

i PACKAGE LEAFLET:
Information for the patient

CIPROFLOKSACINE

Solution for infusion – 200 mg / 100 ml
Concentrate for solution for infusion – 100 mg / 10 ml
(Ciprofloxacin lactate)

Read all of this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious or if you notice side effects not listed in this leaflet, please tell your doctor or pharmacist.

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. Other information

1. WHAT CIPROFLOKSACINE IS AND WHAT IT IS USED FOR

Ciprofloxacin is an antibiotic belonging to the fluoroquinolone family. 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 tract infections in men and women;
- gastro-intestinal tract infections and intra-abdominal infections;
- skin and soft tissue infections;
- bone and joint infections;
- anthrax inhalation exposure.

Ciprofloxacin may be used in the management of patients with low white blood cell count (neutropenia) who have a fever that is suspected to be due to a bacterial infection.

If you have a severe infection or one that is caused by more than one type of bacterium, you may be given another 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 considers this necessary.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE CIPROFLOKSACINE

Do not take Ciprofloxacin:

- if you are allergic (hypersensitive) to the active substance, to other quinolone drugs or to any of the other ingredients of Ciprofloxacin (see section 6);
- if you are taking tizanidine (see Section 2: Taking other medicines).

Take special care with Ciprofloxacin

Before you are given Ciprofloxacin

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 Ciprofloxacin;
- are diabetic because you may experience a risk of hypoglycaemia with ciprofloxacin;
- have myasthenia gravis (a type of muscle weakness), because symptoms can be exacerbated;
- have heart problems; caution should be taken when using Ciprofloxacin if you were born with or have family history of prolonged QT interval (seen on ECG, electrical recording of the heart), have salt imbalance in the blood (especially low level of potassium or magnesium in the blood), have a very slow heart rhythm (called "bradycardia"), have a weak heart (heart failure), have a history of heart attack (myocardial infarction), you are female or elderly or you are taking other medicines that result in abnormal ECG changes (see section 2: Other medicines and Ciprofloxacin);
- 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 anaemia with ciprofloxacin.

For the treatment of some genital tract infections, your doctor can prescribe another antibiotic in addition to ciprofloxacin. If there is no improvement of symptoms after 3 days of treatment, please consult your doctor.

While under treatment with Ciprofloxacin

Tell your doctor immediately, if any of the following occurs during treatment with 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 rare chance that you may experience a severe allergic reaction with the following symptoms: tightness in the chest, feeling dizzy, feeling sick or faint, or experience dizziness on standing. **If this happens, tell your doctor immediately since the administration of Ciprofloxacin will have to be stopped.**
- **Pain and swelling in the joints, and tendonitis** may occur occasionally, particularly if you are elderly and are also being treated with corticosteroids.

Inflammation and ruptures of tendons may occur even within the first 48 hours of treatment or up to several months after discontinuation of Ciprofloxacin therapy. At the first sign of any pain or inflammation, Ciprofloxacin will have to be stopped, 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 symptoms of **neuropathy** such as pain, burning, tingling, numbness and/or muscle weakness. If this happens, stop taking Ciprofloxacin and contact your doctor immediately.
- You may experience **psychiatric reactions** after first administration of ciprofloxacin. If you suffer from depression or psychosis, your symptoms may become worse under treatment with Ciprofloxacin. In rare cases, **depression** or **psychosis** can progress to thoughts of suicide, suicide attempts, or completed suicide. If this happens, contact your doctor immediately.
- **Hypoglycemia** has been reported most often in diabetic patients, predominantly in elderly population. If this happens, contact your doctor immediately.
- **Diarrhoea** may develop while you are on antibiotics, including Ciprofloxacin, or even several weeks after you have stopped using them. If it becomes severe or persistent or you notice that your stool contains blood or mucus, stop taking Ciprofloxacin, tell your doctor immediately, as this can be life-threatening. Do not take medicines that stop or slow down bowel movements.
- If your **eyesight becomes impaired** or if your eyes seem to be otherwise affected, consult an eye specialist immediately.
- Your skin becomes more **sensitive to sunlight or ultraviolet (UV) light** under treatment with Ciprofloxacin. Avoid exposure to strong sunlight or artificial UV light such as sunbeds.
- Tell the doctor or laboratory staff that you are taking Ciprofloxacin if you have to provide a **blood or urine sample**
- If you suffer from **kidney problems**, tell the doctor because your dose may need to be adjusted.
- 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, Ciprofloxacin must be stopped 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.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines.

Do not use 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. Using Ciprofloxacin together with these medicines can influence the therapeutic effect of these medicines. It can also increase the probability of experiencing side effects.

