1. NAME OF THE MEDICINAL PRODUCT

PEFLOTAB (Pefloxacin Tablets 400 mg)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film coated tablet contains:

Pefloxacin Mesilate Dihydrate BP	
Equivalent to Pefloxacin	400 mg
Excipients	q.s.

Approved colours are used.

3. PHARMACEUTICAL FORM

Tablet;White elongated biconvex film coated tablet emboss PEFLOTAB on one side

4. Clinical particulars

4.1 Therapeutic indications

PFLOTAB (Pefloxacin Tablets 400 mg) is indicated in the following cases:

- Bacterial endocarditis
- Gonococcal urethritis in adults
- Neuromeningeal infection
- Prostatitis
- Septicemia
- Severe digestive and/or biliary infection
- Severe osteoarticular infection
- Severe otorhinolaryngeal infection
- Severe respiratory infection
- Severe skin and soft tissue infection
- Severe urogenital infection
- Treatment replacing injection route for osteoarticular infection
- Uncomplicated acute cysitis in females under 65 years old

4.2 P o s o l o g y and method of administration

Oral

Susceptible infections

Adult: 400 mg bid.

Renal impairment: Dose reduction may be necessary.

Oral

Gonococcal urethritis in men

Adult: 800 mg as single dose.

Renal impairment: Dose reduction may be necessary.

Oral

Acute uncomplicated cystitis in women

Adult: 800 mg as single dose.
Renal impairment: Dose reduction may be necessary.
Food (before/after)
Should be taken with food. (Take with meals.)

Method of administration
Oral

4.3 Contraindications
Pefloxacin and Pregnancy
Contraindicated in pregnancy
Pefloxacin and Lactation
Contraindicated in lactation
Pefloxacin and Other Contraindications
Hypersensitivity to quinolones, children <12 years, pregnancy, lactation.

4.4 Special warnings and precautions for use
Children
Children under 12 years of age are not given Pefloxacin
Geriatric use
The effects on older people are similar to those given to young adults.
Pregnant women
The drug belongs to Category Pregnancy N. Its effect on pregnancy is not known. Thus, one should avoid giving it to a pregnant mother or women who are planning for pregnancy.
Lactating women
The use of Pefloxacin in lactating women is contradicted. Thus, do not give the drug to a lactating mother.
Other
Avoid giving the drug to patients with a history of brain or spinal cord disease. Avoid prescribing it to patients with kidney disease, liver impairment or epilepsy.

4.5 Interaction with other medicinal products and other forms of interaction
Reduced absorption with antacids, didanosine (DDI), iron salts, pirenzepine, sucralfate, vincristine, zinc salts; increased levels with cimetidine, probenecid, theophylline; increases the levels of cyclosporine; causes seizures with foscarnet, NSAIDs, piroxicam; hypoglycemia with glimeperide; antagonistic with quercetin.

Fluoroquinolones (oral route) + Iron (salts) (oral route)	
Risks and Mechanisms	Reduced digestive absorption of fluoroquinolones.
Course of Action	Take iron salts sometime after fluoroquinolones (more than 2 hours, if possible).
Fluoroquinolones (oral route) + Strontium (oral route)	
Risks and Mechanisms	Reduced digestive absorption of strontium.
Course of Action	Take strontium sometime after fluoroquinolones (more than 2 hours if possible).
Fluoroquinolones (oral route) + Sucralfate	
Risks and Mechanisms	Reduced digestive absorption of fluoroquinolones.
Course of Action	Take sucralfate sometime after fluoroquinolones (more than 2 hours, if possible).
Fluoroquinolones (oral route) + Zinc (salts) (oral route)	
Risks and Mechanisms	Reduced digestive absorption of fluoroquinolones.
Course of Action	Take zinc salts sometime after fluoroquinolones (more than 2 hours, if possible).
Fluoroquinolones (systemic route) + Antivitamins K	
Risks and Mechanisms	Increased effect of the antivitamin K and hemorrhagic effect.

