Rovantin®

Cefpodoxime

Description: Cefpodoxime Proxetil (**Rovantin®**) is an orally administered extended spectrum, semi-synthetic antibiotic of the cephalosporin.

Composition: Rovantin® 100 mg Tablet: Each film-coated tablet contains Cefpodoxime Proxetil USP 130.45 mg equivalent to Cefpodoxime 100 mg.
Rovantin® 200 mg Tablet: Each film-coated tablet contains Cefpodoxime Proxetil USP 260.90 mg equivalent to Cefpodoxime 200 mg.
Rovantin® Powder for Suspension: After reconstitution each 5 ml contains Cefpodoxime Proxetil USP 52.18 mg equivalent to Cefpodoxime 40 mg.
Rovantin® DS Powder for Suspension: After reconstitution each 5 ml contains Cefpodoxime Proxetil USP 104.36 mg equivalent to Cefpodoxime 80 mg.

Rovantin® Powder for Paediatric Drops: After reconstitution each ml contains Cefpodoxime Proxetil USP 26.09 mg equivalent to Cefpodoxime 20 mg.

Mode of action: Cefpodoxime inhibits bacterial cell wall synthesis by inhibiting transpeptidase enzyme.

Pharmacokinetics: Cefpodoxime Proxetil is a prodrug that is absorbed from the gastrointestinal tract and de-esterified to its active metabolite, Cefpodoxime. Following oral administration of 100 mg of cefpodoxime proxetil to fasting subjects, approximately 50% of the administered cefpodoxime dose was absorbed systemically. Over the recommended dosing range (100 to 400 mg), approximately 29 to 33% of the administered cefpodoxime dose was excreted unchanged in the urine in 12 hours. The extent of absorption (mean AUC) and the mean peak plasma concentration are increased when tablets were administered with food.

Indications: Lower respiratory tract infections, including community-acquired pneumonia caused by S. pneumoniae or H. influenzae (including ß-lactamase-producing strains), acute bacterial exacerbation of chronic bronchitis caused by S. pneumoniae, H. influenzae (non-ß-lactamase-producing strains only), and M. catarrhalis.
Sexually transmitted diseases, including acute, uncomplicated urethral and cervical gonorrhoea caused by Neisseria gonorrhoeae (including penicillinase-producing strains), acute uncomplicated anorectal infections in women due to Neisseria gonorrhoeae (including penicillinase-producing strains).
Skin and skin structure infections, caused by Staphylococcus aureus (including penicillinase-producing strains) or Streptococcus pyogenes.
Upper respiratory tract infections, including acute otitis media caused by Streptococcus pneumoniae, Haemophilus influenzae (including beta-lactamase-producing strains), or Moraxella (Branhamella) catarrhalis, pharyngitis and/or tonsillitis caused by Streptococcus pyogenes.
Urinary tract infections, including uncomplicated urinary tract infections (cystitis) caused by Escherichia coli, Klebsiella pneumoniae, Proteus mirabilis, or Staphylococcus saprophyticus.

Dosage & administration: Tablet should be administered orally with food to enhance absorption. Oral suspension may be given without regard to food. The recommended dosage, duration of treatment, and applicable patient population for cefpodoxime are as described in the following chart.
Adults (age 13 years and older):

Type of Infection	Total Daily Dose	Dose Frequency	Duration
Acute community-acquired pneumonia	400 mg	200 mg 12 hourly	14 days
Acute bacterial exacerbations of chronic bronchitis	400 mg	200 mg 12 hourly	10 days
Uncomplicated gonorrhoea (men and women) and rectal gonococcal infections (women)	200 mg	Single dose	
Skin and skin structure infection	400 mg	200 mg 12 hourly	7 to 14 days
Pharyngitis and/or tonsillitis	200 mg	100 mg 12 hourly	5 to 10 days
Uncomplicated urinary tract infection	200 mg	100 mg 12 hourly	7 days

Children:

Age	Recommended dose	Dose frequency
15 days - 6 months	4 mg/kg	12 hourly
6 months - 2 years	40 mg	12 hourly
3 years - 8 years	80 mg	12 hourly
Over 9 years	100 mg	12 hourly

Patients with renal dysfunction: For patients with severe renal impairment (<30 ml/min creatinine clearance) the dosing intervals should be increased to 24 hourly. In patients maintained on hemodialysis, the dose frequency should be 3 times/week after hemodialysis.

Side effects: The most common adverse effects are gastrointestinal disturbances especially diarrhoea, hypersensitivity reactions, including skin rashes, urticaria, eosinophilia, fever, reactions resembling serum sickness, and anaphylaxis.

Contraindications: Cefpodoxime is contraindicated in patients with known allergy to cefpodoxime or to the cephalosporin group of antibiotics.

Use in pregnancy & lactation: There are no adequate and well-controlled studies of cefpodoxime use 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.

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 concentrations can occur in such individuals following usual doses. Cefpodoxime, like other cephalosporins, should be administered with caution to patients receiving concurrent treatment with potent diuretics.
It should not be given to patients who are hypersensitive to it or other cephalosporins. About 10% of penicillin sensitive patients may also be allergic to cephalosporins although the true incidence is uncertain: Great care should be taken if it is to be given to such patients. Care is also necessary in patients with a history of allergy.

Drug interactions: Antacids: Concomitant administration of high doses of antacids (sodium bicarbonate and aluminium hydroxide) or H2 blockers reduces peak plasma levels by 24 to 42% and the extent of absorption by 27 to 32%, respectively.
Probenecid: As with other beta-lactam antibiotics, renal excretion of cefpodoxime was inhibited by probenecid and resulted in an approximately 31% increase in AUC and 20% increase in peak cefpodoxime plasma levels.
Nephrotoxic drugs: Although nephrotoxicity has not been noted when cefpodoxime was given alone, close monitoring of renal function is advised when cefpodoxime is administered concomitantly with compounds of known nephrotoxic potential.

Overdosage: In acute rodent toxicity studies, a single 5 gm/kg oral dose produces no adverse effects. In the event of serious toxic reaction from overdosage, hemodialysis or peritoneal dialysis may aid in the removal of cefpodoxime from the body, particularly if renal function is compromised. The toxic symptoms following an overdose of beta-lactam antibiotics may include nausea, vomiting, epigastric distress, and diarrhoea.

Storage: Store in a cool (Below 25° C temperature) and dry place protected from light.

Packaging: Rovantin® 100 mg Tablet: Each carton contains 10X1 tablets in blister pack. **Rovantin® 200 mg Tablet:** Each carton contains 10X1 tablets in blister pack. **Rovantin®** Powder for Suspension: Each carton contains a bottle having dry powder to reconstitute 50 ml suspension. **Rovantin® DS** Powder for Suspension: Each carton contains a bottle having dry powder to reconstitute 50 ml suspension. **Rovantin® Powder for Paediatric Drops:** Each carton contains a bottle having dry powder to reconstitute 15 ml paediatric drops.

597-02

Opsonin Pharma
Ideas for healthcare

Manufactured by
Opsonin Pharma Limited
Rupatali, Barishal, Bangladesh.