore be taken in patients receving anticoagulant therapy.
Other forms of interaction: The administration of cefixime may result in a false-positive reaction for glucose in the urine using Benedict's solution.

OVERDOSE :

Mild to moderate adverse GI effects.

STORAGE :

Ceftem ® Capsule should be stored below 30^0 C and away from direct sunlight. Ceftem ® Powder for Suspension: Prior to reconstitution, store below 30^0 C. After reconstitution, the suspension may be kept for 14 days under refrigeration $(2\text{-}8)^0$ C or at room temperature maximum 7 days. Additional use without prescription is strictly prohibited.

DIRECTIONS FOR RECONSTITUTION OF SUSPENSION :

Ceftem ® Powder for Suspension: To prepare 30 ml suspension, 20 ml boiled and cooled water is required. To prepare 40 ml suspension, 25 ml boiled and cooled water is required. To prepare 50 ml suspension, 35 ml boiled and cooled water is required.

INFORMATION FOR THE PATIENT :

1) Shake well before using the suspension.
2) Do not discontinue the therapy suddenly, without consulting your doctor.
3) Discard unused portion of reconstituted suspension after the above mentioned time.
4) Keep away from the reach of the children.

PACKING :

Ceftem ® 200 Capsule: Each box contains 2x7's capsules in blister pack.
Ceftem ® 400 Capsule: Each box contains 2x7's capsules in blister pack.
Ceftem ® Powder for Suspension: Each Bottle contain dry powder for 50 ml suspension with 10 ml measuring cup.
Ceftem-DS ® 50 ml Powder for Suspension: Each Bottle contains dry powder for 50 ml suspension with 10 ml measuring cup.

Manufactured by
Apex Pharma Ltd. Shafipur, Kaliakair, Gazipur, for
Team Pharmaceuticals Ltd.
B 75-79, BSCIC, Rajshahi, Bangladesh