Vercef®

Powder for Suspension

Description

Vercef powder for suspension contains Cefpodoxime Proxetil USP. Cefpodoxime is an orally administered extended spectrum, semi-synthetic third generation cephalosporin. Like other β lactam antibiotics it is a bactericidal drug that acts by inhibition of bacterial cell wall synthesis.

Indications

Cefpodoxime is indicated for the treatment of patients infected with susceptible strains of microorganisms, which include a wide range of Gram-positive and Gram-negative bacteria. As it is highly stable in presence of β lactamase enzyme, it is more effective against Gram-positive bacteria than other third generation oral cephalosporins.

The susceptible organisms include Gram-positive bacteria e.g., *S. aureus* (including penicillinase producing strains), *S. saprophyticus, S. pneumoniae, S. pyogenes, S. agalactiae, P. magnus* and Gram-negative bacteria e.g., *E. coli, K. pneumoniae, H. influenzae* (including β lactamase producer & Ampicillin resistant strains), *M. catarrhalis, N. gonorrhoeae* (including penicillinase producing strains), *P. mirabilis, C. diversus, H. parainfluenzae, K. oxytoca, P. vulgaris, P. rettgeri.*

Vercef is indicated in the following conditions :

- Lower respiratory tract infections : Acute community acquired pneumonia, acute bacterial exacerbation of chronic bronchitis.

- Upper respiratory tract infections : Acute otitis media, acute maxillary sinusitis, pharyngitis, tonsillitis.

- Sexually transmitted diseases : Acute uncomplicated urethral and cervical gonorrhoea, acute ano-rectal infection in woman caused by *N. gonorrhoeae.*

- Uncomplicated urinary tract infection : Cystitis, pyuria.

- Skin & soft tissue infections : Furuncle, cellulitis, subcutaneous abscess, infectious atheroma and periproctic abscess.

Dosage and Administration

Vercef suspension may be given without regard to food.

The recommended doses and duration of treatment applicable to patient are as below :

Adults (Including Children of Aged 13 Years and Older)

Type of Infection	Total Dose/ Daily Dose	Frequency	Duration
Acute community acquired pneumonia	400 mg	200 mg 12 hourly	14 days
Acute bacterial exacerbation of chronic bronchitis	400 mg	200 mg 12 hourly	10 days
Uncomplicated gonorrhoea (men-women)	200 mg	Single dose 200 mg	-
Rectal gonococcal infection in women	200 mg	Single dose 200 mg	-
Skin & soft tissue infection	400 mg	200 mg 12 hourly	7 to 14 days
Pharyngitis or tonsillitis	200 mg	100 mg 12 hourly	5 to 10 days
Uncomplicated urinary tract infection	200 mg	100 mg 12 hourly	7 days
Acute maxillary sinusitis	400 mg	200 mg 12 hourly	10 days

Children

Age		Dose
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 impairment : For patients with severe renal impairment (Creatinine clearance < 30 ml/min) the dosing intervals should be increased to 24 hours.

Patients with liver cirrhosis : The pharmacokinetics of Cefpodoxime Proxetil 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.

Precautions

In patients with transient or persistent reduction in urinary output due to renal insufficiency, the total daily dose of Cefpodoxime Proxetil should be reduced. Cefpodoxime, like other cephalosporins, should be administered with caution to patients concurrently receiving potent diuretics. As with other broad spectrum antibiotics, prolonged use of the drug may result in overgrowth of non-susceptible organisms. Repeated evaluation of the patient's condition is essential.

Drug Interactions

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 Proxetil is administered concomitantly with compounds of known nephrotoxic potential.

Side Effects

The side effects include diarrhoea, nausea, skin & vaginal fungal infection, abdominal pain, headache, chest pain, myalgia, dyspepsia, dizziness, vertigo, cough, etc. In children, incidence of fungal skin rash is more than adults.

Use in Special Populations

Pregnancy : Cefpodoxime was neither teratogenic nor embryocidal in animal studies. There is however, no adequate and well controlled study of Cefpodoxime Proxetil use in pregnant woman. The drug should be used during pregnancy only if clearly needed.

Lactation : Because Cefpodoxime is excreted in human milk, a decision should be made whether to discontinue breast feeding or to discontinue the drug.

Commercial Pack

Vercef® Powder for Suspension : Bottle containing dry powder for preparation of 100 ml or 50 ml suspension. After reconstitution each 5 ml contains Cefpodoxime Proxetil USP equivalent to Cefpodoxime 40 mg.