

Package leaflet: information for the user

ciprofloxacin cinfa 250 mg coated tablets ciprofloxacin

Read all of this leaflet carefully before you start taking 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 tell your doctor or pharmacist. See section 4.

What is in this leaflet:

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

1. What ciprofloxacin cinfa is and what it is used for

ciprofloxacin cinfa is an antibiotic that belongs to the fluoroquinolone family. The active substance is ciprofloxacin. Ciprofloxacin acts by eliminating the bacteria that cause infections. It only works with specific strains of bacteria.

Antibiotics are used to treat bacterial infections. They are not effective in the treatment of viral infections, such as flu or colds.

Please follow your doctor's instructions with regard to dose, times and duration of treatment carefully.

Do not keep this medicine or use it to treat other conditions. If you have any antibiotic remaining at the end of your course of treatment, please return it to your pharmacist, who will dispose of it properly. Do not dispose of any medicines via wastewater or household waste.

Adults:

ciprofloxacin cinfa is used in adults to treat the following bacterial infections:

- infections of the respiratory tract
- recurrent or long-lasting infections of the ear or sinuses
- urinary tract infections
- genital tract infections in men and women
- infections of the gastrointestinal tract and intra-abdominal infections
- infections of the skin and soft tissue
- infections of the bones and joints
- treatment of infections in patients with a very low white blood cell count (neutropenia)
- prevention of infections in patients with a very low white blood cell count (neutropenia)
- prevention of infections caused by the bacterium *Neisseria meningitidis*

- exposure to anthrax by inhalation

If you suffer a severe infection, or if the infection is caused by more than one type of bacterium, it is possible that you will be administered an additional antibiotic treatment, in addition to **ciprofloxacin**.

Children and adolescents:

ciprofloxacin is used in children and adolescents, under specialised medical supervision, to treat the following bacterial infections:

- lung and bronchial infections in children and adolescents suffering from cystic fibrosis
- complicated infections of the urinary tract, including infections that have reached the kidneys (pyelonephritis)
- exposure to anthrax by inhalation

ciprofloxacin can also be used to treat severe infections in children and adolescents when deemed necessary.

2. What you need to know before you take ciprofloxacin

- If you are allergic (hypersensitive) to the active substance, to other quinolone drugs, or to any of the other ingredients of **ciprofloxacin** (listed in section 6).
- If you are taking tizanidine (see section 2: Taking other medicines).

Take special care with ciprofloxacin: Before taking this medicinal product

Do not take antibacterial medicinal products containing fluoroquinolones or quinolones, including ciprofloxacin, if you have previously experienced any serious adverse reaction when taking a quinolone or fluoroquinolone. If you have, you must inform your doctor as soon as possible.

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.

- Talk to your doctor before taking ciprofloxacin if you:

- have ever had kidney problems because your treatment will have to be adjusted
- suffer from epilepsy or other neurological conditions
- have a history of tendon problems during previous treatment with antibiotics like ciprofloxacin.
- suffer from myasthenia gravis (a type of muscle weakness).
- suffer from or have a family history of prolongation of the QT interval (detected in electrocardiograms, recording of heart activity)
- have a salt imbalance in the blood (especially if you have low levels of potassium and magnesium)
- have a very slow heart rate (called ‘bradycardia’)
- have a weak heart (heart failure), or you have suffered a heart attack (myocardial infarction).
- are a female or elderly patient
- are taking other medicines that can cause changes in the electrocardiogram (*see the section Taking other medicines*).

- have been diagnosed with enlargement or a “bulge” in a large blood vessel (aortic aneurysm or large vessel peripheral aneurysm).
- have experienced a previous episode of aortic dissection (tear in the wall of the aorta).
- have a family history of aortic aneurysm or aortic dissection or other risk factors or predisposing conditions (e.g. connective tissue disorders like Marfan syndrome or vascular Ehlers-Danlos syndrome, or vascular disorders such as Takayasu’s arteritis, giant cell arteritis, Behçet’s disease, arterial hypertension or known atherosclerosis).

