

Package leaflet: information for the user  
Ciprinol 250 mg film-coated tablets  
Ciprinol 500 mg film-coated tablets  
Ciprinol 750 mg film-coated tablets  
Ciprofloxacin

Read the entire 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.
- Do you have any questions? Contact your doctor or pharmacist.
- Do not pass this medicine on to others, as it has been prescribed only for you. It can be harmful to others, even if their symptoms are the same as yours.
- Do you experience any side effects listed in section 4? Or do you experience a side effect that is not listed in this leaflet? Then contact your doctor or pharmacist.

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1. What is Ciprinol and what is this medicine used for?

Ciprinol is an antibiotic that belongs to the fluoroquinolone family. Ciprofloxacin works by killing bacteria that cause infections. It only works on specific strains of bacteria.

#### Adults

Ciprinol 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 genital organs in men and women,
- infections of the gastrointestinal tract and infections in the abdominal cavity,
- infections of skin and soft tissues,
- infections of bone and joints,
- to prevent infections caused by the bacterium *Neisseria meningitidis*,
- exposure to anthrax by inhalation.

Ciprofloxacin can be used in the treatment of patients with a very low white blood cell count (neutropenia) who have a fever presumably due to a bacterial infection.

If you have a severe infection or an infection caused by more than one type of bacteria, you may receive additional antibiotic treatment besides Ciprinol.

## Children and adolescents

Ciprinol is used in children and adolescents under the medical supervision of a specialist 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),
- exposure to anthrax through inhalation.

Ciprinol can also be used to treat certain other serious infections in children and adolescents if your doctor deems it necessary.

## 2. When should you not use this medicine or be extra careful?

When should you not use this medicine?

- You are allergic to any of the ingredients in this medicine. You can find these ingredients in section 6 of this leaflet.
- You are allergic to other quinolone medicines.
- You are using tizanidine (see section 2 "Are you taking any other medicines?").

When should you be extra careful with this medicine?

Before you use Ciprinol

If you have had a serious side effect in the past when using a quinolone or fluoroquinolone, you should not use fluoroquinolone/quinolone antibiotics, including Ciprinol. Inform your doctor as soon as possible if this applies to you.

Contact your doctor or pharmacist before using this medicine if you:

- have ever had kidney problems because your treatment may need to be adjusted,
- have epilepsy or another neurological condition,
- have a history of tendon problems during previous treatment with antibiotics, such as Ciprinol,
- have diabetes because you may experience a risk of hypoglycemia (low blood sugar) with ciprofloxacin
- have myasthenia gravis (a type of muscle weakness) because symptoms may worsen
- if you have an enlargement or bulge of a large blood vessel (aortic aneurysm or peripheral aneurysm of a large blood vessel) is diagnosed,
- if you have had a previous episode of aortic dissection (a tear in the wall of the aorta),
- if you have been diagnosed with leaking heart valves (heart valve regurgitation),
- if you have a family history of aortic aneurysm or aortic dissection or congenital heart valve disease, or other risk factors or related conditions (for example, connective tissue disorders such as Marfan syndrome, or vascular Ehlers-Danlos syndrome, Turner syndrome, Sjögren's syndrome [an autoimmune disease with inflammation], or vascular conditions such as Takayasu arteritis, giant cell arteritis, Behçet's disease, high blood pressure, or known atherosclerosis rheumatoid arthritis [a joint disorder] or endocarditis [an infection of the heart]).

- heart problems. Caution is advised when using this type of medication if you were born with or have a family history of prolonged QT interval (observed on the ECG, which records the heart's electrical activity), have an imbalanced salt level in your blood (especially low potassium or magnesium levels in the blood), have a very slow heart rate (called "bradycardia"), have a weak heart (heart failure) have, have a history of heart attack (myocardial infarction), are a woman or an older person, or are taking other medications that lead to abnormal ECG changes (see section 2 "Are you taking any other medications?").
- if you or someone in your family has a deficiency of glucose-6-phosphate dehydrogenase (G6PD), as this increases the risk of anemia when using ciprofloxacin.

