

CIPRO[®] 500 mg, coated tablet

CIPRO[®] 750 mg, coated tablet

Ciprofloxacin

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 and symptoms 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 is CIPRO 500 mg and CIPRO 750 mg, coated tablet and in which case is it used?
2. What you need to know before you take CIPRO 500 mg and CIPRO 750 mg, coated tablet?
3. How to take CIPRO 500 mg and CIPRO 750 mg, coated tablet?
4. Possible side effects?
5. How to store CIPRO 500 mg and CIPRO 750 mg, coated tablet?
6. Content of the packaging and other information.

1. WHAT IS CIPRO 500 mg AND CIPRO 750 mg, COATED TABLET AND IN WHICH CASE IS IT USED?

Pharmacotheapeutic class : Fluoroquinolone - ATC code : J01MA02
CIPRO contains the active substance, ciprofloxacin.
Ciprofloxacin is an antibiotic belonging to the fluoroquinolone family. It acts by killing the bacteria that cause infections. It is only active on certain specific strains of bacteria.
CIPRO 500 mg and CIPRO 750 mg, coated tablet is indicated in the treatment of the following infections. Special attention should be paid to available information on bacterial resistance to ciprofloxacin before starting treatment.
Official recommendations concerning the appropriate use of antibacterials should be taken into account.

- In adults:
 - Lower respiratory tract infections due to Gram-negative bacteria
 - exacerbations of chronic obstructive pulmonary disease
 - bronchopulmonary infections in case of cystic fibrosis or bronchiectasis
 - non-purulent chronic otitis
 - Acute exacerbations of chronic sinusitis, particularly due to Gram-negative bacteria
 - Urinary Infections
 - Reproductive tract Infections
 - Inoculoc conjunctivitis and cervicitis due to susceptible strains of Neisseria gonorrhoeae
 - orch-epididymitis and other infections due to susceptible strains of Neisseria gonorrhoeae
 - high gynecological infections, including infections caused by susceptible Neisseria gonorrhoeae strains
 - Gastrointestinal infections (eg traveler's diarrhea)
- In children and adolescents:
 - Skin and soft tissue infections caused by Gram-negative bacteria
 - External malignant otitis
 - bone and joint infections
 - Prophylaxis of invasive infections due to Neisseria meningitidis
 - Anthrax disease (post-exposure prophylaxis and curative treatment)

Ciprofloxacin can be used for the treatment of febrile neutropenic patients whose bacterial origin is suspected. Ciprofloxacin can also be used for the treatment of:
- Marfan syndrome or vascular Ehlers-Danlos syndrome,
- Broncho-pulmonary infections in cystic fibrosis caused by Pseudomonas aeruginosa

- Complicated urinary infections and pyelonephritis
 - Anthrax disease (post-exposure prophylaxis and curative treatment)
- Ciprofloxacin can also be used to treat severe infections in children and adolescents, if necessary. Treatment should only be initiated by experienced physicians in the treatment of cystic fibrosis and / or severe infections of the child and adolescent.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE CIPRO 500 mg AND CIPRO 750 mg, COATED TABLET?

Never take CIPRO 500 mg and CIPRO 750 mg, coated tablet:

- if you are allergic to the active substance, to other quinolones or to any of the other components of this medicine (listed in section 6).
- if you take tizanidine (see section 2: other medicines and CIPRO 500 mg and CIPRO 750 mg, coated tablet).

Warnings and precautions

- Ask your doctor before you take CIPRO 500 mg and CIPRO 750 mg, coated tablet**
- if you have ever had kidney problems as your treatment may be adjusted ;
 - if you have epilepsy or another neurological condition ;
 - if you have ever had tendon problems with antibiotics from the same family as CIPRO ;
 - if you have diabetes, you may be at risk of hypoglycemia with ciprofloxacin ;
 - if you suffer from myasthenia gravis (a rare disease which causes muscle weakness) as the symptoms may be exacerbated
 - if you have been diagnosed with an enlarged or 'bulging' large blood vessel (aortic aneurysm or peripheral aneurysm of a large vessel) ;
 - if you have ever had a previous episode of aortic dissection (a tear in the aortic wall) ;
 - if you have a family history of aortic aneurysm or aortic dissection or other risk factors or predisposing conditions (such as exanthematous drug eruption, erythema multiforme or allergic Ebers-Danlos syndrome, or vascular disorders such as Takayashi's arteritis, giant cell arteritis, Behcet's disease, high blood pressure or aortic sclerodermis) ;
 - if you have heart problems.

