

**Package Leaflet: Information for the User**  
**Ciprofloxacin 2 mg/ml Solution for Infusion**

**Ciprofloxacin**

**Read all of this leaflet carefully before you are given 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.

**In this leaflet:**

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

**1. What Ciprofloxacin Infusion is and what it is used for**

Ciprofloxacin Infusion contains the active substance ciprofloxacin. 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 Infusion is used in adults to treat the following bacterial infections:

- respiratory tract infections
- long lasting or recurring ear or sinus infections
- Uncomplicated acute cystitis  
In Urinary tract infection Ciprofloxacin Infusion should be used only when it is considered inappropriate to use other antibacterial agents that are commonly recommended for the treatment of these infections.
- Acute pyelonephritis
- Complicated urinary tract infections
- Bacterial prostatitis
- genital tract infections in men and women
- gastro-intestinal tract infections and intra-abdominal infections

- skin and soft tissue infections
- Infections of the bones and joints
- anthrax inhalation exposure
- Gonococcal urethritis and cervicitis due to susceptible *Neisseria gonorrhoeae*

Ciprofloxacin may be used in the management of neutropenic patients 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 infusion.

### Children and Adolescents

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

- Broncho-pulmonary infections due to *Pseudomonas aeruginosa* in patients with cystic fibrosis
- Complicated urinary tract infections and acute pyelonephritis
- anthrax inhalation exposure

Ciprofloxacin Infusion 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 are given Ciprofloxacin Infusion**

### **You must not be given Ciprofloxacin Infusion:**

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

### **Warnings and precautions**

#### **Talk to your doctor before you are given Ciprofloxacin Infusion**

- if you ever had kidney problems because your treatment may need to be adjusted.
- if you suffer from epilepsy or other neurological conditions.
- If you have a history of tendon problems during previous treatment with antibiotics such as Ciprofloxacin infusion.
- if you are diabetic because you may experience a risk of hypoglycaemia with ciprofloxacin
- if you have myasthenia gravis (a type of muscle weakness) because symptoms can be exacerbated.

- if you 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).
- 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 have been diagnosed with an enlargement or "bulge" of a large blood vessel (aortic aneurysm or large vessel peripheral aneurysm).
- if you have experienced a previous episode of aortic dissection (a tear in the aorta wall).
- 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).

If you feel sudden, severe pain in your abdomen, chest or back, go immediately to an emergency room.

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.

You should not take fluoroquinolone/quinolone antibacterial medicines, including Ciprofloxacin infusion, if you have experienced any serious adverse reaction in the past when taking a quinolone or fluoroquinolone. In this situation, you should inform your doctor as soon as possible.

### **While under treatment with Ciprofloxacin Infusion**

Tell your doctor immediately, if any of the following occurs **during treatment with Ciprofloxacin Infusion**. Your doctor will decide whether treatment with Ciprofloxacin Infusion 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 Infusion will have to be stopped.**

- 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 Ciprofloxacin infusion therapy. At the first sign of pain or inflammation of a tendon (for example in your ankle, wrist, elbow, shoulder or knee), stop taking Ciprofloxacin infusion, contact your doctor 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 Infusion 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 Infusion. In rare cases, depression or psychosis can progress to thoughts of suicide, suicide attempts, or completed suicide. If this happens, stop taking Ciprofloxacin Infusion and contact your doctor immediately.
- 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 Ciprofloxacin infusion and inform your doctor immediately in order to prevent the development of potentially irreversible condition.
- 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 Infusion, 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 Infusion 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 Infusion if you have to provide a **blood or urine sample**.

