

## Patient Leaflet Information for the User

## Ciprofloxacin

## 2 mg/ml Solution for Infusion

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 any side effect not listed in this leaflet, please tell your doctor or pharmacist.

**In this leaflet:**

1. What Ciprofloxacin Infusion is and what it is used for
2. Before you receive Ciprofloxacin Infusion
3. How Ciprofloxacin Infusion is administered
4. Possible Side Effects
5. How to Store Ciprofloxacin Infusion
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**1. What Ciprofloxacin Infusion is and what it is used for**

Ciprofloxacin Infusion is an antibiotic.

**Adults**

Ciprofloxacin Infusion is used for the treatment of severe and/or life-threatening infections caused by ciprofloxacin-sensitive microorganisms. The following infections may be treated intravenously (via the blood) with Ciprofloxacin Infusion:

- serious urinary tract infections
- certain lower respiratory tract infections including pneumonia
- serious skin and soft tissue infections
- bone infections

**Children and Adolescents**

Ciprofloxacin Infusion can also be used to treat children and adolescents:

- For serious lung infections in patients aged from 5 years to 17 years with cystic fibrosis (also called mucoviscidosis). Cystic fibrosis affects the lungs, sweat glands and the digestive system causing chronic respiratory and digestive problems.
- For serious urinary tract infections and kidneys infections in patients aged from 1 year to 17 years

Ciprofloxacin Infusion must only be used under medical supervision.

**2. Before you receive Ciprofloxacin infusion****When must you NOT receive Ciprofloxacin infusion ?**

- If you are allergic (hypersensitive) to Ciprofloxacin, to any of the other ingredients, or to any other antibiotic medicines that you may have taken to treat a bacterial infection, including other quinolone antibiotics

The allergic reaction that you experienced may have been itching, reddening of the skin or difficulty with breathing, such as wheezing. If you are not sure about this, ask your doctor.

- Children aged below 5 years
- To treat children and growing adolescents:
  - Except for those between 5 and 17 years old with cystic fibrosis, for the treatment of acute lower respiratory tract infections caused by *Pseudomonas aeruginosa* bacteria
  - Except for those between 1 and 17 years old for the treatment of complicated urinary tract infections and kidneys infections.
- If you have ever suffered from a tendon disorder after being treated with ciprofloxacin or other antibiotics
- If you are pregnant or wish to become pregnant
- If you are breast-feeding
- If you are taking any medicines containing tizanidine (a medicine that is used to treat cramp in your muscles)

**Take special care with Ciprofloxacin Infusion**

You should consult your doctor if any one of the precautions and warnings mentioned below are or were applicable to you in the past.

**Before treatment with Ciprofloxacin Infusion you should tell your doctor if you suffer or have ever suffered from one of the following conditions**

- **Glucose-6-phosphate dehydrogenase deficiency:** an inherited disorder that affects the red blood cells which carry oxygen around your body and makes them break down prematurely. This can make your skin pale and cause weakness or breathlessness. If you, or anyone else in your family, suffer from this problem you must tell your doctor.
- **Epileptic seizures** (convulsions) or any other **brain disease**, for example reduced blood circulation in the brain, stroke or increased sensitivity to fits, since the possible side-effects of ciprofloxacin may cause damage to your brain.
- **Life-threatening irregular heart beat** (Torsades de pointes).
- **A particular type of muscle weakness known as myasthenia gravis.** Ciprofloxacin can aggravate the symptoms of this disease.
- **Liver problems.** Your doctor may wish to check for any changes in your liver function. Please tell your doctor if you recently had a yellowing of the whites of your eyes or your skin.

**During or after treatment with Ciprofloxacin Infusion - you should tell your doctor immediately if during or after the treatment you experience any of the following:**

- **Feeling depressed or confused** after being given this medicine,
- **Pain and inflammation around your tendons.** In particular at the back of your ankles (your Achilles tendon). This medicine may cause these side-effects particularly if you are elderly or taking so-called 'steroid' medicines, such as hydrocortisone. If you develop sore and swollen tendons you should immediately tell your doctor and rest the sore leg.
- An **allergic reaction**, including a serious allergic reaction which causes difficulty in breathing or dizziness. In rare cases this can be life-threatening, so you must tell your doctor immediately.
- **Fever, rash, itching, or small red spots on your skin.**
- **Joint pains** while you are receiving the medicine. The doctor will stop the treatment, rest the affected joint(s) and decide whether to modify the treatment. This is particularly important when children or adolescents are being treated.
- **Severe and persistent diarrhoea and stomach pains** while taking or just after you have stopped taking the medicine, possibly containing blood and mucus. If this happens you should immediately tell your doctor. You may be suffering from severe inflammation of the large intestine (a condition known as "pseudomembranous colitis") which can sometimes be life-threatening.

