

PACKAGE LEAFLET: INFORMATION FOR THE USER

Estecina 2 mg/mL solution for infusion Ciprofloxacin

Read all of this leaflet carefully before you start using this medicine.

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

What is in this leaflet:

1. What Estecina is and what it is used for
2. What you need to know before you use Estecina
3. How to use 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 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.

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

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.
- genital tract infections in women.
- gastro-intestinal tract infections and intra-abdominal infections.
- skin and soft tissue infections.
- bone and joint infections.
- management of infections in patients with very low white blood cell counts (neutropenia).
- prevention of infection in patients with very low white blood cell counts (neutropenia).
- 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 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 specific severe infections in children and adolescents when your doctor considers this necessary.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE ESTECINA

▪ Do not use Estecina

- If you are allergic (hypersensitive) to ciprofloxacin, to 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

Before you are given Estecina

Talk to your doctor if:

- you have ever had kidney problems because your treatment may need to be adjusted
- you suffer from epilepsy or other neurological conditions
- you have a history of tendon problems during previous treatment with antibiotics such as ciprofloxacin
- you have myasthenia gravis (a type of muscle weakness)
- you have a history of abnormal heart rhythms (arrhythmias)
- you have been diagnosed with an enlargement or “bulge” of a large blood vessel (aortic aneurysm or large vessel peripheral aneurysm).
- you have experienced a previous episode of aortic dissection (a tear in the aorta wall).
- you have a family history of aortic aneurysm or aortic dissection or other risk factors or predisposing conditions (e.g., connective tissue disorders such as Marfan syndrome or vascular Ehlers-Danlos syndrome, or vascular disorders such as Takayasu arteritis, giant cell arteritis, Behçet's disease, high blood pressure, or known atherosclerosis).

If you feel sudden, severe pain in your abdomen, chest or back, go immediately to an emergency room.

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

While under treatment with Estecina

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

- Severe, sudden allergic reaction (an anaphylactic reaction/shock, angioedema). 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 Estecina will have to be stopped.
- 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 using Estecina, contact your doctor 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 using Estecina and contact your doctor immediately.
- You may experience psychiatric reactions after first administration of ciprofloxacin. If you suffer from depression or psychosis, your symptoms may become worse under treatment with Estecina. If this happens, stop using Estecina and contact your doctor immediately.
- You may experience symptoms of neuropathy such as pain, burning, tingling, numbness and/or muscle weakness in the limbs. If this happens, stop using Estecina and contact your doctor immediately.
- Diarrhea may develop while you are on antibiotics, including Estecina, 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, contact your doctor immediately. Stop using Estecina immediately, as this can be life-threatening. Do not use medicines that stop or slow down bowel movements.
- Tell the doctor or laboratory staff that you are using Estecina if you have to provide a blood or urine sample.
- Estecina 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, Estecina must be stopped immediately.
- Estecina 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 under treatment with Estecina. Avoid exposure to strong sunlight or artificial UV light such as sunbeds.

▪ **Using other medicines:**

Tell your doctor or pharmacist if you are using, or have recently used, any other medicine, including non-prescription drugs.

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

The following medicines are known to interact with Estecina in your body. Using Estecina 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:

- warfarin or other oral anticoagulants (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)

Estecina may increase the levels of the following medicines in your blood:

- pentoxifylline (for circulatory disorders)
- caffeine

▪ **Estecina with food and drink**

Food and drink does not affect your treatment with Estecina.

▪ **Pregnancy and breast-feeding**

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

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

▪ **Driving and using machines**

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

▪ **Important information on some of the components of Estecina**

Patients with a low sodium diet should consider that this medicine contains 354 mg (15.4 mmol) of sodium per 100 mL of solution.

3. HOW TO USE ESTECINA

Your doctor will explain to you exactly how much Estecina you will be given as well as how often and for how long. Your dose 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.

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 Estecina and 30 minutes for 200 mg Estecina. Administering the infusion slowly helps prevent immediate side effects occurring.

Remember to drink plenty of fluids while you are using Estecina.

▪ **If you stop using 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 using 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, Estecina 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, please inform your doctor or pharmacist.

