Ciropharm®

Ciprofloxacin

Composition

Ciprofloxacin® 250 mg F.C. tablets: Each tablet contains ciprofloxacin hydrochloride equivalent to 250 mg ciprofloxacin

Ciprofloxacin® 500 mg F.C. tablets: Each tablet contains ciprofloxacin hydrochloride equivalent to 500 mg ciprofloxacin.

Pharmacological Properties

Ciprofloxacin® is a broad spectrum, bactericidal antibiotic, belongs to fluoroquinolone group. It acts by inhibiting gyrase enzyme which is essential in the metabolic activity of the bacteria. It is widely distributed to most body tissues.

Ciprofloxacin® is active against a range of gram positive and gram negative bacteria including:

E.coli, Shigella, Salmonella, Klebsiella, Enterobacter, Serratia, Proteus (indole positive and negative), Providencia, Morganella, Yersinia, Vibrio, Plesiomonas, Pasteurella, Haemophilus, Campylobacter, Pseudomonas, Legionella, Neisseria, Moraxella (Branhamella), Acinetobacter, Brucella, Staphylococcus, Listeria, Corynebacterium, Chlamydia, Gardnerella, Streptococcus agalactiae, Streptococcus viridans, Streptococcus faecalis, Streptococcus pneumoniae, Mycoplasma hominis, Mycobacterium tuberculosis.

Among fluoroquinolones, **Ciprofloxacin®** is the most potent against pseudomonas aeruginosa.

Indications

- Respiratory tract infections: bronchitis, pneumonia, sinusitis and otitis media.
- Urinary tract infections
- Gastrointestinal tract infections
- Skin and soft tissue infections.
- Gonorrhea.
- Bone and joint infections.
- Eye infections.
- Blood poisoning (sepsis).
- Prophylaxis or treatment of infections in patients with a compromised immune system.
- For the treatment of anthrax.

For children between 5-17:
Ciprofloxacin® is used for acute infection episode of cystic fibrosis caused by pseudomonas aeruginosa .

Dosage and Administration

Dosage Guidelines			
Type of infection	**Severity**	**Dose**	**Frequency**
- Urinary tract infections. Uncomplicated Complicated Cystitis in women	Mild / moderate Severe	250 mg 500 mg 250 mg	Q 12 hr Q 12 hr Once daily
- Lower respiratory tract infections.	Mild / moderate Severe	250 mg 500 mg	Q 12 hr Q 12 hr
-Bacterial infectious diarrhea.	Mild / moderate / severe	500 mg	Q 12 hr
- Bone and joint infections - Blood poisoning - peritonitis		750 mg	Q 12 hr
Gonorrhea acute, uncomplicated		250 mg	Single dose
Anthrax		500 mg	Q 12 hr
Other infections		250-500 mg	Q 12 hr

- **Ciprofloxacin®** tablets could be taken regardless to meals.
- In case of missed dose, continue treatment with the usual dose.
- Refer to the doctor incase of discontinuing the drug
- Usually the doctor decides the duration of treatment depending on the severity infection. The usual duration of treatment is as follows:

Adults

- Up to 7 days for infections of the kidneys, urinary tract and abdominal cavity,
- In patients with a compromised immune system, therapy should be continued for as long as the total white blood count is depressed.
- A maximum of 2 months for inflammation of the bone marrow (osteomyelitis),
- 7-14 days for all other infections.
- In streptococcal infections therapy should be continued for at least 10 days because of the risk of late complications.
- Chlamydia infections should likewise be treated for at least 10 days.
- In anthrax, 60 days of treatment.

For children and adolescents aged between 5 and 17

10 - 14 days for acute infection episodes of cystic fibrosis caused by P. aeruginosa.

Use in children:

The recommended dose for the treatment of cystic fibrosis is 15-20 mg\kg in 2 divided dose. Maximum dose up to 1500mg\day.

In case of anthrax the dose is 15 mg \ kg twice daily.

Use in elderly:

Elderly patients should receive dose as low as is compatible with the severity of the infection and their kidney function (creatinine clearance

Patients impaired renal and hepatic function.