Ciprofloxacin should be used with caution if you were born with it, or if you have a family history of prolongation of the QT interval (seen on an ECG tracing, recording the electrical tracing of the heart), if you have an electrolyte imbalance in the blood (especially a low level of potassium or magnesium in the blood) or if you have a prolonged QT interval.

If you have a weakened heart (heart failure), if you have ever had a heart attack (myocardial infarction), if you are a woman or an elderly person or if you are taking other medicines which may cause certain abnormalities of the heart. ECG (see section Other medicines and CIPRO 500 mg and CIPRO 750 mg, coated tablet).- if you have a deficiency of your body's main enzyme, glucose-6-phosphate dehydrogenase (G6PD) deficiency, as you may be at risk of anemia with ciprofloxacin.

For the treatment of certain genital tract infections, your doctor may prescribe another antibiotic in combination with CIPRO. If no response is observed after 3 days of treatment, please consult your doctor.

While taking CIPRO 500 mg and CIPRO 750 mg, coated tablet

- Tell your doctor immediately if any of the following conditions occur while taking CIPRO. Your doctor will decide whether treatment with CIPRO should be stopped.
- Tell your doctor **severe allergic reaction** (rash, angioedema, shock). From the first dose, there is a low risk of a severe allergic reaction, manifested by the following symptoms: chest tightness, dizziness, feeling unwell or weak, or dizziness when standing up. **If these symptoms occur, stop taking CIPRO and contact your doctor immediately.**
 - **Joint pain and swelling as well as tendonitis** may occasionally occur, especially if you are elderly and are also being treated with corticosteroids. Inflammation and ruptured tendons can occur within the first 48 hours of treatment and up to several months after stopping treatment with CIPRO. At the slightest sign of pain or redness in the muscles or tendons, immediately contact your doctor and put the painful area to rest. Avoid unnecessary effort as this may increase the risk of ruptured tendons.
 - **If you experience sudden and severe pain in your abdomen, chest or back**, go to a hospital emergency department immediately.
 - If you have **epilepsy** or another neurological disease such as cerebral ischemia or stroke, adverse neurological effects (seizures) may occur. It seizures occur, stop CIPRO and contact your doctor immediately.
 - You may have symptoms suggestive of neuropathy, such as pain, burning, tingling, numbness, and / or loss of reflexes. If these symptoms occur, stop CIPRO and contact your doctor immediately.
 - **Psychiatric reactions** may occur the first time you take CIPRO. If you suffer from depression or psychosis, your symptoms may worsen while taking CIPRO. In rare cases, depression or psychosis can progress to suicidal thoughts, suicide attempts or suicide. If such reactions occur, contact your doctor immediately.
 - Antidotes for the main enzymes of the stomach may cause abnormalities in blood sugar levels, including both a decrease in the blood sugar level below the normal value (hypoglycemia) or an increase in the level of sugar in the blood, above normal value (hyperglycemia) (see section 4: Possible side effects?). These blood sugar abnormalities may occur while taking antibiotics, including with ciprofloxacin. If you have diabetes, there have been reports of loss of consciousness due to a severe drop in blood sugar levels (hypoglycemic coma). If you have diabetes, your blood sugar levels should be closely monitored.
 - **Diarrhea** may occur while taking antibiotics, including with ciprofloxacin, and even several weeks after stopping treatment. If the diarrhea becomes severe or persists, or if you notice blood or mucus in your stool, stop taking CIPRO immediately, and contact your doctor immediately, as your life may be in danger. Do not take medicines intended to stop diarrhea without consulting your doctor.
 - If your eyesight deteriorates or you experience any eye effects, see an ophthalmologist immediately.
 - Your skin becomes **more sensitive to the sun and to ultraviolet (UV) rays** when you take CIPRO. Avoid prolonged exposure to the sun or artificial UV rays such as those in tanning booths.
 - Tell the doctor or laboratory staff that you are taking CIPRO if you need to have **blood or urine** test.
 - If you have **kidney problems**, tell your doctor as the dose of CIPRO may need to be adjusted.
 - CIPRO can cause **liver damage**. If you notice any symptoms such as loss of appetite, jaundice (yellowing of the skin and darkening of the whites of the eyes), or if you experience dark urine, contact your doctor immediately.
 - CIPRO may cause a decrease in white blood cells in your blood and **lower your resistance to infection**. If you have an infection with symptoms such as fever and a significant alteration of your general condition, or fever with blood infection symptoms such as pain in the throat / pharynx / mouth or urinary problems you should immediately consult your doctor. In addition, patients with diabetes receiving concomitant treatment with certain white blood cells (granulocytosis). It is important to tell your doctor that you are taking this medicine.

