

Ciprodiazole[®] Film coated tablets

Company Name: Minapharm Co. For drugs & chemical industries – Egypt

Trade Name : Ciprodiazole Film coated Tablets

Generic Name: Ciprofloxacin hydrochloride monohydrate & Metronidazole

Composition:

Each film coated tablet contains:

Ciprofloxacin hydrochloride monohydrate	524.35 mg
Eq. to ciprofloxacin hydrochloride	500 mg
Metronidazole	500 mg

Excipients : pregelatinized starch, sodium starch glycolate, P.V.P K 30, lactose monohydrate 200 mesh, sodium lauryl sulphate, magnesium stearate, wincoat green.

Pharmaceutical Form:

Film coated tablets

Pharmacological Actions:

Ciprofloxacin is bactericidal and acts by inhibiting DNA gyrase which is essential in the reproduction of bacterial DNA. It has a broad spectrum activity.

Metronidazole is active against infections caused by Trichomonas Vaginalis, Gardnerella Vaginalis, Giardia lamblia and Entamoeba histolytica. Metronidazole & Ciprofloxacin are active against a broad spectrum of obligate anaerobic bacteria, including Bacteroids spp., Fusobacterium spp., Clostridium spp., Treponema spp. and various anaerobic cocci. The action is trichomonocidal, and bactericidal.

Pharmacokinetics:

Ciprofloxacin is well absorbed from the abdominal tract. Oral bioavailability is approximately 70 % and a peak plasma concentration of about 2.5 mcg per ml is achieved after 1 to 2 hours after a dose of 500 mg by mouth. After oral administration, Metronidazole is rapidly absorbed, 80 % is absorbed in one hour. The peak concentration after the oral administration is similar to that after intravenous administration of equivalent dose. Metronidazole passes the placenta and the maternal milk. The essential excretion is through the liver and the bile. They are absorbed readily and almost completely from the gastrointestinal tract. Serum concentrations reach their peak within one hour of oral ingestion.

Indications:

It is used in the treatment of:

- Intra-abdominal and pelvic infections caused by E. coli, Pseudomonas aeruginosa, Proteus mirabilis, Klebsiella pneumonia, or Bacteroides fragilis .
- Diverticulitis.

Dose:

The recommended dosage is 1 tablet taken every 12 hours.

Contraindications :

- 1- It is contraindicated in patients who are hypersensitive to ciprofloxacin or other antibiotics of **Quinolones** group such as Ofloxacin, Norfloxacin, Trovofloxacin, Ofloxacin, as an allergic reaction may occur.
- 2- It is contraindicated with drugs primarily metabolized by CYP1A2 (cytochrome 1A2)
- 3- It is contraindicated with administration of "tizanidine".
- 4- It is contraindicated in patients with epilepsy or other seizure disorders.
- 5- It is contraindicated in children & adolescents below 16 years.
- 6- It is contraindicated in patients who are hypersensitive to the metronidazole or other nitroimidazole derivatives, as an allergic reaction may occur.
- 7- Metronidazole should not be administered to patients with active neurological disorders or a history of blood dyscrasias.
- 8- It is contraindicated in patients with G 6 P D enzyme deficiency.

Side effects :

Some side effects may occur as:

Allergic reactions (rash; itching; swelling of the mouth, face, lips, or tongue), urticaria, erythematous rash, flushing.
Nausea, headache, anorexia, diarrhea, unpleasant metallic taste, furry tongue, stomach cramps pain/discomfort, vomiting, fainting; fever & drug fever.
Reversible neutropenia (leukopenia), blood dyscrasias.
Dysuria, cystitis, bloody or tarry stools, darkening of urine, unusual change in amount of urine, abdominal and vaginal yeast infection.
Unusual fatigue, burning, numbness, tingling, pain, or weakness of the arms, hands, legs, or feet. Redness, swelling & bruising of a tendon or joint area. Rarely, tendon inflammation & damage.
Irregular heartbeat; loss of consciousness; chest pain, chills, or unusual cough.
Moderate to severe sunburn.
Mood or mental changes (eg. new or worsening anxiety, agitation,

confusion, depression, restlessness, sleeplessness).
Convulsive seizures and peripheral neuropathy tremors.
Impaired color vision.
Yellowing of the skin or eyes.
Postmarketing experience : Exacerbation of myasthenia gravis

Drug interactions :

- Metronidazole potentiate the anticoagulant effect of Warfarin and other oral coumarin anticoagulants resulting in a prolongation of prothrombin time.
- The simultaneous administration of drugs that induce microsomal liver enzymes, such as phenytoin or Phenobarbital, may accelerate the elimination of metronidazole.
- The simultaneous administration of drugs that decrease microsomal liver enzymes activity, such as ceftrimeid , may prolong the half-life and decrease plasma clearance of metronidazole.
- Psychotic reactions have been reported in alcoholic patients who are using metronidazole and disulfiram concurrently.
- Serious and fatal reactions have occurred when Ciprofloxacin was taken in combination with theophylline (Theo-Dur). These reactions have included cardiac arrest, seizures, status epilepticus (continuous attacks of epilepsy with no periods of consciousness), and respiratory failure. The following can interfere with the absorption of Ciprofloxacin and should be taken not less than 6 hours before or 2 hours after a dose
- Tendon disorders (tendinitis)have been rarely encountered in some cases related to concomitant use of quinolone with corticosteroids.
- Antacids containing magnesium and aluminum, supplements and other products containing calcium, iron or zinc.
- Ciprofloxacin may increase the effects of caffeine.

Pregnancy & lactation :

The drug should not be used during pregnancy nor during lactation.

Precautions & Warning :

The usual dose should be reduced in patients with severe hepatic disease.

In elderly patients, monitoring of serum levels may be necessary to adjust the metronidazole dosage accordingly. This drug should not be used in pediatric patients. Ciprofloxacin may cause you to become dizzy or light-headed; therefore, you should not drive a car, operate dangerous machinery, or participate in any hazardous activity that requires full mental alertness until you know how the drug affects you.

Tendon disorders (tendinitis)have been rarely encountered in some cases related to concomitant use of quinolone with corticosteroids.

Quinolones should not generally be used in patients aged less than 18 years, pregnant women, or breast-feeding mothers unless the benefits outweigh the risks.

Exacerbation of myasthenia gravis: Fluoroquinolones have neuromuscular blocking activity and may exacerbate muscle weakness in persons with myasthenia gravis. Postmarketing serious adverse events, including death and requirement for ventilator support, have been associated with fluoroquinolone use in persons with myasthenia gravis. Avoid fluoroquinolones in patients with known history of myasthenia gravis

Storage :

Ciprodiazole tablets should be stored at temperature not exceeding 30 °C in a dry place.

Package :

Carton box containing 2(AI/PVC) strips . Each strip contains 10 tablets .

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