PRUFLOX Tablets (Prulifloxacin)

Composition

Each Film coated tablet contains:
Prulifloxacin .......... 600 mg
Colours: Red Oxide of Iron & Titanium Dioxide IP

Dosage Form

Tablet

Pharmacology

Mechanism of Action
Like other fluoroquinolones, prulifloxacin prevents bacterial DNA replication, transcription, repair and recombination through inhibition of bacterial DNA gyrase.

Antibacterial Spectrum
Prulifloxacin is the prodrug of ulifloxacin. Prulifloxacin is immediately and quantitatively transformed into the active metabolite ulifloxacin. Therefore, the *in vitro* antimicrobial activity studies were performed using ulifloxacin (UFX). Prulifloxacin showed potent and broad-spectrum antibacterial activity against Gram-negative and Gram-positive bacteria.

*Gram negative bacteria including community and nosocomial isolates of:*
- *Escherichia coli*
- *Klebsiella spp.*
- *Proteus spp.*
- *Providencia spp.*
- *Moraxella catarrhalis*
- *Morganella spp.*
- *Haemophilus spp."

*Pseudomonas aeruginosa* (Activity varies between countries).

*Gram-positive organisms, including:*
Methicillin- or Oxacillin-susceptible *Staphylococcus aureus, Enterococcus spp.*
*Streptococcus pneumoniae*

Pharmacokinetics

After administration of a single oral dose of prulifloxacin 600mg in young healthy volunteers the peak plasma concentration (\(C_{\text{max}}\)) of ulifloxacin (1.6μg/mL) was achieved in a median time to \(C_{\text{max}} (t_{\text{max}})\) of 1 hour. The area under the
plasma concentration-time curve from zero to infinity (AUC$_{\infty}$) was 7.3 μg - h/mL, and AUC$_{\infty}$ values showed linearity over a dose range of 300-600 mg.
Ulifloxacin is ≈45% bound to serum proteins in vivo. It is extensively distributed throughout tissues, with an apparent volume of distribution of 1231 L after a single dose of prulifloxacin 600 mg, and shows good penetration into many body tissues. The elimination half-life (t$_1/2$) of ulifloxacin after single-dose prulifloxacin 300-600 mg ranged from 10.6 to 12.1 hours.

After absorption from the gastrointestinal tract, prulifloxacin undergoes extensive first-pass metabolism (hydrolysis by esterases, mainly paraoxonase to form ulifloxacin, the active metabolite). Unchanged ulifloxacin is predominantly eliminated by renal excretion.

### Indications

PRUFLOX is indicated for treatment of infections caused by susceptible bacteria, in the following conditions:
- Acute uncomplicated lower urinary tract infections (simple cystitis);
- Complicated lower urinary tract infections;
- Acute exacerbation of chronic bronchitis.

In cases of patients with infectious diseases, the treatment should allow for local characteristics concerning susceptibility to antibiotics.

### Dosage And Method Of Administration

**For Adults Only, Dosage is as Follows**
- Patients with acute uncomplicated lower urinary tract infections (simple cystitis): a single 600-mg tablet is sufficient;
- Patients with complicated lower urinary tract infections: a 600-mg tablet once a day up to a 10-day maximum treatment.
- Patients with acute exacerbation of chronic bronchitis: a 600-mg tablet once a day up to a 10-day maximum treatment.

In cases of complicated lower urinary tract infections and acute exacerbation of chronic bronchitis, the duration of treatment depends on the severity of the disease and on the patient's clinical outcome and should anyway be continued for at least 48-72 hours after remission/recovery of symptoms.

PRUFLOX tablets should be swallowed whole with water.

Owing to lack of specific studies, the dosage cannot be determined in patients with renal function impairment (patients with creatinine clearance

### Contraindications

Hypersensitivity to prulifloxacin, to other quinolone antibacterial agents or to any of the excipients.
Pre-pubertal children or adolescents below the age of 18 years with uncompleted skeletal development.
Patients with anamnesis of tendon diseases related to the administration of quinolones. Pregnancy and lactation.

### Warnings And Precautions

**General**

As with other quinolones, exposure to the sun or ultra-violet rays may cause phototoxicity reactions in patients treated with prulifloxacin. Excessive exposure to the sun or ultra-violet rays should be avoided during treatment with PRUFLOX; in case of phototoxicity reactions, the treatment should be discontinued.
The medication is contraindicated in subjects with celiac disease.
As for other quinolones, PRUFLOX should be used with caution in patients with CNS disorders that may predispose to convulsion or lower the convulsion threshold.

Preclinical studies have not shown prulifloxacin's effect on the QTc interval. However, this possibility cannot be excluded, as this effect has been observed with medications of the same therapeutic group. Therefore, in patients with hypokalemia and hypocalcemia or in patients who suffer from rhythm disorders, the use of quinolones should be carefully weighed, in case associating a QTc interval monitoring.

Following administration of other drugs of the same therapeutic group, Achilles tendon or other tendon damages have been observed, especially in elderly patients and patients under corticosteroid treatment. Patients should be advised to discontinue treatment in case of signs of tendon inflammation, myalgia, pain experience or articular inflammation, and to rest the limb or the limbs concerned until the diagnosis of tendonitis has been excluded.

