

PHARMANIAGA CIPROFLOXACIN TABLET

Ciprofloxacin (as hydrochloride) 500mg

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What Pharmaniaga Ciprofloxacin Tablet is used for

Pharmaniaga Ciprofloxacin Tablet used to treat certain or prevent infections caused by bacteria which include infections of respiratory tract, eyes, ears, urinary tract, genital organs, gastrointestinal tract, skin, bones and joints, sepsis, infection in individuals with reduced immunity.

How Pharmaniaga Ciprofloxacin Tablet works

Pharmaniaga Ciprofloxacin Tablet is an antibiotic belonging to the fluoroquinolone family. The active substance is Ciprofloxacin.

Ciprofloxacin kills bacteria that cause infections by inhibiting the reproduction of essential enzyme for bacterial DNA. It only works with specific strains of bacteria.

Before you use Pharmaniaga Ciprofloxacin Tablet

- When you must not use it

Do not take Pharmaniaga Ciprofloxacin Tablet if:

- you are allergic to the ciprofloxacin hydrochloride, to other quinolone drugs or to any of the other ingredients of Pharmaniaga Ciprofloxacin Tablet

- you are taking a medicine called tizanidine

- Before you start to use it

You should not take fluoroquinolone antibacterial medicines, including Pharmaniaga Ciprofloxacin Tablet, if you have experienced any serious adverse reaction in the past when taking a fluoroquinolone (see section Things to be careful of and Side effects). In this situation, you should inform your healthcare providers as soon as possible.

Informed your doctor or pharmacist before taking this medicine if you:

- have ever had kidney problems because your treatment may need to be adjusted
- suffer from epilepsy or other neurological conditions
- have a history of tendon problems during previous treatment with antibiotics such as Ciprofloxacin
- have myasthenia gravis (a type of muscle weakness)
- have a history of abnormal heart rhythms (arrhythmias)
- have been diagnosed with an enlargement or “bulge” of a large blood vessel (aortic aneurysm or large vessel peripheral aneurysm)
- have experienced a previous episode of aortic dissection (a tear in the aorta wall)
- have a family history of aortic aneurysm or aortic dissection or other risk factors or predisposing conditions (e.g., connective tissue disorders such as Marfan syndrome, or vascular Ehlers-Danlos syndrome, or vascular disorder such as Takayasu arteritis, giant cell arteritis, Behcet’s disease, high blood pressure, or known atherosclerosis)

For the treatment of some genital tract infections, your doctor can prescribe

another antibiotic in addition to ciprofloxacin. If there is no improvement in symptoms after 3 days of treatment, please consult your doctor.

Pregnancy and lactation

It is preferable to avoid the use of Pharmaniaga Ciprofloxacin Tablet during pregnancy. Tell your doctor if you are planning to get pregnant.

Do not take Pharmaniaga Ciprofloxacin Tablet during breast feeding because Ciprofloxacin is excreted in breast milk and can be harmful for your child.

- Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

The following medicines are known to interact with Pharmaniaga Ciprofloxacin Tablet in your body. Taking Pharmaniaga Ciprofloxacin Tablet together with these medicines can influence the therapeutic effect of those medicines. It can also increase the probability of experiencing side effects.

Some medicines reduce the effect of Ciprofloxacin. Tell your doctor if you take or wish to take:

- antacids
- omeprazole
- mineral supplements
- sucralfate
- a polymeric phosphate binder (e.g. sevelamer or lanthanum carbonate)
- medicines or supplements containing calcium, magnesium, aluminium or iron

If these preparations are essential, take Pharmaniaga Ciprofloxacin Tablet about two hours before or no sooner than four hours after them.

Tell your doctor if you are taking:

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- vitamin K antagonists (e.g. warfarin, acenocoumarol, phenprocoumon or fluindione) or other oral anti-coagulants (to thin the blood)
- theophylline (for breathing problems)
- phenytoin (for epilepsy)
- cyclosporin (for skin conditions, rheumatoid arthritis and in organ transplantation)
- probenecid (for gout)
- metoclopramide (to treat nausea and vomiting)
- muscle relaxant
- ropinirole (for the treatment of Parkinson's disease)
- methotrexate (for certain types of cancer, psoriasis, rheumatoid arthritis)
- tizanidine (for muscle spasticity in multiple sclerosis)
- antipsychotic (olanzapine and clozapine)
- other medicines that can alter your heart rhythm: medicines that belong to the group of antiarrhythmics (e.g. quinidine, hydroquinidine, disopyramide, amiodorane, sotalol, dofetilide, ibutilide), tricyclic antidepressants, some antimicrobials (that belong to the group of macrolides), some antipsychotics
- zolpidem (for sleep disorders)

Ciprofloxacin may increase the levels of the following medicines in your blood:

- pentoxifylline (for circulatory disorders)
- caffeine
- duloxetine (for depression, diabetic nerve damage or incontinence)
- lidocaine (for heart conditions or anaesthetic use)

- sildenafil (for erectile dysfunction)
- agomelatine (for depression)

How to use Pharmaniaga Ciprofloxacin Tablet

- How much to use

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

Your doctor will explain to you exactly how much Ciprofloxacin you will have to take as well as how often and for how long. This will depend on the type of infection you have and how bad it is.

