

Package leaflet: information for the user

Estecina 500 mg film-coated tablets

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 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 Estecina is and what it is used for
2. What you need to know before you take Estecina
3. How to take Estecina
4. Possible side effects
5. How to store Estecina
6. Contents of the pack and other information

1. What Estecina is and what it is used for

Estecina is an antibiotic that belongs to a group of medicines called fluoroquinolones. The active substance is ciprofloxacin. It works by killing bacteria that cause infections. It only works with specific strains of bacteria.

Antibiotics are used to treat bacterial infections and do not serve to treat viral infections such as flu or cold.

It is important that you follow the instructions related to doses, dosage interval and duration of treatment indicated by your doctor.

Do not store nor reuse this medicine. If once treatment is completed you have antibiotic tablets left, bring them back to the pharmacy for its correct disposal. Medicines should not be disposed of via wastewater or household waste.

Adults

Estecina 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 and intra-abdominal infections.
- Skin and soft tissue infections.
- Bone and joint infections.
- To prevent of infections due to the bacteria *Neisseria meningitidis*.
- Anthrax inhalation exposure.

Estecina 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 Estecina.

Children and adolescents

Estecina 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.

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

2. What you need to know before you take Estecina

Do not take Estecina:

- If you are allergic (hypersensitive) to active substance, to any other quinolone drugs or to any of the other ingredients of this medicine (see section 6).
- If you are taking tizanidine (see section 2: Other medicines and Estecina).

Warnings and precautions

Talk to your doctor before taking this medicine

If you have experienced any serious adverse reaction in the past when taking a quinolone or fluoroquinolone, you should not take fluoroquinolone/quinolone antibacterial medicines, including Estecina. If this applies to you, you should tell your doctor as soon as possible.

Talk to your doctor before you start taking Estecina:

- 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 Estecina.
- If you have myasthenia gravis (a type of muscle weakness).
- If you have a history of 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 Estecina).
- 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]).

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.

If your eyesight becomes impaired or if your eyes seem to be otherwise affected, consult an eye specialist immediately.

During treatment with this medicine

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

- **Severe, sudden allergic reaction** (an anaphylactic reaction/shock, angioedema). 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 Estecina and contact your doctor immediately.
- **Prolonged, disabling and potentially irreversible serious side effects.** Fluoroquinolone or quinolone antibacterial medicines, including ciprofloxacin, 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 (paresthesia), 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 ciprofloxacin, 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 rupture of tendons may occur even within the 48 hours of treatment or up to several months after discontinuing treatment with ciprofloxacin. At the first sign of any pain or inflammation (for example in your ankle, wrist, elbow, shoulder or knee) stop taking this medicine, contact your doctor immediately 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 this happens, stop taking this medicine and contact your doctor immediately.

- You may rarely experience symptoms of 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 this medicine and contact your doctor immediately in order to prevent the development of a potentially irreversible condition.
- You may experience **psychiatric reactions** the first time you take this medicine. If you suffer from **depression** or **psychosis**, your symptoms may become worse under treatment with this medicine. In rare cases, depression or psychosis may lead to thoughts of suicide, suicide attempts or consummated suicide. If this happens, stop taking this medicine and 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 taking antibiotics, including this medicine, 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 this medicine 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 this medicine if you have to provide a **blood or urine sample**.
- This medicine may cause **liver damage**. If you notice any symptoms such as loss of appetite, jaundice (yellowing of the skin), dark urine, itching or stomach ache, stop taking this medicine and contact your doctor immediately.
- Tell your doctor if you suffer from kidney problems, because your dose may need to be adjusted.
- This medicine 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.
- Talk to 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 anaemia with ciprofloxacin.
- Your skin becomes more **sensitive to sunlight or ultraviolet (UV) light** when taking this medicine. Avoid exposure to strong sunlight, or artificial UV light such as sunbeds.

Other medicines and Estecina

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

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

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:

- Vitamin K antagonists (e.g.: warfarin) or other oral anti-coagulants (to thin the blood),
- Probenecid (used 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 (used for skin conditions, rheumatoid arthritis and in organ transplantation).
- Other medicines that can alter your heart rhythm: medicines that belong to the group of antiarrhythmics (e.g. quinidine, hydroquinidine, disopyramide, amiodarone, sotalol, dofetilide, ibutilide), tricyclic antidepressants, some antimicrobials (that belong to the group of macrolides), some antipsychotics.

This medicine may **increase** the levels of the following medicines in your blood:

- Pentoxifylline (used to treat 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 this medicine. Tell your doctor if you take or wish to take:

- Antacids.
- Omeprazole.
- 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 this medicine about two hours before or no sooner than four hours after them.

