

## PACKAGE LEAFLET: INFORMATION FOR THE USER

### **Ciprofloxacin 2mg/ml Solution for Infusion** (Ciprofloxacin 100mg/50ml, 200mg/100ml and 400mg/200ml)

**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 nurse.
- If you get any side effects, talk to your doctor or nurse. 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 use 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 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 Infusion 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 Infusion.

### Children and adolescents

Ciprofloxacin Infusion 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 Infusion 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 ARE GIVEN CIPROFLOXACIN INFUSION

### You must not be given Ciprofloxacin Infusion if you are:

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

### Warnings and precautions

Before you are given 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 Infusion
- are diabetic because there is a risk of hypoglycaemia with ciprofloxacin
- have myasthenia gravis (a type of muscle weakness)
- or a member of your family is known to have a deficiency in glucose-6-phosphate dehydrogenase (G6PD), since there is a risk of anaemia with ciprofloxacin
- have been diagnosed with an enlargement or "bulge" of a large blood vessel (aortic aneurysm or large vessel peripheral aneurysm)
- have experienced a previous episode of aortic dissection (a tear in the aorta wall)
- 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)

### Heart problems:

Caution should be taken when using this kind of medicine if you:

- were born with or have a family history of prolonged QT interval (seen on ECG, electrical recording of the heart)
- have salt imbalance in the blood (especially low levels 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)
- are female or elderly
- are taking other medicines that result in abnormal ECG changes (see 'Taking other medicines')
- have a history of abnormal heart rhythms (arrhythmias)

### 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 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 Ciprofloxacin Infusion 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 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. If this happens, stop taking Ciprofloxacin Infusion 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 Infusion and contact your doctor immediately.
- **Hypoglycaemia** 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.
- If you feel sudden, severe pain in your abdomen, chest or back, go immediately to an emergency room.

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

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

**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 if you are...").

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.

**You must tell your doctor if you are taking:**

- other medicines that can alter your heart rhythm i.e. medicines that belong to the group of anti-arrhythmics (e.g. quinidine, hydroquinidine, disopyramide, amiodarone, sotalol, dofetilide, ibutilide), tricyclic antidepressants, some antimicrobials (that belong to the group of macrolides), some antipsychotics
- vitamin K antagonists (e.g. warfarin) or other oral anti-coagulants (to thin the blood)
- probenecid (for gout)
- metoclopramide (for indigestion, nausea and vomiting)
- omeprazole (for stomach ulcers and indigestion)
- methotrexate (for certain types of cancer, psoriasis, rheumatoid arthritis)
- theophylline (for breathing problems)
- tizanidine (for muscle spasticity in multiple sclerosis)
- olanzapine or clozapine (antipsychotics)
- ropinirole (for Parkinson's disease)
- phenytoin (for epilepsy)
- ciclosporin (for skin conditions, rheumatoid arthritis and in organ transplantation)
- glibenclamide (for diabetes).

Ciprofloxacin Infusion 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)
- zolpidem (for insomnia)

**Taking Ciprofloxacin Infusion with food and drink**

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

**Pregnancy and breast-feeding**

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

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.

**Ciprofloxacin Infusion contains sodium**

This medicine contains 354.1 mg sodium (main component of cooking/table salt) in each 100ml volume. This is equivalent to 18 % of the recommended maximum daily dietary intake of sodium for an adult.

<b>3. HOW TO USE CIPROFLOXACIN INFUSION</b>
---

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, the 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 more questions about the use of this product, ask your doctor or pharmacist.

## **4. POSSIBLE SIDE EFFECTS**

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

**Tell your doctor immediately** if any of the following occurs during treatment with Ciprofloxacin Infusion (see also section 2)