If you are elderly or have kidney or liver disease, your doctor might prescribe you a lower dose of Pharmaniaga Ciprofloxacin Tablet.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Use Pharmaniaga Ciprofloxacin Tablet for the duration that the doctor recommends.

Do not stop taking medication, even if you feel better after a few days, unless advised by your doctor. Your infection may not clear completely if you stop taking your medicine too soon.

- If you forget to use it

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you or anyone else may have used too much of this medicine. Do this even if there are no signs of

discomfort or poisoning. You may need urgent medical attention.

While you are using it

- Things you must do

Take your medicine exactly as your doctor or pharmacist has told you.

Tell all the doctors, dentists and pharmacists treating you that you are using Pharmaniaga Ciprofloxacin Tablet.

Tell your doctor immediately if you become pregnant while taking this medication.

Take Pharmaniaga Ciprofloxacin Tablet only with a doctor's prescription.

- Things you must not do

Do not stop using the medicine unless advised by your doctor.

Do not use any new medicines without consulting your doctor or pharmacist.

Do not give Pharmaniaga Ciprofloxacin Tablet to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

If you feel sudden, severe pain in your abdomen, chest or back, go immediately to the emergency department.

Prolonged, disabling and potentially irreversible serious side effects

Fluoroquinolone antibacterial medicines, including Pharmaniaga Ciprofloxacin Tablet, have been associated with very rare but serious side effects, some of them being long lasting (continuing months or years), disabling or potentially irreversible.

Stop taking your fluoroquinolone antibiotic and contact your healthcare providers immediately if you have the following signs of a side effect:

- Tendon pain or swelling, often beginning in the ankle or calf. If this happens, rest the painful area until

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you can see your healthcare providers.

- Pain in your joints or swelling in your shoulder, arms, or legs.
- Abnormal pain or sensations (such as persistent pins and needles, tingling, tickling, numbness or burning), weakness in your body, especially in the legs or arms or difficulty walking.
- Severe tiredness, depressed mood, anxiety, problems with your memory, or severe problems sleeping.
- Changes in your vision, taste, smell, or hearing.

Tell your healthcare providers if you have had one of the above effects during or shortly after taking a fluoroquinolone – this means you should avoid them in the future. You and your healthcare providers will decide on continuing the treatment considering also an antibiotic from another class.

You may experience mental health problems even when taking/ using fluoroquinolone antibiotics, including Pharmaniaga Ciprofloxacin Tablet for the first time. In very rare cases depression or mental health problems have led to suicidal thoughts and self-injurious behaviour such as suicide attempts. If you develop such reactions, stop taking/ using Pharmaniaga Ciprofloxacin Tablet and inform your doctor immediately.

Tendinitis and tendon rupture

Pain and swelling in the joints and inflammation or rupture of tendons may occur rarely. Your risk is increased if you are elderly (above 60 years of age), have received an organ transplant, have kidney problems or if you are being treated with corticosteroids. Inflammation and ruptures of tendons may occur within the first 48 hours of treatment and even up to

several months after stopping of Pharmaniaga Ciprofloxacin Tablet therapy. At the first sign of pain or inflammation of a tendon (for example in your ankle, wrist, elbow, shoulder or knee), stop taking Pharmaniaga Ciprofloxacin Tablet, contact your healthcare providers and rest the painful area. Avoid any unnecessary exercise as this might increase the risk of a tendon rupture.

Peripheral neuropathy

You may rarely experience symptoms of nerve damage (neuropathy) such as pain, burning, tingling, numbness and/or weakness especially in the feet and legs or hands and arms. If this happens, stop taking Pharmaniaga Ciprofloxacin Tablet and inform your healthcare providers immediately in order to prevent the development of potentially irreversible condition.

Taking Pharmaniaga Ciprofloxacin Tablet with food and drink

Unless you take Pharmaniaga Ciprofloxacin Tablet during meals, do not eat or drink any dairy products (such as milk or yoghurt) or drinks with added calcium when you take the tablets, as they may affect the absorption of the active substance.

Driving and using machine

This medicine may affect your ability to drive or use machines. If the tablets make you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

Side effects

Fluoroquinolones have been reported to cause serious side effects involving tendons, muscles, joints and the nerves – in a small proportion of patients, these side effects caused long-lasting or permanent disability (see section Before

you start to use it and Things to be careful of).