- **Pain when passing urine** which may be caused by tiny crystals of ciprofloxacin ("crystalluria"). Provided that you do not have a problem with your heart or your kidneys, you can help prevent this from happening by drinking plenty of fluids (at least 1.5 to 2 litres a day). If you experience a new pain or discomfort when passing urine while you are taking this medicine, you must tell your doctor.
- **Skin sensitivity to sunlight or UV light.** This medicine may make your skin become more sensitive to sunlight or to UV light. You should use cream to protect yourself. Avoid exposure to strong sunlight, sunlamps or other sources of UV radiation.
- If you are being **tested for tuberculosis** (a disease caused by the bacterium *Mycobacterium tuberculosis*) you must tell your doctor because this medicine may not allow the test to work properly.
- **Local reactions** after administration of this medicine. These reactions may occur particularly when the medicine is given over 30 minutes or less. They make take the form of local skin reaction, such as reddening, irritation or pain, which usually disappears quickly after the end of the infusion. If these reactions recur or worsen during another infusion further intravenous doses should not be given.

**Taking other Medicines**

Tizanidine (used to treat muscle spasms) must not be given together with Ciprofloxacin Infusion.

If Ciprofloxacin Infusion and one of the following medicines are given at the same time, special care should be taken:

- theophylline (used to treat asthma),
- clozapine (used to treat schizophrenia),
- tacrine (used to treat the symptoms of Alzheimer's disease),
- ropinirole (used to treat Parkinson's disease),

If you use any of these medicines together with ciprofloxacin you will be monitored for signs of overdose.

All of these medicines are broken down in the body by an enzyme called CYP1A2. Ciprofloxacin prevents this enzyme from working properly. This means that the amount of these medicines in your blood may increase.

You must tell your doctor if you are taking any of the following medicines:

- Medicines that are used to relieve pain and inflammation, known as anti-inflammatory medicines (such as ibuprofen and naproxen, but not aspirin). If ciprofloxacin is given in very high doses at the same time as these medicines, this may cause you to have fits.
- Medicines that affect your immune system such as ciclosporin. If you are taking this medicine as well as ciprofloxacin your kidney functions will need to be checked at least twice a week.
- Medicines that you take by mouth and which thin the blood (anticoagulants) such as warfarin,
- Medicines for the treatment of diabetes, such as glibenclamide. Ciprofloxacin may increase the ability of these medicines to lower your blood sugar and may result in hypoglycaemia (a "hypo"),
- Medicines for gout, such as probenecid. [These can increase the amount of ciprofloxacin in your blood]
- Anti-epileptics drugs, such as phenytoin [Ciprofloxacin can change the levels of these medicines in your blood]
- Stimulants, such as caffeine
- Medicines that are used to treat problems with circulation in limbs, such as pentoxifylline
- Medicines that are used to correct irregular heart beats, such as mexiletine.
- Methotrexate, medicine that may be used for the treatment of cancer, or psoriasis, or Crohn's disease of the bowel, or some types of joint disease. Your doctor will monitor you for any signs of methotrexate overdose which may occur because ciprofloxacin can prevent methotrexate from being passed out of the body through the kidneys, which can lead to a build up of the medicine in your blood.

If you are taking any of the medicines above your doctor may decide to modify the dose, or prescribe a different medicine for you, or adjust the dose of Ciprofloxacin Infusion.

Never use several medicines at the same time without asking your doctor about it first.

Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. If you have any further questions about this product ask your doctor or pharmacist.

**Pregnancy and Breast-feeding**

Ask your doctor or pharmacist for advice before taking any medicine.

Ciprofloxacin Infusion must not be given during pregnancy. You must tell your doctor if you are pregnant, or if you suspect that you may be pregnant.

Ciprofloxacin is passed into human breast milk. Do not breast-feed whilst you are taking Ciprofloxacin Infusion. Ciprofloxacin may cause harmful joint problems in breast-fed infants. Ask your doctor or pharmacist for advice if you are breast-feeding.

**Driving and using machines**

Ciprofloxacin can reduce your attention span and may cause dizziness, this may affect your ability to drive and use machines. You should not drive or operate machines if you have taken alcohol with ciprofloxacin.

**Important information about some of the ingredients of Ciprofloxacin Infusion**

If you are on a low-sodium diet please take into account that,

50 ml of Ciprofloxacin contain 7.7mmol (= 177 mg) sodium.  
100 ml of Ciprofloxacin contain 15.4mmol (= 354 mg) sodium.  
200 ml of Ciprofloxacin contain 30.8mmol (= 708 mg) sodium.

