

PACKAGE LEAFLET: INFORMATION FOR THE USER

Ciprofloxacin 250mg Film-Coated Tablets Ciprofloxacin 500mg Film-Coated Tablets Ciprofloxacin 750mg Film-Coated Tablets (Ciprofloxacin Hydrochloride)

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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What are Ciprofloxacin tablets and what are they used for
2. What you need to know before you take Ciprofloxacin tablets
3. How to take Ciprofloxacin tablets
4. Possible side effects
5. How to store Ciprofloxacin tablets
6. Contents of the pack and other information

1. What are Ciprofloxacin tablets and what are they used for

Ciprofloxacin belongs to a group of medicines known as the quinolone antibacterials, fluoroquinolones. It has high anti-bacterial activity against a wide range of organisms. Ciprofloxacin works by killing bacteria that cause infections. It only works with specific strains of bacteria.

Adults:

Ciprofloxacin is used to treat the following bacterial infections:

- respiratory tract infections(e.g. certain types of pneumonia)
- long lasting or recurring ear or sinus infections
- urinary tract infections (bladder and kidneys infection)
- genital tract infections in men and women (e.g. gonorrhoea, a sexually transmitted disease)
- gastro-intestinal tract infections (e.g.severe gastro-enteritis) and intra-abdominal infections
- skin and soft tissue infections
- bone and joint infections
- to prevent infections due to the bacteria *Neisseria meningitides* which causes meningitis(brain and spinal cord inflammation)
- anthrax inhalation exposure (infection that occurs when the spores from bacteria *Bacillus anthracis* enters the body).

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.

Children and adolescents:

Ciprofloxacin should be used under specialist medical supervision, to treat the following bacterial infections for children and adolescents:

- lung and bronchial infections in children and adolescents suffering from cystic fibrosis (genetic disorder known to be an inherited disease of the secretory glands, including the glands that make mucus and sweat).
- complicated urinary tract infections, including infections that have reached the kidneys (pyelonephritis).
- anthrax inhalation exposure (infection that occurs when the spores from bacteria *Bacillus anthracis* enters the body).

Ciprofloxacin may also be used to treat other specific severe infections in children and adolescents when your doctor considers this as necessary.

2. What you need to know before you take Ciprofloxacin tablets

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.

Do not take Ciprofloxacin if you:

- are allergic (hypersensitive) to the Ciprofloxacin, to any other quinolone drugs or to any of the other ingredients of Ciprofloxacin tablets (see section 6).
- are taking tizanidine (see Section 2: Taking other medicines).

Warnings and precautions:

Talk to your doctor, pharmacist or nurse before taking Ciprofloxacin Tablets if:

- you suffer from 'fits' or epilepsy or any other neurological conditions.
- you have ever had kidney problems because your treatment may need to be adjusted
- you have a history of tendon problems during previous treatment with antibiotics such as Ciprofloxacin
- you are diabetic because you may experience a risk of hypoglycaemia with ciprofloxacin. you have myasthenia gravis (a type of muscle weakness) because symptoms can be exacerbated.
- you or a member of your family is known to have a deficiency in glucose-6-phosphate dehydrogenase (G6PD), since you may experience a risk of anaemia with ciprofloxacin.
- If your eyesight becomes impaired or if your eyes seem to be otherwise affected, consult an eye specialist immediately

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 *Taking other medicines*).

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.

Contact your doctor **immediately**, if any of the following occurs **while taking Ciprofloxacin**. 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 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 tablets 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** may occur occasionally, particularly if you are elderly and are also being treated with corticosteroids. Inflammation and ruptures of tendons may occur even within the first 48 hours of treatment or up to several months after discontinuation of Ciprofloxacin tablets therapy. At the first sign of any pain or inflammation stop taking Ciprofloxacin tablets and rest the painful area. Avoid any unnecessary exercise, as this might increase the risk of a tendon rupture.
- If you suffer from **epilepsy** or other **neurological conditions** such as cerebral ischemia or stroke, you may experience side effects associated with the central nervous system. If this happens, stop taking Ciprofloxacin tablets and contact your doctor immediately.
- You may experience **psychiatric reactions** the first time you take Ciprofloxacin tablets. If you suffer from **depression** or **psychosis**, your symptoms may become worse under treatment with Ciprofloxacin tablets. In rare cases, depression or psychosis can progress to thoughts of suicide, suicide attempts, or completed suicide. If this happens, stop taking Ciprofloxacin tablets 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 tablets and contact your doctor immediately.
- **Hypoglycemia** has been reported most often in diabetic patients, predominantly in elderly population. If this happens, contact your doctor immediately.
- **Diarrhoea** may develop while you are taking antibiotics, including Ciprofloxacin tablets, 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 tablets 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 tablets 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 tablets 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 tablets and contact your doctor immediately.