- **During treatment with this medicinal product:**

Tell your doctor immediately if any of the following situations arise while taking **ciprofloxacin cinfa**. Your doctor will decide if the treatment with **ciprofloxacin cinfa** needs to be stopped

If you feel a sudden sharp pain in your abdomen or back, seek emergency medical attention immediately.

Consult an ophthalmologist immediately if you experience impaired vision or any problem with your eyes.

- **Sudden severe allergic reactions** (anaphylactic shock or reaction, angioedema). There is a small possibility that, even with the first dose, 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, do not take any more **ciprofloxacin cinfa** and contact your doctor immediately.

- **Serious, disabling, long-lasting, and potentially irreversible adverse reactions**
Antibacterial medicines containing fluoroquinolones or quinolones, including ciprofloxacin, have been associated with very rare but serious adverse effects, some of which were long-lasting (persisting for months or years), disabling or potentially irreversible. This includes pain in the tendons, muscles and joints of the upper and lower limbs, difficulty in walking, abnormal sensations such as sharp pains, tingling, tickling, numbness or a burning sensation (paraesthesia), disorders of the senses such as impaired vision, taste, smell and hearing, depression, memory impairment, intense fatigue and severe sleep disorders.

If you experience any of these adverse effects after taking ciprofloxacin cinfa, contact your doctor immediately, before continuing with the treatment. You and your doctor will decide whether to continue the treatment or not, also considering the use of a different class of antibiotic.

- On rare occasions, pain and swelling in the joints and inflammation or rupture of the tendons may occur. The risk is greater if you are elderly (over 60 years of age), have received an organ transplant, have kidney problems or are being treated with corticosteroids. Inflammation and rupture of tendons can occur within the first 48 hours of treatment and even up to several months after stopping treatment with ciprofloxacin. At the first sign of pain or inflammation of a tendon (for example, in the ankle, wrist, elbow, shoulder or knee), stop taking ciprofloxacin cinfa, contact your doctor and rest the painful area. Avoid any unnecessary exercise, as this could increase the risk of tendon rupture.
- If you suffer from **epilepsy** or any other **neurological conditions**, such as cerebral ischaemia or stroke, you may suffer adverse effects associated with the central nervous system. If this happens, stop taking **ciprofloxacin cinfa** and contact your doctor immediately.
- You may experience **psychiatric reactions** the first time you take **ciprofloxacin cinfa**. If you suffer **depression** or **psychosis**, your symptoms may worsen with treatment with

ciprofloxacino cinfra. If this happens, stop taking **ciprofloxacino cinfra** and contact your doctor immediately.

- On rare occasions, you may experience symptoms of nerve damage (neuropathy) such as pain, burning, tingling, numbness and/or weakness, especially in the feet and legs or the hands and arms. If this happens, stop taking ciprofloxacin and tell your doctor immediately to prevent the development of a potentially irreversible condition.
- You may develop **diarrhoea** while taking antibiotics, including **ciprofloxacino cinfra**, or even several weeks after you have stopped taking them. If the diarrhoea becomes severe or persistent, or you notice that your stools contain blood or mucus, stop taking **ciprofloxacino cinfra** immediately, as this can be life-threatening. Do not take medicinal products that stop or slow down bowel movements and consult your doctor.
- If you have to take **blood or urine tests** while you are taking **ciprofloxacino cinfra**, tell your doctor or laboratory staff.
- **ciprofloxacino cinfra** may cause liver damage. If you notice symptoms such as loss of appetite, jaundice (yellowing of the skin), dark urine, itching or tenderness of the stomach, stop taking **ciprofloxacino cinfra** and consult your doctor immediately.
- **ciprofloxacino cinfra** may cause a reduction in the white blood cell count and perhaps **decrease your resistance to infections**. If you suffer an infection with symptoms such as fever and severe deterioration in your general state of health, or fever with symptoms of local infection such as pain in the throat/pharynx/mouth or urinary problems, consult your doctor immediately. You will undergo a blood test to check for a possible decrease in white blood cells (agranulocytosis). It is important to tell your doctor about your medicine.
- Tell your doctor if you or a relative is known to have a deficiency in glucose-6-phosphate dehydrogenase (G6PD), since this may present a risk of anaemia with ciprofloxacin.
- Your skin will become more **sensitive to sunlight or ultraviolet (UV) light** when you are taking **ciprofloxacino cinfra**. Avoid exposure to strong sunlight or artificial ultraviolet light such as tanning booths.

