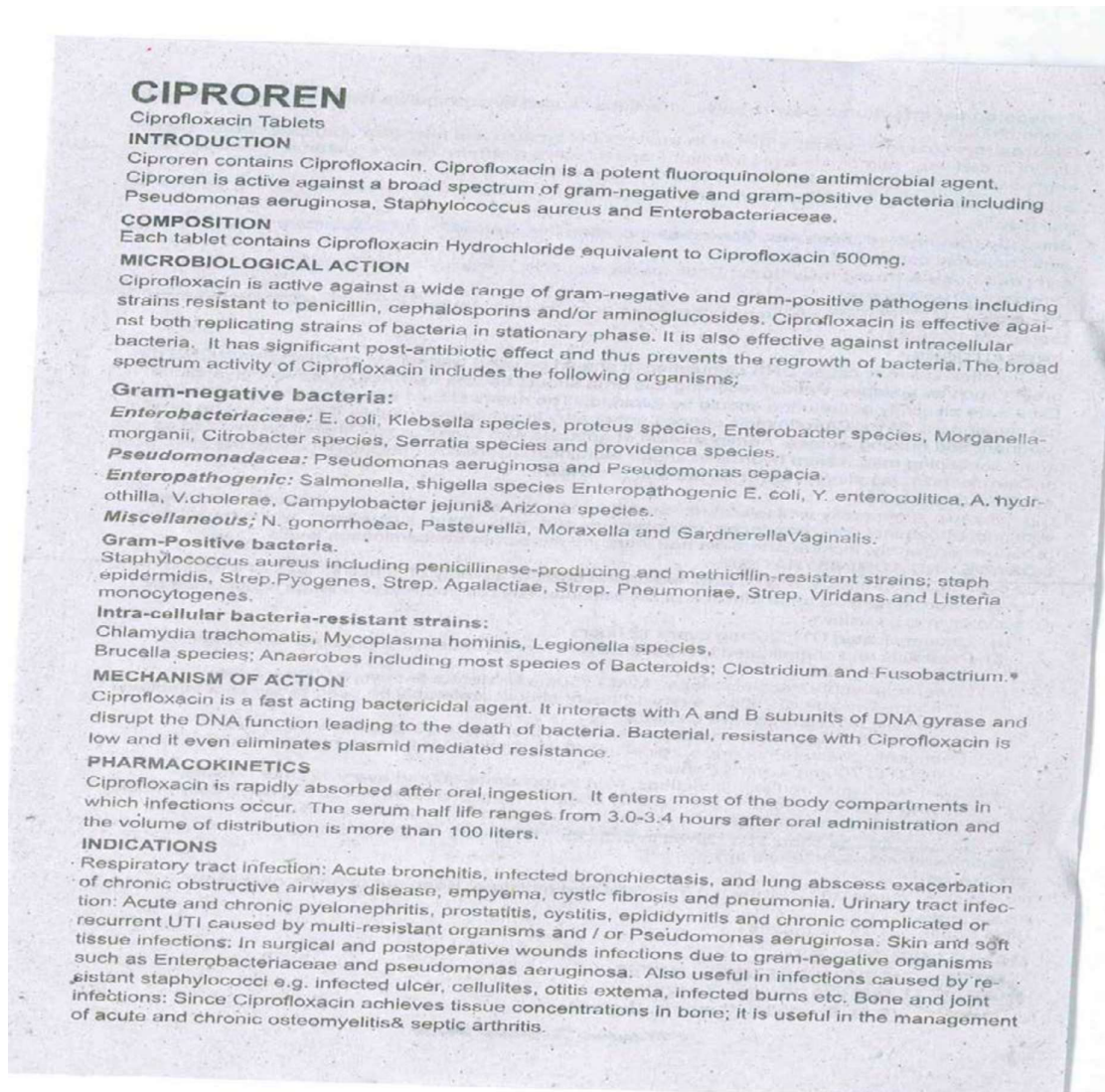


**CTD MODULE 1**  
**ADMINISTRATIVE INFORMATION AND**  
**PRODUCT INFORMATION**

<b>Product Name :</b>	<b>CIPROREN TABLETS</b> <b>(Ciprofloxacin Hydrochloride 500mg)</b>
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**Pack Insert**



