Proctil
Cefpodoxime

COMPOSITION
Proctil PFS: Each 5 ml suspension contains Cefpodoxime Proxetil USP equivalent to Cefpodoxime 40 mg.

PHARMACOLOGY
Proctil (Cefpodoxime) is an oral third generation cephalosporin, which has good stability to beta lactamases and activity against Gram-negative and Gram-positive bacteria. Like other β-lactam antibiotics it is a bactericidal drug that acts by inhibition of bacterial cell wall synthesis.

INDICATION
Proctil is indicated in the following diseases:-
1. Lower respiratory tract infections
2. Upper respiratory tract infections
3. Urinary tract infections including gonorrhoea, cystitis
4. Skin & soft tissue infections
5. Gynecological infections
6. Acute otitis media
7. Childhood infections

DOSAGE AND ADMINISTRATION
Adults: Allergic rhinitis: 120 mg once daily or 60 mg twice daily and Urticaria: 180 mg once daily. *Children:* 2-11 years: 30 mg (1 spoonful) or 5 ml twice daily and 6 months-2 years: 15 mg (1/2 spoonful) or 2.5 ml twice daily.

Proctil should be administered orally with food to enhance absorption. **Proctil** suspension may be given without regard to food.

Child :
15 days - 6 months : 4 mg/kg every 12 hours
6 months - 2 years : 40 mg every 12 hours
3 - 8 years : 80 mg every 12 hours
over 9 years : 100 mg every 12 hours

Patients with renal dysfunction: For patients with severe renal impairment (creatinine clearance <30 ml/min) the dosing intervals should be increased to 24 hourly.
Patients with liver cirrhosis: Cefpodoxime pharmacokinetics in cirrhotic patients are similar to those in healthy subjects. Dose adjustment is not necessary in this population.

CONTRAINDICATION
Cefpodoxime is contraindicated in patients with a known allergy to Cefpodoxime or to the cephalosporin group of antibiotics.

SIDE EFFECTS
Cefpodoxime has very few side-effects. Possible side effects include gastrointestinal disorders (such as diarrhoea, nausea, vomiting and abdominal pain), rash, urticaria and itching.

PRECAUTIONS
In patients with transient or persistent reduction in urinary output due to renal insufficiency, the total daily dose of Cefpodoxime should be reduced because high and prolonged serum antibiotic concentration can occur in such individuals following usual doses. Cefpodoxime should be administered with caution to patients receiving concurrent treatment with potent diuretics. As with other antibiotics, prolonged use of Cefpodoxime may result in overgrowth of nonsusceptible organisms. If superinfection occurs during therapy, appropriate measures should be taken.

USE IN PREGNANCY AND LACTATION
There are no adequate and well-controlled studies on Cefpodoxime use in pregnant woman, but it was found neither teratogenic nor embryocidal in animal trial. However, the drug should be used during pregnancy only if clearly needed. In nursing mother, Cefpodoxime is excreted in breast milk & there is potential risk of serious

reactions in nursing infants, so a decision should be made whether to discontinue breast feeding or to discontinue the drug.

DRUG INTERACTION
Antacids: Concomitant administration of high doses of antacids (sodium bicarbonate and aluminum hydroxide) or H_2 blockers reduces peak plasma level by 24% to 42% and the extent of absorption by 27% to 32% respectively.
Probenecid: Renal excretion of Cefpodoxime was inhibited by Probenecid and resulted in an approximately 31% increase in AUC.
Nephrotoxic drugs: Close monitoring of renal function is advised when Cefpodoxime is administered concomitantly with compounds of known nephrotoxic potential.

OVERDOSAGE
Overdosage may cause toxic reaction. Toxic symptoms include nausea, vomiting, epigastric distress, diarrhoea.

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

HOW SUPPLIED
Proctil PFS: Each amber glass bottle contains dry ingredients to make 50 ml suspension with a measuring cup.

Manufactured by

MEDICON

MEDICON Pharmaceuticals Ltd.
Mirpur, Dhaka, Bangladesh