

Package leaflet: Information for the user

Ciprofloxacin 500 mg Film-Coated Tablets

Ciprofloxacin hydrochloride

Read all of this leaflet carefully before taking this medicine because it contains important information for you:

- Keep this leaflet as 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 of the 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 Ciprofloxacin 500mg Tablets are and what they are used for
2. What you need to know before you take Ciprofloxacin 500mg Tablets
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1. What Ciprofloxacin 500mg Tablets are and what they are used for

Ciprofloxacin 500mg Tablets are an antibiotic belonging to the fluoroquinolone family. Ciprofloxacin Tablets are used for the treatment of severe bacterial infections. They only work with specific strains of bacteria.

Adults

- respiratory tract, urinary tract, genital tract infections in men and women, stomach and intra-abdominal infections, skin and soft tissue, bone and joint infections.
- long lasting or recurring ear or sinus infections
- to prevent infections due to the bacterium *Neisseria meningitidis*
- anthrax inhalation exposure

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

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

Children and adolescents

Ciprofloxacin Tablets are 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 Tablets 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 take Ciprofloxacin 500mg Tablets

Do **NOT** take Ciprofloxacin 500mg Tablets if you or your child:

- have a known allergic reaction to ciprofloxacin, to other quinolone drugs or to any of the other ingredients of this medicine listed in Section 6.
- are taking tizanidine (see section 2: Taking other medicines)

Warnings and precautions

Talk to your doctor before taking Ciprofloxacin 500mg Tablets

- if you have ever had kidney problems because your treatment may need to be adjusted
- if you suffer from epilepsy or other neurological conditions
- if you have a history of tendon problems during previous treatment with antibiotics such as Ciprofloxacin Tablets
- if you are diabetic because you may experience a risk of hypoglycaemia with ciprofloxacin
- if you have myasthenia gravis (a type of muscle weakness)
- if you have heart problems: Caution should be taken when using this kind of medicine, if you were born with or have a family history of prolonged QT interval (seen on ECG, electrical recording of the heart), have salt imbalance in the blood (especially low levels 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 Ciprofloxacin 500mg Tablets)
- if you or a member of your family is known to have a deficiency in glucose-6-phosphate dehydrogenase (G6PD) (disease of the red blood cells based on a hereditary enzyme deficiency) because taking ciprofloxacin may lead to a destruction of red blood cells causing anaemia. Signs of anaemia are a feeling of weakness and in more severe cases, breathlessness and pale skin

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 taking Ciprofloxacin 500mg Tablets

Tell your doctor immediately if any of the following occurs while taking Ciprofloxacin 500mg Tablets. Your doctor will decide whether treatment with Ciprofloxacin 500mg Tablets needs to be stopped.

- **Severe, sudden allergic reaction** (anaphylactic reaction/shock, angio-oedema). Even after the first dose, there is a small chance that you may experience a severe allergic reaction with the following symptoms: tightness in the chest, feeling dizzy, sick or faint or experiencing dizziness when standing up. **If this happens stop taking Ciprofloxacin and contact your doctor immediately.**
- If your eyesight becomes impaired or if your eyes seem to be otherwise affected, **consult an eye specialist immediately.**
- **Pain and swelling in the joints and tendinitis**, in particular of the Achilles (heel) tendon. This medicine may cause these side effects, particularly if you are older or take medicine of the steroid group, such as hydrocortisone. Inflammation and ruptures of tendons may occur even within the first 48 hours of treatment or up to several months after discontinuation of Ciprofloxacin therapy. If you experience these symptoms rest the sore leg and consult your doctor immediately. Avoid any unnecessary exercise as this might increase the risk of tendon rupture.
- **if you suffer from epilepsies** 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** the first time you take Ciprofloxacin. If you suffer from **depression or psychosis**, your symptoms may become worse under treatment with Ciprofloxacin. In rare cases, depression or psychosis can progress to thoughts of suicide, suicide attempts, or completed suicide. If this happens, 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.
- **Hypoglycaemia** has been reported most often in diabetic patients, predominantly in elderly population. If this happens, contact your doctor immediately.
- **Diarrhoea** may develop while you are taking antibiotics including Ciprofloxacin, or even several weeks after you have stopped taking them. If it becomes severe or persistent or you notice that your stool contains blood or mucus, stop taking Ciprofloxacin immediately, as this can be life-threatening. Do not take medicines that stop or slow down bowel movements and contact your doctor.
- Tell the doctor or laboratory staff that you are taking Ciprofloxacin if you have to provide a **blood or urine sample.**
- If you suffer from **kidney problems**, tell the doctor because your dose may need to be adjusted.
- Ciprofloxacin may cause **liver damage**: If you notice any symptoms such as loss of appetite, jaundice (yellowing of the skin), dark urine, itching or tenderness of the stomach, stop taking Ciprofloxacin and contact your doctor 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.
- Your skin becomes more **sensitive to sunlight or ultraviolet (UV) light** when taking Ciprofloxacin. Avoid exposure to strong sunlight, sunlamps or other sources of UV radiation. If exposure to sunlight is inevitable you should use sun cream to protect yourself. If you experience a fever, rash, itching or small red spots on the skin, you should consult your doctor immediately since the treatment may be discontinued.
- **Crystalluria** (presence of crystals in the urine with discomfort when passing urine) may occur. Consult your doctor as your urine needs to be tested. Furthermore, you should drink a sufficient amount of liquid (about 1.5-2 litres per day).
- **Tuberculosis test (*Mycobacterium*)**. Ciprofloxacin may cause a false test result.
- If your **eyesight becomes impaired** or if your eyes seem to be otherwise affected, consult an eye specialist immediately.