Taking other medicines:

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

Do not take ciprofloxacino cinfra at the same time as tizanidine, because this may cause adverse effects, such as low blood pressure and drowsiness (see section 2: “Do not take **ciprofloxacino cinfra**”).

The following medicinal products are known to interact in your body with **ciprofloxacino cinfra**. If you take **ciprofloxacino cinfra** at the same time as these medicines, it can influence the therapeutic effect of these medicines. It can also increase the likelihood of suffering adverse 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 respiratory problems)
- Tizanidine (for muscle spasticity in multiple sclerosis)

- Clozapine (an antipsychotic)
- Ropinirole (for Parkinson's disease)
- Phenytoin (for epilepsy)

Tell your doctor if you are taking other medicines that can alter your heart rate: medicines that belong to the group of antiarrhythmics (quinidine, hydroquinidine, disopyramide, amiodarone, sotalol, dofetilide, ibutilide) tricyclic antidepressants, some antibiotics (that belong to the macrolides group) and some antipsychotics.

ciprofloxacin may increase the levels of the following medicines in the blood:

- Pentoxifylline (for circulatory disorders)
- Caffeine

Some medicines **reduce** the effect of **ciprofloxacin**. Tell your doctor if you are taking or wish to take:

- Antacids
- Mineral supplements
- Sucralfate
- A polymeric phosphate binder (for example, sevelamer)
- Medicines or supplements containing calcium, magnesium, aluminium or iron

If these preparations are essential, take **ciprofloxacin** approximately **two** hours before or **four hours after** taking these formulations.

Taking ciprofloxacin with food and drink

If you take **ciprofloxacin** with meals, you must not eat or drink dairy products (such as milk or yoghurt) or drinks with added calcium when you take the tablets, as they can affect the absorption of the active substance.

Pregnancy and breast-feeding

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

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

Do not take **ciprofloxacin** during the breast-feeding because ciprofloxacin is excreted in breast milk and may harm your baby.

Driving and using machines

ciprofloxacin can reduce your state of alertness. Some neurological effects may occur. Therefore, ensure you know how you react to **ciprofloxacin** before driving vehicles or operating machinery. If you have any doubts, consult your doctor.

3. How to take ciprofloxacin

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

Your doctor will explain exactly how much **ciprofloxacin** you must take, how often and for how long. This will depend on the type of infection you have and its severity.

Tell your doctor if you have kidney problems because it may be necessary to adjust your dose. Treatment generally lasts from 5 to 21 days, but can last longer for severe infections.

Take the tablets exactly as your doctor has indicated. If you have any doubts about how many **ciprofloxacin** tablets to take and how to take them, ask your doctor or pharmacist how many tablets you must take and how you must take them.

- Swallow the tablets with plenty of fluid. Do not chew the tablets because they do not taste nice.
- Try to take the tablets at the same time each day.
- You can take the tablets at mealtimes or between meals. The calcium you consume as part of a meal will not seriously affect the absorption of the medicine. Nevertheless, do not take **ciprofloxacin** tablets with dairy products such as milk or yoghurt, or mineral-enriched fruit juices (for example, orange juice enriched with calcium).

Remember to drink plenty of fluids while you are taking **ciprofloxacin**.

If you take more ciprofloxacin than you should:

If you take more than the prescribed dose, seek medical attention immediately. If possible, take the tablets or the box to show to the doctor.

If you forget to take ciprofloxacin:

Take the normal dose as soon as possible and then continue the treatment as has been prescribed for you. However, if it is almost time for the 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 the course of treatment.

If you stop taking ciprofloxacin

It is important that you **complete the course of treatment**, even if you start to feel better after a few days. If you stop taking this medicine too soon, your infection may not have been cured completely and the symptoms may worsen. You might also develop resistance to the antibiotic.

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

4. Possible side effects

Like all medicines, **ciprofloxacin** 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 tell your doctor or pharmacist.

Common side effects (between 1 and 10 in every 100 people are likely to get these):

- nausea, diarrhoea.
- joint pain in children.