**3. How Ciprofloxacin Infusion is administered****What dose of Ciprofloxacin Infusion you will receive**

Your doctor will decide how much you need, when it will be given to you and the duration of the treatment.

This will depend upon your age, weight, medical history, other medicines that you are taking and the type and severity of bacterial infection that is being treated.

**Adults**

The usual dose for adults is between 200 mg and 400 mg twice daily (400 mg to 800 mg daily dose). The exact dose depends on the type and severity of your infection. The maximum daily dose is 1200 mg (400 mg three times daily) for very severe infections. This may be followed by treatment with oral tablets. It is important that you are given a complete course of treatment even if you begin to feel better

after a few days. Your doctor may decide to continue with treatment for at least three days after the signs and symptoms of infection have disappeared in order to avoid your symptoms returning.

**Children and Adolescents**

For the treatment of serious lung infections in children and adolescents aged from 5 to 17 years with cystic fibrosis, the recommended intravenous dose is either 15 mg/kg twice daily or 10 mg/kg three times a day. The maximum daily dose is 400 mg three times daily (1200 mg a day). The exact dose depends on the severity of your infection. The medicine is usually given over a period of approximately 60 minutes. The full treatment usually lasts 10 to 14 days.

For the treatment of complicated urinary tract infections and kidneys infections in children and adolescents aged from 1 to 17 years, the recommended intravenous dose is 6 to 10 mg/kg three times a day with a maximum of 400 mg for each dose. If followed by treatment with tablets, the recommended oral dose is 10 to 20 mg/kg twice daily with a maximum of 750 mg for each dose.

**Elderly**

If you are older than 65 years your doctor may prescribe a dose of Ciprofloxacin Infusion that is based on how well your kidneys are working and how severe your infection is. If you know that you have kidney problems you must tell your doctor. He/ she may decide to adjust your dose.

**Patients with Kidney problems**

Please tell your doctor if you have problems with your kidneys. Your doctor will probably conduct extra tests before administering the medicine. You may be given a lower dose. Ask your doctor if you want to know what doses are being given.

**Patients with Liver problems**

The dose of this medicine does not usually need to be adjusted. Please tell your doctor if you know that you have severe problems with your liver. Ask your doctor if you want to know what doses are being given.

**How Ciprofloxacin Infusion is given**

Ciprofloxacin Infusion is given as an intravenous "ready-to-use" solution.

It is meant for patients who are not able to take Ciprofloxacin by mouth.

Your doctor or nurse will give you this medicine by a slow injection through a vein into your bloodstream over a period of about 60 minutes.

This medicine should not be mixed with any other drugs before or during infusion.

**If you receive more Ciprofloxacin Infusion than you should**

If you receive more Ciprofloxacin Infusion than you should, your doctor will monitor your kidney function and the acidity of your urine. The doctor will also ensure that you receive plenty of fluids and will decide whether or not you need to have dialysis.

If you have any further questions on the use of this product, ask your doctor, pharmacist or nursing staff.

See section 6. "Further Information" for information intended for medical or healthcare professionals.

**4. Possible side effects**

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

Side effects have been reported in between 5 to 14% of patients receiving this medicine.

The most frequent side-effects affect the stomach and intestines, the nervous system, and the skin and connective tissue.

For more details on some of the side effects see Section 2, "Special Precautions".

**Allergic reaction (Hypersensitivity)**

A few people develop allergic reactions to medicines. If you develop any of the following side-effects you must tell your doctor or nurse **immediately**:

- Sudden wheeziness, difficulty in breathing or tightness of the chest
- Headache
- Fever
- Swelling of the eyelids, face, lips or limbs
- Skin lumps or itchy red spots.
- Itch all over the body

**Other side effects**

**Common** occurring in more than 1 in 100 patients, but in less than 1 in 10 patients

The most common side-effects are:

- Changes in your sense of taste (this usually goes away when the treatment is stopped)
- Dizziness
- Headaches
- Difficulty in sleeping (insomnia)
- Restlessness (feeling agitated)
- Confusion
- Feeling sick (nausea),
- Diarrhoea,
- Skin reactions itching and rash
- Joint disease in children

**Uncommon** occurring in more than 1 in 1,000 patients, but in less than 1 in 100 patients

The following side effects could happen but are uncommon:

- Fungal infections, such as thrush of the mouth or vagina (also known as moniliasis or candidiasis)
- White blood cell, red blood cell and platelet disorders. They may make infections more likely, make the skin pale and cause weakness or breathlessness, and increase the risk of bleeding or bruising.
- Soreness of veins, sometimes because a clot has formed
- Being sick (vomiting)
- Pains in the abdomen,
- Wind (flatulence),
- Loss of appetite,
- Pain in your joints,
- Feeling tired and weak,
- Pain or redness where the infusion needle entered your arm
- Unusual results for blood tests conducted to check how well your liver and kidneys are working.
- Chest pains and breathlessness, which may be caused by a blood clot in the lungs
- Fluid build up in the lungs,
- Coughing up blood,
- Nosebleeds,
- Hiccups