To treat certain genital infections, your doctor may prescribe an additional antibiotic alongside ciprofloxacin. If there is no improvement in symptoms after 3 days of treatment, contact your doctor.

#### While taking Ciprinol

Tell your doctor immediately if any of the following situations occur while taking Ciprinol. Your doctor will decide whether to discontinue treatment with Ciprinol.

- A sudden severe allergic reaction (an anaphylactic reaction/shock, angioedema). Even with the first dose, there is a small chance that you may have a severe allergic reaction with the following symptoms: tightness in the chest, feeling dizzy, sick or faint, or dizziness when standing up. If this happens, stop taking Ciprinol and contact your doctor immediately.
- Long-lasting, disabling, and potentially permanent serious side effects. Fluoroquinolones/quinolones antibiotics, including Ciprinol, have been associated with very rare but serious side effects, some of which last a long time (months or years), lead to disability, or may be permanent. These include pain in tendons, muscles, and joints in the arms and legs, difficulty walking, unusual sensations such as a 'sleeping' feeling, tingling, a prickling sensation, numbness or burning sensation (paresthesia), sensory disorders such as impaired vision, taste, smell, and hearing, depression, memory loss, severe fatigue, and severe sleep disorders.
- If you experience any of these side effects after using Ciprinol, you should contact your doctor immediately before continuing treatment. You and your doctor will then decide together whether you can continue using this medication, with consideration given to an antibiotic from another class.
- In rare cases, pain and swelling in the joints, and tendon inflammation or rupture of tendons can occur. You are at greater risk if you are over 60 years old, have undergone an organ transplant, have kidney problems, or are being treated with corticosteroids. Tendon inflammation and rupture can occur as early as the first 48 hours of treatment and up to several months after stopping Ciprinol. At the first sign of pain or inflammation of a tendon (for example, in your ankle, wrist, elbow, shoulder, or knee), you should stop using Ciprinol. Also, contact your doctor immediately and rest the painful area. Avoid all unnecessary exertion, as this increases the risk of tendon rupture.
- Go to an emergency department immediately if you feel sudden, severe pain in your abdomen, chest, or back. These can be symptoms of an aortic aneurysm and aortic

dissection. The risk may be increased if you are being treated with systemic corticosteroids.

- Contact a doctor immediately if you experience shortness of breath, especially when lying flat in bed, or if you notice that your ankles, feet, or abdomen are swollen, or if you experience new-onset palpitations (feeling of rapid or irregular heartbeat).
- If you have epilepsy or another neurological condition, such as cerebral ischemia or stroke, you may experience side effects related to the central nervous system. If a seizure occurs, stop taking Ciprinol and contact your doctor immediately.
- In rare cases, you may experience nerve damage (neuropathy), such as pain, a burning sensation, tingling, numbness, and weakness, particularly in the feet and legs or hands and arms. If this happens, you should stop using this medication immediately. Also, contact your doctor immediately to prevent a possible permanent condition.
- The first time you take Ciprinol, you may experience psychological reactions, even when taking quinolone antibiotics, such as Ciprinol. If you have depression or psychosis, your symptoms may worsen with treatment with Ciprinol. In rare cases, depression or psychosis can develop into suicidal thoughts and self-harming behavior such as suicide attempts or a successful suicide (see section 4: Possible side effects). If depression, psychosis, suicidal thoughts, or behaviors occur, contact your doctor immediately.
- Quinolone antibiotics can cause an increase in your blood sugar levels above normal values (hyperglycemia) or a decrease in your blood sugar levels below normal values, which can potentially lead to loss of consciousness (hypoglycemic coma) in severe cases (see section 4). This is important for people with diabetes. If you have diabetes, your blood sugar should be carefully monitored.
- Diarrhea can occur while taking antibiotics, including Ciprinol, and even several weeks after stopping them. If it becomes severe or persistent, or if you notice that your stool contains blood or mucus, stop taking Ciprinol immediately, as this can be life-threatening. Do not take medications that can stop or slow down bowel movements.
- If your vision deteriorates or if you experience another eye disorder, consult an ophthalmologist immediately (see section 4 "Possible side effects").
- Your skin becomes more sensitive to sunlight and ultraviolet (UV) light when taking Ciprinol. Avoid exposure to strong sunlight and artificial UV light, such as tanning beds.
- Inform the doctor or laboratory staff that you are taking Ciprinol if you need to provide a blood or urine sample.
- If you suffer from kidney problems, inform the doctor, as your dose may need to be adjusted.
- Ciprinol can damage the liver. If you notice symptoms such as loss of appetite, jaundice (yellowing of the skin), dark urine, itching, or tenderness of the stomach, consult your doctor immediately.
- Ciprinol can cause a decrease in the number of white blood cells and can lower your resistance to infections. If you experience an infection with symptoms such as fever and severe deterioration of your general condition, or fever with symptoms of a localized infection, such as pain in your throat or mouth, or if you have problems urinating, you should see your doctor immediately. Some blood will be taken to check for a possible decrease in the number of white blood cells (agranulocytosis). It is important that you inform your doctor about the use of this medication.