Treatment with antimicrobial agents, including quinolones, may cause development of pseudomembranous colitis. Therefore, this possibility should be considered in case of diarrhea subsequent to administration of antimicrobial agents. When treated with antibacterial agents of the quinolone group, patients with latent or known deficiencies for the glucose-6-phosphate dehydrogenase activity are predisposed to hemolytic reactions and for this reason PRUFLOX should be administered with caution.

As reported for other quinolones, events of rhabdomyolysis, characterized by myalgia, asthenia, increased CPK and myoglobin plasma values, and rapid deterioration of the renal function, may rarely occur. In those cases, the patient should be carefully monitored and appropriate measures, including possible discontinuation of treatment, should be taken.

The use of quinolones is occasionally correlated to appearance of crystalluria; patients under treatment with medicinal products belonging to this therapeutic group should maintain an adequate water balance in order to avoid urine concentration.

Tolerability and efficacy of PRUFLOX in patients with hepatic function impairment have not been assessed. Local and/or national guidelines on the appropriate use of antibacterial agents should be considered, when prescribing an antibiotic therapy.

Drug interactions

- Cimetidine, Antacids containing Al and Mg or Preparations Containing Iron and Calcium
  Concomitant treatment with cimetidine, antacids containing Al and Mg or preparations containing iron and calcium reduces the absorption of PRUFLOX; therefore, PRUFLOX should be administered 2 hours before or at least 4 hours after the administration of these compounds.

- Food/Milk
  Concomitant ingestion of prulifloxacin and milk causes a decrease in the area under the concentration/time curve (AUC) and reduces the rate of prulifloxacin excreted with urine, while the ingestion of food delays and reduces peak levels.

- Probenecid
  Prulifloxacin urinary excretion decreases when concomitantly administered with probenecid.

- Fenbufen
  The concomitant administration of fenbufen with certain quinolones can cause increased risk of convulsions the administration of PRUFLOX and fenbufen should be therefore carefully weighed.

- Hypoglycemic agents
  Quinolones may cause hypoglycemia in diabetic patients under treatment with hypoglycemic agents.

- Theophylline
  Concomitant administration of PRUFLOX and theophylline may cause a slightly decreased theophylline clearance which should have no clinical significance. However, as for other quinolones, theophylline plasma levels should be monitored in
patients with metabolic disorders or presenting risk factors.

**Warfarin**

Quinolones may enhance the effects of oral anticoagulants such as warfarin and its derivatives; when these medicinal products are administered together with PRUFLOX, close monitoring by prothrombin test or other suitable coagulation tests is recommended.

**Nicardipine**

Preclinical data have shown that nicardipine may potentiate the phototoxicity of prulifloxacin.

**Pregnancy**

No clinical data are available concerning use of prulifloxacin in exposed pregnancy. Animal studies did not indicate teratogenic effects. As with other quinolones, prulifloxacin has been shown to cause arthropathies in young animals and therefore its use is contraindicated in pregnancy.

**Lactation**

In rats, prulifloxacin has been observed to cross the placental barrier and pass in large quantities into breast milk. As with other quinolones, prulifloxacin has been shown to cause arthropathies in young animals and therefore its use is contraindicated in lactation.

**Undesirable Effects**

The undesirable effects of mild or moderate intensity are as follows:

Rate values used are as follows: very common (≥10%), common (from 1% to 10%), uncommon (from 0.1% to 1%), rare (from 0.01% to 0.1%) and very rare (<0.01% including isolated reports).

**General Disorders and Administration Site Condition**

Rare: fever

Uncommon: cephalalgia, dizziness.

Rare: altered taste.

**Psychiatric Disturbances**

Rare: sleep disorders, drowsiness, lightheadedness.

**Ear and Labyrinth Disorders**

Rare: hearing impaired.

**Ocular Disorders**

Rare: ocular hyperemia

**Gastrointestinal Disorders**

Common (in prolonged treatment only): epigastralgia, nausea.

Uncommon: diarrhea, epigastralgia, nausea, gastritis and vomiting.

Rare: abdominal pain, gastrointestinal disorders, angular stomatitis, dyspepsia, flatulence, indigestion, oral cavity discomfort, oral moniliasis, glossitis, gastric dilation. In case of prolonged treatment, the rate may be higher for epigastralgia and nausea.
Musculoskeletal and Connective Tissue disorders

- Rare: muscle spasms, rhabdomyolysis.

Skin and Subcutaneous Tissue Disorders

- Uncommon: pruritus, skin rash.
- Rare: facial eczema, phototoxicity and urticaria.

Vascular Disorders

- Rare: hot flush.

Investigations

- Rare: increase in Gamma GTs, increase in bilirubin.

Metabolism and Nutrition Disorders

- Uncommon: anorexia.

The following adverse reactions have been reported very rarely (<0.01%)

- Anaphylactic/anaphylactoid reaction, Steven Johnson syndrome, hypoglycemia, hypoesthesia, dermatitis due to drugs.

The treatment with prulifloxacin may be associated with asymptomatic crystalluria with no change in creatinine levels, with alteration in the hepatic function parameters and with eosinophilia. In the observed cases, those alterations were asymptomatic and transient in nature.

During treatment with prulifloxacin, the development of adverse reaction and altered laboratory parameters not mentioned above, but reported for other quinolones, cannot be excluded.

Overdosage

In the event of acute overdosage, the stomach should be emptied by inducing vomiting or by gastric lavage; the patient should be carefully observed and given supportive treatment.

Packaging Information

PRUFLOX Tablets.............. Blister pack of 5 tablets

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