Adults

1. The doses are recommended for moderate to severe impairment of renal function.
   - For patients with a creatinine clearance between 31 ml/min and 60 ml/min (serum creatinine between 1.4 g/l and 1.7 mg/100 ml), the maximum dose for oral administration is 1000 ciprofloxacin per day.
   - For patients with a creatinine clearance ≤ 30 (serum creatinine ≥ 2 mg/100 ml), the maximum dose for oral administration is 500 mg ciprofloxacin per day.
2. Patients with impaired renal function who are undergoing haemodialysis should receive the same dose after each dialysis session as patients with moderate to severe impairment of renal function point 1).
3. In patients with impaired renal function who use continuous ambulatory peritoneal dialysis (CAPD), 500 mg ciprofloxacin is required 4 x daily at 6-hour intervals for peritonitis.
4. It is not necessary to adjust the dosage for patients with impaired function.
5. In patients with impaired renal and hepatic function, the dosage should be adjusted as for impaired renal function; it may be necessary to monitor the concentration of ciprofloxacin in the blood.

Children and adolescents

No information is available on the influence of impaired renal and hepatic function on the dosage for children and adolescents.

Contraindications

Ciprofloxacin is contraindicated in cases of hypersensitivity to ciprofloxacin or any other drug of the same class, children and adolescents (below 18 years of age), pregnancy and nursing mothers.

Side Effects

General

Occasionally of weakness. Long-term or repeated use

Ciprofloxacin can reduce the susceptibility of the organisms to ciprofloxacin; this means that the patient may become infected again by the same organism or yeast-like organisms before the initial infection has been eradicated.

Rarely: Allergic reactions, drug fever, hypersensitivity reactions (anaphylactic/anaphylactoid reactions, e.g. facial, vascular and laryngeal oedema; dyspnoea ranging up to life-threatening shock), in some instances after the first administration; pain (e.g. pain in the limbs, back, chest).

Very rarely: Reactions similar to those associated with serum sickness (with, for example, fever, swelling of the lymph nodes, reddening of the skin, urticaria, swelling [oedema]), worsening of the symptoms of myasthenia gravis (load-related fatigue of the muscular system, particularly the muscles of the face, pharynx and respiratory tract).

Central nervous system

Occasionally: Headache, dizziness, fatigue, insomnia, agitation, confusion.
Rarely: Hallucinations, sweating, peripheral paraesthesia, anxiety, shivering, depression, tremor, convulsions, decreased sensitivity to touch.
Very rarely: Unsteady gait, increased intracranial pressure, psychotic reactions (psychological impairment, altered perception ranging up to the point of self-endangerment), in some cases after first use, impaired coordination, increased sensitivity to touch, increased muscular tone, muscular twitching.

Gastrointestinal tract

Frequently: Nausea, diarrhoea.
Occasionally: Vomiting, impaired digestion, abdominal pain, flatulence, loss of appetite.
Rarely: Jaundice, inflammation of the large bowel (pseudomembranous colitis).
Very rarely: Liver damage (hepatitis, liver cell necrosis ranging up to life-threatening liver failure), inflammation of the pancreas (pancreatitis).

Cardiovascular

Rarely: Palpitations, migraine, unconsciousness, hot flushes, swelling in (peripheral oedema), low blood pressure.

Blood

Occasionally: Increased levels of a certain type of white blood cell (eosinophilia), reduced levels of white blood cells (leucocytope

Rarely: Reduced levels of red [illegible] blood cells (anaemia, granulocytopenia) or blood platelets (thrombocytopenia), increased levels of while blood cells (leukocytosis) or blood platelets (thrombocytosis), changed blood coagulation factors (prothrombin values)

Very rarely: Increased degradation of red blood corpuscles (haemolytic anaemia), a reduction in all blood cells (pancytopenia, possibly life-threatening), a severe decease in a certain type of white blood cell with the possible symptoms of shivering, fever, blisters in the oral and throat mucosa (agranulocytosis), reduced bone marrow function (possibly life-threatening).