**CTD MODULE 1**  
**ADMINISTRATIVE INFORMATION AND**  
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<b>Product Name :</b>	<b>CIPROREN TABLETS</b> <b>(Ciprofloxacin Hydrochloride 500mg)</b>
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**Gynecological infections:** Severe pelvic infections caused by susceptible bacteria, salpingitis, and endometriosis.

**Gastrointestinal infections:** Effective in treatment of typhoid and may also eradicate carrier stage. Useful in resistant salmonella typhi infections and infective diarrhea. Severe systemic infections like septicemia bacteremia infections in immunocompromised patients.

**Surgical infections:** Peritonitis, intra abdominal abscess, cholangitis, cholecystitis, and empyema of gall bladder.

**Sexually transmitted diseases:** Gonorrhea including that caused by beta-lactamase producing strains chancroid caused by H. ducreyi.

**Eye, ear, nose & throat infections:** Otitis media, sinusitis, mastoiditis, and tonsillitis

**CONTRAINDICATIONS:**

Ciprofloxacin is contraindicated in hypersensitive patients. It is not recommended in children below the age of 12 years.

**PRECAUTIONS:**

As Ciprofloxacin may cause CNS stimulation, it should be used with caution in patients with CNS disorders such as epilepsy. Patient receiving this drug should be well hydrated to prevent crystalluria. Excessive alkalinity of the urine should be avoided. The doses should be reduced in patients with renal impairment. Since Ciprofloxacin caused arthropathy in immature animals, it should not be used in pregnant and nursing women. Administration of antacids with Ciprofloxacin should be avoided as antacids containing magnesium hydroxide and/or aluminium hydroxide may interface with the absorption of Ciprofloxacin, resulting in lower serum and urine level.

**ADVERSE EFFECT:**

Ciprofloxacin is generally well tolerated. Some commonly reported adverse effects are diarrhea, vomiting, abdominal pain, headache, restlessness, and rash. Other side effects, which have been reported very rarely, include arthralgia and increase the serum transaminases levels.

**DOSAGE AND ADMINISTRATION:**

The dosage of Ciprofloxacin is determined on the basis of severity of infection, type of infecting organism and age, weight and renal function of the patients. The recommended dosage schedule of oral Ciprofloxacin is as follows:

- (i) Uncomplicated UTI: 250mg every 12 hours
- (ii) Prostatitis and complicated UTI patients with severe underlying structural abnormalities: 500mg every 12 hours.
- (iii) Lower respiratory tract infections: Mild - 250mg Moderate to severe-500mg every 12 hours. Dosage of 250mg every 12 hours should preferably be used in cases of infections with resistant gram-positive bacteria.
- (iv) Gynecological infections and diarrhea of bacterial origin: 500mg every 12 hours.
- (v) Septicemia, bacteremia and surgical infections: Initially I.V therapy may be followed by oral 500 to 700mg every 12 hours.
- (vi) Skin, soft tissue and joint infections: Mild to moderate-500mg every 12 hour. Severe - 750mg every 12 hours. In the majority of other infections - 500 to 750 mg twice daily should be administered. In enteric fever the dose of 500 to 750mg twice a day for 10-14 days.

The total daily dosage should be halved in patients with severe renal impairment (Creatinine clearance <20ml/min.)

**STORAGE:**

Do not store above 30°C, protected from light and moisture. Keep out of reach of children.

**Presentation:**

Blister pack of 10 x 10 tablets.

**MANUFACTURED BY:**



**RENE INDUSTRIES LIMITED**  
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*A Mission To Golden Health*