

Package leaflet: Information for the patient

Ciprobay 200 (200 mg/100 mL solution for infusion)

ciprofloxacin

Read all of this leaflet carefully before you are given 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 Ciprobay 200 is and what it is used for
2. What you need to know before you are given Ciprobay 200
3. How to use Ciprobay 200
4. Possible side effects
5. How to store Ciprobay 200
6. Contents of the pack and other information

1. What Ciprobay 200 is and what it is used for

Ciprobay 200 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 200 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
- 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 200.

Children and adolescents

Ciprobay 200 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 200 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 are given Ciprobay 200

You must not be given Ciprobay 200:

- if you are allergic to the active substance, to other quinolone drugs or to any of the other ingredients of this medicine (listed in Section 6)
- if you are taking tizanidine (see Section 2: Other medicines and Ciprobay 200)

Warnings and precautions

Before taking this medicine

You should not take fluoroquinolone/quinolone antibacterial medicines, including Ciprobay 200, 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.

Talk to your doctor before you are given Ciprobay 200

- 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 200.
- 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 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 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 200).
- 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 anemia 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 under treatment with Ciprobay 200

Tell your doctor immediately, if any of the following occurs **during treatment with Ciprobay 200**. Your doctor will decide whether treatment with Ciprobay 200 needs to be stopped.

- **Severe, sudden allergic reaction** (an anaphylactic reaction/shock, angio-oedema). Even with the first dose, there is a rare chance that you may experience a severe allergic reaction with the following symptoms: tightness in the chest, feeling dizzy, feeling sick or faint, or experience dizziness on standing.

If this happens, tell your doctor immediately since the administration of Ciprobay 200 will have to be stopped.

- **Prolonged, disabling and potentially irreversible serious side effects.** Fluoroquinolone/ quinolone antibacterial medicines, including Ciprobay 200, 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 Ciprobay 200, 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.
- **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 Ciprobay 200 therapy. At the first sign of pain or inflammation of a tendon (for example in your ankle, wrist, elbow, shoulder or knee), stop taking Ciprobay 200, 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 Ciprobay 200 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 Ciprobay 200 and inform your doctor immediately in order to prevent the development of potentially irreversible condition.
- You may experience **psychiatric reactions** even when taking quinolone antibiotics, including Ciprobay 200, for the first time. If you suffer from **depression** or **psychosis**, your symptoms may become worse under treatment with Ciprobay 200. In rare cases, depression or psychosis can progress to suicidal thoughts and self-injurious behaviors such as suicide attempts, or completed suicide (see section 4: Possible side effects). If depression, psychosis, suicide-related thoughts or behavior occur, 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 develop while you are on antibiotics, including Ciprobay 200, or even several weeks after you have stopped using them. If it becomes severe or persistent or you notice that your stool

contains blood or mucus, stop taking Ciprobay 200 and contact your doctor immediately, as this can be life-threatening. Do not take 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 becomes more **sensitive to sunlight or ultraviolet (UV) light** under treatment with Ciprobay 200. Avoid exposure to strong sunlight or artificial UV light such as sunbeds.
- Tell the doctor or laboratory staff that you are taking Ciprobay 200 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 200 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, contact your doctor immediately.
- Ciprobay 200 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 200

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

Do not use Ciprobay 200 together with tizanidine, because this may cause side effects such as low blood pressure and sleepiness (see Section 2: **You must not be given Ciprobay 200**).

The following medicines are known to interact with Ciprobay 200 in your body. Using Ciprobay 200 together with these medicines can influence the therapeutic effect of these 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)
- 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
- zolpidem (for sleep disorders)

Ciprobay 200 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)
- agomelatine (for depression)

Ciprobay 200 with food and drink

Food and drink does not affect your treatment with Ciprobay 200.

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 200 during pregnancy.

Do not take Ciprobay 200 during breast-feeding because ciprofloxacin is excreted in breast milk and can be harmful for your child.

Driving and using machines

Ciprobay 200 may make you feel less alert. Some neurological adverse events can occur. Therefore, make sure you know how you react to Ciprobay 200 before driving a vehicle or operating machinery. If in doubt, talk to your doctor.

