

PATIENT INFORMATION LEAFLET (PIL)

XIPRO

Ciprofloxacin Intravenous Infusion BP

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, 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 you get any of the 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 is and what it is used for
2. What you need to know before you use Ciprofloxacin
3. How to use Ciprofloxacin
4. Possible side effects
5. How to store Ciprofloxacin
6. Contents of the pack and other information

1. WHAT CIPROFLOXACIN IS AND WHAT IT IS USED FOR

Ciprofloxacin 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 is used in adults to treat the following bacterial infections:

- Respiratory tract infections
- Long lasting or recurring ear or sinus infections
- Urinary tract infections
- Genital tract infections in men and women
- Gastro-intestinal tract infections and intra-abdominal infections
- Skin and soft tissue infections

- Bone and joint infections
- Anthrax inhalation exposure

Ciprofloxacin may be used in the management of patients with low white blood cell counts (neutropenia) who have a fever that is suspected to be due to a bacterial infection.

If you have a severe infection or one that is caused by more than one type of bacterium, you may be given additional antibiotic treatment in addition to Ciprofloxacin.

Children and adolescents

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

- Lung and bronchial infections in children and adolescents suffering from cystic fibrosis.
- Complicated urinary tract infections, including infections that have reached the kidneys (pyelonephritis).
- Anthrax inhalation exposure

Ciprofloxacin may also be used to treat other specific severe infections in children and adolescents when your doctor considered this necessary.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE CIPROFLOXACIN

You must not be given Ciprofloxacin:

- If you are allergic to the active substance, to other quinolone drugs or to any of the other ingredients of this medicine
- If you are taking tizanidine

Warnings and precautions:

Talk to your doctor before you are given Ciprofloxacin:

- If you have 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.
- 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 (Other medicines and 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 or a member of your family is known to have a deficiency in glucose-6-phosphate dehydrogenase (G6PD), since you may experience a risk of anaemia with ciprofloxacin.

For the treatment of some genital tract infections, your doctor can prescribe another antibiotic in addition to ciprofloxacin. If there is no improvement in symptoms after 3 days of treatment, please consult your doctor.

While under treatment with Ciprofloxacin

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

- If you feel sudden, severe pain in your abdomen, chest or back, go immediately to an emergency room.
- Severe, sudden allergic reaction (an anaphylactic reaction/shock, angioedema). Even with the first dose, there is a rare chance that you may experience a severe allergic reaction with the following symptoms: tightness in the chest, feeling dizzy, feeling sick or faint, or experience dizziness on standing. If this happens, tell your doctor immediately since the administration of Ciprofloxacin will have to be stopped.

- Pain and swelling in the joints, and tendinitis may occur occasionally, particularly if you are elderly and are also being treated with corticosteroids. Inflammation and ruptures of tendons may occur even within the first 48 hours of treatment or up to several months after discontinuation of Ciprofloxacin therapy. At the first sign of any pain or inflammation stop taking Ciprofloxacin, 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 seizure happens, stop taking Ciprofloxacin and contact your doctor immediately.
- You may experience symptoms of neuropathy such as pain, burning, tingling, numbness and/or muscle weakness. If this happens, stop taking Ciprofloxacin and contact your doctor immediately.
- You may experience psychiatric reactions after first administration of ciprofloxacin. If you suffer from depression or psychosis, your symptoms may become worse under treatment with Ciprofloxacin. In rare cases, depression or psychosis can progress to thoughts of suicide, suicide attempts, or completed suicide. If this happens, 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, 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, stop taking Ciprofloxacin and contact your doctor immediately, as this can be life-threatening. Do not take medicines that stop or slow down bowel movements.
- If your eyesight becomes impaired or if your eyes seem to be otherwise affected, consult an eye specialist immediately.
- Your skin becomes more sensitive to sunlight or ultraviolet (UV) light under treatment with Ciprofloxacin. Avoid exposure to strong sunlight or artificial UV light such as sunbeds.
- Tell the doctor or laboratory staff that you are taking Ciprofloxacin if you have to provide a blood or urine sample.
- If you suffer from kidney problems, tell the doctor because your dose may need to be adjusted.

- Ciprofloxacin may cause liver damage. If you notice any symptoms such as loss of appetite, jaundice (yellowing of the skin), dark urine, itching, or tenderness of the stomach, Ciprofloxacin must be stopped immediately.
- Ciprofloxacin may cause a reduction in the number of white blood cells and your resistance to infection may be decreased. If you experience an infection with symptoms such as fever and serious deterioration of your general condition, or fever with local infection symptoms such as sore throat/pharynx/mouth or urinary problems you should see your doctor immediately. A blood test will be taken to check possible reduction of white blood cells (agranulocytosis). It is important to inform your doctor about your medicine.

Other medicines and Ciprofloxacin

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

Do not use Ciprofloxacin together with tizanidine, because this may cause side effects such as low blood pressure and sleepiness.

The following medicines are known to interact with Ciprofloxacin in your body. Using Ciprofloxacin together with these medicines can influence the therapeutic effect of these medicines. It can also increase the probability of experiencing side effects.

Tell your doctor if you are taking:

- Vitamin K antagonists (e.g. warfarin, 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 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)

Ciprofloxacin with food and drink

Food and drink does not affect your treatment with Ciprofloxacin.

Pregnancy and breast-feeding

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 during pregnancy.

