

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.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What are Ciprofloxacin tablets and what are they used for
2. Before you take Ciprofloxacin tablets
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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(Eg. certain types of pneumonia)
- long lasting or recurring ear or sinus infections
- urinary tract infections (bladder and kidneys infection)
- infections of the testicles
- genital organ infections in women(e.g. gonorrhoea, a sexually transmitted disease)
- gastro-intestinal tract infections (Eg.severe gastro-enteritis) and intra-abdominal infections
- skin and soft tissue infections
- bone and joint infections
- to treat infections in patients with a very low white blood cell count (neutropenia)
- to prevent infections in patients with a very low white blood cell count (neutropenia)
- to prevent infections 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).

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

Children and adolescents(5 – 17 years old):

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

2. BEFORE YOU TAKE CIPROFLOXACIN TABLETS.

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).
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Take special care with Ciprofloxacin Tablets:

Before taking Ciprofloxacin Tablets, tell your doctor 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 have myasthenia gravis (a type of muscle weakness).
- you have a history of abnormal heart rhythms (arrhythmias).

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*).

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.

- **If you suffer from severe, sudden allergic reaction** (an anaphylactic reaction/shock, angio-oedema), with the following symptoms like tightness in the chest, feeling dizzy, sick or faint, or experience dizziness while standing up.
- If you have a history of brain or spinal cord disorders (e.g. decreases in the blood flow to the brain, changes to the structure of the brain or have you suffered with a stroke or cerebral ischaemia).
- If you have a family history of or have an actual deficiency in the liver enzyme called glucose-6-phosphate dehydrogenase (G6PD), since you may experience a risk of anaemia (decrease in number of red blood cells or less than the normal quantity of haemoglobin in the blood) with ciprofloxacin.
- If you get pain or inflammation in your tendons whilst taking the tablets particularly if you are elderly or taking any medicines known as the corticosteroids (used as anti-inflammatories in many disorders such as asthma, allergic conditions/reactions and arthritis).
- If you are suffering from or develop severe, persistent diarrhoea (pseudomembranous colitis).
- 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.
- If you experience **psychiatric reactions such as depression or psychosis**.
- If you become dehydrated (if you begin to feel thirsty drink plenty of water).
- If your skin becomes more sensitive to sunlight or UV light while using this medicine (may cause your skin to burn more easily or blister). Avoid exposure to strong sunlight or artificial UV light such as sun beds.
- If you go into hospital for surgery, have dental treatment which requires anaesthetic or you need to provide a blood or urine sample, tell the doctor or dentist that you are taking Ciprofloxacin Tablets.
- If you experience symptoms of neuropathy such as pain, burning, tingling, numbness and/or weakness.
- 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 see your doctor immediately. A blood test will be done to check the possible reduction of white blood cells (agranulocytosis).

Taking other medicines:

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

You must tell your doctor if you are taking other medicines that can alter your heart rhythm: medicines that belong to the group of anti-arrhythmics (e.g. quinidine, hydroquinidine, disopyramide, amiodarone, sotalol, dofetilide, ibutilide), tricyclic antidepressants, some antimicrobials (that belong to the group of macrolides), some antipsychotics.

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:

- xanthine derivatives such as theophylline (used to treat asthma), pentoxifylline (for circulatory disorders) or caffeine (stimulates central nervous system)
- phenytoin (used to treat epilepsy)
- any medications or preparations which contain magnesium, aluminium, calcium or iron salts e.g. certain indigestion remedies, antacids, or multi-vitamins, polymeric phosphate binder (eg. sevelamer), sucralfate (used to treat ulcers) or didanosine, (an antiviral drug used to treat HIV), If so these may affect the absorption of ciprofloxacin from the stomach and as such you should either take your Ciprofloxacin Tablets 1 to 2 hours before or 4 hours after any of these products.
- any drugs which thin the blood (known as anti-coagulants e.g. warfarin)
- painkillers known as the non-steroidal anti-inflammatory drugs, other than aspirin (e.g. ibuprofen)
- cyclosporin (used to treat psoriasis, dermatitis, and rheumatoid arthritis)
- glibenclamide (an oral drug used to treat diabetes)
- probenecid (used to prevent gout)
- metoclopramide (used to treat nausea and vomiting (feeling/being sick) and migraine)
- mexiletine (used to treat abnormal heart beats)
- ropinirole (used to treat Parkinson's disease)
- methotrexate (for certain types of cancer)
- tizanidine (for muscle spasticity in multiple sclerosis)
- clozapine (an antipsychotic)

Taking Ciprofloxacin with food and drink

Unless you take Ciprofloxacin during meals, do not eat or drink any dairy products (e.g. milk or yogurt) or drinks with added calcium. 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

Do not drive because Ciprofloxacin tablets may affect your ability to drive, use machinery or to work safely. The tablets are more likely to affect you at the beginning of your treatment, if

the dose of your tablets is increased or you are switched from another medicine, or if you have been drinking alcohol. You should take extra care when you first start taking your tablets.

