



## Package Leaflet: Information for the user

### Ciprofloxacin Amneal 2 mg/ml Solution for infusion

#### Ciprofloxacin

#### Read all of this leaflet carefully before you start taking 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.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

#### What is in this leaflet:

1. What Ciprofloxacin Amneal Solution for infusion is and what it is used for
2. What you need to know before you receive Ciprofloxacin Amneal Solution for infusion
3. How Ciprofloxacin Amneal Solution for infusion is administered
4. Possible side effects
5. How to Store Ciprofloxacin Amneal Solution for infusion
6. Contents of the pack and other information

## 1. What Ciprofloxacin Amneal Solution for infusion is and what it is used for

Ciprofloxacin Amneal Solution for infusion is an antibiotic belonging to the fluoroquinolone family. The active substance is ciprofloxacin. Ciprofloxacin Amneal Solution for infusion works by killing bacteria that cause infections. It only works with specific strains of bacteria.

#### Adults

Ciprofloxacin Amneal Solution for 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
- infections of the testicles
- genital organ infections in women
- gastro-intestinal tract infections and intra-abdominal infections
- skin and soft tissue infections
- bone and joint infections
- to treat infections in patients with a very low white blood cell count (neutropenia)
- to prevent infections in patients with a very low white blood cell count (neutropenia)
- anthrax inhalation exposure

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 Amneal Solution for infusion.

#### Children and adolescents

Ciprofloxacin Amneal Solution for 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 Amneal Solution for 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 Amneal Solution for infusion

#### You must not be given Ciprofloxacin Amneal Solution for infusion if you are:

- allergic (hypersensitive) to the active substance, to other quinolone drugs or to any of the other ingredients of Ciprofloxacin Amneal Solution for infusion (see section 6)
- taking tizanidine (see Section 2: Other medicines and Ciprofloxacin Amneal Solution for infusion)

#### Warnings and precautions

Talk to your doctor, nurse or pharmacist before you are given Ciprofloxacin Amneal Solution for infusion if you:

- have heart problems. Caution should be taken when using this kind of medicine, 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 *Other medicines and Ciprofloxacin Amneal Solution for infusion*).
- 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 Amneal Solution for infusion
- have myasthenia gravis (a type of muscle weakness)

#### While under treatment with Ciprofloxacin Amneal Solution for infusion

Tell your doctor immediately, if any of the following occurs **during treatment with Ciprofloxacin Amneal Solution for infusion**. Your doctor will decide whether treatment with Ciprofloxacin Amneal Solution for 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 Amneal Solution for 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 Amneal Solution for infusion will have to be stopped, rest the painful area. Avoid any unnecessary exercise as this might increase the risk of a tendon rupture. Tendon inflammation and ruptures may occur even up to several months after you stop taking Ciprofloxacin Amneal Solution for infusion.
- 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 Amneal Solution for infusion and contact your doctor immediately.
- You may experience **psychiatric reactions** after first administration of Ciprofloxacin Amneal Solution for infusion. If you suffer from **depression** or **psychosis**, your symptoms may become worse under treatment with Ciprofloxacin Amneal Solution for infusion. If this happens, stop taking Ciprofloxacin Amneal Solution for 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 Amneal Solution for infusion and contact your doctor immediately.
- **Diarrhoea** may develop while you are on antibiotics, including Ciprofloxacin Amneal Solution for 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 Amneal Solution for 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 Amneal Solution for infusion if you have to provide a **blood** or **urine sample**.
- Ciprofloxacin Amneal Solution for 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 Amneal Solution for infusion must be stopped immediately.
- Ciprofloxacin Amneal Solution for 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.
- 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 Amneal Solution for infusion.
- Your skin becomes more **sensitive to sunlight or ultraviolet (UV) light** under treatment with Ciprofloxacin Amneal Solution for infusion. Avoid exposure to strong sunlight or artificial UV light such as sunbeds.

#### Other medicines and Ciprofloxacin Amneal Solution for infusion

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

**Do not use Ciprofloxacin Amneal Solution for 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 Amneal Solution for infusion if you are**“).

You must tell your doctor if you are taking other medicines that can alter your heart rhythm: 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.

The following medicines are known to interact with Ciprofloxacin Amneal Solution for infusion in your body. Using Ciprofloxacin Amneal Solution for 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:

- warfarin, acenocoumarol, phenprocoumon, fluindione or other oral anti-coagulants (to thin the blood)
- probenecid (for gout)
- metoclopramide (used to treat nausea and vomiting (feeling/being sick) and migraine)
- omeprazole (for stomach ulcers, indigestion, heartburn and Zollinger–Ellison syndrome)
- cyclosporin (an immunosuppressant)
- methotrexate (for certain types of cancer, psoriasis, rheumatoid arthritis)
- theophylline (for breathing problems)
- tizanidine (for muscle spasticity in multiple sclerosis)
- clozapine (an antipsychotic)
- ropinirole (for Parkinson's disease)
- phenytoin (for epilepsy)
- olanzapine (an antipsychotic)
- glibenclamide (an oral drug used to treat diabetes)

#### Ciprofloxacin Amneal Solution for infusion may increase the levels of the following medicines in your blood:

- pentoxifylline (for circulatory disorders)
- caffeine
- lidocaine (an anesthetic)
- sildenafil (for erectile dysfunction)
- duloxetine (for depression, anxiety, pain and stress incontinence)

#### Ciprofloxacin Amneal Solution for infusion with food and drink

Food and drink does not affect your treatment with Ciprofloxacin Amneal Solution for infusion.