- Ciprofloxacin tablets 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 tablets. Avoid exposure to strong sunlight, or artificial UV light such as sunbeds.

Other medicines and Ciprofloxacin:

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including those medicines obtained without a prescription.

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").

The following medicines are known to interact with Ciprofloxacin in your body. Taking Ciprofloxacin together with these medicines can influence the therapeutic effect of those medicines. It can also increase the probability of experiencing side effects.

Tell your doctor if you are taking:

- Vitamin K antagonists (e.g. warfarin, acenocoumarol, phenprocoumon or fluindione) or other oral anti-coagulants (to thin the blood)
- theophylline (for breathing problems)
- phenytoin (used to treat epilepsy)
- ropinirole (for Parkinson's disease)
- phenytoin (for epilepsy)
- cyclosporin (used to treat psoriasis, dermatitis, rheumatoid arthritis and in organ transplantation)
- probenecid (used to prevent gout)
- metoclopramide (used to treat nausea and vomiting (feeling/being sick) and migraine)
- ropinirole (used to treat Parkinson's disease)
- methotrexate (for certain types of cancer, psoriasis, rheumatoid arthritis)
- tizanidine (for muscle spasticity in multiple sclerosis)
- clozapine (an antipsychotic)
- olanzapine (an antipsychotic)
- 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.

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 anesthetic 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)
- medicines 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 them.

Taking Ciprofloxacin with food and drink

Unless you take Ciprofloxacin during meals, do not eat or drink any dairy products (such as milk or yogurt) or drinks with added calcium when you take the tablets. These can affect the absorption of ciprofloxacin and so you should take your tablets either 1 to 2 hours before or at least 4 hours after you have such products.

Pregnancy and breast-feeding

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

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

Ask your doctor or pharmacist for advice before taking any other medicine.

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 tablets:

Lactose monohydrate – If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take Ciprofloxacin tablets

Always take ciprofloxacin tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

- a) Take the tablets exactly as your doctor has told you. The tablets should **always** be taken with plenty of water, as this will help to prevent the formation of tiny crystals in your urine (crystalluria).
- b) Do not chew the tablets because they do not taste nice.
- c) Do try to take the tablets at around the same time every day.

You can take the tablets at meal times or between meals. Any calcium you take as a part of a meal will not seriously affect uptake. However, **do not** take ciprofloxacin tablets with dairy

products such as milk or yogurt or with fortified fruit juices (eg. Calcium-fortified orange juice).

Tell your doctor if you suffer from kidney problems because your dose may need to be adjusted. The treatment usually lasts from 5 to 21 days, but may take longer for severe infections.

Your dose will be dependent on the type and severity of your infection, your age, weight and kidney function. Your doctor will choose the best dose for you.

If you take more Ciprofloxacin tablets than you should

If you take more than the prescribed dose, get medical help immediately. If possible, take your tablets or the box with you to show the doctor.

If you forget to take Ciprofloxacin tablets

If you forget to take a dose, take the normal dose as soon as you remember. If it is almost time for your next dose, do not take the missed dose and just carry on as before. Do not take a double dose to make up for a forgotten dose. Be sure to complete your course of treatment.

If you stop taking Ciprofloxacin tablets

It is important that you **finish the course of treatment** even if you begin to feel 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 get worse. You might also develop resistance to the antibiotic.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, ciprofloxacin can cause side-effects, although not everybody gets them.

You may suffer an allergic reaction, symptoms of which include rash, itching, difficulty in breathing or swelling of the face, lips, throat or tongue. If this happens to you, stop taking the tablets immediately and seek medical help.

STOP taking the tablets immediately and seek medical help if any of the following occur:

- 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). If you experience this, rest the affected limb, discontinue treatment and seek medical advice immediately. See section 2.
- Unusual feelings of pain, burning, tingling, numbness or muscle weakness in the extremities (neuropathy)-See section 2.
- infection with symptoms such as fever and serious deterioration of your general condition (there may be a dangerous drop in a type of white blood cells (agranulocytosis)
- Severe allergic reactions manifested as various skin eruptions or rashes, breathing problem (for example, the potentially fatal anaphylactic reaction, Stevens-Johnson syndrome or toxic epidermal necrolysis),
- Hypersensitivity reactions called DRESS drug reaction with eosinophilia and systemic symptoms such as Fever, severe rash, joint pain, enlarged lymph nodes and inflammation of one or more internal organs such as liver leading to abdominal pain,

yellowing of the skin and whites of the eyes and/or heart, lungs and kidneys; with changes to your blood counts, particularly white blood cells called eosinophils. See section 2.

