

## **PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER**

### **(CIPROLEX) Ciprofloxacin Hydrochloride 500 mg tablet**

Ciprofloxacin hydrochloride

#### **Read all of this leaflet carefully before you start taking this medicine.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your health care provider.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects becomes serious, or if you notice any side effects not listed in this leaflet, please tell your health care provider.

#### **In this leaflet:**

1. What CIPROLEX is and what it is used for
2. What you need to know before you take CIPROLEX
3. How to take CIPROLEX
4. Possible side effects
5. How to store CIPROLEX
6. Further information

### **1. WHAT CIPROLEX IS AND WHAT IT IS USED FOR**

Each tablet of CIPROLEX contains Ciprofloxacin hydrochloride equivalent to Ciprofloxacin 500 mg as the active ingredient. Ciprofloxacin is a potent, broad spectrum, synthetic antibacterial agent belonging to the new class of drugs called fluoroquinolones. It is 1-cyclopropyl-1, 6-fluoro-1, and 4-dihydro-4-oxo-7-(1-piperazinyl)-3-quinoline carboxylic acid.

CIPROLEX tablets are indicated for the treatment of a variety of infections caused by two or more organisms. It may also be used for infections caused by multi-drug resistant bacteria. CIPROLEX is indicated for the treatment of the following infections caused by susceptible bacteria:

*Respiratory tract infections:*

Acute bronchitis, exacerbation of chronic obstructive airway disease, empyema, lung abscess, infected bronchiectasis, cystic fibrosis and pneumonia.

*Urinary tract infections:*

Acute and chronic pyelonephritis, prostatitis, cystitis, epididymitis and chronic completed or recurrent UTI caused by multi-resistant organisms and/or *Pseudomonas aeruginosa*.

*Skin and soft tissue infections:*

In surgical and post-operative wound infections due to gram-negative organisms such as *Enterobacteriaceae* and *Pseudomonas aeruginosa*. Also useful in infections caused by resistant *Staphylococci*.

*Surgical infections:*

Peritonitis, intra-abdominal abscess, cholangitis, cholecystitis, empyema of gall bladder

*Bone and joint infections:*

Since CIPROLEX achieves adequate tissue concentrations in the bone, it is useful in the management of acute and chronic osteomyelitis.

*Gynaecological infections:*

Severe pelvic infections caused by susceptible bacteria

*Sexually transmitted diseases:*

Gonorrhoea including that caused by beta-lactamase producing strains. Chancroid caused by *H. ducleryi*

*Gastrointestinal infections:*

Effective in the treatment of typhoid and may also eradicate carrier stage. Useful resistant *Salmonella typhi* infections

*Severe systemic infections:*

Septicemia, bacteremia, infections in immunocompromised patients

## **2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE CIPROLEX**

**Do not take CIPROLEX if;**

- You have a history of hypersensitivity
- CIPROLEX is contra-indicated for persons below the age of 12 years

### **Cautions before you take CIPROLEX**

Talk to your doctor or pharmacist before taking CIPROLEX if you have CNS disorders such as severe cerebral arteriosclerosis or epilepsy because CIPROLEX may cause CNS stimulation. Patients receiving this drug should be well hydrated to prevent crystalluria. Excessive alkalization of urine should be avoided. The dosage should be reduced in patients with renal impairment.

### **Interactions with other medicines**

Serum concentrations and elimination half-life of theophylline toxicity during concurrent use and dosage adjustments made as appropriate. Probenecid delays excretion of CIPROLEX. Antacids containing magnesium hydroxide and/or aluminium hydroxide may interfere with the absorption of CIPROLEX resulting in lower serum and urine levels; hence concurrent administration of antacids with CIPROLEX should be avoided.

### **Taking CIPROLEX with food and drink**

CIPROLEX tablet can be administered without regards to meals. Patients should be advised to drink fluids liberally.

### **Pregnancy and breast-feeding**

Reproduction studies in animal at doses up to 6 times the usual daily human dose have not revealed any evidence of impaired fertility or teratogenicity due to CIPROLEX. Information from well controlled studies in pregnant women is not available. Since CIPROLEX caused arthropathy in immature animals, it should not be used in pregnant or nursing women.

### **Driving and using machines**

CIPROLEX may make you feel less alert. Some neurological adverse events can occur. Therefore, make sure you know how you react to Ciprofloxacin before driving a vehicle or operating machinery. If in doubt, talk to your doctor.

### 3. HOW TO TAKE CIPROLEX

The usual doses are:

Infection Site	Severity of Infection	Dosage
Respiratory tract, Bone and Joint, Skin / Soft tissue	Mild / Moderate	500 mg twice daily
	Severe / Complicated	750 mg twice daily
Urinary Tract	Mild / Moderate	250 mg twice daily
	Severe / Complicated	500 mg twice daily
Infected Diarrhea	Mild / Moderate	500 mg twice daily
Gonorrhea	Uncomplicated	250 mg twice daily
Non-gonococcal urethritis		750 mg twice daily
Chancroid		500 mg twice daily
Other Infections		500 – 750 mg twice daily

The duration of CIPROLEX therapy depends upon the type and severity of the infection and should be determined by the clinical and bacteriological response of the patients. For most infections, therapy should be continued for at least 48 hours after the patient becomes asymptomatic. The usual durations 1-2 weeks, but severe or complicated infections may require more prolonged therapy.

#### **If you take more CIPROLEX than you should**

Contact your nearest casualty department immediately in case of overdose. Symptoms of overdose include dizziness, tremor, headache, tiredness, hallucinations and seizures.

#### **If you forget to take CIPROLEX**

If you forget a dose, take it as soon as you remember unless it is time for the next dose. Do not take two doses at the same time. Do not take a double dose to make up for a forgotten tablet.

**If you have any further questions on the use of this product, ask your health care provider.**

### 4. POSSIBLE SIDE EFFECTS

Like all medicines, CIPROLEX can cause side effects, although not everybody gets them. During clinical trials in a large number of patients, adverse effects related to the drug occurred infrequently and were commonly reported as diarrhea, vomiting, abdominal pain, headache, restlessness and rash. Other side effects which have been reported very rarely include arthralgia and increase in serum transaminases levels.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your health care.

### **Renal impairment**

Dosage adjustment will be required in patients with moderate to severe impairment of renal function. Available information on oral administration of CIPROLEX states that if creatinine clearance is less than 20 ml/minute, half the recommended dosage may be administered.

## **5. HOW TO STORE CIPROLEX**

Keep out of the reach and sight of children. Do not store above 25 °C. Store in the original carton and away from light. Do not use CIPROLEX after the expiry date which is stated on the carton after 'Exp'. CIPROLEX should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

## **6. FURTHER INFORMATION**

### **What CIPROLEX contains:**

The active pharmaceutical ingredient is Ciprofloxacin hydrochloride.

The other ingredients (excipients) are Starch Maize BP, Microcrystalline Cellulose, Sodium Starch Glycolate, Colloidal Silicon Dioxide, Methyl Paraben, Propyl Paraben, Talc Purified Magnesium Stearate and White Pre-Mix.

### **What CIPROLEX looks like and contents of the pack:**

CIPROLEX is a white capsule shaped film coated biconvex tablet having a break line with "CPX/500" embossed on one side and "UNICHEM" on the other side. 10 tablets are packed in PVC/aluminum foil blisters and these blisters are packed in pouches along with an insert and sealed. 10 sealed pouches are packed in printed cartons.

### **Manufacturer**

UNICHEM INDUSTRIES LTD.

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