Bharat Parenterals Limited
Registered Office & Works:
Vill. Haripura, Ta. Savli, Dist. Vadodara - 391520 (Guj.) India.
Tele Fax : (02667)-251679, 251680, 251669, 99099 28332.
E-mail: bplbrd@bplindia.in, info@bplindia.in, Web.: www.bplindia.in
CIN NO: U24231GJ1992PLC018237

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

1. NAME OF THE MEDICINAL PRODUCT

CFPOXIME 50 (Cefpodoxime Proxetil Dispersible Tablets 50 mg)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each Uncoated dispersible tablet contains:
Cefpodoxime Proxetil USP
Eq. to Cefpodoxime ……50 mg
Excipients ……. q.s.
Colour: Sunset Yellow

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Dosage Form: Oral Solid Dosage Form- Tablet

Visual & Physical characteristics of the product: An orange coloured, round shape, uncoated, dispersible tablet, having CHCL on one side and symbol CHANRAI on other side of the tablet.

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications:

CFPOXIME 50 (Cefpodoxime Proxetil Dispersible Tablets 50 mg) is indicated in treatment of patients with mild to moderate infections caused by susceptible strains of the designated microorganisms in the following conditions: Lower Respiratory Tract Infections: Community acquired pneumonia caused by S. Pneumonia or H. Influenza (including β-lactamase –producing strains). Acute bacterial exacerbation of chronic bronchitis caused by S. Pneumonia, H. Influenza (non β-lactamase –producing strains only) or m.atarrhalis. Sexually Transmitted Diseases: Acute, uncomplicated urethral and cervical gonorrhea, and ano –rectal infections caused by Neisseria gonorrhoea (including penicillinase-producing strains) Skin and skin Structure: Uncomplicated skin and skin structure infections caused by Staphylococcus aureus (including penicillinase-producing strains) or Streptococcus pyogenes) Urinary Tract Infections: Uncomplicated urinary tract infections (cystitis) caused by Escherichia coli, Klebsiella pneumonia, Proteus mirabilis or Staphylococcus saprophyticus.

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4.2 Posology and Method of Administration:

Posology

Dosage in Infants and Paediatric Patients (Age 2 Months to 12 Years)

Dosage Based on Body Weight:

- Usual Dose: 10 mg/kg/day in equally divided doses every 12 hours (i.e., 5 mg/kg/dose twice daily).
- Dosage in Typhoid Fever: 16 mg/kg/day in equally divided doses every 12 hours.

Usual Dosage Based on Age Group

Cefpodoxime Proxetil Dispersible Tablets

- 6 months to 2 years (8 to 12 kg): 1 tablet twice daily.
- 2 to 6 years (12 to 20 kg): 1 to 2 tablets twice daily

Method of Administration: For oral administration. Duration of therapy is 5 to 10 days depending on type and severity of infection. Cefpodoxime Proxetil may be administered regardless of meal; however, administration with food results in increased absorption. Or, as prescribed by the physician.

4.3 Contraindications:

Hypersensitivity to Cefpodoxime or to any of the antibiotics in the Cephalosporin group and any of the excipients used in the formulation.

4.4 Special Warnings and Precautions for use:

Before therapy with Cefpodoxime is instituted, careful inquiry should be made to determine whether patient has previously hypersensitivity reactions to Cefpodoxime, other cephalosporin's, penicillins or other drugs. If Cefpodoxime is to be administered to penicillin sensitive patients, caution should be exercised because cross- hypersensitivity among β-lactam antibiotics has been clearly documented and may occur in up to 10% of patients with a history of penicillin allergy. If an allergic reaction to Cefpodoxime occurs, discontinue use. Serious acute hypersensitivity reactions may require treatment with epinephrine and other emergency measures, including oxygen. IV fluids and antihistamine, and airway management, as clinically indicated. Pseudomembranous colitis has been reported with nearly all antibacterial agents, including Cefpodoxime and may range in severity from mild to life –threatening. Therefore, it is important

to consider this diagnosis in patients who present with diarrhoea subsequent to administration of antibacterial agents.

Carcinogenicity: Long term animal carcinogenesis studies of Cefpodoxime have not been performed. Mutagenicity: Mutagenesis studies of Cefpodoxime were all negative.

4.5 Interaction with other medicinal products and other forms of interaction:

Antacids: Concomitant administration of high doses of antacids (sodium bicarbonate and aluminum hydroxide) or H2- blockers reduces peak plasma levels by 24-42 % and the extent of absorption by 27-32%, respectively.

Probenecid: As with other β-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, respectively.

4.6 Pregnancy, Lactation and Fertility

Pregnancy: There are no adequate and well controlled studies of Cefpodoxime use in pregnant women; Cefpodoxime should be used during pregnancy only if needed.

Lactation: Cefpodoxime is excreted in human milk. Because of the potential for serous reactions in nursing infants, a decision should be made whether to discontinue the drug, taking into account the importance of the drug to the mother

Fertility: No fertility data are available

4.7 Effects on Ability to Drive and Use Machines:

Not studies on the effects on the ability to drive and use machines have been performed.

