SWISS PHARMA

Module 1- Administrative information and product information

1.3 Product Information

1.3.1 Summary of Product Characteristics (SmPC)

Enclosed

1.3.1 Summary of Product Characteristics (SPC)

1 NAME OF THE MEDICINAL PRODUCT

MPLON 200 (Cefpodoxime Proxetil Tablets USP 200 mg), 200 mg per Tablets, Film coated Tablets.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each Film coated tablet contains
Cefpodoxime Proxetil USP 200 mg
Eq. to Cefpodoxime
Excipients Q.S.

Kindly refer section 6.1 for full list of Excipients.

3 PHARMACEUTICAL FORM

Film coated tablet

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

MPLON 200 is indicated for use in the short-term treatment of upper and lower respiratory tract infections due to susceptible micro-organisms:
Acute bronchitis and acute exacerbations of chronic bronchitis
Pharyngitis and tonsillitis
Community- acquired bronchopneumonia
Acute sinusitis
For the treatment of typhoid fever
For enteric infection

4.2 Posology and method of administration

Adults and children (age 12 year and above)

Type of Infection	Dose frequency & duration
Pharyngitis and or tonsillitis	100 mg – 12 hourly for 5-10 days
Acute community acquired pneumonia	200 mg – 12 hourly for 14 days
Acute bacterial exacerbations of chronic bronchitis	200 mg – 12 hourly for 10 days
Uncomplicated gonorrhoea and rectal gonococcal infection (women)	200 mg single dose
Skin and skin structure	400 mg- 12 hourly for 7-14 days
Acute maxillary sinusitis	200 mg- 12 hourly for 10 days
Uncomplicated urinary tract infections	100 mg -12 hourly for 7 days

4.3 Contraindications

Cefpodoxime proxetil is contra indicated in patients who are allergic to the cephalosporin group of anti-biotic. Safety of cefpodoxime proxetil for use in pregnancy and lactation has not been established.

4.4 Special warnings and precautions for use

Before initiating therapy with cephalosporins, careful enquiry should be made concerning previous hypersensitivity reactions to penicillin and other beta- lactam antibiotics.

Cephalosporin cross reactivity has been observed in patients with a documented history of beta lactam allergy. Extreme cation and strict medical supervision is recommended when cephalosporins are administered to patients with a history of beta- lactam anaphylaxis since serious occasionally fatal anaphylaxis may also occur after cephalosporin administration. If an allergic reaction occurs, treatment should be stopped immediately.

Precautions:

Prolonged use may result in overgrowth of non-susceptible organisms and, as with other broad-spectrum antibiotics, pseudomembranous colitis may develop. It is important to consider its diagnosis in patients who develop diarrhea in association with the use of antibiotics, such colitis may range in severity from mild to life threatening. Treatment should be discontinued if symptoms suggestive of pseudomembranous colitis arise, mild cases of pseudomembranous colitis usually respond to drug discontinuance alone. When the colitis does not improve after the drug has been discontinued, or when it is severe, oral vancomycin is the medicine of choice for antibiotic associated pseudomembranous colitis produced by C. difficile. Cephalosporins should be given with caution to patients with renal impairment. There may be a positive response to the coombs test during treatment with cephalosporins.

Geriatrics: cefpodoxime proxetil may be used at the normal recommended dosage in elderly patients even with mild to moderate renal impairment; however, appropriate modification in dosage is advised in patients with severe renal impairment.

4.5 Interaction with other medicinal products and other forms of interaction

No clinically significant drug interactions have been reported during the course of clinical studies. Histamine H2-antagonists and antacids reduce the bioavailability of cefpodoxime. Probenecid reduces the excretion of cephalosporins. Cephalosporins potentially enhance the anticoagulant effect of coumarins and reduce the contraceptive effect of oestrogens. Studies have shown that bioavailability is decreased by approximately 30% when Cefodox is administered with drugs which neutralise gastric pH or inhibit acid secretions. Therefore, such drugs as mineral antacids and histamine blocking H2 blockers, which cause an increase in gastric pH, should be taken 2 or 3 hours after Cefodox administration. In contrast, a decrease in gastric pH (pentagastrin) will increase bioavailability.

Changes in renal function have been observed with antibiotics of the same class, particularly when given concurrently with potentially nephrotoxic drugs such as aminoglycosides and/or potent diuretics. In such cases, renal function should be monitored . A false positive reaction for glucose in the urine may occur with Benedicts or Fehlings solutions or with copper sulphate test tablets, but not with tests based on enzymatic glucose oxidase reactions. The bioavailability increases if the product is administered during meals.

4.6 Pregnancy and lactation

Study carry out in several animal species have not shown any teratogenic or fetotoxic effects. There are no adequate well controlled studies of Cefpodoxime proxetil use in pregnant women. Cefpodoxime proxetil may be administrated to pregnant women only if clearly indicated. Cefpodoxime proxetil is excreted in human milk. Because of the potential for serious reaction in nursing infants, a decision should be made whether to discontinue nursing or to discounting the drug.