#### Pregnancy and breast-feeding

It is preferable to avoid the use of Ciprofloxacin Amneal Solution for infusion during pregnancy.

Do not take Ciprofloxacin Amneal Solution for infusion during breast feeding because Ciprofloxacin Amneal Solution for infusion is excreted in breast milk and can be harmful for your child.

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.

#### Driving and using machines

Ciprofloxacin Amneal Solution for infusion may make you feel less alert. Some neurological adverse events can occur. Therefore, make sure you know how you react to Ciprofloxacin Amneal Solution for infusion before driving a vehicle or operating machinery. If in doubt, talk to your doctor.

#### Ciprofloxacin Amneal Solution for infusion contains sodium

50 ml of Ciprofloxacin Amneal Solution for infusion contains 7.7mmol (= 177 mg) sodium.  
100 ml of Ciprofloxacin Amneal Solution for infusion contains 15.4mmol (= 354 mg) sodium.  
200 ml of Ciprofloxacin Amneal Solution for infusion contains 30.8mmol (= 708 mg) sodium.

Therefore this medicine may not be suitable for you if you are on a low sodium diet. Check with your doctor if you are unsure about this.

## 3. How Ciprofloxacin Amneal Solution for infusion is administered

Your doctor will explain to you exactly how much Ciprofloxacin Amneal Solution for 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.

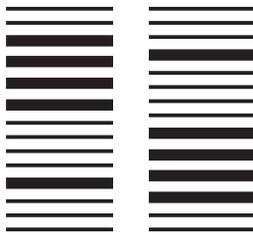
Your doctor will give you each dose by slow infusion through a vein into your bloodstream. For children, the infusion duration is 60 minutes. In adult patients, infusion time is 60 minutes for 400 mg Ciprofloxacin Amneal and 30 minutes for 200 mg Ciprofloxacin Amneal. Administering the infusion slowly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

Remember to drink plenty of fluids while you are taking Ciprofloxacin Amneal Solution for infusion.

#### If you stop your course of Ciprofloxacin Amneal Solution for 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 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)
- 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
- 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):

- 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 (hyperglycemia)
- anxiety reaction, strange dreams, depression and mental disturbances (psychotic reactions) which in rare cases may lead to thoughts of suicide or suicidal behaviour (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 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)
- 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
- heart problems: 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)
- acute generalised exanthematous pustulosis (AGEP) – type of skin disease with red blistered skin
- blood thinning increases if taken with an anti-coagulant such as warfarin

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

## 5. How to store Ciprofloxacin Amneal Solution for 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.

Do not store above 25°C. Do not refrigerate or freeze.

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

### After first opening:

Single dose container. Use immediately after first opening.

### After dilution:

Chemical and physical in-use stability has been demonstrated for 42 hours at 25 °C. 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.

Do not use this medicine if you notice the container is leaking or solution is not clear. Solutions containing visible solid particles must not be used.

Do not throw away any medicines via wastewater or household waste. These measures will help protect the environment.

## 6. Contents of the pack and other information

### What Ciprofloxacin Amneal Solution for infusion contains

- The active substance is ciprofloxacin.  
1 ml of solution for infusion contains 2 mg ciprofloxacin as 2.544 mg ciprofloxacin lactate.
- The other ingredients are lactic acid, sodium chloride, hydrochloric acid and water for injections.

### What Ciprofloxacin Amneal Solution for infusion looks like and contents of the pack

#### Solution for infusion.

Ciprofloxacin Amneal Solution for infusion is a clear and colourless to slightly yellow solution.

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

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

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

Pack size: Individual vial / bottle in unit carton. Not all pack sizes may be marketed.

### Marketing Authorisation Holder

Amneal Pharma Europe Limited  
70 Sir John Rogerson's Quay  
Dublin 2  
Ireland

### Manufacturer

Pfizer Service Company BVBA  
Hoge Wei 10,  
1930,  
Zaventem. Belgium

Pfizer PGM Zone industrielle,  
29 route des Industries, 37530 Poée-Sur-Cisse, France

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

|                |  |
|----------------|--|
| Denmark        | Ciprofloxacin Amneal                                     |
| Finland        | Ciprofloxacin Amneal 2 mg/ml infuusioneste, liuos        |
| Germany        | Ciprofloxacin Amneal 2mg/ml Infusionslösung              |
| Ireland        | Ciprofloxacin Amneal 2mg/ml Solution for infusion        |
| Netherlands    | Ciprofloxacin Amneal 2mg/ml Oplossing voor infusie       |
| Norway         | Ciprofloxacin Amneal 2 mg/ml Infusjonsvæske, oppløsning  |
| Portugal       | Ciprofloxacin Amneal                                     |
| Spain          | Ciprofloxacin Amneal 2 mg/ml solución para perfusión EFG |
| Sweden         | Ciprofloxacin Amneal 2mg/ml Infusionsvätska, lösning     |
| United Kingdom | Ciprofloxacin 2mg/ml Solution for infusion               |

### This leaflet was last revised in 01/2014

### 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.

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

Ciprofloxacin Solution for infusion 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 Solution for infusion and 30 minutes for 200 mg Ciprofloxacin Solution for 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: 3.90-4.50).

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