Package leaflet: Information for the patient

Ciproflox IV 2mg/ml
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.

What is in this leaflet

1. What Ciproflox is and what it is used for

Ciproflox 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

Ciproflox 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 Ciproflox .

Children and adolescents

Ciproflox 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

Ciproflox 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 Ciproflox

You must not be given Ciproflox:

- 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 Ciproflox)

Warnings and precautions

Talk to your doctor before you are given Ciproflox

- 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 Ciproflox .

- 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 Ciproflox).
- 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 Ciproflox

Tell your doctor immediately, if any of the following occurs **during treatment with Ciproflox** . Your doctor will decide whether treatment with Ciproflox 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 Ciproflox 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 Ciproflox therapy. At the first sign of any pain or inflammation stop taking Ciproflox , 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 Ciproflox 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 Ciproflox 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 Ciproflox . In rare cases, depression or psychosis can progress to thoughts of suicide, suicide attempts, or completed suicide. If this happens, contact your doctor immediately.

- **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 Ciproflox , 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 Ciproflox 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 Ciproflox . Avoid exposure to strong sunlight or artificial UV light such as sunbeds.

- Tell the doctor or laboratory staff that you are taking Ciproflox 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.

- Ciproflox 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, contact your doctor immediately.

- Ciproflox 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 Ciproflox

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

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

The following medicines are known to interact with Ciproflox in your body. Using Ciproflox 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)

Ciproflox 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)

Ciproflox with food and drink

Food and drink does not affect your treatment with Ciproflox .

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 Ciproflox during pregnancy.

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

Driving and using machines

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

Ciproflox contains sodium

Ciproflox contains 900mg sodium chloride per 100ml of solution, 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 to use Ciproflox

Your doctor will explain to you exactly how much Ciproflox 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 Ciproflox and 30 minutes for 200 mg Ciproflox . 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 Ciproflox , 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 about 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.

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

Stop taking Ciproflox 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) (see Section 2: Warnings and precautions)
- 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 Ciproflox 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) (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, bonemarrow depression which may also be fatal
- allergic reaction, allergic swelling (oedema), rapid swelling of the skin and mucous membranes
  (angiooedema) (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 (see Section 2: Warnings and precautions)
- 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) (see Section 2: Warnings and precautions)
- allergic reaction called serum sickness-like reaction (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
- worsening of the symptoms of myasthenia gravis (see Section 2: Warnings and precautions)

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)

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
Pharmaceutical Services
Ministry of Health
CY-1475 Nicosia
Fax: + 357 22608649
http://www.moh.gov.cy/phs

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

5. How to store Ciproflox

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 carton and the bottle after "EXP": The expiry date refers to the last day of that month.

Keep the bottle in the outer carton in order to protect from light. Do not refrigerate or freeze.

At cool storage temperatures precipitation may occur, which will re-dissolve at room temperature (15°C – 25°C).

Chemical and physical in-use stability has been demonstrated for 24 hours at room temperature (15°C to 25°C). From a microbiological point of view, unless the method of opening and mixing with coinfusion solutions precludes the risk of microbial contamination, the product should be used immediately. If not used immediately, in-use storage times and conditions are the responsibility of the user.

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 Ciproflox contains

The active substance is ciprofloxacin.

Each glass bottle with 200 mL infusion solution contains 400 mg of ciprofloxacin.

The other ingredients are: lactic acid solution, sodium chloride (9mg/ml), hydrochloric acid concentrated, water for injections.

What Ciproflox looks like and contents of the pack

Solution for infusion

Clear, nearly colourless to slightly yellowish solution.

It is available in glass vials containing 50ml, 100ml or 200ml of solution. The 50ml vial contains 100mg of ciprofloxacin, the 100ml vial containing 200mg of ciprofloxacin and the 200ml vial containing 400mg of ciprofloxacin.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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