Front

PRULIFLOXACIN

PRULIBACT

600 mg Film-Coated Tablet
ANTIBACTERIAL

PRODUCT NAME: Prulibact

NAME AND STRENGTH:
Prulifloxacin Tablets 600 mg

PHARMACOLOGIC CATEGORY:
Antibiotic of the fluoroquinolone class

PRODUCT DESCRIPTION:
Brownish pink coloured, oval shaped film coated tablets with a breakline on one surface.

FORMULATION/COMPOSITION:
Each film-coated tablets contains:
Prulifloxacin ..... 600 mg

PHARMACODYNAMICS/PHARMACOKINETICS:
Pharmacodynamics:
Like other fluoroquinolones, Prulifloxacin prevents bacterial DNA replication, transcription, repair and recombination through inhibition of bacterial DNA gyrase. Quinolones and fluoroquinolones are bactericidal drugs, eradicating bacteria by interfering with DNA replication. Quinolones are synthetic agents that have a broad spectrum of antimicrobial activity as well as a unique mechanism of action, resulting in inhibition of bacterial DNA gyrase and topoisomerase IV. Quinolones inhibit the bacterial DNA gyrase or the topoisomerase IV enzyme, thereby inhibiting DNA replication and transcription. For many gram-negative bacteria, DNA gyrase is the target, whereas topoisomerase IV is the target for many gram-positive bacteria. It is believed that eukaryotic cells do not contain DNA gyrase or topoisomerase IV.

Pharmacokinetics:
After administration of a single oral dose of Prulifloxacin 600mg in young healthy volunteers the peak plasma concentration (C_{max}) of Prulifloxacin (1.6µg/mL) was achieved in a median time to C_{max} (t_{max}) of 1 hour. The area under the plasma concentration-time curve from zero to infinity (AUC∞) was 7.3 µg - h/mL, and AUC∞ values showed linearity over a dose range of 300-600mg.
Prulifloxacin 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 Prulifloxacin 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 Prulifloxacin, the active metabolite). Unchanged Prulifloxacin is predominantly eliminated by renal excretion.

INDICATIONS:
Treatment of hypercholesterolemia
It is indicated in the treatment of infections caused by susceptible organisms, in the following conditions:
- Acute uncomplicated lower urinary tract infections (simple cystitis);
- Complicated lower urinary tract infections;
- Acute exacerbation of chronic bronchitis.

The local antibiotic susceptibility pattern should be considered in the treatment of patients with infectious diseases.

DOSAGE AND MODEL ROUTE OF ADMINISTRATION:
For adults only, the indicative dosage is as follows:
- Patients with acute uncomplicated lower urinary tract infections (simple cystitis): one 600 mg tablet is sufficient;
- Patients with complicated lower urinary tract infections: one 600 mg tablet once daily for up to a maximum of 10 days of treatment.
- Patients with acute exacerbation of bronchitis: one 600 mg tablet once daily for up to a maximum of 10 days of treatment.

In case of complicated lower urinary tract infections and acute exacerbation of chronic bronchitis, the length of treatment depends on the severity of the disease and the patient's clinical outcome and should in any case be continued for at least 48-72 hours after remission/disappearance of symptoms.
Prulifloxacin tablets should be swallowed whole with water and should be taken considering food intake.
Because of the lack of specific studies, it is not possible to determine the dosage in patients with renal insufficiency (patients with creatinine clearance < 60 ml/min) and in patients with hepatic insufficiency. Thus, in these patients, monitoring of the plasma levels of the drug is the most reliable method for adjustment of the dosage.

