1.3.1
Summary Of Product Characteristics (SPC)

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1.3.1.1 Invented Name of the Medicinal Product

FLOXAL

Pefloxacin Tablets 400 mg

1.3.1.2 Strength

Pefloxacin Mesilate Dihydrate BP

Eq. to Pefloxacin……400 mg

1.3.1.3 Dosage Form

Solid oral dosage form

1.3.1.4. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film coated tablet contains

Pefloxacin Mesilate Dihydrate BP

Eq. to Pefloxacin……400 mg

Excipients ……..q.s.

Approved colour used.

For a full list of excipients see section 1.3.1.8.1

1.3.1.5 PHARMACEUTICAL FORM

Tablets

White coloured capsule shaped biconvex film coated tablet with “FLOXAL 400 ” Embossed on one side & other side plain.

1.3.1.6 CLINICAL PARTICULARS

1.3.1.6.1 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.

1.3.1.6.2 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.

1.3.1.6.3 CONTRAINDICATIONS

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

1.3.1.6.4 WARNING AND PRECAUTION

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.

1.3.1.6.5 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

1.3.1.6.6 PREGNANCY AND LACTATION

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.

1.3.1.6.7 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.

1.3.1.6.8 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.

1.3.1.6.9 OVERDOSE

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

1.3.1.7 PHARMACOLOGICAL PROPERTIES

1.3.1.7.1 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.

1.3.1.7.2 Pharmacokinetic properties

- 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%.
- Elimination half-life is 11-12 hours maily through metabolites.
- Pefloxacin is metabolised in the liver (85%-90%)
- Major route of elimination is renal – 9-16% of the drug is eliminated unchanged. Limited excretion via bile.
- 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.

1.3.1.7.3 Preclinical safety data

Data not available

1.3.1.8 PHARMACEUTICAL PARTICULARS

1.3.1.8.1 List of Excipients

Maize starch
Lactose
Magnesium stearate
Talcum powder
Sodium starch glycolate
Fused silica
Hydroxypropyl Methyl Cellulose 15 CPS
Titanium dioxide
Polyethylene glycol 4000
Isopropyl alcohol
Methylene chloride
Purified Water

1.3.1.8.2 Incompatibilities

Not applicable.

1.3.1.8.3 Shelf life

48 months.

1.3.1.8.4 Special precautions for storage

Store below 30°C. Protected from light.

1.3.1.8.5 Nature and contents of container

Floxal is available as Alu-Alu blister pack of 7 tablets such 2 blisters are packed in a carton along with pack insert.

1.3.1.8.6 Special precautions for disposal and other Special handling

Not Applicable

1.3.1.9 Marketed by:

AQUATIX PHARMACEUTICALS LIMITED.

No. 14, Prince Bode Oluwo Street, Mende,

Maryland, Lagos Nigeria.