

CIPROX TABLET

Ciprofloxacin (250mg & 500mg)

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What CIPROX is used for

CIPROX is used to treat the following bacterial infections:

- Uncomplicated and complicated infections caused by ciprofloxacin-sensitive pathogens.
- Infections of the respiratory tract.
- In the treatment of outpatients with pneumonia due to Pneumococcus, ciprofloxacin should not be used as a first choice of drug. Ciprofloxacin can be regarded as an advisable treatment for pneumonias caused by Klebsiella, Enterobacter, Proteus, E. coli, Pseudomonas, Haemophilus, Branhamella, Legionella and Staphylococcus.
- Infections of the middle ear (otitis media), of the paranasal sinuses (sinusitis), especially if these are caused by gram-negative organisms including Pseudomonas or by Staphylococcus.
- Infections of the eyes.
- Infections of the kidneys and/or the efferent urinary tract.
- Infections of the genital organs, including adnexitis, gonorrhoea, prostatitis.
- Infections of the abdominal cavity (eg, infections of the gastrointestinal tract or of the biliary tract, peritonitis).
- Infections of the skin and soft tissue.
- Infections of the bones and joints.
- Sepsis.
- Infections or imminent risk of infection (prophylaxis) in patients whose immune system has been weakened (eg, patients on immunosuppressants or have neutropenia).

How it works

CIPROX is an antibiotic belonging to the fluoroquinolone family. The active substance is ciprofloxacin. Ciprofloxacin works by killing bacteria that cause

infections. It only works with specific strains of bacteria.

Before you use CIPROX

- When you must not use it

Do not take CIPROX if you are:

- allergic (hypersensitive) to the active substance, to other quinolone drugs or to any of the other ingredients of CIPROX
- taking tizanidine
- pregnant or breast-feeding

- Before you start to use it

- Tell your healthcare providers if you have been diagnosed with an enlargement or “bulge” of a large blood vessel (aortic aneurysm or large vessel peripheral aneurysm).
- Tell your healthcare providers if you have experienced a previous episode of aortic dissection (a tear in the aorta wall).
- Tell your healthcare providers if you 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 CIPROX, 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.

Tell your doctor 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 CIPROX
- have myasthenia gravis (a type of muscle weakness)
- have a history of abnormal heart rhythms (arrhythmias)

- Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including any that you obtained without a prescription.

Do not take CIPROX together with tizanidine, because this may cause side effects such as low blood pressure and sleepiness (see Section be cautious with CIPROX). The following medicines are known to interact with CIPROX in your body. Taking CIPROX together with these medicines can influence the therapeutic effect of those medicines. It can also increase the probability of experiencing side effects.

Tell your doctor if you are taking:

- warfarin or other oral anti-coagulants (to thin the blood)
- probenecid (for gout)
- methotrexate (for certain types of cancer, psoriasis, rheumatoid arthritis)
- theophylline (for breathing problems)
- tizanidine (for muscle spasticity in multiple sclerosis)
- clozapine (an antipsychotic)
- ropinirole (for Parkinson’s disease)
- phenytoin (for epilepsy)

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

- pentoxifylline (for circulatory disorders)
- caffeine

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

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

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

How to use CIPROX

- How much to use

Your doctor will explain to you exactly how much CIPROX you will have to

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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.

Tell your doctor if you suffer from kidney problems because your dose may need to be adjusted.

The treatment usually lasts from 5 to 21 days, but may take longer for severe infections. Take the tablets exactly as your doctor has told you. Ask your doctor or pharmacist if you are not sure how many tablets to take and how to take CIPROX.

- Swallow the tablets with plenty of fluid. Do not chew the tablets because they do not taste nice.
- Do try to take the tablets at around the same time every day.
- You can take the tablets at mealtimes or between meals. Any calcium you take as part of a meal will not seriously affect uptake. However, do not take CIPROX tablets with dairy products such as milk or yoghurt or with fortified fruit juices (e.g. calcium-fortified orange juice).

Remember to drink plenty of fluids while you are taking CIPROX.

