

CIPRODAC TABLET

Ciprofloxacin Hydrochloride (500mg)

What is in this leaflet

1. What *Ciprodac* is used for
2. How *Ciprodac* works
3. Before you use *Ciprodac*
4. How to use *Ciprodac*
5. While you are using it
6. Side effects
7. Storage and Disposal of *Ciprodac*
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision

What *Ciprodac* is used for

Ciprodac is used to treat:

- bacterial infection in blood
- respiratory tract infections
- kidney or urinary tract infection
- genital organs infections, including inflammation of uterus, sexually transmitted infection, inflammation of the prostate
- stomach, intestine and abdomen infection
- skin and soft tissue infections
- bone and joint infections
- eyes, ear, or sinus infections
- anthrax inhalation exposure in adults and in children

How *Ciprodac* works

Ciprodac contains the active ingredient, ciprofloxacin, which is an antibiotic belonging to a group of medicines called quinolones.

This medicine works by killing the bacteria which cause these infections.

Before you use *Ciprodac*

- When you must not use *Ciprodac*

Do not take this medicine if:

- you are allergic to ciprofloxacin, to other quinolone medicines or to any of the other ingredients of this medicine (listed in Product Description)
- you have history of tendon rupture or inflammation

Do not give to children or growing teenagers

Pregnancy and lactation

Avoid the use of *Ciprodac* during pregnancy. Tell your doctor if you are pregnant, planning to get pregnant or think that you might be pregnant.

Do not take *Ciprodac* during breast feeding because ciprofloxacin is secreted into breast milk and may cause harm to your child.

- Before you start to use it

Tell your doctor if you:

- suffer from epilepsy or other neurological disorder
- have kidney problems
- are organ transplant recipients.
- 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 disorders such as Takayasu arteritis, giant cell arteritis, Behcet’s disease, high blood pressure, or known atherosclerosis)

You should not take fluoroquinolone antibacterial medicines, including *Ciprodac*, 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.

- Taking other medicines

Tell your doctor if you are taking:

- warfarin or other oral anti-coagulants (to thin the blood)
- probenecid (for gout)
- metoclopramide (for nausea and vomiting)
- cyclosporin (for skin conditions, rheumatoid arthritis and in organ transplantation)
- theophylline (for asthma)
- corticosteroids (to reduce inflammation)
- NSAIDs (as pain killer)
- glibenclamide (for diabetes)

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

- antacids, medicines or supplements containing calcium, magnesium, aluminium or iron

How to use *Ciprodac*

Take *Ciprodac* exactly as your doctor has prescribed.

Follow all directions given to you by your doctor or pharmacist. They may differ from the information contained in this leaflet.

- How much to use

Your doctor will tell you how much *Ciprodac* you need to take each day. Do not take more than the recommended dose.

The dose given may range from half a tablet (250mg) to one and half tablet (750mg), to be taken twice daily or one tablet as single dose. The dose will be determined by your doctor as it depends upon the type of infection you have.

If you are elderly or have kidney problems, your doctor might adjust the dose for you.

- When to use it

Swallow the tablet whole with a full glass of water.

Take your tablet twice daily about the same time each day, in the morning and evening.

You can take the tablets at mealtimes or between meals. It is best taken with an empty stomach because the medicine can be absorbed more quickly.

- How long to use it

- Take *Ciprodac* for the duration that your 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.
- Some types of infection may need long term therapy

CIPRODAC TABLET

Ciprofloxacin Hydrochloride (500mg)

- *If you forget to use it*

Take the missed dose as soon as you remember. Skip the missed dose if it is almost time for your next scheduled dose. Do not take a double dose to make up for the dose you missed.

- *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. In cases of overdose, reversible rapid deterioration in the kidney function has been occasionally reported.