Tell your doctor if you are taking:

- Vitamin K antagonists (e.g. warfarin, acenocoumarol, phenprocoumon or flunidione) or other oral anticoagulants (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);
- olanzapine (an antipsychotic);
- clozapine (an antipsychotic);
- ropinirole (for Parkinson's disease);
- phenytoin (for epilepsy);
- cyclosporin (for skin conditions, rheumatoid arthritis and in organ transplantation);
- other medicines that can alter your heart rhythm: medicines that belong to the group of antiarrhythmics (e.g. quinidine, hydroquinidine, disopyramide, amiodarone, 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 (e.g. for erectile dysfunction);
- agomelatine (for depression).

Taking Ciprofloxacin with food and drinks

Food and drinks do not affect your treatment with Ciprofloxacin.

Pregnancy and breast-feeding

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.

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.

Important information about some of the ingredients of Ciprofloxacin – 200 mg / 100 ml – solution for infusion

Ciprofloxacin – 200 mg / 100 ml – solution for infusion contains approximately 354 mg sodium (main component of cooking/table salt) per 100 ml of solution. This is equivalent to 17.7 % of the adult recommended maximum daily dietary intake for sodium.

Talk to your pharmacist or doctor if you need 110 ml or more Ciprofloxacin on a daily basis for a prolonged period of time, especially if you have been advised to have a low salt diet.

3. HOW TO TAKE CIPROFLOKSACINE

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

Tell your doctor if you suffer from kidney problems because your dose may need to be adjusted. Treatment usually lasts between 5 and 21 days, but may be longer for severe infections.

Before infusion, Ciprofloxacin, concentrate for solution for infusion – 100 mg / 10 ml, should be diluted to a concentration of 1 – 2 mg / ml with a compatible solution for infusion.

Your doctor will give you each dose by slow infusion through a vein into your bloodstream. For children, the infusion duration is 60 minutes. In adult patients, infusion time is 60 minutes for 400 mg ciprofloxacin and 30 minutes for 200 mg ciprofloxacin. Administering the infusion slowly helps prevent immediate side effects occurring.

Remember to drink plenty of fluids while you are taking this medicine.

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 using 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 about the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

As with other medicines, Ciprofloxacin may cause side effects, although not everybody gets them.

The following section contains the most serious side effects that you can recognize yourself:

Stop taking Ciprofloxacin and contact your doctor immediately in order to consider another antibiotic treatment if you notice any of the following serious side effects:

Uncommon (may affect up to 1 in 100 people)

- Seizure (see Section 2: Take special care with Ciprofloxacin).

Rare (may affect up to 1 in 1,000 people)

- Severe, sudden allergic reaction with symptoms such as tightness in the chest, feeling dizzy, sick or faint, or experience dizziness when standing up (anaphylactic shock) (see Section 2: Take special care with Ciprofloxacin).
- Tendon rupture, particularly affecting the large tendon at the back of the ankle (Achilles tendon) (see Section 2: Take special care with Ciprofloxacin).
- Very rare** (may affect up to 1 in 10,000 people)
- Severe, sudden allergic reaction with symptoms such as tightness in the chest, feeling dizzy, sick or faint, or experience dizziness when standing up (anaphylactic reaction) (see Section 2: Take special care with Ciprofloxacin).
- Muscle weakness, inflammation of the tendons which could lead to rupture of the tendon, particularly affecting the large tendon at the back of the ankle (Achilles tendon) (see Section 2: Take special care with Ciprofloxacin).
- A serious life-threatening skin rash, usually in the form of blisters or ulcers in the mouth, throat, nose, eyes and other mucous membranes such as genitals which may progress to widespread blistering or peeling of the skin (Stevens-Johnson syndrome, toxic epidermal necrolysis).

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

- Unusual feelings of pain, burning tingling, numbness or muscle weakness in the extremities (neuropathy) (see Section 2: Take special care with Ciprofloxacin).
- A drug reaction that causes rash, fever, inflammation of internal organs, hematologic abnormalities and systemic illness (DRESS Drug Reaction with Eosinophilia and Systemic Symptoms, AGEP Acute Generalised Exanthematous Pustulosis).

Other side effects which have been observed during treatment with ciprofloxacin are listed below by how likely they occur:

Common (may affect up to 1 in 10 people)

- nausea, diarrhoea, vomiting;
- joint pain and joint inflammation in children;
- local reaction at the injection site, rash;
- temporary increased amounts of substances in the blood (transaminases).