Are you taking any other medications?

Are you taking any other medications besides Ciprinol, have you done so recently, or are you planning to do so soon? If so, inform your doctor or pharmacist.

Do not take Ciprinol together with tizanidine, as this can cause side effects such as low blood pressure and drowsiness (see section 2: "When should you not use this medicine?").

The following medications are known to interact with Ciprinol in your body. When Ciprinol is taken together with these medications, it can affect the effectiveness of those medications. The risk of possible side effects may also be increased.

Tell your doctor if you are taking the following:

- vitamin K antagonists (warfarin, acenocoumarol, phenprocoumon, or fluindione) or other oral anticoagulants (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 (an antipsychotic),
- ropinirole (for Parkinson's disease),
- phenytoin (for epilepsy),
- metoclopramide (for nausea and vomiting),
- ciclosporin (for skin conditions, rheumatoid arthritis, and in organ transplants),
- other medicines that can change your heart rhythm: medicines belonging to the group of antiarrhythmics (e.g., quinidine, hydroquinidine, disopyramide, amiodarone, sotalol, dofetilide, ibutilide), tricyclic antidepressants, some antibiotics (belonging to the group of macrolides), some antipsychotics,
- zolpidem (for sleep disorders).

Ciprinol can increase the concentration of the following medicines in your blood:

- pentoxifylline (for blood circulation disorders),
- caffeine,
- duloxetine (for depression),
- lidocaine (a local anesthetic),
- sildenafil (for example, for the treatment of erectile dysfunction),
- agomelatine (for depression).

Some medicines reduce the effect of Ciprinol. Tell your doctor if you are taking or plan to take the following:

- antacids,
- omeprazole,
- mineral supplements,
- sucralfate,
- a polymeric phosphate binder (e.g., sevelamer or lanthanum carbonate),
- medicines or supplements containing calcium, magnesium, aluminum, or iron.

If these medicines are essential, take Ciprinol about two hours before or at least four hours after taking these medicines.

What should you pay attention to with food and drink?

Calcium taken as part of a meal, including dairy products and drinks rich in calcium (such as milk or yogurt) or fortified fruit juices (such as orange juice with added calcium), does not significantly affect the absorption of this medicine. However, taking ciprofloxacin tablets simultaneously with dairy products and calcium-rich drinks, when these dairy products or drinks are consumed separately from meals, may reduce the effect of this medicine. Therefore, ciprofloxacin tablets should be taken 1-2 hours before or not earlier than 4 hours after dairy products or calcium-rich drinks separately from the meal (see also section 3).

Pregnancy and breastfeeding

Are you pregnant, do you think you might be pregnant, do you want to become pregnant, or are you breastfeeding? Then contact your doctor before using this medicine. It is better not to use Ciprinol if you are pregnant. Tell your doctor if you plan to become pregnant.

Do not take Ciprinol while breastfeeding, as Ciprinol is excreted in breast milk and may be harmful to your child.

