# Module I – Administrative Information and Product Information



## **Qualitative and Quantitative Composition (Active Ingredient Only)**

#### CIPROFLOXACIN TABLETS USP

## CIPROQUIN - 250

Each film coated tablets contains Ciprofloxacin Hydrochloride USP equivalent to Ciprofloxacin .......250 mg.

## CIPROQUIN-500

Each film coated tablets contains Ciprofloxacin Hydrochloride USP equivalent to Ciprofloxacin.....500 mg.

#### PHARMACOLOGY:

Ciprofloxacin is a fluorinated quinolone, with the most potent in vitro antibacterial activity against most antibacterial species of all the newer quinolones marketed to date. The primary mechanism of action of Ciprofloxacin and other quinolones involve inhibition of bacterial DNA Gyrase.In general, against Gram-negative aerobes in vitro, Ciprofloxacin has equivalent activity, or was more potent by 1 or 2 dilutions than Ofloxacin, and was consistently more potent than other quinolones such as Norfloxacin, Enoxacin or Pefloxacin. The antibacterial activity of Ciprofloxacin is influenced little, if at all, by inoculum size, growth medium or the presence of serum.

#### **INDICATIONS:**

For the treatment of infections caused by susceptible strains of the designated micro-organisms in the conditions listed below: Lower respiratory infections, Skin & skin structure infections bone and joint infections, urinary tract infections and infections diarrhoea caused by e. coli (enterotoxigenic strains), campylobacter jejuni, shigella flexneri and shigella sonnei when antibacterial therapy is indicated.



#### **CONTRAINDICATIONS:**

Hypersensitivity to Ciprofloxacin or any other quinolones is a contraindication to its use. Children below 12 years should not to be put on Ciprofloxacin therapy.

#### **SIDE EFFECTS:**

Ciprofloxacin is generally well tolerated. Most frequent adverse effects are nausea, diarrhoea, vomiting, abdominal discomfort, headache, restlessness and rash. Other effects are GI effects, CNS, Skin / Hypersensitivity, Special Senses like blurred vision, disturbed vision (change in colour, perception , overbrightness of lights), decreased visual acuity, diplopia, eye pain, tinnitus, bad taste, Musculloskeletal, Renal/Urogenital.

Most of these events were described as only mild or moderate in severity, abated soon after the drug was discontinued and required no treatment.

#### **PRECAUTIONS:**

CNS stimulation may occur with ciprofloxacin, as with other quinolones, which may lead to tremor, restlessness, lightheadedness, confusion and very rarely to hallucinations or convulsive seizures. Use with caution in patients with known or suspected CNS disorders, such as severe cerebral arteriosclerosis or epilepsy, or other factors which predispose to seizures. Crystalluria related to ciprofloxacin has been reported only rarely in man because human urine is usually acidic. Patients receiving ciprofloxacin should be well hydrated and should avoid alkalinity of the urine. Do not exceed the recommended daily dose. Superinfection: Use of antibiotics (especially prolonged or repeated therapy) may result in bacterial or fungal overgrowth of nonsusceptible organisms. Such overgrowth may lead to a secondary infection. Take appropriate measures if superinfection occurs.

# Kopran

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### **WARNINGS:**

Tendinitis: At any sign of tendinitis (e. g. painful swelling) the administration of Ciprofloxacin should be discontinued, physical exercises be avoided, and a physician consulted.

Usage in Pregnancy: Category C. Since ciprofloxacin, like other drugs in its class, causes arthropathy in immature animals, it should not be used in pregnant women.

Usage in Lactation: It is unknown whether ciprofloxacin is excreted in human milk, however, ciprofloxacin is excreted in the milk of lactating rats, and other drugs of this class are excreted in human milk. Because of the potential for serious adverse effects from ciprofloxacin in nursing infants, decide whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Usage in Children: Ciprofloxacin should not be used in children because it causes arthropathy in immature animals.

#### **DOSAGE:**

Urinary tract infections: 250 mg. every 12 hours. Complicated infections caused by organisms not highly susceptible: 500 mg. every 12 hours. Respiratory tract infections, skin and skin structure infections and bone and joint infections: 500 mg. every 12 hours. More severe or complicated infections: 750 mg. every 12 hours.

Infectious diarrhoea: 500 mg. every 12 hours. The duration of treatment depends upon the severity of infection. Generally, continue ciprofloxacin for at least 2 days after the signs and symptoms of infection have disappeared. The usual duration is 7 to 14 days; however, for severe and complicated infections, more prolonged therapy may be required. Bone and joint infections may require treatment for 4 to 6 week or longer. Infectious diarrhoea may be treated for 5 to 7 days.

The need for liberal water intake during Ciprofloxacin therapy should be impressed upon the patients.



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# **STORAGE:**

Store below 30<sup>o</sup>C. Protect from moisture.

# PRESENTATION:

Box of 10x10s, 10x1x10s

Jar of 100s, 500s and 1000s

KEEP OUT OF REACH OF CHILDREN. PRESCRIPTION ONLY MEDICINE.

Manufactured in India by:

KOPRAN LIMITED

Village Savroli,

Tal. Khalapur,

Dist. Raigad - 410 202.