

Cipro-Denk 500

Film-coated tablet – oral use
Antibiotic - fluoroquinolone
Active substance: ciprofloxacin

Package leaflet: Information for the patient

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.
- 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 Cipro-Denk 500 is and what it is used for
2. What you need to know before you take Cipro-Denk 500
3. How to take Cipro-Denk 500
4. Possible side effects
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6. Contents of the pack and other information

1. What Cipro-Denk 500 is and what it is used for

Cipro-Denk 500 contains the active substance ciprofloxacin. Ciprofloxacin is an antibiotic belonging to the fluoroquinolone group. Ciprofloxacin works by killing bacteria that cause infections. It only works in certain strains of bacteria.

Adults

Cipro-Denk 500 is used in adults to treat the following bacterial infections:

- certain respiratory tract infections
- certain forms of ear or sinus inflammations
- urinary tract infections
- infections of the male and female genitalia
- infections of the gastrointestinal tract and infections of the abdominal cavity
- certain skin and soft-tissue infections
- infections of the bones and joints
- to prevent infections caused by the bacterium *Neisseria meningitidis*
- treatment after inhalation of anthrax pathogens.

Ciprofloxacin may be used in the management of patients with a low number of certain white blood cells (neutropenia) and fever and that is suspected to be due to a bacterial infection.

If you have a severe infection or an infection caused by several types of bacteria, you may be given other antibiotic treatment in addition to Cipro-Denk 500.

Children and adolescents

Cipro-Denk 500 is used in children and adolescents, under the supervision of a specialist doctor, to treat the following bacterial infections:

- lung and bronchial infections in children and adolescents suffering from cystic fibrosis

- complicated urinary tract infections, including infections involving the renal pelvis (acute pyelonephritis)
- treatment after inhalation of anthrax pathogens.

2. What you need to know before you take Cipro-Denk 500

Do not take Cipro-Denk 500

- if you are allergic to ciprofloxacin, other quinolone preparations or any of the other ingredients of this medicine (listed in section 6)
- if you are taking tizanidine (see section 2 “Other medicines and Cipro-Denk 500”).

Warnings and precautions

Talk to your doctor or pharmacist before taking Cipro-Denk 500:

- if you have ever had kidney problems, as your treatment may have 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 Cipro-Denk 500
- if you are diabetic because you may experience a risk of hypoglycaemia with ciprofloxacin
- if you suffer from myasthenia gravis (a type of muscle weakness), because symptoms can be exacerbated
- 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 Cipro-Denk 500”).
- 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 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 predisposing conditions (e.g. connective tissue disorders such as Marfan syndrome or Ehlers-Danlos syndrome, Turner syndrome, Sjögren’s syndrome [an inflammatory autoimmune disease], or vascular disorders such as Takayasu arteritis, giant cell arteritis, Behcet’s disease, high blood pressure, or known atherosclerosis, rheumatoid arthritis [a disease of the joints] or endocarditis [an infection of the heart])
- if you or a member of your family is known to have a deficiency in a glucose-6-phosphate dehydrogenase (G6PD), as you may experience a risk of anaemia with ciprofloxacin.

You should not take fluoroquinolone/quinolone antibacterial medicines, including Cipro-Denk 500, if you have experienced any serious adverse reaction in the past when taking a quinolone or fluoroquinolone. In this situation, you should inform your doctor as soon as possible.

For the treatment of certain genital tract infections, your doctor may prescribe another antibiotic in addition to Cipro-Denk 500. If there is no improvement in symptoms after 3 days of treatment, please consult your doctor.

When taking this medicine

Tell your doctor immediately if any of the following events occurs whilst taking Cipro-Denk 500. Your doctor will decide whether treatment with Cipro-Denk 500 needs to be stopped.