- Ciprofloxacin Infusion 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 Infusion must be stopped immediately.
- Ciprofloxacin Infusion 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.
- 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 Infusion. Avoid exposure to strong sunlight or artificial UV light such as sunbeds.
- If your eyesight becomes impaired or if your eyes seem to be otherwise affected, consult an eye specialist immediately.
- Prolonged, disabling and potentially irreversible serious side effects  
Fluoroquinolone/quinolone antibacterial medicines, including Ciprofloxacin infusion, have been associated with very rare but serious side effects, some of them being long lasting (continuing months or years), disabling or potentially irreversible. This includes tendon, muscle and joint pain of the upper and lower limbs, difficulty in walking, abnormal sensations such as pins and needles, tingling, tickling, numbness or burning (paraesthesia), sensory disorders including impairment of vision, taste and smell, and hearing, depression, memory impairment, severe fatigue, and severe sleep disorders.
- If you experience any of these side effects after taking Ciprofloxacin infusion, contact your doctor immediately prior to continuing treatment. You and your doctor will decide on continuing the treatment considering also an antibiotic from another class.

### **Other medicines and Ciprofloxacin Infusion**

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

**Do not use Ciprofloxacin Infusion together with tizanidine**, because this may cause side effects such as low blood pressure and sleepiness (see Section 2: **You must not be given Ciprofloxacin Infusion**).

The following medicines are known to interact with Ciprofloxacin Infusion in your body. Using Ciprofloxacin Infusion 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 fluindione) 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)
- 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 Infusion may **increase** the levels of the following medicines in your blood:

- pentoxifylline (for circulatory disorders)
- caffeine
- lidocaine (for heart conditions or anaesthetic use)
- sildenafil (e.g. for erectile dysfunction)
- duloxetine (for depression, diabetic nerve damage or incontinence).
- Agomelatone (for depression)

**Ciprofloxacin Infusion with food and drink**

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

**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 Infusion during pregnancy.

Do not take Ciprofloxacin Infusion 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 Infusion before driving a vehicle or operating machinery. If in doubt, talk to your doctor.

### **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 to take 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 100mg and 200 mg Ciprofloxacin Infusion. 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 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 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:**

may affect up to 1 in 10 people

nausea, diarrhoea, vomiting

- joint pains 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

- 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, 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 (for example pain of the extremity, back pain, breast pain), 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

- 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 (angiooedema), severe allergic reaction (anaphylactic shock), which can be life-threatening (see Section 2: Warnings and precautions)
- increased blood sugar (hyperglycemia)
- decreased blood sugar (hypoglycaemia) (see Section 2: Warnings and precautions)
- 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 vessel (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:**

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)
- 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 and pseudotumor cerebri)
- 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)

- Very rare cases of long lasting (up to months or years) or permanent adverse drug reactions, such as tendon inflammations, tendon rupture, joint pain, pain in the limbs, difficulty in walking, abnormal sensations such as pins and needles, tingling, tickling, burning, numbness or pain (neuropathy), depression, fatigue, sleep disorders, memory impairment, as well as impairment of hearing, vision, and taste and smell have been associated with administration of quinolone and fluoroquinolone antibiotics, in some cases irrespective of pre-existing risk factors.

### **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 (peripheral neuropathy and polyneuropathy)
- 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)
- Syndrome associated with impaired water excretion and low levels of sodium (SIADH)

### **Reporting of side effects**

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

### **Ireland**

#### **HPRA Pharmacovigilance**

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Website: [www.hpra.ie](http://www.hpra.ie), e-mail: [info@hpra.ie](mailto:info@hpra.ie)

### **5. How to store Ciprofloxacin Infusion**

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

Do not use this medicine after the expiry date which is stated on the packaging after “Exp”. The expiry date refers to the last day of that month.

Ciprofloxacin solution should be inspected visually for particulate matter or

discoloration prior to administration. The solution should only be used if clear and free from particles.

Store below 25°C. Do not refrigerate or freeze.  
Keep vial/bottle in outer carton in order to protect from light.

Store below 30°C. Do not refrigerate or freeze.  
Keep the bag in overwrap pouch 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:  
For single use only. Any unused product or waste material should be disposed of in accordance with local requirements, immediately after use.