Estecina with food and drink

Unless you take this medicine during meals, do not eat or drink any dairy products (such as milk or yogurt) or drinks containing added calcium when you take the tablets, as they may affect the absorption of the active substance.

Pregnancy and breastfeeding

It is preferable to avoid the use of this medicine during pregnancy. Tell your doctor if you are planning to become pregnant.

Do not take this medicine during breastfeeding because ciprofloxacin is excreted in breast milk and can be harmful for your child.

Driving and using machines

This medicine may make you feel less alert. Some neurological side events can occur. Therefore, make sure you know how you react to this medicine before driving a vehicle or operating machinery. Check with your doctor if you are not sure.

Estecina contains sodium

This medicinal product contains less than 1 mmol sodium (23 mg) per tablet, i.e. it is essentially 'sodium-free'.

3. How to take Estecina

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Your doctor will explain to you exactly how much Estecina you will have to take, as how often and for how long. This will be dependent on the type and severity of your infection.

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 tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure about how many tablets of Estecina you must take or how to take them.

a. Swallow the tablets with plenty of liquid. Do not chew the tablets because they do not taste nice.

b. Try to take the tablets at the same time every day.

c. You can take the tablets at mealtimes or between meals. Any calcium you take as a part of a meal will not seriously affect uptake. However, **do not** take Estecina 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 liquids while you are taking this medicine.

If you take more Estecina than you should

In case of overdose or accidental ingestion, contact your doctor or pharmacist at once, or go to the nearest hospital, indicating the medicine and the amount taken.

If you forget to take Estecina

If you forget to take a dose, 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 Estecina

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 may also develop resistance to the antibiotic.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

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

- Nausea, diarrhoea.
- Joint pains in children.

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

- 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),
- Skin rash, itching, or hives.
- Joint pains 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 (may affect up to 1 in 1,000 people):

- Intestine inflammation (colitis) associated with the use of antibiotics (it may be fatal in rare cases) (see section 2: Take special care with Estecina).
- Changes to the blood count (leukopenia, leucocytosis, neutropenia, anaemia), increased or decreased amounts of the 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, (potentially leading to thoughts of suicide, suicide attempts or consummated suicides) or hallucinations.
- Numbness and tingling, unusual sensitivity to sensory stimuli, decreased skin sensitivity, tremors, seizures (see section 2: Take special care with Estecina) or giddiness.
- Eyesight problems (including double vision).
- Tinnitus (ringing in the ear), loss of hearing, impaired hearing.
- Increase heart rate (tachycardia).
- Widening 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 Estecina).
- Muscle pain, inflammation of the joints, increased muscle tone, or cramping.
- Kidney failure, blood or crystals in the urine (see section 2: Take special care with Estecina), urinary tract inflammation.
- Fluid retention or excessive sweating.
- Increased levels of the enzyme amylase.

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

- A special type of reduced red blood cell count (haemolytic anaemia); a dangerous reduction 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 Estecina).
- Severe allergic reactions (anaphylactic reaction/shock), which may be fatal, serum sickness (see section 2: Take special care with Estecina).
- Mental disturbances (psychotic reactions potentially leading to thoughts of suicide, suicide attempts and consummate suicides) (see section 2: Take special care with Estecina).

- 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.
- Liver cells death (liver necrosis) that very rarely can lead 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 the toxic epidermal necrolysis).
- Muscle weakness, inflammation of the tendons, tendon rupture –particularly affecting the large tendon at the back of the ankle (Achilles tendon) (see section 2: Take special care with Estecina); exacerbation of the symptoms of myasthenia gravis (see section 2: Take special care with Estecina).

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 the limbs.
- 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).
- Syndrome associated with impaired water excretion and low levels of sodium (SIADH),
- 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.

5. How to store Estecina

Keep this medicine out of the sight and reach of children.

Store below 30 °C. Store in the original package in order to protect from moisture.

Do not use this medicine after the expiry date, which is stated on the container: The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. If you are not sure, ask your pharmacist how to throw away medicines and packs you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

Composition of Estecina

- The active substance is ciprofloxacin. Each tablet contains 500 mg of ciprofloxacin (hydrochloride).
- The other ingredients (excipients) are: microcrystalline cellulose, carboxymethyl starch (type A) (potato), povidone, magnesium stearate, talc, titanium dioxide (E-171), macrogol 6000, ammonio methacrylate copolymer type A and propylene glycol (E-1520).

What the product looks like and contents of the pack

White or slightly cream, elongated, biconvex film-coated tablets scored on one side.

Each pack contains 1, 10, 14, or 500 tablets.

Not all pack sizes may be marketed in all countries.

Marketing Authorization Holder and Manufacturer

LABORATORIOS NORMON, S.A.

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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:

- 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.