1.4 PRODUCT INFORMATION

1.4.1 Summary of Product Characteristics (SmPC)

1. Name of the Medicinal Product

FRESHBORN PEFLOXACIN TABLET

Pefloxacin Tablets BP 400 mg

2. Qualitative and Quantitative Composition

Each Film Coated Tablets Contains:

Pefloxacin Mesylate Dihydrate BP

Eq. to Pefloxacin… ..... 400 mg

Excipients…..... QS

Approved Colours used.

3. Pharmaceutical Form

Film coated Tablet

White to off white coloured, biconvex caplet shaped, film coated tablets having breakline on one side and plain otherside.

The scoreline is not intended for division of the tablet. The tablet should swallow as a whole.

4. Clinical Particulars

4.1 Therapeutic Indications

Pefloxacin Tablet is recommended for the treatment of infections caused by susceptible Gram-positive and Gram-negative bacteria. The infections may include:

Urinary tract infections

Skin and soft-tissue infections

Severe systemic infections

Urethritis and Cervicitis gonorrhoea

Gastrointestinal tract infections, including typhoid fever and paratyphoid fever

Respiratory tract infections

Bone and joint infections

Surgical infections.

4.2 Posology and Method of Administration

Adults:

Adults with normal liver function: 400 mg twice daily. An initial dose of 800 mg may be given in order to produce effective blood concentrations more rapidly. In Gonorrhoea: 800 mg of single dose

Children: Not recommended.

4.3 Contraindications

Pefloxacin Tablet is contraindicated in patients who are hypersensitive to Quinolone carboxylic acid derivatives.

4.4 Special Warnings and Precautions for Use

Severe hepatic insufficiency: the dosage should be adjusted.

As Streptococcus Pneumoniae and other Streptococci are not consistently sensitive to Pefloxacin, should not be prescribed as the initial treatment in respiratory infections when a bacteriological examination has not been carried out.

Exposure to sunlight and UV radiation should be avoided during treatment and for a few days afterwards because of the risk of photosensitivity

4.5 Interaction with Other Medicinal Products and Other Forms of Interaction

Antineoplastic drugs: Decrease serum levels of pefloxacin.

Caffeine: Enhanced efficacy of caffeine

Oral anti-coagulants: Enhanced efficacy of anti-coagulants

Cyclosporin: Nephrotoxicity increased by pefloxacin

Theophylline: Increased plasma levels of theophylline resulting in toxicity

NSAIDs: CNS excitation may occur

Rifampicin: Decreases serum concentration of pefloxacin

Chloramphenicol: Antagonises effects of pefloxacin

4.6 Pregnancy and Lactation

Pregnancy

Pregnancy: This medicine is not recommended for use in pregnant women unless absolutely necessary.

Breast-feeding: This medicine is not recommended for use in breastfeeding women unless absolutely necessary.

4.7 Effects on Ability to Drive and Use Machines

Use of this medicine may cause symptoms such as confusion, dizziness, etc. in some patients. It is advised not to perform any activities such as driving a vehicle or operating machinery if any of these symptoms are experienced during treatment with this medicine.

4.8 Undesirable Effects

Generally well tolerated. However, gastrointestinal disturbances, muscle and/or joint pains, photosensitivity reactions, neurological disturbances (headache, insomnia), and thrombocytopenia have been reported by patients in rare cases.

4.9 Overdose

Seek emergency medical treatment or contact the doctor in case of an overdose.

5. Pharmacological Properties

5.1 Pharmacodynamic Properties

Pharmacotherapeutic Group: : Fluoroquinolone antibiotic

,**ATC code:** J01MA03

Pefloxacin is a fluoroquinolone antibiotic. Fluoroquinolones such as pefloxacin possess excellent activity against gram-negative aerobic bacteria such as E. coli and Neisseria gonorrhoea as well as gram-positive bacteria including S. pneumonia and Staphylococcus aureus. They also possess effective activity against Shigella, salmonella, Campylobacter, Gonococcal organisms, and multi drug resistant Pseudomonas and enterobacter. Its bactericidal action results from interference with the activity of bacterial enzymes DNA gyrase and topoisomerase IV, which are needed for the transcription and replication of bacterial DNA. DNA gyrase appears

to be the primary quinolone target for gram-negative bacteria. Topoisomerase IV appears to be the preferential target in gram-positive organisms. Interference with these two topoisomerases results in strand breakage of the bacterial chromosomes, supercoiling, and resealing. As a result, DNA replication and transcription is inhibited.

5.2 Pharmacokinetic Properties

U Half-life of 8.6 hours. Unchanged pefloxacin and its metabolites may be identified in the urine 84 hours after intake of the product. In elderly, in comparison with younger pateients, the plasma clearance and the apparent volume of distribution is decreased approximately by 50%.

U Elimination half-life is 11-12 hours maily through metabolites.

U Pefloxacin is metabolised in the liver (85%-90%)

U Major route of elimination is renal – 9-16% of the drug is eliminated unchanged. Limited excretion via bile.

U Major metabolites constitute up to 84% of drugs recovered in urine.

Biotransformation:

Cytochrome P450 1A2 (CYP 1A2) hepatic metabolism is considerable. The main metabolites are demethylated pefloxacin, norfloxacin and pefloxacin N-oxide.

There are marked changes in pharmacokinetics in patients with hepatic impairment. Careful monitoring of plasma levels together with appropriate dosage adjustment will be necessary.

5.3 Preclinical Safety Data

Not Applicable

6. Pharmaceutical Particulars

6.1 List of Excipients

Micro Crystalline Cellulose 101

Maize Starch Powder

Sodium Starch Glycolate

P.V.P.K-30

Sodium Starch Glycolate

Purified Talcum

Colloidal Silicon Dioxide

Magnesium Stearate

Colorcoat FC4W-P (White) Titanium Dioxide

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

36 months

6.4 Special Precautions for Storage

Do not store above 30 °C, Protect from light and moisture.

6.5 Nature and Contents of Container

10 tablets in an ALU/ALU blister and such 1 blister pack in one inner carton with a packing insert.

6.6 Special Precautions for Disposal

Not Applicable

7. APPLICANT/SUPPLIER

FRESHBORN INDUSTRIES LTD,

Lagos, Nigeria.

Plot 3164, Block 68, Marian Road, Amuwo Odofin Lagos, State.

CLAROID PHARMACEUTICAL LTD.

Survey No. 217/P Opp. Gurukul English Medium School Kamod, Satpanth Mandir Pirana Rd, TA, Ahmedabad- 382425, Gujarat, India.

8. WHO PREQUALIFICATION REFERENCE NUMBER

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9. DATE OF PREQUALIFICATION/RENEWAL OF PREQUALIFICATION

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10. Date of Revision of the Text