Ciprobay 200 contains sodium

This medicine contains 354.1 mg sodium (main component of cooking/table salt) in each bottle. This is equivalent to 17.7 % of the recommended maximum daily dietary intake of sodium for an adult.

The maximum recommended daily dose of this medicinal product contains 2124.6 mg sodium (found in table salt). This is equivalent to 106.2 % of the adult recommended maximum daily dietary intake for sodium.

Talk to your pharmacist or doctor if you need Ciprobay 200 on a daily basis for a prolonged period of time, especially if you have been advised to have a low salt diet.

3. How to use Ciprobay 200

Your doctor will explain to you exactly how much Ciprobay 200 you will be given 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.

Treatment usually lasts between 5 and 21 days, but may be longer for severe infections.

Your doctor will give you each dose by slow infusion through a vein into your bloodstream. For children, the infusion duration is 60 minutes. In adult patients, infusion time is 60 minutes for 400 mg ciprofloxacin and 30 minutes for 200 mg ciprofloxacin. Administering the infusion slowly helps prevent immediate side effects occurring.

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

If you stop your course of Ciprobay 200, it is important that you **finish the course of treatment** even if you begin to feel better after a few days. If you stop using 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.

The following section contains the most serious side effects that you can recognize yourself:

Stop taking Ciprobay 200 and contact your doctor immediately in order to consider another antibiotic treatment if you notice any of the following serious side effects:

Uncommon (may affect up to 1 in 100 people)

- Seizure (see Section 2: Warnings and precautions)

Rare (may affect up to 1 in 1,000 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 shock) (see Section 2: Warnings and precautions)
- Tendon rupture, particularly affecting the large tendon at the back of the ankle (Achilles tendon) (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) (see Section 2: Warnings and precautions)
- Muscle weakness, inflammation of the tendons which could lead to rupture of the tendon, particularly affecting 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 Ciprobay 200 are listed below by how likely they are:

Common (may affect up to 1 in 10 people)

- nausea, diarrhoea, vomiting
- joint pain and joint inflammation in children
- local reaction at the injection site, rash
- temporary increased amounts of substances in the blood (transaminases)

Uncommon (may affect up to 1 in 100 people)

- joint pain in adults
- fungal superinfections

- a high concentration of eosinophils, a type of white blood cell, increased or decreased amounts of a blood clotting factor (thrombocytes)
- decreased appetite
- hyperactivity, agitation, confusion, disorientation, hallucinations
- headache, dizziness, sleeping problems, taste disorders, pins and needles, unusual sensitivity to stimuli of the senses, giddiness
- eyesight problems including double vision
- loss of hearing
- rapid heartbeat (tachycardia)
- expansion of the blood vessels (vasodilation), low blood pressure
- abdominal pain, digestive problems such as stomach upset (indigestion/heartburn), wind
- liver disorders, increased amounts of one substance in the blood (bilirubin), jaundice (cholestatic icterus)
- itching, hives
- poor kidney function, kidney failure
- pains in your muscles and bones, feeling unwell (asthenia), fever, fluid retention
- increase in blood alkaline phosphatase (a certain substance in the blood)