Other medicines and CIPRO 500 mg and CIPRO 750 mg, coated tablets

- If you are taking other medicines, tell your doctor. Some medicines may interact with ciprofloxacin.
- **Do not take CIPRO together with tizanidine** as this may cause side effects such as low blood pressure and drowsiness (see section 2: Never take CIPRO 500 mg and CIPRO 750 mg, coated tablet).
- The following medicines are known to interact with CIPRO. Taking CIPRO along with these medicines could affect the therapeutic effects of these products, and increase the probability of occurrence of side effects.

Tell your doctor if you are taking:

- anti-vitamin K (for example : warfarin, acenocoumarol, phenprocoumon or flutidione) or other oral anticoagulants (used to thin the blood)
- probenecid (used to treat gout)
- methotrexate (used in certain type of cancer, psoriasis, rheumatoid arthritis)
- theophylline (used in respiratory problems)
- tizanidine (used for muscle spasticity problems associated with multiple sclerosis)
- olanzapine (an antipsychotic)
- clozapine (used in certain psychiatric illnesses)
- ropinirole (used in Parkinson's disease)
- phenytoin (used in epilepsy)
- metoclopramide (used in nausea and vomiting)
- ciclosporin (used in skin diseases, rheumatoid arthritis, and organ transplants)
- other medicines that can affect your heart rate, especially recently taken or might take your antiarrhythmics (for example, quinidine, hydroquinidine, disopyramide, amiodarone, sotalol, dofetilide, ibutilide), tricyclic antidepressants, certain antibiotics (which belong to the macrolide family), certain antipsychotics
- zolpidem (used in sleep disorders).

CIPRO may increase the level of the following medicines in your blood:

- pentoxifylline (used in circulation disorders)
- caffeine
- duloxetine (used for depression, diabetes-related nerve damage or urinary incontinence)
- lidocaine (used in heart disease or for anesthetic use)
- sildenafil (for example, in erectile dysfunction)
- agomelatine (used in depression).

Some medicines reduce the effect of CIPRO. Tell your doctor if you are taking or plan to take:

- anti-acids
- omeprazole
- mineral supplements
- bicarbonates
- a polymeric phosphate binder (e.g. sevelamer or lanthanum carbonate)
- calcium-containing medicines or supplements, magnesium, aluminum or iron.

If it is essential for you to take these medicines, take CIPRO at least two hours before or four hours after these medicines.

CIPRO 500 mg and CIPRO 750 mg, coated tablet with food or drinks

If you take CIPRO without food, do not consume dairy products (eg milk or yogurt) or calcium fortified drinks while taking ciprofloxacin tablets. Milk products may be done to look for a possible decrease in the level of certain white blood cells (granulocytosis). It is important to tell your doctor that you are taking this medicine.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, 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 better to avoid using CIPRO during pregnancy.

Do not take CIPRO while breastfeeding because ciprofloxacin passes into breast milk and may harm the health of your baby.

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

Driving and using machines

CIPRO may lower your level of alertness. Neurological adverse effects can occur. Therefore, make sure you know how you react to CIPRO before driving or operating machinery. Do not drink and drive or do not take CIPRO while driving or operating machinery.

3. HOW TO TAKE CIPRO 500 mg AND CIPRO 750 mg, COATED TABLET

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if in doubt.

Your doctor will tell you exactly how much CIPRO to take, how often and for how long. This will depend on the type of infection and your condition.

Tell your doctor if you have kidney problems as the dose of medicine to take may need to be adjusted. Treatment usually lasts 5 to 21 days but may be longer in severe infection. Always take the dose recommended by your doctor. Check with your doctor or pharmacist if you are not sure how many CIPRO tablets to take or how to take them.

a. Swallow the tablets with plenty of drink. Do not chew the tablets because they have bad taste.

b. Try to take the tablets at around the same time each day.

c. You can take the tablets with or without food. Calcium in a meal does not seriously affect the effect of the medicine. However, **do not take CIPRO tablets with dairy products** such as milk or yogurt or fortified fruit juices (eg orange juice fortified with calcium).

Remember to drink plenty while taking this medicine.

If you take more than the prescribed dose, consult your doctor immediately. If possible, take any leftover tablets or the box with you to show the doctor.

If you forget to take CIPRO 500 mg and CIPRO 750 mg, coated tablet:

If you miss a dose: Take the missed dose as soon as possible, then continue treatment as normal. However, if it is almost time for the next dose, skip the missed dose and continue treatment as normal. Do not take a double dose to make up for the dose you forgot to take. Make sure you stay with your treatment until the end.