- Severe, sudden hypersensitivity reaction (anaphylactic reaction/shock, angioedema). Even after the first dose, there is a slight risk that you may experience a severe allergic reaction, which can manifest in the following symptoms: tight-chestedness, feeling dizzy, nausea or sense of imminent fainting, or feeling dizzy on standing. If this happens, stop taking Cipro-Denk 500 and consult your doctor immediately.
- Pain and swelling in the joints and inflammation or rupture of tendons may occur rarely. Your risk is increased if you are elderly (above 60 years of age), have received an organ transplant, have kidney problems or if you are being treated with corticosteroids. Inflammation and ruptures of tendons may occur within the first 48 hours of treatment and even up to several months after stopping of ciprofloxacin therapy. At the first sign of pain or inflammation of a tendon (for example in your ankle, wrist, elbow, shoulder or knee), stop taking Cipro-Denk 500, contact your doctor and rest the painful area. Avoid any unnecessary exercise as this might increase the risk of a tendon rupture.
- If you feel sudden, severe pain in your abdomen, chest or back, which can be symptoms of aortic aneurysm and dissection, go immediately to an emergency room. Your risk may be increased if you are being treated with systemic corticosteroids.
- If you start experiencing a rapid onset of shortness of breath, especially when you lie down flat in your bed, or you notice swelling of your ankles, feet or abdomen, or a new onset of heart palpitations (sensation of rapid or irregular heartbeat), you should inform a doctor immediately.
- 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 Cipro-Denk 500 and contact your doctor immediately.
- You may rarely experience symptoms of nerve damage (neuropathy) such as pain, burning, tingling, numbness and/or weakness especially in the feet and legs or hands and arms. If this happens, stop taking Cipro-Denk 500 and inform your doctor immediately in order to prevent the development of potentially irreversible condition.
- Psychiatric reactions may occur after taking the first dose of ciprofloxacin. If you suffer from depression or psychosis, your symptoms may get worse during treatment with Cipro-Denk 500. In rare cases, a depression or psychosis can progress to suicidal thoughts, suicide attempts or completed suicide. If this happens, contact your doctor immediately.
- Quinolone antibiotics may cause an increase of your blood sugar levels above normal levels (hyperglycaemia), or lowering of your blood sugar levels below normal levels, potentially leading to loss of consciousness (hypoglycaemic coma) in severe cases (see section 4). This is important for people who have diabetes. If you suffer from diabetes, your blood sugar should be carefully monitored.
- Diarrhoea may occur during treatment with antibiotics, including Cipro-Denk 500, or even several weeks after you have finished treatment. If diarrhoea is severe or persistent, or if you notice that your stool contains blood or mucus, stop taking Cipro-Denk 500 and contact your doctor immediately, as this may be life-threatening. Do not take any 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 will become more sensitive to sunlight or ultraviolet (UV) light when you take Cipro-Denk 500. For this reason, avoid exposure to strong sunlight or artificial UV light such as sun beds.
- Tell the doctor or laboratory staff that you are taking Cipro-Denk 500 if you have to provide a blood or urine sample.
- Please tell your doctor if you suffer from kidney problems, as your dose may need to be adjusted.
- Cipro-Denk 500 can cause liver damage. If you notice any of the following symptoms, such as loss of appetite, jaundice (yellowing of the skin), dark urine, itching, or tenderness of the stomach, consult your doctor immediately.
- Cipro-Denk 500 may lead to a reduction in the number of white blood cells and your resistance to infections may be decreased. If you experience an infection with symptoms such as fever and a serious deterioration in your general condition, or fever together with local symptoms such as sore infections of the throat/mouth, or pain when passing water, you should consult your doctor immediately. A blood sample may show a possible reduction in white blood cells (agranulocytosis). It is important to tell your doctor about all medicines that you are taking.

Prolonged, disabling and potentially irreversible serious side effects

Fluoroquinolone/quinolone antibacterial medicines, including Cipro-Denk 500, have been associated with very rare but serious side effects, some of them being long lasting (continuing months or years), disabling or potentially irreversible. This includes tendon, muscle and joint pain of the upper and lower limbs, difficulty in walking, abnormal sensations such as pins and needles, tingling, tickling, numbness or burning (paraesthesia), sensory disorders including impairment of vision, taste and smell, and hearing, depression, memory impairment, severe fatigue, and severe sleep disorders.

If you experience any of these side effects after taking Cipro-Denk 500, contact your doctor immediately prior to continuing treatment. You and your doctor will decide on continuing the treatment considering also an antibiotic from another class.

Other medicines and Cipro-Denk 500

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

Do not take Cipro-Denk 500 together with tizanidine, as this may cause side effects such as low blood pressure and sleepiness (see section 2 “Do not take Cipro-Denk 500”).

The following medicines are known to cause interactions with ciprofloxacin in your body. If Cipro-Denk 500 is taken together with these medicines, the therapeutic effect of these medicines may be impaired. The probability of developing side effects may also be increased.