Locomotor system

Occasionally: Joint pain.

Rarely: Muscle pain, swelling in the joints.

Very rarely: Inflammation of the tendons (tendinitis), inflammation of the tendon sheath (tendovaginitis) and torn tendons (e.g. the Achilles tendon), muscular weakness (myasthenia).

Skin

Frequently: Skin rash.

Occasionally: Itching, elevated blotchy skin rash (maculopapular exanthem), nettle rash (urticaria).

Rarely: Light sensitivity with reddening of the skin (photosensitivity),

Very Rarely: Punctate skin haemorrhages (petechiae), blister formation with accompanying haemorrhages (haemorrhagic bullae) and small nodules (papules) with crust formation showing vascular involvement (vasculitis), erythema nodosum, rash on the skin and mucous membranes close to the skin fixed drug eruption), erythema exsudativum multiforme (minor) ranging up to severe forms (Stevens-Johnson syndrome), blister-like loss of the skin and oral nasal mucosa (Lyell's syndrome).

Sensory organs

Occasionally: Impaired sense of taste and smell.

Rarely: Tinnitus, transient loss of hearing, particularly with high tones, visual disturbances (e.g. **double vision,** coloured vision), loss of the sense of taste which is usually reversible after discontinuation of therapy.

Very rarely: Loss of the sense of smell which is usually reversible after discontinuation of therapy.

Urogenital tract

Rarely: Inflammation of the kidney (interstitial nephritis), transient impairment in kidney function ranging up to transient kidney failure.

Laboratory findings

Occasionally: Particularly in patients with pre-existing liver damage, temporary effect on liver function with an increase in liver enzymes (transaminases, alkaline phosphatase) ranging up to jaundice, transient increase in the levels of urea, creatinine and bilirubin (a bile pigment) in the blood.

Rarely: Raised levels of blood glucose (hyperglycaemia) and blood or crystals in the urine (haematuria and crystalluria).

Very rarely: Increased levels of certain enzymes (amylase, lipase).

Warnings and Precautions

In patients with epilepsy or central nervous system damage, risk-benefits consideration should be measured carefully. If persistant diarrhea occurred during or after treatment with ciprofloxacin, possible life threatening pseudomembranous colitis which need immediate therapy.

Excessive exposure to sunlight should be avoided during treatment with ciprofloxacin. Caution should be taken when operating machinery or activities requiring mental awareness.

Drug Interactions

Antacids, sucralfate, calcium, magnesium, aluminum , iron, drugs containing the antiviral agent didanosine , oral nutrient solutions ,drinks enriched with minerals and large quantities of dairy products may decrease the absorption of ciprofloxacin, thus if used concomitantly, its preferable to take ciprofloxacin 1-2 hours before or 4 hours after.

The following drugs have showed interactions with ciprofloxacin:

Xanthines, NSAIDs, cyclosporin, warfarin, glibenclamide, probenecid, metoclopramide, mexiletine, phenytoin, diazepam, methotrexate, omeprazole.

Overdosage

Administration of products containing magnesium or calcium neutralizes stomach acid and thus reduces the absorption of ciprofloxacin into the bloodstream.

A few cases of transient (reversible) kidney damage have been reported following extremely large overdoses.

Use in pregnancy and lactation

There is no experience for the use of ciprofloxacin in pregnant women, therefore Ciprofloxacin should not be used during pregnancy or lactation.

Presentation

Cipropharm® 250 mg: 10 F\C tablets per pack.
Cipropharm® 500 mg: 10 F\C tablets per pack.

(This is a medicament - keep medicaments out of reach of children)

Φ
Pharma International

- **Medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you**
- **Follow strictly the doctor's proscription, method for use and the instructions of the pharmacist who sold the medicament .**
- **The doctor and the pharmacist are experts in medicine, its benefits and risks .**
- **Do not by yourself interrupt the period of treatment prescribed for you.**
- **Do not repeat the same prescription without consulting your doctor.**