- Liver problems (eg. Jaundice –yellowing of skin and white part of eyes)- very rarely can lead to life-threatening liver failure
- mental disturbances (psychotic reactions and depression potentially leading to thoughts of suicide and suicide attempts), hallucinations (apparent perception of something not present)
- inflammation of the bowel (colitis) which causes attacks of diarrhoea, sometimes containing blood and/or mucus) linked to antibiotic use (can be fatal in very rare cases)
- blood or crystals in the urine, decreased urination (kidney failure)

These are potentially serious side effects and you will need to seek urgent medical attention.

Other side effects are as below-

Common: may affect up to 1 in 10 people

- nausea, diarrhoea
- joint pains in children

Uncommon: may affect up to 1 in 100 people

- fungal superinfections
- a high concentration of eosinophils, a type of white blood cell
- decreased appetite
- hyperactivity or agitation
- headache, dizziness, sleeping problems, or taste disorders
- vomiting, abdominal pain, digestive problems such as stomach upset (indigestion/heartburn), or wind
- increased amounts of certain substances in the blood (transaminases and/or bilirubin)
- hives
- 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)
- Feeling highly excited (mania) or feeling great optimism and overactivity (hypomania),

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

- 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 (hyperglycaemia)
- decreased blood sugar (hypoglycaemia) (see Section 2: Warnings and precautions)
- confusion, disorientation, anxiety reactions, strange dreams
- tremors, seizures or giddiness
- eyesight problems including double vision
- tinnitus, loss of hearing, impaired hearing

- rapid heartbeat (tachycardia)
- expansion of blood vessels (vasodilation), low blood pressure, or fainting
- shortness of breath, including asthmatic symptoms
- liver disorders, jaundice (cholestatic icterus), or hepatitis
- sensitivity to light (see Section 2: Warnings and precautions)
- urinary tract inflammation
- fluid retention or excessive sweating
- increased levels of the enzyme amylase

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

- a special type of reduced red blood cell count (haemolytic anaemia); a 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)
- allergic reaction known as serum sickness
- migraine, disturbed coordination, unsteady walk (gait disturbance), disorder of sense of smell (olfactory disorders), pressure on the brain (intracranial pressure and pseudotumor cerebri)
- visual colour distortions
- inflammation of the wall of the blood vessels (vasculitis)
- pancreatitis
- small, pin-point bleeding under the skin (petechiae);

Not known: frequency cannot be estimated from the available data

- 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)
- periods of overactive and excited behaviour
- Feeling highly excited (mania) or feeling great optimism and overactivity (hypomania), hypersensitivity reaction called DRESS (Drug Reaction with Eosinophilia and Systemic Symptoms)
- 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.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: 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 tablets

Do not store above 25°C. Store in the original package.

Keep out of the reach and sight of children.

Do not use your tablets after the expiry date stated on the label or carton.

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

6. Contents of the pack and other information

What Ciprofloxacin tablet contains?

The **Active** ingredient in your tablet is Ciprofloxacin Hydrochloride.

The **Other** ingredients are croscarmellose sodium, microcrystalline cellulose, povidone, magnesium stearate. The tablet coating is made of hypromellose, lactose monohydrate, macrogol 4000, sodium citrate and the colouring agent titanium dioxide (E171) (*see section 2 for Important information about some of the ingredients of Ciprofloxacin tablets*).

What Ciprofloxacin tablet looks like and contents of the pack?

Ciprofloxacin 250mg tablets are White to off-white, round, biconvex film coated, marked with 'AM' on one side and plain on the other side.

Ciprofloxacin 500mg tablets are White to off-white, capsule shape, biconvex, film coated, marked with 'CI' on one side and plain on the other side.

Ciprofloxacin 750mg tablets are White to off-white, capsule shape, biconvex, film coated, marked with 'CJ' on one side and plain on the other side.

Ciprofloxacin 250mg Tablets are available in blister packs of 10, 12, 20, 50, and 100 tablets.

Ciprofloxacin 500mg Tablets are available in blister packs of 10, 12, 20, and 100 tablets.

Ciprofloxacin 750mg Tablets are available in blister packs of 10, 20, 50 and 100 tablets.

(Not all pack sizes may be marketed).

Marketing Authorisation holder and Manufacturer

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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:

- dosages
- schedules
- duration of treatment

Consequently, to preserve the efficacy of this drug:

- 1 - Use antibiotics only when prescribed.
- 2 - Strictly follow the prescription.
- 3 - Do not re-use an antibiotic without medical prescription, even if you want to treat a similar illness.
- 4 - Never give your antibiotic to another person; maybe it is not adapted to her/his illness.
- 5 - After completion of treatment, return all unused drugs to your chemist's shop to ensure they will be disposed of correctly.