

PACKAGE LEAFLET: INFORMATION FOR THE USER

Ciprofloxacin Teva 2 mg/ml Solution for Infusion
Ciprofloxacin (as lactate)

Read all of this leaflet carefully before you start using this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Ciprofloxacin Teva 2 mg/ml Solution for Infusion is and what it is used for
2. Before you use Ciprofloxacin Teva 2 mg/ml Solution for Infusion
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1. WHAT CIPROFLOXACIN TEVA 2 mg/ml SOLUTION FOR INFUSION IS AND WHAT IT IS USED FOR

Ciprofloxacin 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.

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
- 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)
- to prevent infections caused by the bacteria *Neisseria meningitidis*
- 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.

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. BEFORE YOU ARE GIVEN CIPROFLOXACIN TEVA 2 mg/ml SOLUTION FOR INFUSION

You must NOT be given Ciprofloxacin Teva if you are:

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

Take special care with Ciprofloxacin Teva

You should consult your doctor if one of the precautions and warnings mentioned below are or were applicable to you in the past.

Before you are given Ciprofloxacin Teva

Tell your doctor if you

- have ever had kidney problems because dose adjustment may be needed
- suffer from epilepsy or other neurological conditions
- have a history of tendon problems during previous treatment with antibiotics such as Ciprofloxacin
- have myasthenia gravis (a type of muscle weakness)
- have had heart problems.

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 2: *Taking other medicines*).

While under treatment with Ciprofloxacin Teva

Tell your doctor immediately, if any of the following occurs **during treatment with Ciprofloxacin Teva**. Your doctor will decide whether treatment with Ciprofloxacin 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 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 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 and contact your doctor immediately.

- You may experience **psychiatric reactions** after first administration of ciprofloxacin, in rare cases leading to suicidal thoughts/ideas. If you suffer from **depression** or **psychosis**, your symptoms may become worse under treatment with Ciprofloxacin. If this happens, stop taking Ciprofloxacin 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 and 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 tell your doctor immediately. Ciprofloxacin Teva 2 mg/ml 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 if you have to provide a **blood or urine sample**.
- 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.
- 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 anemia with ciprofloxacin.
- 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.

Taking other medicines

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 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 Teva if you are**").

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:

- warfarin 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)
- clozapine or olanzapine (an antipsychotic)
- duloxetine (for treatment of depression)

- ropinirole (for Parkinson's disease)
- phenytoin (for epilepsy)
- metoclopramide (for treatment of nausea and vomiting)
- omeprazole (for acid reflux, chronic heartburn)
- ciclosporin (used in organ transplantation).

Ciprofloxacin may **increase** the levels of the following medicines in your blood:

- pentoxifylline (for circulatory disorders)
- caffeine
- glibenclamide (for diabetes)
- lidocaine (local anaesthetic)
- sildenafil (used for treatment of erectile dysfunction or high blood pressure in the blood vessels in the lungs).

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.

Taking Ciprofloxacin Teva with food and drink

Food and drink does not affect your treatment with Ciprofloxacin.

Pregnancy and breast-feeding

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

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.

Important information about some of the ingredients of Ciprofloxacin Teva 2 mg/ml Solution for Infusion

Ciprofloxacin 2 mg/ml solution for infusion contains 5000 mg glucose monohydrate per 100 ml solution for infusion. This should be taken into account in patients with diabetes mellitus.

3. HOW TO USE CIPROFLOXACIN TEVA 2 mg/ml SOLUTION FOR INFUSION

Your doctor will explain to you exactly how much Ciprofloxacin Teva 2 mg/ml 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 Teva 2 mg/ml Solution for Infusion and 30 minutes for 200 mg Ciprofloxacin Teva 2 mg/ml Solution for Infusion. Administering the infusion slowly helps prevent immediate side effects occurring.

Remember to drink plenty of fluids while you are taking Ciprofloxacin 2 mg/ml.

If you stop your course of Ciprofloxacin 2 mg/ml

- 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, this medicine can cause side effects, although not everybody gets them.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, tell your doctor or pharmacist.

