

Pharmacode position may change as per Supplier's m/c requirement & additional small pharma code may appear on the front / back panel



Package leaflet: Information for the user

Ciprofloxacin 250 mg film-coated tablets Ciprofloxacin 500 mg film-coated tablets Ciprofloxacin 750 mg film-coated tablets

Ciprofloxacin hydrochloride

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Ciprofloxacin is and what it is used for
2. What you need to know before you take Ciprofloxacin
3. How to take Ciprofloxacin
4. Possible side effects
5. How to store Ciprofloxacin
6. Contents of the pack and other information

1. What Ciprofloxacin is and what it is used for

Ciprofloxacin 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.

Adults

Ciprofloxacin is used in adults to treat the following bacterial infections:

- respiratory tract infections
- long lasting or recurring ear or sinus infections
- urinary tract infections
- genital organ infections in women
- gastro-intestinal tract infections and intra-abdominal infections
- skin and soft tissue infections
- bone and joint infections
- to treat infections in patients with a very low white blood cell count (neutropenia)
- to prevent infections in patients with a very low white blood cell count (neutropenia)
- to prevent infections due to the bacterium *Neisseria meningitidis*
- anthrax inhalation exposure

If you have a severe infection or one that is caused by more than one type of bacterium, you may be given additional antibiotic treatment in addition to Ciprofloxacin.

Children and adolescents

Ciprofloxacin is used in children and adolescents, under specialist medical supervision, to treat the following bacterial infections:

- lung and bronchial infections in children and adolescents suffering from cystic fibrosis
- complicated urinary tract infections, including infections that have reached the kidneys (pyelonephritis)
- anthrax inhalation exposure

Ciprofloxacin may also be used to treat other specific severe infections in children and adolescents when your doctor considered this necessary.

2. What you need to know before you take Ciprofloxacin

Do not take Ciprofloxacin:

- if you are allergic to ciprofloxacin, to other quinolone drugs or any of the other ingredients of this medicine (listed in section 6).
- taking tizanidine (see Section 2: Other medicines and Ciprofloxacin)

Warnings and precautions

Talk to your doctor or pharmacist before taking Ciprofloxacin.

- 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)

While taking ciprofloxacin

Tell your doctor immediately, if any of the following occurs **while taking Ciprofloxacin**. Your doctor will decide whether treatment with Ciprofloxacin 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 Ciprofloxacin 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 Ciprofloxacin 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 Ciprofloxacin and contact your doctor immediately.
- You may experience **psychiatric reactions** the first time you take Ciprofloxacin. If you suffer from **depression** or **psychosis**, your symptoms may become worse under treatment with

Ciprofloxacin. If this happens, stop taking Ciprofloxacin and contact your doctor immediately.

- You may experience symptoms of neuropathy such as pain, burning, tingling, numbness and/or weakness. If this happens, stop taking Ciprofloxacin and contact your doctor immediately.
- **Diarrhoea** may develop while you are taking antibiotics, including Ciprofloxacin, 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 Ciprofloxacin 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 Ciprofloxacin if you have to provide a **blood or urine sample**.
- Ciprofloxacin 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 Ciprofloxacin and contact your doctor immediately.
- Ciprofloxacin may cause a reduction in the number of white blood cells and 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 Ciprofloxacin. Avoid exposure to strong sunlight, or artificial UV light such as sunbeds.

Other medicines and Ciprofloxacin

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Do not take Ciprofloxacin together with tizanidine, because this may cause side effects such as low blood pressure and sleepiness (see Section 2: "Do not take Ciprofloxacin").

The following medicines are known to interact with Ciprofloxacin in your body. Taking Ciprofloxacin 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)
- theophylline (for breathing problems)
- phenytoin (for epilepsy)
- probenecid (for gout)
- ropinirole (for Parkinson's disease)
- methotrexate (for certain types of cancer, psoriasis, rheumatoid arthritis)
- tizanidine (for muscle spasticity in multiple sclerosis)
- clozapine (an antipsychotic)

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

- pentoxifylline (for circulatory disorders)
- caffeine

Some medicines **reduce** the effect of Ciprofloxacin. 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 Ciprofloxacin about two hours before or no sooner than four hours after them.

Ciprofloxacin with food, drink and alcohol

Unless you take Ciprofloxacin 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.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

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

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

Driving and using machines

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

3. How to take Ciprofloxacin

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

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 Ciprofloxacin.

- 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 Ciprofloxacin 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 Ciprofloxacin.

If you take more Ciprofloxacin than you should

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.