While you are using Ciprodac

- *Things you must do*

- Drink enough water to avoid formation of crystals in urine
- Take *Ciprodac* only with a doctor's prescription.
- Tell any other doctors, dentists and pharmacists who are treating you that you are taking *Ciprodac*.
- If you become pregnant while taking *Ciprodac* tell your doctor immediately.
- If you are taking *Ciprodac* for an infection and your symptoms do not improve within a few days, or if they become worse, tell your doctor.
- If you get severe diarrhea, tell your doctor or pharmacist immediately.

- *Things you must not do*

- Do not stop taking the medicine unless advised by your doctor.
- Do not use any new medicines without consulting your doctor or pharmacist.
- Do not give *Ciprodac* 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

Therefore, make sure you know how you react to *Ciprodac* before driving a vehicle or operating machinery. If in doubt, talk to your doctor.

Prolonged, disabling and potentially irreversible serious side effects.

Fluoroquinolone antibacterial medicines, including *Ciprodac*, 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 doctor 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 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.

You may experience mental health problems even when taking/ using fluoroquinolone antibiotics, including *Ciprodac* 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 *Ciprodac* and inform your doctor immediately.

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.

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 *Ciprodac* therapy. At the first sign of pain or inflammation of a tendon (for example in your ankle, wrist, elbow, shoulder or knee), stop taking *Ciprodac*, 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 *Ciprodac* and inform your healthcare providers immediately in order to prevent the development of a potentially irreversible condition.

Side effects

Like all medicines, *Ciprodac* can cause side effects, although not everybody gets them.

Fluoroquinolones have been reported to cause serious side effects involving tendons, muscles, joints, and the nerves – in a small proportion of people. These side effects caused long-lasting or permanent disability (see section Before you start to use it and Things to be careful of)

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, tell your doctor or pharmacist.

Liver failure, kidney failure, serious allergic reactions, destruction of red blood cells and low blood glucose level (especially when concomitantly used with glibenclamide) can occur upon *Ciprodac* therapy and could be life-threatening, if not treated.

Gastrointestinal:

Nausea, diarrhea, vomiting, indigestion, abdominal pain, flatulence, eating disorder, which are generally mild

Driving and using machines

Ciprodac may make you less responsive.

CIPRODAC TABLET

Ciprofloxacin Hydrochloride (500mg)

and transient

Central Nervous System:

Dizzy, headaches, weakness, restlessness, shaking or trembling.

Hypersensitivity reactions

Skin reactions such as rashes, hives, itching.

Cardiovascular:

Irregular heartbeat and rare instances of abnormal heart rhythms, fainting, high blood pressure, chest pain, heart attack, heart stop beating, blood clot in brain, migraine, unconscious.

Liver:

Increase in liver enzymes such as ALT and AST, alkaline phosphatase, lactate dehydrogenase, serum bilirubin

Blood:

Lower white blood cell, lower platelet count, changes in red blood cell count, or combination of blood changes as stated above.

Kidney:

Poor kidney function, the presence of crystals or renal casts or blood in urine have been reported.

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

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Ciprodac

- Storage

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

Do not use your medicine after the expiry date which is stated on the pack after 'EXP'. The expiry date refers to the last day of that month.

- 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-coloured, capsule-shaped, smooth film-coated tablet and plain on both sides.

- Ingredients

Active ingredient
Ciprofloxacin Hydrochloride

Inactive ingredients

Microcrystalline Cellulose, Colloidal Silicon Dioxide, Sodium Starch Glycolate, Magnesium Stearate, Purified Talc, Hydroxypropyl Methylcellulose, Polyethylene Glycol 6000, Titanium Dioxide

- MAL Number

MAL20034629AZ

Manufacturer

Cadila Pharmaceuticals Limited, 1389, Trasad Road, Dholka - 382 225, District: Ahmedabad, Gujarat, India.

Product Registration Holder

Pahang Pharmacy Sdn. Bhd.
Lot 5979, Jalan Teratai,
5 ½ Miles off Jalan Meru,
41050 Klang, Selangor, Malaysia.

Date of revision

01/08/2024

Serial Number:

NPRA(R2/1)241122/1380