Common side effects (may affect up to 1 and 10 in every 100 people):

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

Uncommon side effects (may affect up to 1 and 10 in every 1,000 people):

- fungal superinfections (infections caused by fungi)
- a high concentration of eosinophils, a type of white blood cell, increased or decreased amounts of a blood clotting factor (thrombocytes)
- decreased appetite (anorexia)
- hyperactivity, agitation, confusion, disorientation, hallucinations
- headache, dizziness, sleeping problems, taste disorders, pins and needles, unusual sensitivity to stimuli of the senses, giddiness (see section 2: Warnings and precautions), dizziness, vertigo
- eyesight problems
- hearing loss
- 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
- joint pain in adults
- 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 side effects (may affect up to 1 and 10 in every 10,000 people):

- inflammation of the bowel (colitis) linked to antibiotic use (can be fatal in very rare cases) (see section 2: Warnings and precautions)
- changes to the blood count (leukopenia, leukocytosis, neutropenia, anemia), 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 (see section 2: Warnings and precautions)
- allergic reaction, allergic swelling (edema), rapid swelling of the skin and mucous membranes (angioedema), life-threatening serious allergic reaction (anaphylactic shock) (see section 2: Warnings and precautions)
- increased blood sugar (hyperglycemia)
- anxiety reaction, strange dreams, depression, mental disturbances (psychotic reactions) (see section 2: Warnings and precautions)
- decreased skin sensitivity, tremor, migraine, disorder of sense of smell
- 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
- sensitivity to light (see section 2: Warnings and precautions), nonspecific formation of blisters, small, pin-point bleeding under the skin (petechiae)
- muscle pain, inflammation of the joints, increased muscle tone and cramping, tendon rupture, particularly affecting the large tendon at the back of the ankle (Achilles tendon) (see section 2: Warnings and precautions)
- blood or crystals in the urine, (see section 2: Warnings and precautions), urinary tract inflammation
- excessive sweating
- abnormal levels of the coagulation factor (prothrombin) or increased levels of the enzyme amylase

Very rare side effects (may affect less than 1 in every 10,000 people):

- a special type of reduced red blood cell count (hemolytic anemia); a dangerous drop in a type of white blood cells (agranulocytosis)
- severe allergic reactions (anaphylactic reaction and anaphylactic shock, serum sickness) that can be life-threatening (see section 2: Warnings and precautions)
- disturbed coordination, unsteady walk (gait disturbance), pressure on the brain (intracranial pressure)
- visual color distortions
- different skin rashes (e.g. Stevens-Johnson syndrome or toxic epidermal necrolysis)
- muscle weakness, inflammation of the tendons, exacerbation of the symptoms of myasthenia gravis (see section 2: Warnings and precautions)

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

- side effects associated with the nervous system such as pain, burning, tingling, numbness and/or muscle weakness in the extremities
- severe anomalies of the heartbeat, irregular heartbeat (*torsade de pointes*)
- syndrome associated with impaired water excretion and low levels of sodium (SIADH)

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. 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 out of the sight and reach of children.

Bags: Store below 25°C. Store in the original package to protect from light. Do not freeze or refrigerate.

Because ciprofloxacin is sensitive to light, the bag should only be removed from the overpouch immediately prior to administration.

Discard if alterations are observed in the container or in the liquid it contains.

Do not use Estecina after the expiry date which is stated on the container after “EXP”. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. 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

What Estecina contains

The active substance is ciprofloxacin.

Each 100 mL of solution contains 200 mg of ciprofloxacin as lactate.

Each 200 mL of solution contains 400 mg of ciprofloxacin as lactate.

The other ingredients (excipients) are: lactic acid, sodium chloride, hydrochloric acid and water for injection.

Not all pack sizes are marketed in all countries.

What Estecina looks like and contents of the pack

Solution for infusion

Estecina is a clear, colorless or slightly yellow solution for infusion.

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:

- dosage

- schedules
- duration of treatment

1. **Consequently, to preserve the efficacy of this drug:** 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

Estecina 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 Estecina and 30 minutes for 200 mg Estecina. Slow infusion into a large vein will minimize patient discomfort and reduce the risk of venous irritation. The infusion solution can be infused either directly or after mixing with other compatible solutions for infusion.

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

Estecina 2 mg/mL solution for infusion is compatible with isotonic saline solution, Ringer's solution, 5% and 10% dextrose solution, glucosaline solution and 10% fructose solution. Once the solution is prepared, it should be used within 24 hours.

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