Other medicines and Ciprofloxacin 500mg Tablets.

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

Ciprofloxacin can increase the level of the following substances in the blood:

- Agomelatine
- Zolpidem

Do not take Ciprofloxacin together with tizanidine, because this may cause side effects such as low blood pressure and sleepiness (see section 2: "Do not take Ciprofloxacin").

If Ciprofloxacin 500mg Tablets and one of the following medicines are given at the same time, special care must be taken:

Tell your doctor if you are taking:

- **Vitamin K antagonists** (e.g. 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)
- **olanzapine and clozapine** (antipsychotics)
- **ropinrole** (for Parkinson's disease)
- **phenytoin** (for epilepsy)
- **metoclopramide** (for nausea and vomiting)
- **cyclosporin** (for skin conditions, rheumatoid arthritis and in organ transplantation)
- **anti-arrhythmics**: medicines that can alter your heart rhythm (e.g. **quinidine, hydroquinidine, disopyramide, amiodarone, sotalol, dofetilide, ibutilide**), **tricyclic antidepressants, some antimicrobials** (that belong to the group of macrolides), **some antipsychotics.**

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

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

Some medicines **reduce** the effect of Ciprofloxacin. Tell your doctor if you take or wish to take:

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

If these preparations are essential, take Ciprofloxacin about two hours before or no sooner than four hours after taking them.

Ciprofloxacin 500mg Tablets with food and drink

Large amounts of **dairy products** particularly **milk or yoghurt** may slow ciprofloxacin uptake, therefore ciprofloxacin should be taken 1 to 2 hours before or at least 4 hours after these products.

Surgical procedures

Tell your doctor that you are taking ciprofloxacin because pain relief and sedative medicines administered prior to surgery can also be affected by ciprofloxacin.

If one of the above-mentioned situations is applicable to you, your doctor may decide to prescribe another medicine or to adjust the dose of Ciprofloxacin 500mg Tablets or the other medicine.

It is advisable never to use several medicines at the same time without consulting your doctor first.

Pregnancy

If you are pregnant or breast feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

It is preferable to avoid the use of Ciprofloxacin during pregnancy.

Breast-feeding

Ciprofloxacin is passed into human breast milk. You must not breast-feed your child during treatment with ciprofloxacin, due to the risk of malformation of joint cartilage and other harmful effects in the breast-fed infant.

Driving and using machines

Ciprofloxacin can reduce your attention. If you suffer from dizziness, do not drive or operate machines, which require your full concentration.

3. How to take Ciprofloxacin 500mg Tablets

You should follow your doctor's instructions and check the pharmacist's label for how many tablets to take, and when. The usual doses for different types of infections treated with Ciprofloxacin 500mg Tablets are given below as a guide:

Respiratory tract infections 1 tablet twice a day for 7 to 14 days.

Pyelonephritis 1 tablet twice a day for 7 to 14 days.

Prostatitis 1 tablet twice a day for up to 28 days

Severe gastroenteritis 1 tablet twice a day for 3 to 7 days.

Skin and soft tissue infections 1 tablet twice a day for 5 to 10 days.

Bone and joint infections 1 tablet twice a day for 4 to 6 weeks or longer.

Severe systemic infections 1 tablet twice a day.

Acute, uncomplicated gonorrhoea a single dose of 1 tablet.

The actual dose may be adjusted to take into account your age, severity of infection and how well your kidneys are working. If you have a severe infection and serious kidney problems your doctor may take regular blood samples to check your recovery and ensure you are receiving the correct dose. Ideally these tablets should be swallowed whole with a glass of water. These tablets can be taken at any time, with or without food. Taking the tablets on an empty stomach will speed up the uptake, whilst dairy products such as milk or yoghurt may slow down the uptake of ciprofloxacin in the stomach.

If you take more Ciprofloxacin 500mg Tablets than you should

If you take more than you should, or in the event of an overdose, seek medical advice immediately and, if possible, take any remaining tablets or this leaflet with you to show the doctor.

If you forget to take Ciprofloxacin 500mg Tablets

If you forget to take your medicine take the missed dose as soon as possible and then continue as normal. However, if it is almost time for your next dose, do not take the missed dose and continue as usual. Do not take a double dose to make up for the forgotten one.

If you stop taking Ciprofloxacin 500mg Tablets

You should continue to take these tablets for as long as directed by your doctor. It is important that you complete the course of treatment, even if you begin to feel better after a few days. If you stop taking this medicine too soon, your symptoms may return.

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.

