Vanprox[™]

Cefpodoxime

COMPOSITION

Vanprox[™] powder for suspension: Each 5 ml reconstituted suspension contains Cefpodoxime 40 mg as Cefpodoxime Proxetil USP.

Vanprox[™] paediatric drops: Each ml reconstituted suspension contains Cefpodoxime 20 mg as Cefpodoxime Proxetil USP.

INDICATIONS AND USES

- 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 & ADMINISTRATION

Vanprox[™] (Cefpodoxime) capsule should be administered orally with food to enhance absorption.Vanprox[™] (Cefpodoxime) suspension may be given without regard to food. The recommended doses, duration of treatment, applicable patient population are as below:

Adults (Including age 13 years & older):

Type of Infection	Dose Frequency	Duration
Acute community-acquired pneumonia	200 mg 12 hour l y	14 days
Acute bacterial exacerbation of chronic bronchitis	200 mg 12 hour l y	10 days
Uncomplicated gonorrhea (men/women)	Single dose 200 mg	
Rectal gonococcal infection in women	Single dose 200 mg	
Skin & Soft tissue infection	200 mg 12 hour l y	7 to 14 days
Pharyngitis and/or tonsi∎itis	100 mg 12 hour l y	5 to 10 days
Uncomplicated urinary tract infection	100 mg 12 hour l y	7 days
Acute maxillary sinusitis	200 mg 12 hourly	10 days

Children:

15 days - 6 months 6 months - 2 years 3 - 8 years Over 9 years :100 mg every 12 hours :100 mg every 12 hours

CONTRAINDICATIONS

Cefpodoxime is contraindicated in patients with known allergy to the cephalosporin class of antibiotics.

Renal Impairment:

Patients with renal dysfunction: For patients with severe renal impairment (creatinine clearance <30 ml/min) the dosing intervals should be increased to 24 hourly.

Hepatic Impairment:

The dosage does not require modification in cases of hepatic impairment.

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.

PRECAUTION

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 & LACTATION

There are no adequate and well-controlled studies on Cefpodoxime Proxetil 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 bicarbonates and aluminium hydroxide) or $\rm H_2$ 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.

DIRECTION FOR RECONSTITUTION OF SUSPENSION

Vanprox[™] Powder for Suspension: Shake the bottle well before adding water. Then add 30 ml of boiled and cooled water to make 50 ml suspension. Continue shaking the bottle until the powder is mixed properly.

VanproxTM Paediatric Drops: Shake the bottle well before adding water. Then add 10 ml of boiled and cooled water to make 15 ml suspension. Continue shaking the bottle until the powder is mixed properly.

STORAGE CONDITION

Powder for suspension: Store below $25^{\rm o}$ C, protected from light and moisture.

After reconstitution the suspension can be used within 7 days if be kept at room temperature and within 14 days if be kept in refrigerator (2°-8°C). Always keep the bottle tightly closed.

HOW SUPPLIED

Vanprox[™] Powder for Suspension: Bottle containing dry powder to reconstitute 50 ml suspension and a measuring cup.

Vanprox TM Paediatric Drops: Bottle containing dry powder to reconstitute 15 ml suspension with a 5 ml spoon and a dropper.

Manufactured by