If you stop taking CIPRO 500 mg and CIPRO 750 mg, coated tablet:

It is important that you follow the treatment until the end, even if you start feeling 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 come back or get worse. You could also develop bacterial resistance to this antibiotic.

Always have any further questions on the use of this medicine, ask your doctor or pharmacist for more information.

4. POSSIBLE SIDE EFFECTS?

Like all medicines, this medicine can cause side effects, although not everybody gets them. The most serious side effects that you may recognize on your own are listed in the section below.

Stop taking CIPRO and contact your doctor immediately to consider another antibiotic treatment, if you notice any of the serious side effects listed below:

Rare side effects (may affect up to 1 in 100 people)

- seizures (see section 2: Warnings and precautions)

Very rare side effects (may affect up to 1 in 10 000 people)

- severe and sudden allergic reactions manifested by symptoms such as tightness in the chest, dizziness, feeling unwell or weak, or dizziness when standing up (anaphylactic reaction, anaphylactic shock) (see section 2: Warnings and precautions)

• muscle weakness, inflammation of the tendons which can lead to ruptured tendons, especially the large tendon at the back of the ankle (Achilles tendon) (see section 2: Warnings and precautions)

• severe rash that can be life threatening, usually appearing as blisters or ulcers in the mouth, throat, nose, eyes and other mucous membranes such as the genitals, and may progress to the appearance of blisters or peeling of the skin all over the body (Stevens-Johnson syndrome, Lyell syndrome)

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

- unusual sensations of pain, burning, tingling, numbness or muscle weakness in the extremities (neuropathy) (see section 2: Warnings and precautions)

• side effects that caused by inflammation of internal organs, blood abnormalities and systemic disease (drug hypersensitivity syndrome with eosinophilia and systemic symptoms called ERESS syndrome [Drug Reaction with Eosinophilia and Systemic Symptom], P.E.A.G : Acute Generalized Exanthematous Pustulosis)

Other side effects, which have been observed during treatment with CIPRO are listed below, depending on the indication and dose:

Common side effects (may affect up to 1 in 10 people)

- nausea, diarrhea
- pain in the joints and inflammation of the joints in children
- pain in the joints in adults
- fungal superinfection (caused by fungi)
- high level of a type of white blood cell (eosinophils)
- decreased appetite
- hyperactivity, restlessness
- headache, dizziness, sleep disturbance, taste disturbance
- vomiting, abdominal pain, digestive problems such as stomach problems (indigestion / heartburn) or gas
- increase in the amount of certain substances in the blood (transaminases and / or bilirubin)
- rash, itching, hives
- impaired kidney function
- pain in muscles and bones, feeling generally tired (asthenia), fever
- an increase in the level of a substance in the blood (alkaline phosphatase).
- muscle pain, joint inflammation, increased muscle tone and cramps
- inflammation of the intestines (colitis) associated with the use of antibiotics (which can be fatal in very rare cases) (see section 2: Warnings and precautions)
- change in the number of white blood cells or red blood cells (leukopenia, leukocytosis, neutropenia, anemia), increase or decrease in the amount of factors in the blood used for blood clotting (platelets)
- allergic reaction, swelling (edema) or rapid swelling of the skin and mucous membranes (angioedema) (see section 2: Warnings and precautions)
- increased blood sugar level (hyperglycemia)
- decrease in blood sugar level (hypoglycemia) (see section 2: Warnings and precautions)
- confusion, disorientation, anxiety reactions, strange dreams, depression (which can lead to suicidal thoughts, suicide attempts or suicide) (see section 2: Warnings and precautions)
- hallucinations
- tingling, unusual sensitivity to sensory stimuli, decreased sensitivity of the skin, tremors, dizziness
- vision disturbances, including double vision (see section 2: Warnings and precautions)
- ringing in the ears, disturbance or loss of hearing
- rapid heart rate (tachycardia)
- dilation of blood vessels (vasodilation), drop in blood pressure, fainting
- shortness of breath, including asthmatic symptoms
- liver problems, jaundice (cholestatic jaundice), hepatitis
- light sensitivity (see section 2: Warnings and precautions)
- kidney failure, blood or crystals in the urine, inflammation of the urinary tract
- water retention, excessive sweating
- increased concentration of an enzyme from the pancreas (amylase).