Driving and using machines

Ciprinol may make you less alert. Some neurological side effects may occur. Therefore, make sure you know how you react to Ciprinol before driving a vehicle or operating machinery. Consult your doctor if in doubt.

Ciprinol contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, which means it is essentially 'sodium-free'.

### 3. How do you use this medicine?

Always use this medicine exactly as your doctor or pharmacist has told you. Are you unsure about the correct use? Then contact your doctor or pharmacist.

Your doctor will explain exactly how much Ciprinol you need to take and also how often and for how long. This depends on the type of infection you have and how severe it is.

Tell your doctor if you have kidney problems, as your dose may need to be adjusted.

The treatment usually lasts 5 to 21 days, but in severe infections, the treatment may last longer. Follow your doctor's advice closely when taking the tablets. Check with your doctor or pharmacist if you are unsure how many tablets to take and how to take Ciprinol.

- Swallow the tablets with plenty of liquid.
- Do not chew the tablets or crush them. Contact your doctor if you cannot swallow the tablet, so he can prescribe another form more suitable for you. Try to take the tablets at about the same time every day.
- Try to take the tablets at approximately the same time each day.
- dairy products or drinks rich in calcium are consumed separately from meals. Ciprofloxacin tablets should be taken one to two hours before or not earlier than four hours after dairy products or drinks rich in calcium when these are consumed separately from the meal.

Remember to drink plenty of fluids when taking Ciprinol. Have you used too much of this medicine?

If you have taken more Ciprinol than you should, contact your doctor immediately. Show the doctor the packaging with some tablets.

Have you forgotten to use this medicine?

Have you forgotten to take Ciprinol and it is:

6 hours or more until your next scheduled dose, take the normal dose as soon as possible.

Did you forget to take Ciprinol and it is:

- 6 hours or more until your next scheduled dose, take the normal dose as soon as possible. Then take the next dose at the usual time.
- less than 6 hours until your next scheduled dose, then do not take the missed dose. Take the next dose at the usual time.

Do not take a double dose to make up for a forgotten dose. Make sure to complete your treatment.

If you stop using this medicine

It is important that you complete the course of treatment, even if you start feeling better after a few days. If you stop taking this medicine too soon, your infection may not be completely cured and the symptoms of the infection may return or worsen. Additionally, you may develop resistance to the antibiotic.

Do you have any other questions about using this medicine? Then contact your doctor or pharmacist.

#### 4. Possible side effects

Like any medicine, this medicine can cause side effects. Not everyone experiences them.

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

Stop taking Ciprinol and contact your doctor immediately to consider treatment with another antibiotic if you experience any of the following serious side effects:

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

- seizure (see section 2: When should you be extra careful with this medicine?)

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

- Severe, sudden allergic reaction with symptoms such as chest tightness, feeling dizzy, nauseous or faint, or becoming dizzy when standing up (anaphylactic reaction/shock) (see section 2: When should you be extra careful with this medicine?)
- Muscle weakness, inflammation of the tendons which can lead to a tendon rupture, especially of the thick tendon at the back of the ankle (Achilles tendon) (see section 2: When should you be extra careful with this medicine?)

- A severe, life-threatening skin rash, usually in the form of blisters or sores in the mouth, throat, nose, eyes, and other mucous membranes such as the genitals, which can worsen to widespread blistering or peeling of the skin (Stevens-Johnson syndrome, toxic epidermal necrolysis).

Not known (cannot be determined from the available data)

- Unusual feelings of pain, burning sensation, tingling, numbness, or muscle weakness in the extremities (neuropathy) (see section 2: When should you be extra careful with this medicine?)
- A reaction to the drug causing skin rash, fever, inflammation of internal organs, hematological abnormalities, and systemic disease (DRESS - drug reaction with eosinophilia and systemic symptoms, AGEP - acute generalized exanthematous pustulosis).

Other side effects observed during treatment with Ciprinol are listed below according to how likely they are to occur:

Common (affects less than 1 in 10 users):

- nausea, diarrhea
- joint pain and joint inflammation in children.