CONTRAINDICATIONS &PRECAUTION(S), WARNING(S)
Hypersensitivity to Prulifloxacin, other quinolone antibacterial or any of the excipients
- Pre-pubertal children or adolescents below 18 years of age with incomplete skeletal development.
- Patients with a history of tendon diseases related to the administration of quinolones.
- Pregnancy and lactation

PRECAUTIONS & WARNINGS:
As for other quinolones, Prulifloxacin should be used with caution in patients with CNS disorders that may predispose to seizures or lower the seizure threshold.
Preclinical studies have not shown any effect of Prulifloxacin on the QTc interval. However, this possibility cannot be excluded, since this effect has been observed with drugs of the same class. Thus, in patients with hypokalaemia and hypocalcaemia or in patients who have arrhythmias, the use of quinolones should be carefully assessed, possibly combining monitoring of the QTc interval.
As after the administration of other drugs of the same class, tendonitis rarely appears. It most frequently involves the Achilles tendon and may lead to rupture of it. The risk of tendonitis and tendon rupture is increased in elderly patients and in patients on corticosteroid treatment. Patients should be advised to discontinue treatment if there are signs of tendon inflammation, myalgia, joint pain or inflammation, and to rest the affected limb(s) until the diagnosis of tendonitis has been excluded.
Treatment with antimicrobials, including quinolones, may result in the development of pseudomembranous colitis. Thus, in the event of diarrhoea following the administration of antimicrobials, it is important to consider this possibility.
Patients with latent or known defects of glucose-6-phosphate dehydrogenase activity are predisposed to haemolytic reactions when they are treated with antibacterial drugs of the quinolone class and for this reason Prulifloxacin should be used with caution.
As reported for other quinolones, signs of rhabdomyolysis may rarely occur, in the form of myalgia, asthenia, increase in plasma CPK and myoglobin levels and a rapid deterioration of renal function. In these cases, the patient should be closely monitored and the appropriate corrective measures should be adopted, including the possible discontinuation of treatment.
This use of quinolones is sometimes associated with the appearance of crystalluria; patients on treatment with this class of products should maintain an adequate water balance in order to prevent urine concentration.
The tolerability and efficacy of Prulifloxacin in patients with hepatic insufficiency have not been evaluated.
When prescribing antibiotic therapy, the local and/or national guidelines on the appropriate use of antibacterials should be considered.

PREGNANCY AND LACTATION:
There are no clinical data on the use of Prulifloxacin during confirmed pregnancy.
Animal studies did not show teratogenicity. Other toxic effects on reproduction were seen only in case of maternal toxicity. However, in rats, Prulifloxacin was noted to cross the placenta and pass into maternal milk in large quantities. As with other quinolones, Prulifloxacin has been shown to cause arthropathy in young animals and thus its use during pregnancy and lactation is contraindicated.

INTERACTIONS:
Concomitant treatment with cimetidine, aluminum- or magnesium-containing antacids or preparations containing iron and calcium reduces the absorption of Prulifloxacin, so Prulifloxacin should be administered 2 hours before or at least 4 hours after these preparations are taken.
Concomitant ingestion of Prulifloxacin and milk results in a decrease in the area under the concentration-time curve (AUC) and reduces the urinary elimination of Prulifloxacin, while the ingestion of food slows and reduces the peak levels.
The urinary excretion of Prulifloxacin decreases when it is administered together with Probenecid. The concomitant administration of fenbufen with some quinolones may result in an increase in the risk of seizures; the administration of Prulifloxacin and fenbufen should therefore be carefully evaluated.
Quinolones may give rise to hypoglycemia in diabetic patients taking hypoglycemic drugs.
The concomitant administration of Prulifloxacin and theophylline may cause a slight decrease in the clearance of theophylline, which should not have any clinical significance. Nevertheless, as for other quinolones, the monitoring of plasma theophylline levels is recommended in patients with metabolic disorders or who have risk factors.
Quinolones may increase the effects of oral anticoagulants such as warfarin and its derivatives; when these products are administered together with Prulifloxacin; close monitoring using the prothrombin test or other reliable tests of coagulation is recommended. Preclinical data have shown that nicardipine may potentiate the photo toxicity of Prulifloxacin.
No clinically significant interaction has been observed during the clinical development of Prulifloxacin following concomitant administration with other medicinal products commonly used in the treatment of patients with the diseases listed under "Therapeutic Indications."