Very rare side effects (may affect up to 1 in 10 000 people)

- special type of low number of red blood cells in the blood (hemolytic anemia), very severe drop in the number of red blood cells and platelets (pancytopenia) (which can be fatal, depletion of the bone marrow of blood cells (myelosuppression) which can also be fatal).
- allergic reaction called a serum sickness-like reaction (see section 2: Warnings and precautions)
- psychomotor and coordination disorders which may lead to suicidal thoughts, suicide attempts or suicide) (see section 2: Warnings and precautions)
- migraine, coordination disorders, unsteady gait (gait disturbance), smell disturbances (olfactory dysfunction), pressure on the brain (intracranial hypertension and cerebral pseudotumor)
- disorders of color vision
- inflammation of the lining of blood vessels (vasculitis)
- inflammation of the pancreas (pancreatitis)
- psychomotor and coordination disorders (hepatic necrosis) very rarely leading to life-threatening liver failure (see section 2: Warnings and precautions)
- small bleeding in the form of red dots under the skin (petechiae), various rashes
- worsening of symptoms of myasthenia gravis (see section 2: Warnings and precautions).

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

- syndrome associated with reduced water excretion and low sodium levels (SIADH)
- feeling very excited (mania) or feeling very optimistic with hyperactivity (hypomania)
- unusually fast heart rate, life-threatening irregular heartbeat, altered heartbeat (called "prolongation of the QT interval" seen on an ECG, recording of the electrical tracing of the heart)
- changes in blood clotting (in patients treated with vitamin K antagonists).

Reporting Side Effects

If you get any side effects talk to your doctor or pharmacist. This also applies to any side effects not listed in this leaflet. You can also report side effects directly via the national reporting system.

By reporting side effects, you can help provide more information on the safety of this medicine.

5. COMMENT CONCERNING CIPRO 500 mg AND CIPRO 750 mg, COATED TABLET

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 on the carton after "EXP". The expiration date refers to the last day of that month.

Keep away from heat, especially away from direct sunlight.

Do not throw away any medicine via wastewater or household waste. Ask your pharmacist to throw away any medicines you no longer use. These measures will help protect the environment.

6. CONTENT OF THE PACKAGING AND OTHER INFORMATION

What CIPRO 500 mg and CIPRO 750 mg, coated tablet contains

For CIPRO 500mg

- the active substance is: Ciprofloxacin.
- Each coated tablet contains 500 mg of ciprofloxacin (as hydrochloride) For CIPRO 750mg
- the active substance is: Ciprofloxacin.

Each coated tablet contains 750 mg of ciprofloxacin (as hydrochloride).

Other components are: Sodium Carboxymethyl Starch, Microcrystalline Cellulose, Opadry II HP White, Magnesium Stearate

What does CIPRO 500 mg and CIPRO 750 mg, coated tablet look like and content of the outer packaging

This medication is in the form of a coated tablet in PVC / Alu blisters in boxes of 14.

Supply and prescription condition: List I/ Table A

AMM N°:

CIPRO 500 mg: 9233293

CIPRO 750 mg: 9233294

Marketing authorization holder and manufacturer

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LES LABORATOIRES Médis, S.A.

Route de Tunis - BP 206 - 8000 Nabeul - Tunisia

This is a medicine

- A medicine is a product but not like any other product.
- A medicine is a product that affects your health if it's not used properly : it can be health threatening.
- Strictly adhere to the prescription of your Doctor and the use instructions prescribed, follow your pharmacist advice.
- Your doctor and your pharmacist know the medicine, its use and side effect.
- Don't stop the use of the treatment on your own during the prescribed time.
- Don't retake. Don't increase the doses without doctor's advice.

Keep the medicines out of reach of children

Board of health education: WHAT TO KNOW ABOUT ANTIBIOTICS?

Antibiotics are used to fight infections caused by bacteria. They are not effective against infections caused by viruses.

Also, your doctor has chosen to prescribe this antibiotic because it is right for you and your current illness. Bacteria have the ability to survive or reproduce despite the action of an antibiotic. This phenomenon is called resistance: it makes certain antibiotics treatments inactive.

Resistance grows through overuse or inappropriate use of antibiotics. You risk promoting the appearance of resistant bacteria and therefore delaying your recovery or make this medication inactive, if you do not follow:

• the dose to take,

• the moment of taking,

• and the duration of treatment.

Consequently, to preserve the effectiveness of this medicine:

1- Only use an antibiotic when your doctor tells you to.

2- Strictly follow your prescription.

3- Do not use again an antibiotic without a doctor's prescription even if you think you are fighting a disease that appears to be similar.

4- Never give an antibiotic to another person, it may not be suitable for their illness.

5- Once your treatment is finished, return to your pharmacist all opened boxes for a correct and appropriate destruction of this medicine.