Uncommon (affects less than 1 in 100 users):

- superinfections with a fungus
- a high concentration of eosinophils, a certain type of white blood cell
- decreased appetite
- hyperactivity or excitement
- headache, dizziness, sleep problems, or taste disorders
- vomiting, abdominal pain, digestive problems such as stomach discomfort (indigestion/heartburn) or flatulence
- increased amounts of certain substances in the blood (transaminases and/or bilirubin)
- rash, itching, or hives
- joint pain in adults
- poor kidney function
- pain in your muscles and bones, feeling unwell (asthenia) or fever
- increased alkaline phosphatase in blood (a certain substance in the blood).

Rare (affects less than 1 in 1,000 users):

- muscle pain, inflammation of the joints, increased muscle tension and muscle cramp
- inflammation of the colon (colitis) as a result of using an antibiotic (can be fatal in very rare cases) (see section 2: "When should you be extra careful with this medicine?")
- changes in blood values (leukopenia, leukocytosis, neutropenia, anemia), increased or decreased amounts of a blood clotting factor (platelets)
- allergic reaction, swelling (edema) or rapid swelling of the skin and mucous membranes (angio-edema) (see section 2: When should you be extra careful with this medicine)
- increased blood sugar (hyperglycemia)
- decreased blood sugar (hypoglycemia) (see section 2 "When should you be extra careful with this medicine?")

- confusion, disorientation, anxiety reactions, strange dreams, depression (which may lead to suicidal thoughts, suicide attempts or a completed suicide) (see section 2: When should you be extra careful with this medicine?), or hallucinations
- pins and needles sensation, unusual sensitivity to sensory stimuli, reduced skin sensitivity, tremors or dizziness
- vision problems including double vision (see section 2: When should you be extra careful with this medicine?)
- tinnitus, hearing loss, hearing disorder
- rapid heartbeat (tachycardia)
- dilation of blood vessels (vasodilation), low blood pressure or fainting
- shortness of breath, including asthmatic symptoms
- liver disorders, jaundice (cholestatic jaundice) or hepatitis
- sensitivity to light (see section 2: "When should you be extra careful with this medicine?")
- kidney failure, blood or crystals in the urine, urinary tract infection
- fluid retention or excessive sweating
- elevated levels of the enzyme amylase.

Very rarely (affects less than 1 in 10,000 users):

- a certain form of deficiency of red blood cells (hemolytic anemia); a dangerous drop in a type of white blood cells (agranulocytosis) (see section 2: When should you be extra careful with this medicine?); a decrease in the number of red and white blood cells and platelets (pancytopenia) which can be fatal, and bone marrow depression which can also be fatal
- allergic reactions called serum sickness-like reaction (see section 2: When should you be extra careful with this medicine?)
- mental disorders (psychotic reactions) (see section 2: "When should you be extra careful with this medicine?").
- migraine, coordination disorder, unsteady gait (gait disorder), sensory or olfactory disorder; pressure on the brain (intracranial pressure and pseudotumor cerebri)
- abnormalities in color perception
- inflammation of the blood vessel walls (vasculitis)
- pancreatitis
- death of liver cells (liver necrosis), very rarely leading to life-threatening liver failure (see section 2: When should you be extra careful with this medicine?)
- small bleedings under the skin the size of a pinprick (petechiae); various types skin rash
- worsening of the symptoms of myasthenia gravis (see section 2: "When should you be extra careful with this medicine?").

Not known (frequency cannot be determined with the available data)

- Condition associated with reduced water excretion and low sodium levels (SIADH);
- feeling very elated (mania) or feeling very optimistic and overactive (hypomania);
- abnormally fast heart rate, life-threatening arrhythmias, change in heart rhythm (called 'prolongation of the QT interval', visible on the ECG, electrical activity of the heart);
- influence on blood clotting (in patients treated with vitamin K antagonists);
- loss of consciousness due to severe lowering of your blood sugar level (hypoglycemic coma). See section 2.