Uncommon (may affect up to 1 in 100 people)

- joint pain in adults;
- fungal superinfections;
- a high concentration of eosinophils, a type of white blood cell, increased or decreased amounts of a blood clotting factor (thrombocytes);
- decreased appetite;
- hyperactivity, agitation, confusion, disorientation, hallucinations;
- headache, dizziness, sleeping problems, taste disorders, pins and needles, unusual sensitivity to stimuli of the senses;
- eyesight problems including double vision;
- loss of hearing;
- rapid heartbeat (tachycardia), expansion of the blood vessels (vasodilation), low blood pressure;
- abdominal pain, digestive problems such as stomach upset (indigestion / heartburn), wind;
- liver disorders, increased amounts of one substance in the blood (bilirubin), jaundice (cholestatic icterus);
- itching, hives;
- poor kidney function, kidney failure;
- pain in your muscles and bones, feeling unwell (asthenia), fever, fluid retention;
- increase in blood alkaline phosphatase (a certain substance in the blood).

Rare (may affect up to 1 in 1,000 people)

- muscle pain, inflammation of the joints, increased muscle tone and cramping;
- inflammation of the bowel (colitis) linked to antibiotic use (can be fatal in very rare cases) (see Section 2: Take special care with Ciprofloxacin);

- changes to the blood count (leukopenia, leukocytosis, neutropenia, anaemia), a drop in the number of red and white blood cells and platelets (pancytopenia), which may be fatal, bone-marrow depression which may also be fatal;
- allergic reaction, allergic swelling (oedema), rapid swelling of the skin and mucous membranes (angioedema) (see Section 2: Take special care with Ciprofloxacin);
- increased blood sugar (hyperglycaemia);
- decreased blood sugar (hypoglycaemia) (see Section 2: Take special care with Ciprofloxacin);
- anxiety reaction, strange dreams, depression (potentially leading to thoughts of suicide, suicide attempts, or completed suicide), mental disturbances (psychotic reactions potentially leading to thoughts of suicide, suicide attempts, or completed suicide) (see Section 2: Take special care with Ciprofloxacin);
- decreased skin sensitivity, tremor, migraine, disorder of sense of smell (olfactory disorders), tinnitus, impaired hearing;
- fainting, inflammation of the blood vessel (vasculitis);
- shortness of breath including asthmatic symptoms;
- pancreatitis;
- hepatitis, death of liver cells (liver necrosis) very rarely leading to life-threatening liver failure (see Section 2: Take special care with Ciprofloxacin);
- sensitivity to light (see Section 2: Take special care with Ciprofloxacin), small, pin-point bleeding under the skin (petechiae);
- blood or crystals in urine, urinary tract inflammation, excessive sweating;
- increased levels of the enzyme amylase.

Very rare (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) (see Section 2: Take special care with Ciprofloxacin);
- allergic reaction called serum sickness-like reaction (see Section 2: Take special care with Ciprofloxacin);
- disturbed coordination, unsteady walk (gait disturbance), pressure on the brain (intracranial pressure and pseudotumor cerebri);
- visual colour distortions, various skin eruptions or rashes;
- worsening of the symptoms of myasthenia gravis (see Section 2: Take special care with Ciprofloxacin).

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

- feeling highly excited (mania) or feeling great optimism and overactivity (hypomania);
- abnormal fast heart rhythm, life-threatening irregular heart rhythm, alteration of the heart rhythm (called "prolongation of QT interval", seen on ECG, electrical activity of the heart);
- influence on blood clotting (in patients treated with vitamin K antagonists).

5. HOW TO STORE CIPROFLOKSACINE

Keep the medicine out of the sight and reach of children!

Do not use Ciprofloxacin after the expiry date which is stated on the packaging.

Do not store above 25°C!

Store in the original packaging to protect it from light.

6. OTHER INFORMATION

Ciprofloxacin – solution for infusion – 200 mg / 100 ml

The active substance is ciprofloxacin lactate.

100 ml solution contain ciprofloxacin lactate equivalent to 200 mg ciprofloxacin base.

The other ingredients are: sodium chloride, lactic acid, disodium edetate, hydrochloric acid and water for injection.

Ciprofloxacin – Concentrate for solution for infusion – 100 mg / 10 ml

The active substance is ciprofloxacin lactate.

Each ampoule 10 ml contains ciprofloxacin lactate equivalent to 100 mg ciprofloxacin base.

The other ingredients: lactic acid, disodium edetate, hydrochloric acid and water for injection.

Contents of the pack

Solution for infusion:

Glass bottle of 100 ml.

Concentrate for solution for infusion:

Box with 5 ampoules of 10 ml.

Box with 100 ampoules of 10 ml (for hospital use only).

Explanatory of the illustration icons on the packaging:



According to medical prescription.



Content.



Warning.



Solution for infusion.

Marketing Authorisation Holder (MAH) and Manufacturer:



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