**Rare** occurring in more than 1 in 10,000 patients, but in less than 1 in 1,000 patients

The following side-effects occur rarely:

- Increase in the level of glucose in your blood resulting in a feeling of being unwell, an increased need to pass water or drink more than usual (hyperglycaemia).
- Feeling anxious or depressed
- Nightmares
- Seeing things or hearing voices that do not exist (hallucinations)
- Change in sense of smell (sometimes loss of sense of smell)
- Tingling or numbness in the hands and feet
- Shaking
- Epileptic seizures
- Migraine headaches
- Disturbance of your vision (blurred or double vision and/or inability to see colours properly)
- Partial or complete hearing loss
- Ringing in the ears (tinnitus)
- Faster heart beat,
- Fainting
- Hot flushes
- Severe abdominal pain and diarrhoea (which may mean that you have a condition known as "pseudomembranous colitis")
- Yellowing of the skin or whites of the eyes caused by liver or blood problems
- Increased sensitivity to light (photosensitivity)
- Pain in your muscles and/or swollen bone joints
- Kidney problems, including pain in your kidneys which leads to pain and discomfort when passing water (crystalluria) or blood in the urine (haematuria) or your kidneys may temporarily not work properly.
- Excessive sweating,

**Very rare** occurring in less than 1 in 10,000 patients, not known (cannot be estimated from the available data)

The following side-effects occur very rarely:

- Fluid build up in the lungs (pulmonary oedema) with allergic reactions - sudden wheeziness, difficulty in breathing or tightness of the chest
- Psychiatric and psychological problems, sometimes leading to the urge to self-harm
- Coordination problems, such as unsteady gait, increased muscle tone, heightened senses and difficulty in controlling movement
- Increased pressure in the brain, which may appear in the form of visual disturbance, disorientation, loss of memory or concentration, vomiting, dizziness and pins and needles in the hands
- Irregular heart beat, which can be life-threatening
- Serious illness with blistering of the skin, mouth, eyes and genitals
- Severe skin reactions including redness, blistering or discolouration of the skin or reddish tender lumps on the skin
- Inflammation of the pancreas, which causes severe pain in the abdomen and back
- Liver problems (very rarely leading to liver failure)
- Severe skin reactions including redness, blistering or discolouration of the skin or reddish tender lumps on the skin
- Inflammation of your tendon and /or tendon rupture (in particular the Achilles tendon)
- If you suffer from myasthenia gravis (a rare disorder of the nervous system) the symptoms of your disease may become worse.
- Intolerance to light (photosensitivity)

If any of the side effects gets serious or if you notice any side effects not listed in this leaflet please tell your doctor or nursing staff. The treatment should be stopped. Your doctor will decide what action to take.

**5. How to store Ciprofloxacin Infusion**

Keep out of the reach and sight of children.

Do not use Ciprofloxacin after the expiry date which is stated on the packaging after "Exp". The expiry date refers to the last day of that month.

Store below 25°C. Do not refrigerate or freeze.

Keep vial/bottle in outer carton in order to protect from light.

After dilution:

Use within 42 hours if diluted with the administration fluids.

From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user.

After first opening:

Single dose container. Use immediately after first opening.

Medicines should not be disposed via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.

**6. FURTHER INFORMATION****What Ciprofloxacin Infusion contains:**

The active substance is ciprofloxacin.

1 ml of Solution for Infusion contains 2mg Ciprofloxacin as 2.544mg 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 and colourless to slightly yellow solution.

Ciprofloxacin 100 mg/50 ml solution for infusion is available in colourless glass vials, each containing 50 ml solution for infusion.

Ciprofloxacin 200 mg/100 ml solution for infusion is available in colourless glass vials, each containing 100 ml solution for infusion.

Ciprofloxacin 400 mg/200 ml solution for infusion is available in colourless glass bottles, each containing 200 ml solution for infusion.

Pack size: Individual vial/ bottle in unit carton.

In United Kingdom this leaflet was last approved in. **07/2008**

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

Ciprofloxacin Claris in Austria, Estonia, Germany, Ireland, Italy, Latvia, Lithuania, Poland, Portugal and Slovenia.  
Ciprofloxacin EG in Belgium & Luxembourg and Drastin in Greece.

YOU WILL FIND MORE ABOUT  
CIPROFLOXACIN 2 MG/ML INFUSION  
ON THE BACK OF THIS LIFLET