Uncommon side effects (between 1 and 10 in every 1,000 people are likely to get these):

- mycotic superinfections (fungal)
- a high concentration of eosinophils, a type of white blood cell
- loss of appetite (anorexia)
- hyperactivity or agitation
- headache, dizziness, sleep problems or taste disorders
- vomiting, abdominal pain, gastrointestinal problems such as slow digestion (indigestion/acidity) or flatulence
- increase in the amount of certain substances in the blood (transaminases and/or bilirubin)
- rash, itching or hives
- joint pain in adults

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

Rare side effects (between 1 and 10 in every 10,000 people are likely to get these):

- inflammation of the bowel (colitis) linked to the use of antibiotics (can be fatal in very rare cases) (see section 2: Take special care with **ciprofloxacin cifa**)
- changes in the blood cell count (leukopenia, leukocytosis, neutropenia, anaemia), increased or decreased amounts of a blood coagulation factor (thrombocytes)
- allergic reaction, swelling (oedema) or rapid swelling of the skin and mucous membranes (angioedema)
- increased sugar in the blood (hyperglycaemia)
- confusion, disorientation, anxiety reactions, strange dreams, depression or hallucinations.
- tingling sensation and numbness, unusual sensitivity to sensory stimuli, decreased skin sensitivity, tremors, seizures (see section 2: Take special care with **ciprofloxacin cifa**) or dizziness
- eyesight problems
- tinnitus (ringing in the ears), loss of hearing, deterioration of hearing
- increased heart rate (tachycardia)
- expansion of the blood vessels (vasodilatation), drop in arterial blood pressure or fainting
- shortness of breath including symptoms of asthma
- liver disorders, jaundice (cholestatic jaundice), hepatitis
- sensitivity to light (see section 2: Take special care with **ciprofloxacin cifa**)
- muscle pain, inflammation of the joints, increased muscle tone or cramps
- kidney failure, blood or crystals in the urine (see section 2: Take special care with **ciprofloxacin cifa**), inflammation of the urinary tract
- fluid retention or excessive perspiration
- abnormal coagulation factor levels (prothrombin) or increased concentrations of the enzyme amylase

Very rare side effects (less than 1 in every 10,000 people are likely to get these):

- a particular type of reduction of the white blood cell count (haemolytic anaemia), a dangerous reduction of a type of white blood cell (agranulocytosis), a reduction of the amount of white and red 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 **ciprofloxacin cifa**)
- serious allergic reactions (anaphylactic reaction or anaphylactic shock, with risk of death - serum sickness) (see section 2: Take special care with **ciprofloxacin cifa**)
- mental disorders (psychotic reactions) (see section 2: Take special care with **ciprofloxacin cifa**)
- migraine, impaired coordination, instability when walking (abnormal gait), impaired sense of smell (olfactory disorders); pressure in the brain (intracranial pressure)
- visual distortions of colours
- inflammation of the blood vessel walls (vasculitis)
- pancreatitis
- death of liver cells (hepatic necrosis), which very rarely leads to liver failure with risk of death
- small localised bleeds under the skin (petechiae), diverse skin rashes or exanthema (for example, Stevens-Johnson syndrome which can be fatal or toxic epidermal necrolysis).
- muscle weakness, inflammation of the tendons, rupture of the tendons –especially the long tendon at the rear of the ankle (Achilles tendon) (see section 2: Take special care with **ciprofloxacin cifa**), worsening of symptoms of myasthenia gravis (see section 2: Take special care with **ciprofloxacin cifa**)

Frequency unknown (frequency cannot be estimated from the available data).

- problems related to the nervous system such as pain, burning, tingling, numbness and/or weakness in the limbs
- severe heart rhythm abnormalities, life-threatening irregular heart rate, altered heart rate (called "prolongation of QT interval" detected in electrocardiograms, recording of heart activity)
- pustular rash
- syndrome related to poor water secretion and low sodium concentrations (SIADH).
- Loss of consciousness due to severe decrease in blood sugar levels (hypoglycaemic coma). See Section 2.

The administration of antibiotics containing quinolones and fluoroquinolones has been linked to very rare cases of long lasting (up to months or years) or permanent adverse drug reactions, such as inflammation of tendons, tendon rupture, joint pain, pain in the limbs, difficulty 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, taste and smell, in some cases regardless the presence of pre-existing risk factors.