- When to use it
Use as directed by your doctor or pharmacist.
- How long to use it
Continue taking CIPROX for as long as your doctor recommends.

It is important that you finish the course of treatment even if you begin to feel better after a few days. If you stop taking this medicine too soon, your infection may not be completely cured and the symptoms of the infection may return or get worse. You might also develop resistance to the antibiotic.

- If you forget to take it
Take the normal dose as soon as possible and then continue as prescribed. However, if it is almost time for your next dose, do not take the missed dose and continue as usual. Do not take a double dose to make up for a forgotten dose. Be sure to complete your course of treatment.

- If you use too much (overdose)
If you take more than the prescribed dose, get medical help immediately. If possible, take your tablets or the box with you to show the doctor.

While you are using it

- Things you must do
Tell your doctor immediately, if any of the following occurs while taking CIPROX. Your doctor will decide whether treatment with CIPROX needs to be stopped.

- Severe, sudden allergic reaction (an anaphylactic reaction/shock, angio-oedema). Even with the first dose, there is a small chance that you may experience a severe allergic reaction with the following symptoms: tightness in the chest, feeling dizzy, sick or faint, or experiencing dizziness when standing up. If this happens, stop taking CIPROX and contact your doctor immediately.
- Pain and swelling in the joints and tendinitis may occur occasionally, particularly if you are elderly and are also being treated with corticosteroids. At the first sign of any pain or inflammation stop taking CIPROX and rest the painful area. Avoid any unnecessary exercise, as this might increase the risk of a tendon rupture.
- If you suffer from epilepsy or other neurological conditions such as cerebral ischemia or stroke, you may experience side effects associated with the central nervous system. If this happens, stop taking CIPROX and contact your doctor immediately.
- You may experience psychiatric reactions the first time you take CIPROX. If you suffer from depression or psychosis, your symptoms may become worse under treatment with CIPROX. 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 CIPROX and inform your doctor immediately.
- You may experience symptoms of neuropathy such as pain, burning, tingling, numbness and/or weakness. If this happens, stop

taking CIPROX and contact your doctor immediately.

- Diarrhoea may develop while you are taking antibiotics, including CIPROX, or even several weeks after you have stopped taking them. If it becomes severe or persistent or you notice that your stool contains blood or mucus, stop taking CIPROX immediately, as this can be life-threatening. Do not take medicines that stop or slow down bowel movements and contact your doctor.
- Tell the doctor or laboratory staff that you are taking CIPROX if you have to provide a blood or urine sample.
- CIPROX may cause liver damage. If you notice any symptoms such as loss of appetite, jaundice (yellowing of the skin), dark urine, itching, or tenderness of the stomach, stop taking CIPROX and contact your doctor immediately.
- CIPROX may cause a reduction in the number of white blood cells and may cause your resistance to infection may be decreased. If you experience an infection with symptoms such as fever and serious deterioration of your general condition, or fever with local infection symptoms such as sore throat/ pharynx/ mouth or urinary problems you should see your doctor immediately. A blood test will be taken to check possible reduction of white blood cells (agranulocytosis). It is important to inform your doctor about your medicine.
- Tell your doctor if you or a member of your family is known to have a deficiency in glucose-6-phosphate dehydrogenase (G6PD), since you may experience a risk of anemia with ciprofloxacin.
- Your skin becomes more sensitive to sunlight or ultraviolet (UV) light when taking CIPROX. Avoid exposure to strong sunlight, or artificial UV light such as sunbeds.

- Things you must not do
Unless you take CIPROX 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.
- It is preferable to avoid the use of CIPROX during pregnancy. Tell

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your doctor if you are planning to get pregnant.

- Do not take CIPROX during breast feeding because ciprofloxacin is excreted in breast milk and can be harmful for your child.

- Things to be careful of

CIPROX may make you feel less alert. Some neurological adverse events can occur. Therefore, make sure you know how you react to CIPROX before driving a vehicle or operating machinery. If in doubt, talk to your doctor.

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 CIPROX, 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 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.

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

Side Effects

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

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.

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).