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

Driving and using machines

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

Ciprofloxacin contains glucose

Contains 9 g glucose in 200 ml solution for infusion. This should be taken into account in patients with diabetes mellitus.

3. HOW TO USE CIPROFLOXACIN

Use intravenously.

The formulation should be administered as an intravenous drip for 30 minutes (200 mg) or 60 minutes (400 mg). The infusion solution can be mixed with 0.9% sodium chloride solution, Ringer's solution, 5% and 10% dextrose solution, 10% fructose solution, as well as with solutions containing 5% dextrose solution and 0.45% sodium Chloride solution.

The ciprofloxacin dose depends upon the severity of the disease, type of infection, body condition, age, weight and renal function of the patient. The usually recommended doses are as follows:

Single intravenous dose is 200 mg (in severe infections 400 mg); frequency is twice daily; duration of treatment depends upon the severity of the disease – 1-2 weeks or more if necessary. A single intravenous dose of 100 mg is recommended in acute gonorrhoea. The dose for prophylaxis of post-operative infections is 200-400 mg intravenous 30- 60 minutes before the operation.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The following section contains the most serious side effects that you can recognise yourself:

Stop taking Ciprofloxacin and contact your doctor immediately in order to consider another antibiotic treatment if you notice any of the following serious side effects:

Uncommon (may affect up to 1 in 100 people)

- Seizure (see section 2: Warnings and precautions)

Rare (may affect up to 1 in 1,000 people)

- Severe, sudden allergic reaction with symptoms such as tightness in the chest, feeling dizzy, sick or faint, or experience dizziness when standing up (anaphylactic shock) (see section 2: Warnings and precautions).
- tendon rupture, particularly affecting the large tendon at the back of the ankle (Achilles tendon) (see section 2: Warnings and precautions).

Very rare (may affect up to 1 in 10,000 people)

- Severe, sudden allergic reaction with symptoms such as tightness in the chest, feeling dizzy, sick or faint, or experience dizziness when standing up (anaphylactic reaction) (see section 2: Warnings and precautions)
- Muscle weakness, inflammation of the tendons which could lead to rupture of the tendon, particularly affecting the large tendon at the back of the ankle (Achilles tendon)
- A serious life-threatening skin rash, usually in the form of blisters or ulcers in the mouth, throat, nose, eyes and other mucous membranes such as genitals which may progress to widespread blistering or peeling of the skin (Stevens-Johnson syndrome, toxic epidermal necrolysis).

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

- Unusual feelings of pain, burning tingling, numbness or muscle weakness in the extremities (neuropathy) (see section 2: Warnings and precautions).
- A drug reaction that causes rash, fever, inflammation of internal organs, hematologic abnormalities and systemic illness (DRESS Drug Reaction with Eosinophilia and Systemic Symptoms, AGEP Acute Generalised Exanthematous Pustulosis).

Other side effects which have been observed during treatment with Ciprofloxacin are listed below by how likely they are:

Common (may affect up to 1 in 10 people)

- Nausea, diarrhoea, vomiting
- Joint pain and joint inflammation 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)
- Joint pain in adults
- 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

- 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
- 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 (may affect up to 1 in 1,000 people)

- Muscle pain, inflammation of the joints, increased muscle tone and cramping
- Inflammation of the bowel (colitis) linked to antibiotic use (can be fatal in very rare cases)
- 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
- Allergic reaction, allergic swelling (oedema), rapid swelling of the skin and mucous membranes (angiooedema)
- Increased blood sugar (hyperglycemia)
- Decreased blood sugar (hypoglycaemia)
- Anxiety reaction, strange dreams, depression (potentially leading to thoughts of suicide, suicide attempts, or completed suicide), mental disturbances (psychotic reactions potentially leading to thoughts of suicide, suicide attempts, or completed suicide)
- 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)
- Blood or crystals in the urine, 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)
- Allergic reaction called serum sickness-like reaction
- Disturbed coordination, unsteady walk (gait disturbance), pressure on the brain (intracranial pressure and pseudotumor cerebri)
- Visual colour distortions
- various skin eruptions or rashes
- worsening of the symptoms of myasthenia gravis

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

- Feeling highly excited (mania) or feeling great optimism and overactivity (hypomania)
- 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)
- Influence on blood clotting (in patients treated with Vitamin K antagonists)

5. HOW TO STORE CIPROFLOXACIN

Keep out of the reach and sight of children.

Do not use this medicine after the expiry date (or EXP) on the container and on the carton. The expiry date refers to the last day of that month.

This medicinal product does not require any special temperature storage conditions. Store in a dry place, below 30°C. Protect from light. Do not refrigerate or freeze

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 to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Ciprofloxacin Intravenous Infusion contains

The active substances is Ciprofloxacin Hydrochloride BP.

The other ingredients are Disodium Edetate, Citric Acid Monohydrate, Lactic Acid, Sodium Hydroxide, Sodium Chloride and Hydrochloric Acid, Water for Injection.

Ciprofloxacin Intravenous Infusion is a clear & colourless solution free from visible particle

Pack sizes:

100 ml FFS bottle is packed in a carton along with the leaflet.

Marketing Authorisation Holder:

ASTERISK LIFESCIENCES (GH) LIMITED

Address: P.O. Box CT 3160,

Accra, Ghana

Contact No. : +233 242501878