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 ciprofloxacin

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

Do not store at a temperature above 25°C.

Expiry

Do not use **ciprofloxacin** after the expiry date stated on the package 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 you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What ciprofloxacin 250 mg coated tablets contains

- The active substance is ciprofloxacin.
- The other ingredients are: croscarmellose sodium, microcrystalline cellulose (E-460), anhydrous colloidal silica, cornstarch, sodium lauryl sulphate, magnesium stearate (E-470b), talc (E-553b), hypromellose (E-464), titanium dioxide (E-171), macrogol 400.

What ciprofloxacin looks like and contents of the pack

ciprofloxacin 250 mg coated tablets are presented in tablet form. Each package contains 14 tablets.

Marketing authorisation holder and manufacturer:

Laboratorios Cinfa, S.A.
Carretera Olaz-Chipi, 10. Polígono Industrial Areta,
31620, Huarte (Navarra) Spain

Distributor

Reich Pharm Limited
Unit 3001, 30/F, Citicorp Centre,
18 Whitfield Road,
Hong Kong
Tel.: 2470 1927
Fax: 2470 3448

HK Reg.No. : HK-51580

This leaflet was last revised in: April 2019

Advice/medical guidance

Antibiotics are used to treat bacterial infections. They are not effective against viral infections. If your doctor has prescribed you antibiotics, you need them specifically for your current illness. Despite the antibiotics, some bacteria can survive or grow. This phenomenon is known as resistance: some treatments with antibiotics are becoming ineffective.

Improper use of antibiotics increases resistance. You may even help the bacteria to become more resistant and, therefore, delay your cure or reduce the effectiveness of antibiotics if you do not comply with:

- dosage
- the schedule
- the duration of the treatment

Consequently, to maintain the effectiveness of this medicine:

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 antibiotics to another person; they might not be suitable for their illness.
5. When you finish your treatment, return all unused medicines to the chemist, to ensure they are disposed of correctly.

Package leaflet: information for the user

ciprofloxacin cinfa 500 mg coated tablets ciprofloxacin

Read all of this leaflet carefully before you start taking 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 tell your doctor or pharmacist. See section 4.

What is in this leaflet:

1. What **ciprofloxacin cinfa** is and what it is used for
2. What you need to know before you take **ciprofloxacin cinfa**
3. How to take **ciprofloxacin cinfa**
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6. Contents of the pack and other information

1. What ciprofloxacin cinfa is and what it is used for

ciprofloxacin cinfa is an antibiotic that belongs to the fluoroquinolone family. The active substance is ciprofloxacin. Ciprofloxacin acts by eliminating the bacteria that cause infections. It only works with specific strains of bacteria.

Antibiotics are used to treat bacterial infections. They are not effective in the treatment of viral infections, such as flu or colds.

Please follow your doctor's instructions with regard to dose, times and duration of treatment carefully.

Do not keep this medicine or use it to treat other conditions. If you have any antibiotic remaining at the end of your course of treatment, please return it to your pharmacist, who will dispose of it properly. Do not dispose of any medicines via wastewater or household waste.

Adults:

ciprofloxacin cinfa is used in adults to treat the following bacterial infections:

- infections of the respiratory tract
- recurrent or long-lasting infections of the ear or sinuses
- urinary tract infections
- genital tract infections in men and women
- infections of the gastrointestinal tract and intra-abdominal infections
- infections of the skin and soft tissue
- infections of the bones and joints
- treatment of infections in patients with a very low white blood cell count (neutropenia)
- prevention of infections in patients with a very low white blood cell count (neutropenia)
- prevention of infections caused by the bacterium *Neisseria meningitidis*

- exposure to anthrax by inhalation

If you suffer a severe infection, or if the infection is caused by more than one type of bacterium, it is possible that you will be administered an additional antibiotic treatment, in addition to **ciprofloxacin**.