If you forget to take Ciprofloxacin

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 stop taking Ciprofloxacin

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 have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

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

Common side effects (may affect up to 1 in 10 people):

- nausea, diarrhoea
- joint pains in children

Uncommon side effects (may affect up to 1 in 100 people):

- 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 (may affect up to 1 in 1,000 people):

- inflammation of the bowel (colitis) linked to antibiotic use (can be fatal in very rare cases) (see Section 2: Warnings and precautions)
- 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 (angio-oedema)
- increased blood sugar (hyperglycaemia)
- confusion, disorientation, anxiety reactions, strange dreams, depression or hallucinations
- pins and needles, unusual sensitivity to stimuli of the senses, decreased skin sensitivity, tremors, seizures (see Section 2: Warnings and precautions), 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 (see Section 2: Warnings and precautions)
- muscle pain, inflammation of the joints, increased muscle tone, or cramp
- kidney failure, blood or crystals in the urine (see Section 2: Warnings and precautions), urinary tract inflammation
- fluid retention or excessive sweating
- abnormal levels of a clotting factor (prothrombin) or increased levels of the enzyme amylase

Very rare side effects (may affect up to 1 in 10,000 people):

- 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 (see Section 2: Warnings and precautions)
- severe allergic reactions (anaphylactic reaction or anaphylactic shock, which can be fatal - serum sickness) (see Section 2: Warnings and precautions)
- mental disturbances (psychotic reactions) (see Section 2: Warnings and precautions)
- 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) (see Section 2: Warnings and precautions) worsening of the symptoms of myasthenia gravis (see Section 2: Warnings and precautions)

Not known (frequency cannot be estimated from the available data)

- 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)

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

The United Kingdom

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard

5. How to store Ciprofloxacin

Keep this medicine out of the sight and reach of children.

This medicinal product does not require any special storage conditions.

Do not use this medicine after the expiry date which is stated on the carton and blister after EXP. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Ciprofloxacin contains

- The active substance is ciprofloxacin (as hydrochloride). Each film-coated tablet contains 250 mg ciprofloxacin (as hydrochloride). Each film-coated tablet contains 500 mg ciprofloxacin (as hydrochloride). Each film-coated tablet contains 750 mg ciprofloxacin (as hydrochloride).

The other ingredients are:

Tablet core: Cellulose microcrystalline, sodium starch glycolate (Type A), povidone (K 30), silica, colloidal anhydrous, magnesium stearate.

Film coating: Hypromellose, titanium dioxide (E 171), macrogol 400.

What Ciprofloxacin looks like and contents of the pack

Film-coated tablet.

Ciprofloxacin 250 mg film-coated tablets

White to off white, round shaped (diameter 11.1 mm), film coated tablets, with a score line on one side and debossed with 'F' and '23' with a score line in between on the other side. The tablet can be divided into equal doses.

Ciprofloxacin 500 mg film-coated tablets

White to off white, capsule shaped, film coated tablets, with a score line on one side and debossed with 'F22' on the other side. The tablet can be divided into equal doses. The size is 18.2 mm x 8.1 mm

Ciprofloxacin 750 mg film-coated tablets

White to off white, capsule shaped, film coated tablets, debossed with 'C' on one side and '93' on the other side. The size is 22.3 mm x 8.2 mm

Ciprofloxacin film-coated tablets are available in PVC/PVdC-Aluminum foil blister pack.

Pack sizes: 1, 8, 10, 14, 16, 20 and 100 film-coated tablets

Not all pack sizes may be marketed

Marketing Authorisation Holder

Milpharm Limited
Ares Block, Odyssey Business Park
West End Road
Ruislip HA4 6QD
United Kingdom

Manufacturer

APL Swift Services (Malta) Limited
HF26, Hal Far Industrial Estate, Hal Far,
Birzebbugia, BBG 3000.
Malta

Or

Milpharm Limited
Ares Block, Odyssey Business Park
West End Road
Ruislip HA4 6QD
United Kingdom

This medicinal product is authorised in the Member States of the EEA under the following names:

Belgium:	Ciprofloxacin AB 250 mg/ 500 mg/ 750 mg, filmomhulde tabletten
Bulgaria:	Ципрофлоксацин Ауробиндо 250 mg/ 500 mg/ 750 mg Филмирана таблетки
Latvia:	Ciprofloxacin Aurobindo 500 mg apvalkotās tabletes
Lithuania:	Ciprofloxacin Aurobindo 500 mg plėvele dengtos tabletės
Luxemburg:	Ciprofloxacin AB 250 mg/ 500 mg/ 750 mg, filmomhulde tabletten/ Filmtabletten
The Netherlands:	Ciprofloxacin Aurobindo 250 mg/ 500 mg/ 750 mg, filmomhulde tabletten
Portugal:	Ciprofloxacin Aurobindo
Romania:	Ciprofloxacin Aurobindo 250 mg/ 500 mg/ 750 mg comprimate filmate
Spain:	CIPROFLOXACINO AUROBINDO 250 mg/ 500 mg/ 750 mg comprimidos recubiertos con película EFG
The United Kingdom:	Ciprofloxacin 250 mg/ 500 mg/ 750 mg film-coated tablets

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