Very rare cases of long-lasting (up to months or years) or permanent side effects, such as tendonitis, tendon rupture, joint pain, pain in arms or legs, walking difficulties, unusual sensations such as a 'sleeping' feeling, tingling, a prickling sensation, a burning or numb feeling, or pain (neuropathy), fatigue, memory and concentration disorders, effects on mental health (including sleep disorders, anxiety, panic attacks, depression, and suicidal thoughts), and also reduction of hearing, vision, taste, and smell, have been associated with the use of quinolone and fluoroquinolone antibiotics. In some cases, independent of pre-existing risk factors.

In patients who received fluoroquinolones, cases have been reported of enlargement and weakening of the aorta wall or a tear in the inner wall of the aorta (aneurysms and dissections). This can cause the aorta to rupture, which can be fatal. Cases of leaking heart valves have also been reported. See also section 2.

#### Reporting side effects

If you experience side effects, contact your doctor or pharmacist. This also applies to side effects not listed in this leaflet. You can also report side effects via the Dutch

Side Effects Center Lareb, website [www.lareb.nl](http://www.lareb.nl). By reporting side effects, you help us obtain more information about the safety of this medicine.

#### 5. How do you store this medicine?

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date. You will find this on the blister pack or the box after "EXP". It includes a month and a year. The last day of that month is the expiry date.

Store in the original packaging to protect from light.

Do not flush medicines down the sink or toilet and do not throw them in the trash. Ask your pharmacist what to do with medicines you no longer use. Proper disposal ensures they are destroyed correctly and do not enter the environment.

#### 6. Contents of the package and other information.

What substances are in this medicine? -

- The active substance in this medicine is ciprofloxacin (as hydrochloride monohydrate).  
Each film-coated tablet of 250 mg contains 291.0 mg ciprofloxacin hydrochloride monohydrate equivalent to 250 mg ciprofloxacin.  
Each film-coated tablet of 500 mg contains 582.0 mg ciprofloxacin hydrochloride monohydrate equivalent to 500 mg ciprofloxacin.  
Each film-coated tablet of 750 mg contains 873.0 mg ciprofloxacin hydrochloride monohydrate equivalent to 750 mg ciprofloxacin.
- The other ingredients are croscarmellose sodium, colloidal anhydrous silica, microcrystalline cellulose, sodium starch glycolate (type A), povidone K-25 and magnesium stearate in the core, and hypromellose, propylene glycol, talc, and titanium dioxide (E171) in the coating. See section 2 "Ciprinol contains sodium".

What does Ciprinol look like and what is in a package?

250 mg film-coated tablets are white, round, film-coated tablets, flat on one side and scored on the other. The tablet can be divided into equal doses.

500 mg film-coated tablets are white, oval, film-coated tablets, flat on one side and scored on the other. The tablet can be divided into equal doses.

750 mg film-coated tablets are white, oval, film-coated tablets, scored on both sides. The tablet can be divided into equal doses.

For each strength, boxes of 10, 20, 30, or 100 film-coated tablets are available in a blister pack (1, 2, 3, or 10 blister strips of 10 film-coated tablets), 500 mg film-coated tablets are also available in boxes of 6 film-coated tablets (1 blister strip of 6 film-coated tablets) and 16 film-coated tablets (2 blister strips of 8 film-coated tablets) and 750 mg film-coated tablets in boxes of 12 tablets (2 blister strips of 6 film-coated tablets). The film-coated tablets are also available in a hospital pack of 50 film-coated tablets (10 blister strips of 5 film-coated tablets). Not all mentioned pack sizes are marketed.

Marketing authorization holder and manufacturer

Marketing authorization holder

KRKA, d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia

Manufacturer

KRKA, d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia

These products are marketed with

Ciprinol 250 mg      RVG 32444

Ciprinol 500 mg      RVG 32445

Ciprinol 750 mg      RVG 32446

This medicine is registered in member states of the European Economic Area under the following names:

Name of the member state	Name of the medicine
Netherlands	Ciprinol
Austria, Denmark, Finland, Sweden	Ciprofloxacin Krka
Italy	Ciprofloxacina Krka

This leaflet was last approved in February 2025.