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.

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).

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.

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.

Adults

The usual adult dose is between 100 – 750mg twice daily. In Respiratory infections the usual dose is 500mg-750mg twice daily. In infections of the bladder and kidneys, the usual dose is 250 - 500mg twice daily. In gonorrhoea, the usual dose is 250 - 500mg as a single dose. In gastro-intestinal infections, the usual dose is 500 mg twice daily. In intra-abdominal infections, skin and soft tissue infections, bone and joint infections, and in neutropenic patients the usual dose is 500-750mg twice daily. In infections due to Bacterium Neisseria meningitidis the usual dose is 500mg as a single dose. Inhalation anthrax exposure the usual dose is 500mg twice daily.

Elderly Patients

Your doctor will decide what dose to give you. This may be lower than the usual adult dose depending on the severity of your infection and your kidney function.

Kidney/Liver problems

Your doctor will decide what dose to give you depending on your kidney and liver function. Special dosing instructions are needed if you are on haemodialysis or having CAPD (continuous ambulatory peritoneal dialysis).

Children and adolescents (5 – 17 years old)

The use of Ciprofloxacin Tablets is not generally recommended in children. However in some cases treatment with these tablets is of benefit and your doctor may decide to treat your child with this drug particularly for the below mentioned infections.

Cystic fibrosis the usual dose is 20mg/kg body weight twice daily with a maximum daily dose of 750 mg.

Complicated urinary tract infections and pyelonephritis the usual dose is 10 to 20 mg/kg body weight twice daily with a maximum of 750 mg per dose.

Inhalation anthrax exposure the usual dose is 10 to 15 mg/kg body weight twice daily with a maximum of 500mg per dose.

Other severe infections the usual dose is 20mg /kg body weight twice daily with a maximum of 750mg per dose.

It is very important that you follow your doctor's instructions as to how many Ciprofloxacin Tablets to take, how often to take them and for how long you should continue to take your tablets. The normal duration of treatment is between 5 to 21 days (although this may be longer), depending on the type and severity of infection.

If you take more Ciprofloxacin tablets than you should

If you or someone else swallows several of these tablets all together, or you think a child has swallowed any of these tablets, contact your doctor or pharmacist or hospital emergency department immediately. Always take any tablets left over with you ,also the box and leaflet as this will allow easier identification of the tablets.

If you forget to take Ciprofloxacin tablets

If you forget to take a dose, take it 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.

If you stop taking Ciprofloxacin tablets

Even when you start to feel better it is important for you to finish the course of treatment as long as your doctor tells you to stop. If you stop taking this medicine too soon, the infection may not be cured completely and may start up again.

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.

About 5 –14% of patients have side-effects and the most common side-effects involve the gut and the nervous system.

If any of the following symptoms occur soon after taking your tablets, **stop** taking the tablets and tell your doctor **immediately**. This kind of reaction is rare and may mean you are suffering from an allergic reaction to the tablets:

- Rash, itching, a lumpy skin rash ('hives'), fever, small red spots on the body, increased sensitivity to sunlight or very rarely severe skin reactions such as large fluid filled blisters, peeling, sores and ulceration. Ulceration can also occur in the mouth and throat, around the anus and genital region and on the surface of the eyes
- Sudden wheeziness or tightness of the chest
- Swelling of the eyelids, face, lips or blood vessels in the skin
- Sickness and headache

You should also tell your doctor **immediately** and **stop** taking your tablets if you notice:

- Pain or inflammation in the tendons. This effect occurs in isolated cases. If these symptoms are experienced you should stop taking your tablet, rest the affected limb and consult your doctor immediately.
- Severe diarrhoea with bleeding or mucus. This effect occurs in less than one in a thousand but more than one in ten thousand people.
- A feeling that you want to physically harm yourself. This only occurs in isolated cases.