- muscle pain and/or weakness, inflammation of the joints and joint pain, increased muscle tone and cramping, inflammation of the tendons or tendon rupture, particularly affecting the large tendon at the back of the ankle (Achilles tendon) (see Section 2: Warnings and precautions)
- unusual feelings of pain, burning tingling, numbness or muscle weakness in the extremities (neuropathy) (see Section 2: Warnings and precautions)
- severe allergic reactions (anaphylactic reaction or anaphylactic shock, which can be fatal – serum sickness) (see Section 2: Warnings and precautions)
- mental disturbances (psychotic reactions potentially leading to thoughts of suicide, suicide attempts, or completed suicide) (see Section 2 Warnings and precautions)
- depression (potentially leading to thoughts of suicide, suicide attempts, or completed suicide)
- flu-like symptoms, followed by a painful red or purplish rash that spreads, blisters on your skin, mouth, nose or genitals, or red, painful, watery eyes, signs of the potentially fatal Stevens-Johnson syndrome or toxic epidermal necrolysis
- yellow and/or itchy skin, a sign of jaundice (cholestatic icterus).

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

- nausea, diarrhoea
- joint pains in children.

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

- fungal superinfections
- a high concentration of eosinophils, a type of white blood cell.
- loss of appetite (anorexia)
- hyperactivity or agitation
- headache, dizziness, sleeping problems or taste disorders
- vomiting, abdominal pain, digestive problems such as stomach upset (indigestion/heartburn), or wind
- increased amount of certain substances in the blood (transaminase and/or bilirubin)
- rash, itching or hives
- joint pain in adults
- poor kidney function
- pains in your muscles and bones, feeling unwell (asthenia), or fever
- 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 very rare cases) (see Section 2: Warnings and precautions)
- changes to the blood count (leukopenia, leukocytosis, neutropenia, anaemia), increased or decreased amounts of a blood clotting factor (thrombocytes)
- allergic reaction, swelling (oedema), or rapid swelling of the skin and mucous membranes (angio-oedema)
- increased blood sugar levels (hyperglycaemia)
- decreased blood sugar levels (hypoglycaemia) (see Section 2: Warnings and precautions)
- confusion, disorientation, anxiety reactions, strange dreams, or hallucinations
- pins and needles, unusual sensitivity to stimuli of the senses, decreased skin sensitivity, tremors, seizures (see Section 2: Warnings and precautions), or giddiness
- eyesight problems including double vision (diplopia)
- ringing in the ear (tinnitus), temporary hearing loss (particularly high frequencies), impaired hearing
- increased heart rate (tachycardia)
- widening of blood vessel (vasodilation), low blood pressure, or fainting
- shortness of breath (dyspnoea) including asthmatic symptoms, swelling of the voice box (larynx) with difficulties in breathing (larynx oedema)
- liver disorders, or hepatitis
- sensitivity to light (see Section 2: Warnings and precautions)
- sudden (acute) kidney failure, blood or crystals in the urine with discomfort when passing urine (crystalluria) (see Section 2: Warnings and precautions), urinary tract inflammation
- fluid retention or excessive sweating
- increased levels of the enzyme amylase.

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

- reduction in red blood cells due to extensive destruction of these cells (haemolytic anaemia), a dangerous drop in a type of white blood cells (agranulocytosis), a drop in the number of red and white blood cells and platelets (pancytopenia), which may be fatal; and bone marrow depression, which may also be fatal (see Section 2: Warnings and precautions)
- migraine, disturbed coordination, unsteady walk (gait disturbance), disorder of sense of smell (olfactory disorders), pressure on the brain (intracranial pressure and psuedotumor cerebri)
- visual colour distortions
- inflammation of the wall of the blood vessels (vasculitis)
- pancreatitis
- death of liver cells (liver necrosis) very rarely leading to life-threatening liver failure
- small pin-point bleeding under the skin (petechiae); various skin eruptions or rashes
- worsening of the symptoms of myasthenia gravis (see Section 2: Warnings and precautions).

Frequency not known (cannot be estimated from the available data)

- trouble associated with the nervous system such as pain, burning, tingling, numbness and/or weakness in the 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)
- pustular rash
- 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 via the Yellow Card Scheme, Website: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Ciprofloxacin 500mg Tablets

Keep this medicine out of the sight and reach of children. Do not store above 25°C and keep in the original container. Do not use this medicine after the expiry date which is stated on the label after 'Exp (MM/YY)'. The expiry date refers to the last day of that month. 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 Ciprofloxacin 500mg Tablets contain:

Each tablet contains ciprofloxacin hydrochloride equivalent to 500mg ciprofloxacin. The other ingredients are maize starch, microcrystalline cellulose, sodium starch glycolate, anhydrous colloidal silica, magnesium stearate, hypromellose, macrogol 400 and titanium dioxide (E171).

What Ciprofloxacin 500mg Tablets looks like and contents of the pack:

Ciprofloxacin 500mg Tablets are white, oval shaped film-coated tablets debossed 'C500' on one side with a breakline on the other. They are packaged in blister packs of 10, 12, 20 or 100 tablets or also in high-density polyethylene containers of 50, 100 or 500 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder:

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Manufacturer:

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Ciprofloxacin 500mg Tablets PL08553/0174

Date of preparation 11/2015

