Profix
Cefixime

COMPOSITION:
Profix 200 Capsule: Each capsule contains Cefixime Trihydrate USP equivalent to Cefixime 200 mg.
Profix Dry Syrup: Each 5 ml suspension contains Cefixime Trihydrate USP equivalent to Cefixime 100 mg.

PHARMACOLOGY:
Cefixime is a semi-synthetic, broad spectrum cephalosporin antibiotic of third generation for oral administration. It is a bactericidal antibiotic, kills bacteria by interfering in the synthesis of the bacterial cell wall. Cefixime is highly stable in the presence of beta-lactamase enzymes. Cefixime has marked *in-vitro* bactericidal activity against a wide variety of Gram-positive and Gram-negative organisms including beta lactamase producers.
Clinical efficacy of Cefixime has been demonstrated in infections caused by commonly occurring pathogens including Gram-positive organism *Streptococcus pneumoniae*, *Streptococcus pyogenes*, Gram-negative organism *Escherichia coli*, *Proteus mirabilis, Klebsiella spp.*, *Haemophilus influenzae* (beta-lactamase positive and negative), *Moraxella catarrhalis* (beta-lactamase positive and negative), *Salmonella typhi* and *Enterobacter species*.

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

DOSAGE AND ADMINISTRATION:
Profix 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.
Profix Dry Syrup: 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.

CONTRAINDICATION:
Patients with known hypersensitivity to Cefixime or cephalosporin group of drugs.

SIDE EFFECTS:
Cefixime is generally well tolerated. The majority of adverse reactions observed in clinical trials are mild and self limiting in nature.
Gastro-intestinal disturbance: Diarrhea (if severe diarrhea occurs, Cefixime should be discontinued), changes in the color of stool, nausea, abdominal pain, dyspepsia, vomiting, flatulence have been reported.
CNS disturbances: Headache, dizziness.
Others: Hypersensitivity reactions which usually subsided upon discontinuation of therapy; infrequent and reversible hematological changes; elevation of serum amylase.

PRECAUTIONS:
Cefixime 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).

USE IN PREGNANCY AND LACTATION:
Pregnancy: Pregnancy category B. There are no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.
Lactation: It is not known whether Cefixime is excreted in human milk. Consideration should be given to discontinuing nursing temporarily during treatment with this drug.

DRUG INTERACTION:
No data are available.

OVERDOSAGE:
Gastric lavage may be indicated; otherwise, no specific antidote exists. 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 doses up to 2 g of Cefixime did not differ from the profile seen in patients treated at the recommended doses.

PHARMACEUTICAL PRECAUTION:
It should be stored in a cool and dry place, protected from light and moisture.

HOW SUPPLIED:
Profix 200 Capsule: Each box contains 2x4 capsules in Alu-Alu blister pack.
Profix Dry Syrup: Each amber glass bottle contains dry ingredients to make 30 ml & 50 ml suspension with a measuring cup & a dropper.

Manufactured by:
MEDICON Pharmaceuticals Ltd.
Mirpur, Dhaka, Bangladesh