Other possible side-effects, which may occur, are listed below:

Common side effects (between 1 and 10 in every 100 people are likely to get these):

- nausea, diarrhoea
- Joint pains in children

Uncommon side effects (between 1 and 10 in every 1,000 people are likely to get these):

- Palpitations (increased awareness of your heartbeat) or increased heart rate.
- Blood clots in the lungs, breathlessness, nosebleeds or coughing up blood.
- Hiccups/hiccoughs.
- Joint pain or swelling in adults.
- Anaemia or an increased risk of bleeding or infection. An abnormal increase in the number of red blood cells.
- 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 amounts of certain substances in the blood (transaminases and/or bilirubin)
- rash, itching, or 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)

Rare side effects (between 1 and 10 in every 10,000 people are likely to get these):

- inflammation of the bowel (colitis) linked to antibiotic use (can be fatal in very rare cases) (see Section 2: Take special care with Ciprofloxacin)
- Pseudomembranous colitis
- 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 (angioedema)
- increased blood sugar (hyperglycaemia)
- confusion, disorientation, anxiety reactions, strange dreams, depression, or hallucinations
- pins and needles, unusual sensitivity to stimuli of the senses, decreased skin sensitivity, tremors, seizures (see Section 2: Take special care with Ciprofloxacin), or giddiness
- eyesight problems
- 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: Take special care with Ciprofloxacin)
- muscle pain, inflammation of the joints, increased muscle tone, or cramp
- kidney failure, blood or crystals in the urine (see Section 2: Take special care with Ciprofloxacin), urinary tract inflammation
- fluid retention or excessive sweating
- abnormal levels of a clotting factor (prothrombin) or increased levels of the enzyme amylase

Very rare side effects (less than 1 in every 10,000 people are likely to get these):

- Hot flushes, fainting, oedema (fluid retention, which may cause swelling of the face or limbs) or pain in the muscles.
- Inability to sleep (insomnia), numbness and tingling, sweating, unsteadiness, convulsions (fits), anxiety, nightmares, migraine, disturbed coordination, unsteady walk (gait disturbance), disorder of sense of smell (olfactory disorders), pressure on the brain (intracranial pressure) depression or hallucinations.
- Visual disturbances e.g. double vision and colour disturbances, impaired taste and smell. Ringing in the ears and temporary loss of hearing (particularly at high frequencies).
- Increased risk of sunburn
- Inflammation of the liver (hepatitis), yellowing of the skin and whites of the eyes (jaundice), death of liver cells (liver necrosis) very rarely leading to life-threatening liver failure, kidney pain or discomfort when passing water (crystalluria).
- Increases or decreases in some types of cells in the blood or cells which help the blood to clot, changes in some blood proteins which are needed for normal clotting or haemolytic anaemia (a form of anaemia due to the breaking down of red blood cells, may occur with

jaundice), 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: Take special care with Ciprofloxacin)

- severe allergic reactions (anaphylactic reaction or anaphylactic shock, which can be fatal - serum sickness) (see Section 2: Take special care with Ciprofloxacin)
- mental disturbances (psychotic reactions) (see Section 2: Take special care with Ciprofloxacin)
- inflammation of the wall of the blood vessels (vasculitis)
- pancreatitis
- small, pin-point bleeding under the skin (petechiae); various skin eruptions or rashes (for example, the potentially fatal Stevens-Johnson syndrome or toxic epidermal necrolysis)
- muscle weakness, tendon inflammation, tendon rupture – especially of the large tendon at the back of the ankle (Achilles tendon) (see Section 2: Take special care with Ciprofloxacin); worsening of the symptoms of myasthenia gravis (see Section 2: Take special care with Ciprofloxacin)

In isolated cases

- Worsening of the symptoms of myasthenia gravis (a disease of the muscles often associated with muscle fatigue)
- Alterations in blood sugar levels or blood or tiny crystals (crystalluria) in the urine.

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

- troubles associated with the nervous system such as pain, burning, tingling, numbness and/or weakness in extremities

- Abnormal fast heart rhythm, life-threatening irregular heart rhythm, alteration of the heart rhythm (called ‘prolongation of QT interval’, seen on ECG, electrical activity of the heart)

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

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. FURTHER 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, oblong shape, biconvex, film coated, marked with 'CI' on one side and plain on the other side.

Ciprofloxacin 750mg tablets are White to off-white, oblong 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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This leaflet was last approved in {08/2012}.