

CIPROBAY® 750 MG BAYER MIDDLE EAST

Film-coated tablets

Active ingredient: Ciprofloxacin

1. WHAT CIPROBAY 750 MG IS AND WHAT IT IS USED FOR

Ciprobay 750 mg is an antibiotic belonging to the fluoroquinolone family. The active substance is ciprofloxacin. Ciprofloxacin works by killing bacteria that cause infections. It only works with specific strains of bacteria.

Adults

Ciprobay 750 mg is used in adults to treat the following bacterial infections:

- respiratory tract infections
- long lasting or recurring ear or sinus infections
- urinary tract infections
- infections of the testicles
- genital organ infections in women
- gastro-intestinal tract infections 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 bacterium *Neisseria meningitidis*
- anthrax inhalation exposure

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 750 mg.

Children and adolescents

Ciprobay 750 mg 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 750 mg may also be used to treat other specific severe infections in children and adolescents when your doctor considered this necessary.

2. BEFORE YOU TAKE CIPROBAY 750 MG

Do not take Ciprobay 750 mg if you are:

- allergic (hypersensitive) to the active substance, to other quinolone drugs or to any of the other ingredients of Ciprobay 750 mg (see section 6)
- taking tizanidine (see Section 2: Taking other medicines)

Take special care with Ciprobay 750 mg

Before taking Ciprobay 750 mg

Tell your doctor if you:

- have ever had kidney problems because your treatment may need to be adjusted
- suffer from epilepsy or other neurological conditions
- have a history of tendon problems during previous treatment with antibiotics such as Ciprobay 750 mg
- have myasthenia gravis (a type of muscle weakness)
- have a history of abnormal heart rhythms (arrhythmias)

While taking Ciprobay 750 mg

Tell your doctor immediately, if any of the following occurs **while taking Ciprobay 750 mg**. Your doctor will decide whether treatment with Ciprobay 750 mg 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 750 mg 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. At the first sign of any pain or inflammation stop taking Ciprobay 750 mg 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 750 mg and contact your doctor immediately.
- You may experience **psychiatric reactions** the first time you take Ciprobay 750 mg. If you suffer from **depression or psychosis**, your symptoms may become worse under treatment with Ciprobay 750 mg. If this happens, stop taking Ciprobay 750 mg 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 750 mg and contact your doctor immediately.
- **Diarrhoea** may develop while you are taking antibiotics, including Ciprobay 750 mg, 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 750 mg 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 Ciprobay 750 mg if you have to provide a **blood or urine sample**.
- Ciprobay 750 mg 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 750 mg and contact your doctor immediately.
- Ciprobay 750 mg 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.

- Tell your doctor 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.
- Your skin becomes more **sensitive to sunlight or ultraviolet (UV) light** when taking Ciprobay 750 mg. Avoid exposure to strong sunlight, or artificial UV light such as sunbeds.

Taking other medicines

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

Do not take Ciprobay 750 mg together with tizanidine, because this may cause side effects such as low blood pressure and sleepiness (see Section 2: «Do not take Ciprobay 750 mg»).

The following medicines are known to interact with Ciprobay 750 mg in your body. Taking Ciprobay 750 mg 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:

- warfarin or other oral anti-coagulants (to thin the blood)
- probenecid (for gout)
- methotrexate (for certain types of cancer, psoriasis, rheumatoid arthritis)
- theophylline (for breathing problems)
- tizanidine (for muscle spasticity in multiple sclerosis)
- clozapine (an antipsychotic)
- ropinirole (for Parkinson's disease)
- phenytoin (for epilepsy)

Ciprobay 750 mg may **increase** the levels of the following medicines in your blood:

- pentoxifylline (for circulatory disorders)
- caffeine

Some medicines reduce the effect of Ciprobay 750 mg. Tell your doctor if you take or wish to take:

- antacids
- mineral supplements

- sucralfate
- a polymeric phosphate binder (e.g. sevelamer)
- medicines or supplements containing calcium, magnesium, aluminium or iron

If these preparations are essential, take Ciprobay 750 mg about two hours before or no sooner than four hours after them.

