

Ciprofloxacin 2 mg/ml Solution for Infusion

Ciprofloxacin

Read all of this leaflet carefully before you start using 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:

- What Ciprofloxacin Infusion is and what it is used for
- What you need to know before you use Ciprofloxacin Infusion
- How to use Ciprofloxacin Infusion
- Possible side effects
- How to store Ciprofloxacin Infusion
- Contents of the pack and other information

What Ciprofloxacin Infusion is and what it is used for

Ciprofloxacin is an antibiotic belonging to the fluoroquinolones 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 counts (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 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.

What you need to know before you use Ciprofloxacin Infusion

Do not use Ciprofloxacin Infusion:

- if you are allergic (hypersensitive) to ciprofloxacin or to other quinolone drugs or to any of the other ingredients of Ciprofloxacin Infusion (see section 6)
- taking tizanidine (see section 2: Other medicines and Ciprofloxacin Infusion).

If any of these apply to you, talk to a doctor or nurse before you are given this medicine.

Warning and precautions

Before using Ciprofloxacin Infusion

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
- have myasthenia gravis (a type of muscle weakness)
- have diabetes
- 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 Infusion)
- 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 in symptoms after 3 days of treatment, please consult your doctor.

If any of these apply to you, talk to a doctor or nurse before you are given this medicine.

While under treatment with Ciprofloxacin Infusion

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, angioedema). 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 tendinitis** 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 **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, 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 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 tell your doctor immediately. Ciprofloxacin treatment will have to be stopped immediately, as this can be life-threatening. Do not take medicines that stop or slow down bowel movements.
- 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, 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.

- 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 anaemia with ciprofloxacin.
- If you suffer from **kidney problems**, tell the doctor because your dose may need to be adjusted.
- 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.

Other medicines and Ciprofloxacin Infusion:

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

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 use Ciprofloxacin Infusion).

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) 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)
- olanzapine (an antipsychotic)
- clozapine (an antipsychotic)
- ropinirole (for Parkinson's disease)
- phenytoin (for epilepsy)
- cyclosporin (for skin conditions, rheumatoid arthritis and in organ transplantation)
- glibenclamide (for diabetes)
- 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.

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)



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- lidocaine (for heart conditions or anaesthetic use)
- sildenafil (e.g. for erectile dysfunction)

Taking Ciprofloxacin Infusion with food and drink

Food and drink does not affect your treatment with Ciprofloxacin Infusion.

Pregnancy, breast-feeding and fertility

Ask your doctor for advice before taking any medicine. It is preferable to avoid the use of ciprofloxacin during pregnancy. Tell your doctor if you are planning to get 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 Infusion 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 Infusion

Ciprofloxacin Infusion contains 900 mg sodium chloride in 100 ml of infusion. This may make the infusion unsuitable for you if you are on a low sodium diet.

3 How to use Ciprofloxacin Infusion

Your doctor will explain to you exactly how much Ciprofloxacin Infusion 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 bad 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.

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 Infusion and 30 minutes for 200 mg Ciprofloxacin Infusion. Administering the infusion slowly helps prevent immediate side effects occurring.

Remember to drink plenty of fluids while you are taking Ciprofloxacin Infusion.

If you stop your course of Ciprofloxacin Infusion

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 on the use of this product, ask your doctor or pharmacist.

4 Possible side effects

Like all medicines, this medicine can have side effects although not everyone 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.

Common side effects (between 1 and 10 in every 100 people are likely to get these):

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

Uncommon side effects (between 1 and 10 in every 1,000 people are likely to get these):

- fungal superinfections
- a high concentration of eosinophils (a type of white blood cell), increased or decreased amounts of a blood clotting factor (thrombocytes)
- loss of appetite (anorexia)
- hyperactivity, agitation, confusion, disorientation, hallucinations
- headache, dizziness, sleeping problems, taste disorders, pins and needles, unusual sensitivity to stimuli of the senses, seizures (see Section 2: Warnings and precautions), giddiness
- 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
- joint pain in adults
- poor kidney function, kidney failure
- pains in your muscles and bones, feeling unwell (asthenia), fever, fluid retention
- increase in blood alkaline phosphatase (a certain substance in the blood)