Common side effects

- nausea, diarrhea
- joint pains in children

Uncommon side effects

- fungal superinfections
- a high concentration of eosinophils, a type of white blood cell

- loss of appetite (anorexia)
- hyperactivity or agitation
- headache, dizziness, sleeping problems, or taste disorders
- vomiting, abdominal pain, digestive problems such as stomach upset (indigestion/heartburn), or wind
- increased amounts of certain substances in the blood (transaminases and/or bilirubin)
- rash, itching, or hives
- joint pain in adults
- poor kidney function
- pains in your muscles and bones, feeling unwell (asthenia), or fever
- increase in blood alkaline phosphatase (a certain substance in the blood)

Rare side effects

- inflammation of the bowel (colitis) linked to antibiotic use (can be fatal in very rare cases)
- changes to the blood count (leukopenia, leukocytosis, neutropenia, anaemia), increased or decreased amounts of a blood clotting factor (thrombocytes)
- allergic reaction, swelling (oedema), or rapid swelling of the skin and mucous membranes (angiooedema).
- increased blood sugar (hyperglycaemia)
- confusion, disorientation, anxiety reactions, strange dreams, depression (potentially leading to thoughts of suicide, suicide attempts, or completed suicide), or hallucinations
- pins and needles, unusual sensitivity to stimuli of the senses, decreased skin sensitivity, tremors, seizures, or giddiness
- eyesight problems
- tinnitus, loss of hearing, impaired hearing
- rapid heartbeat (tachycardia)
- expansion of blood vessels (vasodilation), low blood pressure, or fainting
- shortness of breath, including asthmatic symptoms
- liver disorders, jaundice (cholestatic icterus), or hepatitis
- sensitivity to light
- muscle pain, inflammation of the joints, increased muscle tone, or cramp
- kidney failure, blood or crystals in the urine
- urinary tract inflammation
- fluid retention or excessive sweating

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- abnormal levels of a clotting factor (prothrombin) or increased levels of the enzyme amylase

Very rare side effects

- a special type of reduced red blood cell count (haemolytic anaemia); a dangerous drop in a type of white blood cells (agranulocytosis); a drop in the number of red and white blood cells and platelets (pancytopenia), which may be fatal; and bone marrow depression, which may also be fatal.
- severe allergic reactions (anaphylactic reaction or anaphylactic shock, which can be fatal - Serum sickness)
- mental disturbances (psychotic reactions) potentially leading to thoughts of suicide, suicide attempts, or completed suicide
- migraine, disturbed coordination, unsteady walk (gait disturbance), disorder of sense of smell (olfactory disorders), pressure on the brain (intracranial pressure)
- visual colour distortions
- inflammation of the wall of the blood vessels (vasculitis)
- pancreatitis
- death of liver cells (liver necrosis) very rarely leading to life-threatening liver failure
- 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)
- muscle weakness, tendon inflammation, tendon rupture – especially of the large tendon at the back of the ankle (Achilles tendon)
- worsening of the symptoms of myasthenia gravis

Frequency not known

- troubles associated with the nervous system such as pain, burning, tingling, numbness and/or weakness in extremities
- severe cardiac rhythm abnormalities, irregular heart beat (Torsades de Pointes)

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 CIPROX

- Storage

- Keep them out of the reach of the children.
- Do not store in temperature over 30°C. Keep it at its original pack. Protect it from light and humidity. Do not use it after its expiring date, recorded on the packaging.

- 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, 17.3 x 8.3 mm, film coated tablet, scored on both side

- Ingredients

- Active ingredient:
Ciprofloxacin

- Inactive ingredients:
Hydroxypropyl cellulose, sodium starch glycolate and magnesium stearate.

Film coating ingredients:
Hydroxypropylmethyl cellulose, polyethelene glycol 400 and titanium dioxide.

- MAL number:

CIPROX Tablet 250mg:
MAL08082713ACZ

CIPROX Tablet 500mg:
MAL08082706ACZ

Manufacturer

Delorbis Pharmaceuticals Ltd.,
17 Athinon Street,
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Product Registration Holder

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