4.8 Undesirable Effects:

- nausea
- vomiting
- diarrhea
- stomach pain
- swelling, redness, irritation, burning, or itching of the vagina
- white vaginal discharge
- headache
- watery or bloody stools, stomach cramps, or fever during treatment or for up to two or more months after stopping treatment
- rash

- itching
- hives
- difficulty breathing or swallowing
- wheezing
- a return of fever, sore throat, chills, or other signs of infection

4.9 Overdose:

In the event of serious toxic reaction from overdosage, haemodialysis or peritoneal dialysis may aid in the removal of Cefpodoxime from the body, particularly if renal function is compromised.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic Properties:

Pharmacotherapeutic Group: Antibacterials

ATC Code: J01DD13

Cefpodoxime, like other beta-lactam antibiotics (e.g., penicillins), is mainly bactericidal. It inhibits the third and final stage of bacterial cell wall synthesis by preferentially binding to specific penicillin-binding proteins (PBPs) that are located inside the bacterial cell wall. Penicillin-binding proteins are responsible for several steps in the synthesis of the cell wall and are found in quantities of several hundred to several thousand molecules per bacterial cell. Penicillin-binding proteins vary among different bacterial species. Thus, the intrinsic activity of Cefpodoxime as well as the other cephalosporin's and penicillins against a particular organism depends on its ability to gain access to and bind with the necessary PBP. Like all beta-lactam antibiotics, the ability of Cefpodoxime to interfere with PBP-mediated cell wall synthesis ultimately leads to cell lysis. Lysis is mediated by bacterial cell wall autolytic enzymes (i.e., autolysins). The relationship between PBPs and autolysins is unclear, but it is possible that the beta-lactam antibiotic interferes with an autolysin inhibitor. Cefpodoxime retains activity in the presence of some beta-lactamases (both penicillinase and cephalosporinases); however, hydrolysis by beta-lactamase, as well as alteration of the PBPs and decreased intracellular permeability, can result in bacterial resistance to Cefpodoxime.

5.2. Pharmacokinetic Properties:

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Over the recommended dosing range (100 to 400 mg), the rate and extent of Cefpodoxime absorption is dose-dependent. In patients with normal renal function, neither accumulation nor significant changes in other pharmacokinetic parameters were noted following multiple oral dosage of up to 400 mg every 12 hours.

Absorption: 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. The extent of absorption (mean AUC) and the mean peak plasma concentration increased when Cefpodoxime Proxetil were administered with food. Over the recommended dosing range, the Tmax was approximately 2 to 3 hours. Mean Cmax was 1.4 mcg/ml for the 100 mg dose, 2.3 mcg/ml for the 200 mg dose, and 3.9 mcg/ml for the 400 mg dose.

Distribution: The volume of distribution of Cefpodoxime is 32.3 liters. Plasma protein binding of Cefpodoxime ranges from 21 to 29%. Concentrations of Cefpodoxime in excess of the minimum inhibitory concentration (MIC) for common pathogens can be achieved in lung parenchyma, bronchial mucosa, pleural fluid, tonsils, interstitial fluid and prostate tissue.

Metabolism: There is minimal metabolism of Cefpodoxime in vivo.

Excretion: Cefpodoxime is primarily excreted by renal route; 80% is excreted unchanged in the urine, with an elimination half-life of approximately 2.4 hours.

Pharmacokinetic Data in Paediatric Population: In children, studies have shown the maximum plasma concentration occurs approximately 2 to 4 hours after dosing. A single 5 mg/kg dose in 4 to 12-year-old children produces a maximum concentration similar to that in adults (200 mg dose). In patients below 2 years receiving repeated doses of 5 mg/kg 12 hourly, the average plasma concentrations, 2 hours post dose, are between 2.7 mg/l (1 to 6 months) and 2.0 mg/l (7 months to 2 years). In patients between 1 month and 12 years receiving repeated doses of 5 mg/kg 12 hourly, the residual plasma concentrations at steady state are between 0.2 to 0.3 mg/l (1 month to 2 years) and 0.1 mg/l (2 to 12 years).

5.3. Preclinical Safety Data

Not Known

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6. PHARMACEUTICAL PARTICULARS:

6.1 List of Excipients:

- Microcrystalline cellulose
- Maize starch
- Lactose
- Sodium starch Glycolate
- Sunset Yellow Supra
- Magnesium stearate
- Purified talc
- Colloidal silicon dioxide
- Cross carmellose sodium
- Aspartame
- Kyron-T-314 (Polacrilin Potassium)

6.2 Incompatibilities:

Not applicable.

6.3 Shelf Life:

2 years

6.4 Special Precautions for Storage:

Store at a temperature not exceeding 25°C. Protect from light.

6.5 Nature and Contents of Container:

Primary Packing: 10 tablets are packed in ALU-ALU blister.

Secondary Packing: Each blister packed in printed mono carton along with package insert.

6.6 Special Precautions for Disposal:

No special requirements

7. APPLICANT/ MANUFACTURER

APPLICANT:

Name : **CHANRAI HEALTH CARE LIMITED**

Address : Plot 122-132, Oshodi Apapa Expressway,
Isolo, Lagos, Nigeria.

MANUFACTURER:

Name : **BHARAT PARENTERALS LTD.**

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Address : Survey No. 144-A, Jarod-Samlaya Road,
Vill.: Haripura, Tal. Savli, Dist. Vadodara
-391520, Gujarat, India
Telephone Number : 9909984235
E-mail : bplbrd@bplindia.in.