Taking Ciprobay 750 mg with food and drink

Unless you take Ciprobay 750 mg 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

It is preferable to avoid the use of Ciprobay 750 mg during pregnancy. Tell your doctor if you are planning to get pregnant.

Do not take Ciprobay 750 mg during breast feeding because ciprofloxacin is excreted in breast milk and can be harmful for your child.

Driving and using machines

Ciprobay 750 mg may make you feel less alert. Some neurological adverse events can occur. Therefore, make sure you know how you react to Ciprobay 750 mg before driving a vehicle or operating machinery. If in doubt, talk to your doctor.

3. HOW TO TAKE CIPROBAY 750 MG

Your doctor will explain to you exactly how much Ciprobay 750 mg 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. Take the tablets exactly as your doctor has told you. Ask your doctor or pharmacist if you are not sure how many tablets to take and how to take Ciprobay 750 mg.

- Swallow the tablets with plenty of fluid. Do not chew the tablets because they do not taste nice.
- Do try to take the tablets at around the same time every day.
- 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 750 mg 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 Ciprobay 750 mg.

If you take more Ciprobay 750 mg 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 750 mg

- 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 750 mg

- 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 more questions about the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Ciprobay 750 mg can cause side effects, although not everybody gets them.

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

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):

- 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
- joint pain in adults
- poor kidney function
- pains in your muscles and bones, feeling unwell (asthenia), or fever
- increase in blood alkaline phosphatase (a certain substance in the blood)

Rare side effects (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 Ciprobay 750 mg)
- 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)
- 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 Ciprobay 750 mg), 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 Ciprobay 750 mg)
- 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 Ciprobay 750 mg), 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):

- 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: Take special care with Ciprobay 750 mg)
- severe allergic reactions (anaphylactic reaction or anaphylactic shock, which can be fatal - serum sickness) (see Section 2: Take special care with Ciprobay 750 mg)
- mental disturbances (psychotic reactions) (see Section 2: Take special care with Ciprobay 750 mg)
- migraine, disturbed coordination, unsteady walk (gait disturbance), disorder of sense of smell (olfactory disorders), pressure on the brain (intracranial pressure)
- 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: Take special care with Ciprobay 750 mg); worsening of the symptoms of myasthenia gravis (see Section 2: Take special care with Ciprobay 750 mg)
- 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
- severe cardiac rhythm abnormalities, irregular heart beat (Torsades de Pointes)

5. HOW TO STORE CIPROBAY 750 MG

Keep out of the reach and sight of children.

Do not use Ciprobay 750 mg after the expiry date, which is stated on the blister or carton after "EXP": The expiry date refers to the last day of the month concerned.

Medicines should not be disposed of down the drain or with household rubbish. Ask your pharmacist how to dispose of any medicines no longer required. These measures will help to protect the environment.

- Not to be stored above 30°C.

6. FURTHER INFORMATION**What Ciprobay 750 mg contains**

The active ingredient is: Ciprofloxacin

1 film-coated tablet contains 873 mg ciprofloxacin hydrochloride

1 H₂O, equivalent to 750 mg ciprofloxacin.

The other ingredients are: Microcrystalline cellulose, crospovidone, hydroxypropyl methylcellulose, macrogol 4000, magnesium stearate, maize starch, colloidal silicon dioxide, titanium dioxide (E 171).

What Ciprobay 750 mg looks like and contents of the pack

Film-coated tablet

Ciprobay 750 mg film-coated tablets are oblong, white to yellowish, marked "Cip 750" on one side and "BAYER" on the other.

Ciprobay 750 mg is available in pack containing 10 film-coated tablets.

Manufacturer

Bayer Schering Pharma AG

Site: 51368 Leverkusen

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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.