Rare side effects (between 1 and 10 in every 10,000 people are likely to get these):

- inflammation of the bowel (colitis) linked to antibiotic use (can be fatal in rare cases) (see Section 2: Warnings and precautions)
- 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 (see Section 2: Warnings and precautions)
- allergic reaction, allergic swelling (oedema), rapid swelling of the skin and mucous membranes (angioedema), severe allergic reaction (anaphylactic shock) which can be life-threatening (see Section 2: Warnings and precautions)
- increased blood sugar (hyperglycaemia)
- low blood sugar (hypoglycaemia)
- 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: Warnings and precautions)

- decreased skin sensitivity, tremor, migraine, disorder of sense of smell (olfactory disorders)
- tinnitus, impaired hearing
- fainting, inflammation of the blood vessels (vasculitis)
- shortness of breath including asthmatic symptoms
- pancreatitis
- hepatitis, death of liver cells (liver necrosis) very rarely leading to life-threatening liver failure
- sensitivity to light (see Section 2: Warnings and precautions), small, pin-point bleeding under the skin (petechiae)
- muscle pain, inflammation of the joints, increased muscle tone, cramping, tendon rupture – especially of the large tendon at the back of the ankle (Achilles tendon) (see Section 2: Warnings and precautions)
- blood or crystals in the urine (see Section 2: Warnings and precautions), urinary tract inflammation
- excessive sweating
- increased levels of the enzyme amylase

Very rare side effects (less than 1 in every 10,000 people are likely to get these):

- a special type of reduced red blood cell count (haemolytic anaemia); a dangerous drop in a type of white blood cells (agranulocytosis)
- severe allergic reaction (anaphylactic reaction, anaphylactic shock, serum sickness) which can be fatal (see Section 2: Warnings and precautions)
- disturbed coordination, unsteady walk (gait disturbance), pressure on the brain (intracranial pressure)
- visual colour distortions
- various skin eruptions or rashes (e.g. the potentially fatal Stevens-Johnson syndrome or toxic epidermal necrolysis)
- muscle weakness, tendon inflammation, worsening of the symptoms of myasthenia gravis (see Section 2: Warnings and precautions)

Frequency not known (cannot be estimated from the available data)

- troubles associated with the nervous system such as pain, burning, tingling, numbness and/ or weakness in extremities
- 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)
- pustular rash
- influence on blood clotting (in patients treated with Vitamin K antagonists).

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report

side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

IRELAND: FREEPOST, Pharmacovigilance Section, Irish Medicines Board, Kevin O'Malley House, Earlsfort Centre, Earlsfort Terrace, Dublin 2, Ireland.
Tel: +353 1 6764971, Fax: +353 1 6762517, Website: www.imb.ie, e-mail: imbpharmacovigilance@imb.ie.

5 How to store Ciprofloxacin Infusion

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

Do not use Ciprofloxacin Infusion after the expiry date which is stated on the carton and vial. The expiry date refers to the last date of that month.

Do not refrigerate or freeze.

Keep container in the outer carton.

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.

6 Contents of the pack and other information

What Ciprofloxacin Infusion contains

The active substance is ciprofloxacin (as ciprofloxacin lactate).

The other ingredients are lactic acid, sodium chloride, hydrochloric acid and water for injections.

What Ciprofloxacin Infusion looks like and contents of the pack

Ciprofloxacin Infusion is a clear, yellowish to slightly yellow solution, and comes in 50 ml, 100 ml and 200 ml vials containing 100 mg, 200 mg and 400 mg ciprofloxacin (as lactate). You will normally be given this infusion in hospital.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Teva UK Limited, Brampton Road, Hampden Park, Eastbourne, BN22 9AG, United Kingdom.

Manufacturer:

Pharmathen S.A., Dervenakion 6, Pallini 15351, Attiki, Greece.

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

United Kingdom: Ciprofloxacin 2 mg/ml Solution for Infusion

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