

**Mexlo<sup>®</sup>**Lomefloxacin  
**Fluoroquinolone****COMPOSITION**

Mexlo<sup>®</sup> Tablet : Each film-coated tablet contains Lomefloxacin INN 400 mg as Hydrochloride.

**PHARMACOLOGY**

Mexlo<sup>®</sup> (Lomefloxacin HCl) is a synthetic quinolone broad-spectrum antimicrobial agent.

Approximately 95% to 98% of oral dose of lomefloxacin is absorbed rapidly. The elimination half-life with normal renal function is approximately 8 hours. At 24 hours post-dose, subjects with normal renal function receiving single doses of 400 mg have mean plasma Lomefloxacin concentrations of 0.24 mg/ml. Steady state concentrations were achieved within 48 hours of initiation therapy with once-a-day dosing. There is no drug accumulation with single-daily dosing in patients with normal renal function. The urinary excretion of Lomefloxacin was virtually complete within 72 hours after cessation of dosing, with approximately 65% of the dose being recovered as parent drug, serum protein binding is approximately 10%. The following are mean tissue- or fluid-to-plasma ratios of Lomefloxacin following oral administration.

<i>Tissue or Body Fluid</i>	<i>Mean Tissue-or Fluid-to-plasma Ratio</i>
Bronchial mucosa	2.1
Bronchial secretion	0.6
Prostatic tissue	2.0
Sputum	1.3
Urine	140.0

**INDICATION**

Mexlo<sup>®</sup> is indicated for the treatment of infections of lower respiratory tract, urinary tract caused by susceptible organisms and prophylaxis of the patients under going transurethral surgical procedures.

**DOSAGE AND ADMINISTRATION**

Mexlo<sup>®</sup> may be taken without regard to meals.

For treatment of lower respiratory tract infections or uncomplicated and complicated urinary tract infections, the usual adult dosage of Mexlo<sup>®</sup> is 400 mg once daily.

For prophylaxis in patients undergoing transurethral surgical procedures Mexlo<sup>®</sup> is administered a single 400 mg dose 2-6 hours prior to the procedure in adults.

Lower respiratory tract infection and uncomplicated urinary tract infections usually require 10 days of therapy. Complicated urinary tract infections usually require 14 days of therapy.

Geriatric patients generally can receive usual adult dosages of Mexlo® unless creatinine clearance is less than 40 ml/min. No dosage adjustment is needed for elderly patients with normal renal function.

Modification of dosage is recommended in patients with renal dysfunction. In patients with a creatinine clearance > 10 ml/min but < 40 ml/min the recommended dosage is an initial loading dose of 400 mg followed by daily maintenance dose of 200 mg (½ tablet) once daily for the duration of treatment.

#### **CONTRAINDICATION AND PRECAUTION**

Lomefloxacin is contraindicated in patients with a history of hypersensitivity to Lomefloxacin or to any of the quinolone group of antimicrobial agents.

*Patient should be advised*

to avoid the maximum extent of possible direct or indirect sunlight during therapy.

to discontinue therapy if any sign/symptom of phototoxicity reaction such as sensation of skin burning, redness, swelling, blisters, rash, itching or dermatitis appears.

to drink fluids liberally.

#### **SIDE EFFECT**

In clinical trials, most of the adverse events reported were mild to moderate in severity and transient in nature. Adverse clinical events are nausea, headache, photosensitivity, dizziness and diarrhoea.

#### **DRUG INTERACTION**

No clinically significant hazardous interactions have been reported.

#### **USE IN PREGNANCY AND LACTATION**

Pregnancy is a relative contraindication for lomefloxacin. It is not known if lomefloxacin is excreted in breast milk.

#### **HOW SUPPLIED**

Mexlo® tablet: Box containing 1 x 10 tablets in blister pack.