Common side effects (may affect up to 1 in 10 people):

- nausea, diarrhoea, vomiting
- joint pains in children
- rash
- temporary increased amounts of substances in the blood (transaminases)

Uncommon side effects (may affect up to 1 in 100 people):

- allergic swelling (oedema)
- 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: Take special care with Ciprofloxacin), giddiness (vertigo)
- 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 substances 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: Take special care with Ciprofloxacin)
- 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: Take special care with Ciprofloxacin)

- allergic reaction, rapid swelling of the skin and mucous membranes (angioedema), severe allergic reaction (anaphylactic shock) which can be life-threatening (see Section 2: Take special care with Ciprofloxacin)
- increased blood sugar (hyperglycemia)
- anxiety reaction, strange dreams, depression which can lead to suicidal thoughts or suicide attempts, mental disturbances (psychotic reactions) (see Section 2: Take special care with Ciprofloxacin)
- decreased skin sensitivity, tremor, seizures (including persistent brain seizure), 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: Take special care with Ciprofloxacin), 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: Take special care with Ciprofloxacin.)
- blood or crystals in the urine (see Section 2: Take special care with Ciprofloxacin.), 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, serum sickness) which can be fatal (see Section 2: Take special care with Ciprofloxacin.)
- 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: Take special care with Ciprofloxacin.).

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
- 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).rare skin eruption accompanied by blood disorders characterised by fever or chills, sore throat, ulcers in your mouth or throat.
- change to laboratory tests measuring blood clotting time (increase in test results).

5. HOW TO STORE CIPROFLOXACIN TEVA 2 mg/ml SOLUTION FOR INFUSION

Keep out of the reach and sight of children.

Do not use Ciprofloxacin 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 refrigerate or freeze.

Store the infusion bag in the overpouch until it is used in order to protect from light.

After first opening and / or following dilution, the solution should be used immediately.

Medicines should not be disposed via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.

6. FURTHER INFORMATION

What Ciprofloxacin Teva 2 mg/ml Solution for Infusion contains

The active substance is ciprofloxacin (as lactate).

Each bag of 100 ml contains 200 mg of ciprofloxacin.

Each bag of 200 ml contains 400 mg of ciprofloxacin.

The other ingredients are glucose monohydrate, lactic acid, hydrochloric acid and water for injections.

What Ciprofloxacin Teva 2 mg/ml Solution for Infusion looks like and contents of the pack

Ciprofloxacin 2mg/ml solution for infusion is an isotonic sterile, clear and colourless solution. The medicine is supplied to the hospital in plastic (polycine) infusion bags fitted with polypropylene infusion port. The ports are sealed with a rubber stopper and a polypropylene snap-cap. The infusion bags are contained in an aluminium overpouch.

Pack sizes: 100 ml bags (200 mg ciprofloxacin) in packs of 1 or 10 bags

200 ml bags (400 mg ciprofloxacin) in packs of 1 or 10 bags

Not all package sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Teva Pharma B.V.

Computerweg 10, 3542 DR Utrecht, The Netherlands

Manufacturer:

Teva pharmaceutical Works Private Limited Company

H-2100 Gödöllő, Táncsics Milály út 82, Hungary

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

Belgium	Ciprofloxacin Teva
Cyprus	Ciprofloxacin TEVA 2 mg/ml διάλυμα για έγχυση σε μικροσάκκους
Denmark	Ciprofloxacin Teva, 2 mg/ml Infusionvæske, opløsning
Germany	Ciprofloxacin-ratiopharm 2 mg/ml Infusionslösung
Greece	Ciprofloxacin TEVA 2 mg/ml διάλυμα για έγχυση σε μικροσάκκους
Ireland	Ciprofloxacin Teva 2 mg/ml Solution for Infusion
Luxembourg	Ciprofloxacin Teva
United Kingdom	Ciprofloxacin 2 mg/ml solution for infusion in minibag

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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

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

This section contains practical information about the administration. Read the SmPC to be completely informed about the posology and method of administration (including dose adjustment for patients with renal function damage), contra-indications and warnings.

Ciprofloxacin should be administered by intravenous infusion.

For single use only.

For children, the infusion duration is 60 minutes. In adult patients, infusion time is 60 minutes for 400 mg Ciprofloxacin and 30 minutes for 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.

Ciprofloxacin Teva 2 mg/ml Solution for Infusion has been shown to be compatible with:

- isotonic sodium chloride solution,
- Ringer's solution,
- Ringer's lactate solution,
- 10% fructose solution,
- 50 mg/ml (5%) or 100 mg/ml (10%) glucose solution and,
- 50 mg/ml (5%) glucose solution with 2.25 mg/ml (0.225%) or 4.5 mg/ml (0.45%) sodium chloride solution.

Unless compatibility is proven, the solution for infusion should always be administered separately.

The reconstituted solution should be inspected visually for particulate matter and discoloration prior to administration. The reconstituted solution is clear and colourless.

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: 3.5-4.6).

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

Use only clear solutions and undamaged containers

Any unused solution and the bag should be adequately disposed of, in accordance with local requirements.

Do not remove the bag from the protective packaging until ready for use. To be used immediately after the bag is opened.

Do not prepare admixtures in glass bottles.