Like all medicines, Pharmaniaga Ciprofloxacin Tablet can cause side effects, although not everybody gets them.

Visit your doctor or pharmacist immediately if you experience any side effects after using this medicine.

Psychiatric disorder:

- Rare: Depression (potentially leading to thoughts of suicide, suicide attempts, or completed suicide), or hallucinations
- Very rare: Psychotic reactions potentially leading to thoughts of suicide, suicide attempts, or completed suicide

Infection and infestation:

- Uncommon: fungal infection
- Rare: colon inflammation associated with antibiotic

Blood and Lymphatic System Disorder:

- Uncommon: high white blood cells
- Rare: low or high white blood cells, anemia, low or high blood platelet count
- Very rare: a special type of reduced red blood cell count (haemolytic anaemia), a dangerous drop in a type of white blood cells (agranulocytosis), drop in the number of red and white blood cells and platelets (pancytopenia), bone marrow depression

Immune system disorder:

- Rare: Allergic reaction, swelling
- Very rare: severe allergic reaction, hives

Metabolism and nutrition disorder:

- Uncommon: Decrease appetite and food intake

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- Rare: High blood sugar, low blood sugar

Nervous System Disorder:

- Uncommon: Headache, dizziness, difficulty in sleeping, taste disorder
- Rare: Par- and dysaesthesia, hypoaesthesia, tremor, seizure, vertigo
- Very rare: Migraine, disturbed coordination, smell disorder, extreme sensitivity to stimuli, pressure on the brain (intracranial pressure)
- Not known: Nerve damage

Eye disorder:

- Rare: Visual disturbance
- Very Rare: Change in colour perception

Ear and Labyrinth Disorders

- Rare: Tinnitus (ringing in the ear), hearing loss
- Very rare: Hearing impaired

Cardiac disorders:

- Rare: Fast or irregular heartbeats.
- Not known: Heart rhythm disorder

Vascular disorder:

- Rare: Low blood pressure, syncope (fainting)
- Very rare: Inflammation of blood vessels

Respiratory, Thoracic and Mediastinal Disorder:

- Rare: Dyspnea (difficulty in breathing)

Gastrointestinal disorder:

- Common: Nausea, diarrhea
- Uncommon: Vomiting, gastrointestinal and abdominal pain, indigestion, bloating
- Very rare: Inflammation of the pancreas

Hepatobiliary Disorder:

- Uncommon: Elevated liver enzyme values, increase bilirubin
- Rare: Liver damage, jaundice, liver inflammation
- Very rare: Death of liver cells very rarely leading to life-threatening liver failure

Skin and Subcutaneous Tissue Disorders:

- Uncommon: Rash, pruritus, urticaria
- Rare: Photosensitivity reaction, blistering
- Very rare: Small, pin-point bleeding under the skin (petechiae), various skin eruptions or rashes (for example, the potentially fatal Stevens-Johnson syndrome or toxic epidermal necrolysis)
- Not known: Acute generalised exanthematous pustulosis

Musculoskeletal Connective Tissue and Bone Disorders:

- Uncommon: Arthralgia (joint pain) or back pain
- Rare: Muscle pain, arthritis, increase muscle tone and cramping
- Very rare: muscular weakness, tendon inflammation, tendon rupture, worsening of the symptoms of myasthenia gravis

Renal and Urinary Disorders:

- Uncommon: Renal impairment
- Rare: Renal failure, blood in urine, pain and discomfort when passing water (crystalluria)

General disorder:

- Uncommon: Unspecified pain, feeling unwell, fever
- Rare: Swelling, sweating
- Very rare: Walking problems

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug

Reaction Monitoring visiting the website npra.gov.my [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Pharmaniaga Ciprofloxacin Tablet**- Storage**

Keep out of the reach and sight of children. Store below 30°C. Protect from light.

Do not take Pharmaniaga Ciprofloxacin Tablet after the expiry date which stated on the label.

- Disposal

Medicines 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.

Product Description**- What it looks like**

White, oblong film-coated tablet with Pharmaniaga icon on one side and scored on the other.

- Ingredients

- Active ingredient(s): Ciprofloxacin Hydrochloride 500mg

- Inactive ingredients: Colloidal Silicone Dioxide, Croscarmellose Sodium, Opadry White, Microcrystalline Cellulose, Lactose Monohydrate, Magnesium Stearate, Purified Water

- MAL number(s):

MAL20021000AZ

Product Registration Holder & Manufacturer

Pharmaniaga Manufacturing Berhad
11A, Jalan P/1, Kawasan Perusahaan Bangi, 43650 Bandar Baru Bangi, Selangor Darul Ehsan, Malaysia

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