ADVERSE EFFECTS:
The undesirable effects listed below are based on the clinical studies conducted with Prulifloxacin. The majority of the adverse events were of mild or moderate severity.
The following frequencies were used: very common (≥ 1/10), common (≥1/100 to <1/10), uncommon (≥1/1,000 to <1/100), rare (≥1/10,000 to <1/1,000) and very rare (< 1/10,000 including isolated reports).
General disorders and administration site conditions – Rare: fever
Nervous system disorders – Uncommon: headache, dizziness. *Rare*: taste disturbances.
Psychiatric disorders - Rare: sleep disorders, somnolence, and confusion.
Ear and labyrinth disorders – Rare: impaired hearing.
Eye disorders – Rare: ocular hyperaemia
Gastrointestinal disorders - Common (only in case of prolonged treatment): epigastralgia, nausea. *Uncommon*: diarrhoea, epigastralgia, nausea, gastritis and vomiting. *Rare*: abdominal pain, gastrointestinal disorders, angular stomatitis, dyspepsia, flatulence, indigestion, oral cavity disorders, oral moniliasis, Glossitis, gastric dilation. The frequency of epigastralgia and nausea may be higher in case of prolonged treatments.
Musculoskeletal and connective tissue disorders – Rare: muscle spasms, rhabdomyolysis.
Skin and subcutaneous tissue disorders – Uncommon: pruritus, skin rash. *Rare*: facial eczema, photo toxicity and urticaria.
Vascular disorders – Rare: hot flushes.
Investigations – Rare: increase in γ-GT, increase in bilirubin.
Metabolism and nutrition disorders – Uncommon: anorexia.

OVERDOSAGE AND TREATMENT:
There is no specific treatment in the event of overdose. In the event of overdose, the patient should be treated symptomatically and supportive measures instituted as required. Liver function and CK levels should be monitored. Hemodialysis is unlikely to be of benefit.

STORAGE CONDITION:
Store at temperatures not exceeding 30°C.

DOSAGE FORMS AND PACKAGING AVAILABLE:
Alu/Clear PVC/PVDC Blister Pack of 3x10's (Box of 30's)
Alu/Clear PVC/PVDC Blister Pack of 1x5's (Box of 5's)

INSTRUCTIONS AND SPECIAL PRECAUTIONS FOR HANDLING AND DISPOSAL (IF APPLICABLE):
Not Applicable

NAME AND ADDRESS OF MARKETING AUTHORIZATION HOLDER:
Marketing Authorization Holder
Brown & Burk Philippines Inc
U-501, 5/F., SEDCCO 1 Bldg., 120 Rada cor.,
Legaspi Sts., Legaspi Village, Makati City, Philippines

NAME AND ADDRESS OF MANUFACTURER:
MICRO LABS LIMITED
92, Sipcot, Hosur-635 126.
Tamil Nadu, INDIA.

CAUTION STATEMENT:
FOODS, DRUGS, DEVICES, AND COSMETICS ACT PROHIBITS DISPENSING WITHOUT PRESCRIPTION.

ADR REPORTING STATEMENT:
FOR SUSPECTED ADVERSE DRUG REACTION,
REPORT TO THE FDA: www.fda.gov.ph
Seek medical attention immediately at the first sign of Adverse Drug Reaction.

REGISTRATION NUMBER:
DR-XY43630

DATE OF FIRST AUTHORIZATION:
14 August 2014

DATE OF REVISION OF PACKAGE INSERT:
July 2019

EXG-ML01I-1128/B

Size: 170 (L) x 240 (H) mm
Folding size: 42 x 60 mm
Carton size: 63 x 30 x 94 mm
Carton size: 45 x 15 x 103 mm

Back

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Folding size: 42 x 60 mm
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MICRO LABS LIMITED, BANGALORE, INDIA

1	Product Name	Prulibact
2	Strength	600 mg
3	Component	Leaflet
4	Category	Export - Philippines
5	Dimension	170 x 240 mm
6	Artwork Code	EXG-ML01I-1128/B
7	Pharma Code	N/A
8	Reason for Change	Size and New Regulation

Colours Used

BLACK

	Prepared by (DTP)	Checked by (PD)	Approved by			
			Head CQA	Head Production/ Packing (Site)	Head QC (Site)	Head QA (Site)
Sign	Kantharaju L.					
Date	23-07-2022					