Please tell your doctor if you are taking any of the following medicines:

- vitamin K antagonists (e.g. warfarin, acenocoumarol, phenprocoumon or fluidione) or other oral anticoagulants (blood thinners)
- probenecid (for gout)
- methotrexate (for certain types of cancer, psoriasis, rheumatoid arthritis)
- theophylline (for breathing complaints)
- tizanidine (to relax the musculoskeletal system in multiple sclerosis)
- olanzapine (an antipsychotic)
- clozapine (an antipsychotic)
- ropinirole (for Parkinson’s disease)

- phenytoin (for epilepsy)
- metoclopramide (for nausea and vomiting)
- cyclosporin (for skin diseases, rheumatoid arthritis and organ transplantation)
- 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
- zolpidem (for sleep disorders)

Cipro-Denk 500 can increase the concentration of the following medicines in your blood:

- pentoxifylline (for circulatory disorders)
- caffeine
- duloxetine (for depression, diabetic nerve damage or incontinence)
- lidocaine (for heart diseases or anaesthetic use)
- sildenafil (e.g. for erectile dysfunction)
- agomelatine (for depression)

Some medicines reduce the effect of Cipro-Denk 500. Please tell your doctor if you are taking or wish to take any of the following medicines:

- antacids (used to treat overacidity of the stomach)
- omeprazole
- mineral supplements
- sucralfate
- a polymeric phosphate binder (e.g. sevelamer or lanthanum carbonate)
- medicines or dietary supplements containing calcium, magnesium, aluminium or iron

If you absolutely need these products, take Cipro-Denk 500 about two hours before or four hours afterwards as a minimum.

Cipro-Denk 500 with food and drink

Unless you take Cipro-Denk 500 during meals, do not eat or drink any dairy products (such as milk or yoghurt) or drinks with added calcium when you take the tablets, as they may affect the absorption of the active substance.

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.

You should preferably avoid taking Cipro-Denk 500 during pregnancy.

Do not take Cipro-Denk 500 if you are breast-feeding, as ciprofloxacin passes into breast milk and may harm your child.

Driving and using machines

Cipro-Denk 500 may make you feel less alert.

Some side effects may occur on the nervous system. Therefore, make sure that you know how you react to Cipro-Denk 500 before driving a vehicle or using machines. If in doubt, please ask your doctor.

Cipro-Denk 500 contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially “sodium-free”.

3. How to take Cipro-Denk 500

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Your doctor will explain to you exactly how much Cipro-Denk 500 to take, as well as how often and for how long. This will depend on the type and severity of the infection that you have.

Please tell your doctor if you suffer from kidney problems, as your dose may have to be adjusted.

Treatment usually lasts for 5 to 21 days, but may be longer for severe infections. Always take this medicine exactly as your doctor has told you.

Take the film-coated tablets whole (not chewed) with plenty of liquid. You should not chew the film-coated tablets due to their unpleasant taste. The tablet can be divided into equal doses.

Wherever possible, try to take Cipro-Denk 500 at roughly the same time each day.

You can take Cipro-Denk 500 with a meal or independently of meals. Absorption of the active substance is only marginally affected by a meal containing calcium. However, do not take Cipro-Denk 500 with dairy products, such as milk or yoghurt, or with mineral-enriched drinks (e.g. calcium-enriched orange juice).

Please make sure that you drink sufficient liquid during treatment with Cipro-Denk 500.

If you take more Cipro-Denk 500 than you should

If you have taken more than the prescribed dose, seek medical help immediately. If possible, take your film-coated tablets or the pack with you to show the doctor.

If you forget to take Cipro-Denk 500

Take the usual dose as soon as possible and then continue treatment as prescribed. However, if it is almost time for your next dose, do not take the forgotten dose, but continue taking your tablets as normal. Do not take a double dose to make up for a forgotten dose.

Please make sure that you finish your full course of treatment.

If you stop taking Cipro-Denk 500

It is important that you finish your full course of treatment even if you feel better after a few days. If you stop taking this medicine too soon, your infection may not be completely cured and symptoms of the infection may return or your condition may get worse. You may also develop resistance to this 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.

The following section contains the most serious side effects that you can recognize yourself: Stop taking Cipro-Denk 500 and contact your doctor immediately in order to consider another antibiotic treatment if you notice any of the following serious side effects.

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

- seizure (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/shock) (see section 2 “Warnings and precautions”)
- muscle weakness, inflamed tendons, tendon rupture – especially of 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 ciprofloxacin are listed below by how likely they are.