Course of Action	More frequent INR monitoring. Possible dose adjustment of the antivitamin K during the fluoroquinolone treatment and after its discontinuation.
Fluoroquinolones (systemic route) + Phenprocoumone	
Risks and Mechanisms	Increased effect of the antivitamin K and hemorrhagic risk.
Course of Action	More frequent INR monitoring. Possible dose adjustment of the antivitamin K during and after stopping the treatment with fluoroquinolone.
Orally administered drugs + Cholestyramine	
Risks and Mechanisms	Cholestyramine can reduce intestinal absorption, and potentially, the effectiveness of other drugs taken at the same time. This interaction was proved for some substances or therapeutic classes (thyroid hormones, statins, digoxin, oral anticoagulants, hydrochlorothiazide, paracetamol, bile acids) but probably concerns also many other drugs.
Course of Action	In general, Cholestyramine should be taken sometime after the other drugs (more than two hours, if possible).
Orally administered drugs + Topical gastrointestinal agents, antacids and adsorbents	
Risks and Mechanisms	Reduced absorption of certain other drugs ingested simultaneously.
Course of Action	As a precaution, these topical agents or antacids should be taken some time after any other drug (more than 2 hours, if possible).
Pefloxacin + Theophylline (and by extrapolation, aminophylline)	
Risks and Mechanisms	Increased theophyllinemia with risk of overdose (reduced metabolism of theophylline).
Course of Action	Clinical monitoring and possible monitoring of theophyllinemia.

4.6 Pregnancy and Lactation
Pefloxacin and Pregnancy
Contraindicated in pregnancy
Pefloxacin and Lactation
Contraindicated in lactation

4.7 Effects on ability to drive and use machines
Caution while driving the vehicle or operating machine or involved in any hazardous activities

4.8 Undesirable effects
The side effects of Pefloxacin include allergic reactions. It leads to swelling of the lips, mouth, face, tongue; hives; breathing difficulty.
Other side effects include:

- Stomach pain
- Nausea and Vomiting
- Muscular pain
- Headache
- Photosensitivity (rash, itching, burning sensation) due to sunlight exposure
- Peripheral neuropathy
- Nervousness
- Agitation
- Anxiety
- When not to take the medicine

Do not take the medicine in case of hypersensitivity, pregnancy or when nursing a baby.

4.9 Overdose
Give supportive measures and symptomatic treatment.

5. PHARMACOLOGICAL PROPERTIES
5.1 Pharmacodynamics properties
Pharmacotherapeutic group: A synthetic 2nd generation fluoroquinolone, Broad-spectrum antibiotic.
ATC code: J01MA03

Mechanism of Action of Pefloxacin
Pefloxacin is a bacteriostatic at low concentration and bactericidal at high concentration. It act by inhibiting the enzyme DNA gyrase (Topoisomerase 2) and Topoisomerase 4.DNA gyrase helps in the formation of a highly condensed three dimensional structure of the DNA by its nicking and closing activity and also by introducing negative supercoil in to the DNA double helix. Pefloxacin inhibits DNA gyrase which results in abnormal linkage between opened DNA and gyrase and negative super coiling is also impaired. This will inhibits transcription of DNA in to RNA and subsequent protein synthesis.

5.2 Pharmacokinetic properties
Absorption: They are rapidly absorbed after oral administration.
Distribution: It is widely distributed in the body.
Metabolism: It undergoes hepatic metabolism and form active and inactive metabolites.
Excretion: Drug is excreted mainly through urine.

5.3 Preclinical safety data
Not Applicable

6. PHARMACEUTICAL PARTICULARS
6.1 List of excipients
Lactose
Starch
Povidone K-30
Purified Water
Sodium Starch Glycolate
Magnesium Stearate
Purified Talc
Hypromellose
Diethyl Phthalate
Titanium Dioxide
Carnauba Wax
Methylene Chloride
Isopropyl Alcohol

6.2 Incompatibilities
Not Applicable

6.3 Shelf life
36 months.

6.4 Special precautions for storage
Store below 30 ^{0}C. Protect from direct sun light.
Keep all medicines out of the reach of children.
Store tablets in the blisters in the provided carton

6.5 Nature and contents of container <and special equipment for use, administration or implantation>
1 Alu- Alu blister of 10 tablets is packed in a printed carton along with pack insert.
Pack sizes: 1x10 tablets

6.6 Special precautions for disposal <and other handling>
Any unused product or waste material should be disposed of in accordance with local requirements.

7. APPLICANT
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