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

- muscle pain, inflammation of the joints, increased muscle tone and cramping
- 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), a drop in the number of red and white blood cells and platelets (pancytopenia), which may be fatal, bone-marrow depression which may also be fatal
- allergic reaction, allergic swelling (oedema), rapid swelling of the skin and mucous membranes (angiooedema) (see Section 2: Warnings and precautions)
- increased blood sugar (hyperglycemia)
- decreased blood sugar (hypoglycaemia) (see Section 2: Warnings and precautions)
- anxiety reaction, strange dreams, depression (potentially leading to thoughts of suicide, suicide attempts, or completed suicide), mental disturbances (psychotic reactions potentially leading to thoughts of suicide, suicide attempts, or completed suicide) (see Section 2: Warnings and precautions)
- decreased skin sensitivity, tremor, migraine, disorder of sense of smell (olfactory disorders)
- tinnitus, impaired hearing
- fainting, inflammation of the blood vessel (vasculitis)
- shortness of breath including asthmatic symptoms
- pancreatitis
- hepatitis, death of liver cells (liver necrosis) very rarely leading to life-threatening liver failure (see Section 2: Warnings and precautions)
- sensitivity to light (see Section 2: Warnings and precautions), small, pin-point bleeding under the skin (petechiae)
- blood or crystals in the urine, urinary tract inflammation
- 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) (see Section 2: Warnings and precautions)
- allergic reaction called serum sickness-like reaction (see Section 2: Warnings and precautions)
- disturbed coordination, unsteady walk (gait disturbance), pressure on the brain (intracranial pressure and pseudotumor cerebri)
- visual colour distortions
- various skin eruptions or rashes
- worsening of the symptoms of myasthenia gravis (see Section 2: Warnings and precautions)

Not known (frequency cannot be estimated from the available data)

- syndrome associated with impaired water excretion and low levels of sodium (SIADH)
- 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)
- influence on blood clotting (in patients treated with Vitamin K antagonists)
- 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.

To report any side effect(s):

The National Pharmacovigilance Centre (NPC).

Fax: + 966 - 11 - 205 - 7662.

SFDA call center: 19999.

E - mail: npc.drug@sfd.gov.sa.

Website: <https://ade.sfd.gov.sa>

5. How to store Ciprobay 200

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

Not to be stored above 30°C.

Keep the bottle in the outer carton in order to protect from light. Do not refrigerate or freeze.

At cool storage temperatures precipitation may occur, which will re-dissolve at room temperature (15°C - 25 °C).

Chemical and physical in-use stability has been demonstrated for 24 hours at room temperature (15 °C to 25 °C). From a microbiological point of view, unless the method of opening and mixing with co-infusion solutions precludes the risk of microbial contamination, the product should be used immediately. If not used immediately, in-use storage times and conditions are the responsibility of the user.

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 Ciprobay 200 contains

The active substance is ciprofloxacin.

Each glass bottle with 100 mL infusion solution contains 200 mg of ciprofloxacin.

The other ingredients are: lactic acid solution 20%, sodium chloride, hydrochloric acid concentrated, water for injections

What Ciprobay 200 looks like and contents of the pack

Solution for infusion

Clear, nearly colourless to slightly yellowish solution.

Pack size of 5 bottles containing 100 mL of solution for infusion each

Marketing Authorisation Holder

Bayer AG

Kaiser-Wilhelm-Allee 1

51368 Leverkusen, Germany.

Manufacturer

Fresenius Kabi Italia s.r.l.

41/43 Via Camagre,

37063 Isola della Scala (VR), Italy.

Secondary Packed by:

DEEF Pharmaceutical Ind. Co.,

Saudi Arabia - Al Qassim

This leaflet was last revised in December 2020.

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:

- dosage
- 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

The following information is intended for medical or healthcare professionals only

Ciprobay 200 should be administered by intravenous infusion. For children, the infusion duration is 60 minutes. In adult patients, infusion time is 60 minutes for 400 mg ciprofloxacin and 30 minutes for 200 mg ciprofloxacin. Slow infusion into a large vein will minimise patient discomfort and reduce the risk of venous irritation. The infusion solution can be infused either directly or after mixing with other compatible infusion solutions.

Unless compatibility with other infusion solutions/drugs has been confirmed, the infusion solution must always be administered separately. The visual signs of incompatibility are e.g. precipitation, clouding, and discolouration.

Incompatibility appears with all infusion solutions/drugs that are physically or chemically unstable at the pH of the solution (e.g. penicillin, heparin solutions), especially in combination with solutions adjusted to an alkaline pH (pH of the ciprofloxacin infusion solutions: 3.9-4.5).

After intravenous initiation of treatment, the treatment can be continued orally as well.

This is a medicament

- A medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.

Keep medicament out of reach of children

Council of Arab Health Ministers

Union of Arab Pharmacists