

## 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).

### **▪ Take special care with Estecina**

#### **Before you are given Estecina**

You should not take fluoroquinolone/quinolone antibacterial medicines, including ciprofloxacin, 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 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),
- if you have been diagnosed with leaking heart valves (heart valve regurgitation),
- 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, Behçet’s disease, high blood pressure, or known atherosclerosis, rheumatoid arthritis (a disease of the joints) or endocarditis (an infection of the heart)).

## **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 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 ciprofloxacin therapy. At the first sign of pain or inflammation of a tendon (for example in your ankle, wrist, elbow, shoulder or knee), stop taking ciprofloxacin, 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 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 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 ciprofloxacin and inform your doctor immediately in order to prevent the development of potentially irreversible condition.
- 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.
- If your eyesight becomes impaired or if your eyes seem to be otherwise affected, consult an eye specialist immediately.
- 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.
- 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.

### **Prolonged, disabling and potentially irreversible serious side effects**

Fluoroquinolone/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 (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 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.

### **▪ 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 do 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: Take special care with Estecina), 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: Take special care with Estecina),
- 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: Take special care with Estecina),
- allergic reaction, allergic swelling (edema), rapid swelling of the skin and mucous membranes (angioedema), life-threatening serious allergic reaction (anaphylactic shock) (see section 2: Take special care with Estecina),
- increased blood sugar (hyperglycemia),
- anxiety reaction, strange dreams, depression, mental disturbances (psychotic reactions) (see section 2: Take special care with Estecina),
- 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: Take special care with Estecina), 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: Take special care with Estecina),
- blood or crystals in the urine, (see section 2: Take special care with Estecina), 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: Take special care with Estecina),
- 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: Take special care with Estecina).

**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),
- 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, 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. 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.

It is presented in plastic bags of 100 and 200 mL.

Not all pack sizes are marketed in all countries.

### **Marketing Authorization Holder and Manufacturer**

LABORATORIOS NORMON, S.A.

Ronda de Valdecarrizo, 6 – 28760 Tres Cantos – Madrid (SPAIN).

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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 colour change.

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.