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

- nausea, diarrhoea
- joint pain and joint inflammation in children

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

- joint pain in adults
- fungal superinfections
- high concentration of eosinophil granulocytes, certain white blood cells
- decreased appetite
- hyperactivity or restlessness
- headache, light-headedness, sleeping or taste disorders
- vomiting, stomach ache, digestive disorders such as upset stomach (feeling full/heartburn) or wind
- increase in certain substances in the blood (transaminases and/or bilirubin)
- rash, itching or nettle rash
- kidney dysfunction
- muscle and bone pain, generally feeling unwell (asthenia) or fever
- increase in blood alkaline phosphatase (a certain substance in the blood)

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

- muscle pain, inflamed joints, increased muscle tension or cramps
- inflammation of the large bowel lining triggered by antibiotics (colitis), very rarely with a fatal outcome (see section 2 “Warnings and precautions”)
- changes in the blood count (leukocytopenia, leukocytosis, neutropenia, anaemia), decrease or increase in a certain blood coagulation factor (platelets)
- allergic reaction, swelling (oedema) or rapid swelling of the skin and mucous membranes (angioedema) (see section 2 “Warnings and precautions”)
- increase in blood sugar (hyperglycaemia)
- decreased blood sugar (hypoglycaemia) (see section 2 “Warnings and precautions”)
- confusion, disorientation, anxiety, nightmares, depressions (potentially leading to suicidal thoughts, suicide attempts or completed suicide) (see section 2 “Warnings and precautions”) or hallucinations
- tingling, unusual sensitivity to sensory stimuli, reduced sensitivity of the skin, tremor or dizziness
- visual disturbances, including double vision (see section 2 “Warnings and precautions”)

- ringing in the ears (tinnitus) or hearing loss or reduced hearing
- racing heart (tachycardia)
- widening of the blood vessels (vasodilation), low blood pressure or fainting
- shortness of breath, including asthmatic symptoms
- liver dysfunction, jaundice (bile accumulation) or liver inflammation
- sensitivity to light (see section 2 “Warnings and precautions”)
- kidney failure, blood or crystals in the urine, inflammation of the urinary tract
- fluid retention or excessive sweating
- increased levels of the amylase enzyme

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

- a special type of reduced red blood cell count (haemolytic anaemia), a dangerous decrease in certain white blood cells (agranulocytosis) (see section 2 “Warnings and precautions”), possibly life-threatening decrease in certain red and white blood cells and platelets (pancytopenia) and reduced bone marrow function, which can also be life-threatening
- allergic reaction called serum sickness-like reaction (see section 2 “Warnings and precautions”)
- psychiatric disorders (psychotic reactions, potentially leading to suicidal thoughts, suicide attempts or a completed suicide) (see section 2 “Warnings and precautions”)
- migraine, impaired coordination, unsteady walking (impaired gait), impaired sense of smell (olfactory disorder), pressure on the brain (intracranial pressure and pseudotumor cerebri)
- problems in colour vision
- inflammation of the blood vessel walls (vasculitis)
- inflammation of the pancreas (pancreatitis)
- liver cell death (liver necrosis), very rarely progressing to life-threatening liver failure (see section 2 “Warnings and precautions”)
- small, pinpoint bleeding into the skin (petechiae); various skin changes and types of rash
- worsening of myasthenia gravis symptoms (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)
- impairment of blood clotting (in patients, treated with vitamin K antagonists)
- syndrome associated with impaired water excretion and low levels of sodium (SIADH)
- loss of consciousness due to severe decrease in blood sugar levels (hypoglycaemic coma). See section 2.

Very rare cases of long lasting (up to months or years) or permanent adverse drug reactions, such as tendon inflammations, tendon rupture, joint pain, pain in the limbs, difficulty in walking, abnormal sensations such as pins and needles, tingling, tickling, burning, numbness or pain (neuropathy), depression, fatigue, sleep disorders, memory impairment, as well as impairment of hearing, vision, and taste and smell have been associated with administration of quinolone and fluoroquinolone antibiotics, in some cases irrespective of pre-existing risk factors.

Cases of an enlargement and weakening of the aortic wall or a tear in the aortic wall (aneurysms and dissections), which may rupture and may be fatal, and of leaking heart valves have been reported in patients receiving fluoroquinolones. See also section 2.

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

5. How to store Cipro-Denk 500

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 blister after “Exp.”. The expiry date refers to the last day of that month.

Shelf life: 3 years
Store below 30 °C.

Do not throw away any medicines via wastewater. 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 Cipro-Denk 500 contains

- The active substance is ciprofloxacin. Each film-coated tablet contains 500 mg ciprofloxacin (as ciprofloxacin hydrochloride).
- The other ingredients are: sodium starch glycolate (type A), low-substituted hydroxypropyl cellulose, magnesium stearate [vegetable], hypromellose, macrogol 400, titanium dioxide, talc.

General classification for supply

Medicinal product subject to medical prescription

What Cipro-Denk 500 looks like and contents of the pack

White, oblong film-coated tablets with a score on both sides and imprint “Cipro 500” on one side.

Cipro-Denk 500 is available in PVC/PVDC/aluminium blisters.

Pack size: 10 film-coated tablets

Marketing Authorisation Holder

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