- Severe, sudden allergic reaction with the following symptoms: tightness in the chest, feeling dizzy, feeling sick or faint, or experience dizziness on standing.
- Muscle pain and/or weakness, inflammation of the joints and joint pain, increased muscle tone and cramping, inflammation of the tendons or tendon rupture, particularly affecting the large tendon at the back of the ankle (achilles tendon).
- Unusual feelings of pain, burning, tingling, numbness or muscle weakness in the extremities (neuropathy).
- Seizures (see also section 2).
- Mental disturbances potentially leading to thoughts of suicide or suicidal attempts.
- Severe or persistent diarrhoea or you notice that your stool contains blood or mucus.
- Symptoms of liver damage such as loss of appetite, jaundice (yellowing of the skin), dark urine, itching, or tenderness of the stomach.
- 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
- Your eyesight becomes impaired (including double vision and colour distortions) or if your eyes seem to be otherwise affected.
- Serious life-threatening skin rash, usually in the form of blisters or ulcers in the mouth, nose, eyes and other mucous membranes such as genitals which may progress to widespread blistering or peeling of the skin ('Stevens-Johnson syndrome' or 'Toxic Epidermal Necrolysis')
- A reaction that causes rash, fever, inflammation of the internal organs, blood abnormalities and systemic illness ('DRESS' ['Drug Reaction with Eosinophilia and Systemic Symptoms']) or 'Acute Generalised Exanthematous Pustulosis'.

**Common side effects** (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 side effects** (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, giddiness
- 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** (may affect up to 1 in 1,000 people):

- 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)
- increased blood sugar (hyperglycaemia)
- decreased blood sugar (hypoglycaemia) (see section 2)
- anxiety reaction, strange dreams and depression
- 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
- sensitivity to light (see Section 2 ), small, pin-point bleeding under the skin (petechiae)
- blood or crystals in the urine (see Section 2), urinary tract inflammation
- excessive sweating
- abnormal levels of a clotting factor (prothrombin), 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)
- disturbed coordination, unsteady walk (gait disturbance), pressure inside the skull which many cause headaches or vision problems (intracranial pressure or ‘pseudomotor cerebri’)
- worsening of the symptoms of myasthenia gravis (see Section 2)

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

- heart problems: abnormal fast heart rhythm, life-threatening irregular heart rhythm, alteration of heart rhythm (called ‘prolongation of QT interval’, seen on ECG, electrical activity of the heart)
- feeling highly excited (mania) or feeling great optimism and overactivity (hypomania)
- influence in 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly:

**United Kingdom:**

Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow card in the Google Play or Apple App Store.

## **Malta**

ADR Reporting Website: [www.medicinesauthority.gov.mt/adrportal](http://www.medicinesauthority.gov.mt/adrportal).

By reporting side effects you can help provide more information on the safety of this medicine

## **5. HOW TO STORE CIPROFLOXACIN INFUSION**

Store in the original package. Do not refrigerate or freeze.

Keep out of the reach and sight of children.

Do not use Ciprofloxacin Infusion after the expiry date which is stated on the carton after "EXP": The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. These measures will help to protect the environment.

## **6. CONTENTS OF THE PACK AND OTHER INFORMATION**

### **What Ciprofloxacin Infusion contains**

The active ingredient is ciprofloxacin (as ciprofloxacin lactate).

The other ingredients are lactic acid solution, sodium chloride and water for injection.

### **What Ciprofloxacin Infusion looks like and contents of the pack**

Ciprofloxacin Infusion is available in 50ml, 100ml or 200ml PVC bags. The 50ml bag contains 100mg Ciprofloxacin, the 100ml bag contains 200mg Ciprofloxacin and the 200ml bag contains 400mg Ciprofloxacin.

### **Marketing Authorisation Holder**

Villerton Invest SA, Rue Edward Steichen 14, 2540 Luxembourg

### **Manufacturer**

S.C. Infomed Fluids S.r.l., Str. Theodor Pallady nr. 50, Sector 3, Bucarest - Romania.

**This leaflet was last revised in June 2019**

### **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 medicine:**

- 1 - Use antibiotics only when prescribed.
- 2 - Strictly follow the prescription.
- 3 - Do not re-use an antibiotic without a medical prescription, even if you want to treat a similar illness.

- 4 - Never give your antibiotic to another person; it may not be suitable for 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

---

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

Ciprofloxacin Infusion should be administered by intravenous infusion. For children, the infusion duration is 60 minutes. In adult patients, the infusion time is 60 minutes for 400 mg Ciprofloxacin Infusion and 30 minutes for 200 mg Ciprofloxacin Infusion. 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. penicillins, 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.