4.7 Effects on ability to drive and use machines

Attention should be drawn to the risk of dizzy sensations.

4.8 Undesirable effects

The following side-effects have been reported with the use of cefpodoxime proxetil.
Gastro-intestinal: diarrhoea, nausea, vomiting and abdominal pains.
Central nervous system: Headache, dizziness, tinnitus, paraesthesia, asthenia.
Hypersensitivity: Cutaneous eruptions and pruritus, urticaria and purpura and bullous. Anaphylactic reactions e.g. angioedema, bronchospasm, malaise, possibly culminating in shock may rarely occur.
Haematological: Reduction of haemoglobin, thrombocytosis, thrombocytopenia, leucopoenia and eosinophilia, Neutropenia and agranulocytosis may occur during treatment with cefpodoxime particularly if given over long periods.
Laboratory tests alterations: Elevations of AST, ALT and alkaline phosphate, increase of blood urea and creatinine.

4.9 Overdose

Overdosage with Cefpodoxime proxetil ay manifest in any of the symptoms described under side-effects and special precautions. There is no specific antidote for Cefpodoxime proxetil. Gastric lavage and other appropriate supportive treatment should be employed. Convulsions and other signs of CNS toxicity have been associated with High doses, especially in patients with several renal impairment. Treatment is symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Mechanism of action:

Cefpodoxime proxetil is a semi-synthetic beta lactam antibiotic belonging to the third-generation oral cephalosporin group. Cefpodoxime proxetil is the prodrug of the Bactericidal antibiotic cefpodoxime. The antibacterial action of cefpodoxime is through inhibition of bacterial cell wall synthesis probably by acylation of membrane bound transpeptidase enzymes; this prevents cross linkage of peptidoglycan chains, which is necessary for bacterial cell wall strength and rigidity.

Antibacterial Spectrum:

In vitro studies have demonstrated the susceptibility of most strains of the following micro-organisms to cefpodoxime proxetil, however, such in vitro activity does not necessarily imply in vivo efficacy.

Gram-positive organisms:

Streptococcus pneumoniae, S. pyogenes, S. agalactiae, S. mitis, S. sanguis and S. salivarius; Propionibacterium acnes; Corynebacterium diphtheriae; methicillin-sensitive penicillinase and non- penicillinase producing strains of S. aureus.

Gram negative organisms:

Beta lactamase and non-beta lactamase producing strains of Haemophilus influenza, Haemophilus para- influenza, Moraxella, catarrhalis and Neisseria gonorrhoea; Escherichia coli: Klebsiella pneumonia klebsiella oxytoca; proteus mirabilis.

The following organisms are not sensitive: Group D. Streptococci, Methicillin- resistant staphylococci, Staphylococcus saprophyticus, Corynebacterial, groups J and K. Listeria monocytogenes, pseudomonas aeruginosa and pseudomonas spp. Acinetobacter baumanii, Clostridium difficile, Bacteroides fragilis and related species.

5.2 Pharmacokinetic properties

Cefpodoxime proxetil is absorbed orally and rapidly hydrolysed by non-specific esterases in the gastro-intestinal wall to cefpodoxime. The active acid. absorption is decreases in conditions of low gastric acidity. After oral administration of a single dose of 200 mf of cefpodoxime , the maximum plasma concentration obtained is 2.23 mg/L. Afetr oral administration of a single 5 mg/kg dose of cefpodoxime proxetil suspension in children, the maximum plasma concentration obtained is on average 2.6 mg/L. with cefpodoxime proxetil tablets the time taken to reach the maximum concentration is about 2.7 hr. with the suspension the time taken to reach the maximum concentration is about 2 to 4 hours. The drug diffuses well into respiratory tissues. The serum half-life is about 2.46 hours. About 27% of cefpodoxime in the plasma is bound to plasma protiens. The volume of distribution is about 0.46 L/kg and the clearance is around 2.4 ml/min/kg. About 81% of unchanged cefpodoxime is excreted in the urine.

5.3 Preclinical safety data

No inhouse preclinical safety data has been performed.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Micro crystalline cellulose phosphate
Starch
Kyron T-314
Lactose
Sodium lauryl sulphate
Magnesium stearate
Polyvinyl pyrrolidone
Colloidal anhydrous silica
Microcrystalline cellulose PH-102
Tabcoat white TC-580029

6.2 Incompatibilities

Not applicable

6.3 Shelf life

36 Months

6.4 Special precautions for storage

Store in a cool, dry place below 30°C temp & protected from sun light.
keep out of the reach and sight of children.

6.5 Nature and contents of container <and special equipment for use, administration or implantation>

10 tablets are packed in one blister pack. Such 1 blister pack is packed in Carton along with Insert.

6.6 Special precautions for disposal and other handling

No special requirements.

7. APPLICANT/ MANUFACTURER

APPLICANT:

M/s. FECCOX PHARMACY & GEN ENT LTD.
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Kano, Nigeria

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