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 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 or Non-PVC bags, each containing 50 ml solution for infusion.

Ciprofloxacin 200 mg/100 ml solution for infusion is available in colourless glass vials or Non-PVC bags, each containing 100 ml solution for infusion.

Ciprofloxacin 400 mg/200 ml solution for infusion is available in colourless glass bottles or Non-PVC bags, each containing 200 ml solution for infusion.

Pack size: Individual vial / bottle in unit carton.

Pack size: Individual Non-PVC bag in unit Overwrap.

**Marketing Authorisation Holder:**

Baxter Holding B.V.  
Kobaltweg 49,  
3542CE Utrecht, Netherlands

**Manufacturer:**

**Sia Unifarma**  
Brivibas Gatve, 414/K-2,  
LV-1024, Riga,  
Latvia

**UAB Norameda**

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**Tramco sp. Z.o.o**

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

Belgium	Ciprofloxacin BAXTER 2 mg/ml solution pour perfusion
Estonia	Ciprofloxacin Baxter, 2mg/ml, infusioonilahus
Germany	Ciprofloxacin Baxter 2 mg/ml Infusionslösung
United Kingdom	Ciprofloxacin 2mg/ml, Solution for Infusion
Italy	Ciprosol 2mg/ml, Soluzione per Infusione
Latvia	CIPROFLOXACIN BAXTER 2 mg/ml šķīdums infūzijām
Lithuania	Ciprofloxacin Baxter 2 mg/ml infuzinis tirpalas

Luxembourg	Ciprofloxacin Baxter -2mg/mL Sol. Perf.
Austria	Ciprofloxacin Baxter 2 mg/ml - Infusionslösung
Poland	Ciprofloxacin Baxter, 2mg/ml, roztwór do infuzji
Portugal	Ciprofloxacina Baxter, 2 mg/ml, Solução para perfusão
Slovenia	Ciprofloksacin Baxter 2 mg/ml raztopina za infundiranje

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### **Advice/medical education**

Antibiotics are used to cure bacterial infections. They are ineffective against viral infections. If your doctor has prescribed antibiotics, you need them precisely for your current illness. Despite antibiotics, some bacteria may survive or grow. This phenomenon is called resistance: some antibiotic treatments become ineffective.

Misuse of antibiotics increases resistance. You may even help bacteria become resistant and therefore delay your cure or decrease antibiotic efficacy if you do not respect appropriate:

- dosage
- schedules
- duration of treatment

### **Consequently, to preserve the efficacy of this drug:**

- 1 - Use antibiotics only when prescribed.
- 2 - Strictly follow the prescription.
- 3 - Do not re-use an antibiotic without medical prescription, even if you want to treat a similar illness.
- 4 - Never give your antibiotic to another person; maybe it is not adapted to her/his illness.
- 5 - After completion of treatment, return all unused drugs to your chemist's shop to ensure they will be disposed of correctly.

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### **The following information is intended for medical or healthcare professionals only**

Ciprofloxacin should be administered by intravenous infusion. For children, the infusion duration is 60 minutes. In adult patients, infusion time is 60 minutes for 400 mg Ciprofloxacin and 30 minutes for 100 mg and 200 mg Ciprofloxacin. Slow infusion into a large vein will minimise patient discomfort and reduce the risk of venous irritation. The infusion solution can be infused either directly or after mixing with other compatible infusion solutions.

Unless compatibility with other infusion solutions/drugs has been confirmed, the infusion solution must always be administered separately. The visual signs of incompatibility are e.g. precipitation, clouding, and discolouration.

Incompatibility appears with all infusion solutions/drugs that are physically or chemically unstable at the pH of the solution (e.g. penicillin, heparin solutions), especially in combination with solutions adjusted to an alkaline pH (pH of the ciprofloxacin infusion solutions: 3.9-4.5).

After intravenous initiation of treatment, the treatment can be continued orally as well.