

PACKAGE LEAFLET: INFORMATION FOR THE USER

CIPROBAY

500mg film-coated tablets

CIPROFLOXACIN

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • 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 •

What is in this leaflet?

1. What Ciprobay is and what it is used for
2. What you need to know before you take Ciprobay
3. How to take Ciprobay
4. Possible side effects
5. How to store Ciprobay

1. WHAT CIPROBAY IS AND WHAT IT IS USED FOR

Ciprobay contains the active substance ciprofloxacin. Ciprofloxacin is an antibiotic belonging to the fluoroquinolone family. Ciprofloxacin works by killing bacteria that cause infections. It only works with specific strains of bacteria.

Adults

Ciprobay is used in adults to treat the following bacterial infections:

- respiratory tract infections
- long lasting or recurring ear or sinus infections
- urinary tract infections
- genital tract infections in men and women
- gastro-intestinal tract infections and intra-abdominal infections
- skin and soft tissue infections
- bone and joint 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 Ciprobay.

Children and adolescents

Ciprobay is 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

Ciprobay 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 CIPROBAY

Do not take Ciprobay:

- if you are allergic to the active substance, to other quinolone drugs or to any of the other ingredients of this medicine
- if you are taking tizanidine (see Section 2: Other medicines and Ciprobay)

Warnings and precautions

Talk to your doctor before taking Ciprobay

- 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 Ciprobay.
- if you are diabetic because you may experience a risk of hypoglycaemia with ciprofloxacin.
- if you have myasthenia gravis (a type of muscle weakness) because symptoms can be exacerbated.
- if you have heart problems. Caution should be taken when using Ciprofloxacin, 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 2: Other medicines and Ciprobay).
- if 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.

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 Ciprobay

Tell your doctor immediately, if any of the following occurs while taking Ciprobay. Your doctor will decide whether treatment with Ciprobay 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 Ciprobay and contact your doctor 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 Ciprobay therapy. At the first sign of any pain or inflammation stop taking Ciprobay 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 Ciprobay and contact your doctor immediately.
- You may experience psychiatric reactions the first time you take Ciprobay. If you suffer from depression or psychosis, your symptoms may become worse under treatment with Ciprobay. In rare cases, depression or psychosis can progress to thoughts of suicide, suicide attempts, or completed suicide. If this happens, stop taking Ciprobay 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 Ciprobay 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 Ciprobay, 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 Ciprobay immediately, as this can be life-threatening. Do not take medicines that stop or slow down bowel movements and contact your doctor.
- If your eyesight becomes impaired or if your eyes seem to be otherwise affected, consult an eye specialist immediately.
- Your skin becomes more sensitive to sunlight or ultraviolet (UV) light when taking Ciprobay. Avoid exposure to strong sunlight, or artificial UV light such as sunbeds.
- Tell the doctor or laboratory staff that you are taking Ciprobay 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.
- Ciprobay 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 Ciprobay and contact your doctor immediately.
- Ciprobay 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.

Other medicines and Ciprobay

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

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

The following medicines are known to interact with Ciprobay in your body. Taking Ciprobay 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)
- probenecid (for gout)
- methotrexate (for certain types of cancer, psoriasis, rheumatoid arthritis)
- theophylline (for breathing problems)
- tizanidine (for muscle spasticity 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 conditions, rheumatoid arthritis and in 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.

Ciprobay 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 Ciprobay. 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 Ciprobay about two hours before or no sooner than four hours after them.

Ciprobay with food and drink

Unless you take Ciprobay 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.

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

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

Driving and using machines

Ciprobay may make you feel less alert. Some neurological adverse events can occur. Therefore, make sure you know how you react to Ciprobay before driving a vehicle or operating machinery. If in doubt, talk to your doctor.

3. HOW TO TAKE CIPROBAY

Your doctor will explain to you exactly how much Ciprobay you will have to take as well as how often and for how long. This will depend on the type of infection you have and how bad it is.

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. Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure how many tablets to take and how to take Ciprobay.

- a. Swallow the tablets with plenty of fluid. Do not chew the tablets because they do not taste nice.
- b. Do try to take the tablets at around the same time every day.
- c. You can take the tablets at mealtimes or between meals. Any calcium you take as part of a meal will not seriously affect uptake. However, do not take Ciprobay tablets with dairy products such as milk or yoghurt or with fortified fruit juices (e.g. calcium-fortified orange juice).

Remember to drink plenty of fluids while you are taking this medicine.

If you take more Ciprobay 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 Ciprobay

Take the normal dose as soon as possible and then continue as prescribed. 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 a forgotten dose. Be sure to complete your course of treatment.

If you stop taking Ciprobay

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 about 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.

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)
- 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:

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 (hyperglycaemia)
- decreased blood sugar (hypoglycaemia) (see Section 2: Warnings and precautions)
- confusion, disorientation, anxiety reactions, strange dreams, depression (potentially leading to thoughts of suicide, suicide attempts, or completed suicide), 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
- 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)
- muscle pain, inflammation of the joints, increased muscle tone, or cramp
- kidney failure, blood or crystals in the urine (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 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)
- 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)
- 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
- 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 (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: Warnings and precautions); worsening of the symptoms of myasthenia gravis (see Section 2: Warnings and precautions)

Not known: frequency cannot be estimated from the available data

- troubles associated with the nervous system such as pain, burning, tingling, numbness and/or weakness in extremities (peripheral neuropathy and polyneuropathy)
- 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. By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE CIPROBAY

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 blister and carton after "EXP": The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

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 to protect the environment.

This leaflet was last revised in July 2015