Children and adolescents:

ciprofloxacin is used in children and adolescents, under specialised medical supervision, to treat the following bacterial infections:

- lung and bronchial infections in children and adolescents suffering from cystic fibrosis
- complicated infections of the urinary tract, including infections that have reached the kidneys (pyelonephritis)
- exposure to anthrax by inhalation

ciprofloxacin can also be used to treat severe infections in children and adolescents when deemed necessary.

2. What you need to know before you take ciprofloxacin

- If you are allergic (hypersensitive) to the active substance, to other quinolone drugs, or to any of the other ingredients of **ciprofloxacin** (see section 6).
- If you are taking tizanidine (see section 2: Taking other medicines).

Take special care with ciprofloxacin: Before taking this medicinal product

Do not take antibacterial medicinal products containing fluoroquinolones or quinolones, including ciprofloxacin, if you have previously experienced any serious adverse reaction when taking a quinolone or fluoroquinolone. If you have, you must inform your doctor as soon as possible.

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.

Talk to your doctor before taking ciprofloxacin if you:

- have ever had kidney problems because your treatment will have to be adjusted
- suffer from epilepsy or other neurological conditions
- have a history of tendon problems during previous treatment with antibiotics like ciprofloxacin.
- suffer from myasthenia gravis (a type of muscle weakness)
- suffer from or have a family history of prolongation of the QT interval (detected in electrocardiograms, recording of heart activity)
- have a salt imbalance in the blood (especially if you have low levels of potassium and magnesium)
- have a very slow heart rate (called ‘bradycardia’).
- have a weak heart (heart failure), or you have suffered a heart attack (myocardial infarction).
- are a female or elderly patient
- are taking other medicines that can cause changes in the electrocardiogram (*see the section Taking other medicines*).

- have been diagnosed with enlargement or a “bulge” in a large blood vessel (aortic aneurysm or large vessel peripheral aneurysm).
- have experienced a previous episode of aortic dissection (tear in the wall of the aorta).
- have a family history of aortic aneurysm or aortic dissection or other risk factors or predisposing conditions (e.g. connective tissue disorders like Marfan syndrome or vascular Ehlers-Danlos syndrome, or vascular disorders such as Takayasu’s arteritis, giant cell arteritis, Behçet’s disease, arterial hypertension or known atherosclerosis).

- **During treatment with this medicinal product:**

Tell your doctor immediately if any of the following situations arise while taking **ciprofloxacin cinfa**. Your doctor will decide if the treatment with **ciprofloxacin cinfa** needs to be stopped

If you feel a sudden sharp pain in your abdomen or back, seek emergency medical attention immediately.

Consult an ophthalmologist immediately if you experience impaired vision or any problem with your eyes.

- **Sudden severe allergic reactions** (anaphylactic shock or reaction, angioedema). There is a small possibility that, even with the first dose, 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, do not take any more **ciprofloxacin cinfa** and contact your doctor immediately.

Serious, disabling, long-lasting, and potentially irreversible adverse reactions

Antibacterial medicines containing fluoroquinolones or quinolones, including ciprofloxacin, have been associated with very rare but serious adverse effects, some of which were long-lasting (persisting for months or years), disabling or potentially irreversible. This includes pain in the tendons, muscles and joints of the upper and lower limbs, difficulty in walking, abnormal sensations such as sharp pains, tingling, tickling, numbness or a burning sensation (paraesthesia), disorders of the senses such as impaired vision, taste, smell and hearing, depression, memory impairment, intense fatigue and severe sleep disorders.

If you experience any of these adverse effects after taking ciprofloxacin cinfa[®], contact your doctor immediately, before continuing with the treatment. You and your doctor will decide whether to continue the treatment or not, also considering the use of a different class of antibiotic.

- On rare occasions, pain and swelling in the joints and inflammation or rupture of the tendons may occur. The risk is greater if you are elderly (over 60 years of age), have received an organ transplant, have kidney problems or are being treated with corticosteroids. Inflammation and rupture of tendons can occur within the first 48 hours of treatment and even up to several months after stopping treatment with ciprofloxacin. At the first sign of pain or inflammation of a tendon (for example, in the ankle, wrist, elbow, shoulder or knee), stop taking ciprofloxacin cinfa, contact your doctor and rest the painful area. Avoid any unnecessary exercise, as this could increase the risk of tendon rupture.
- If you suffer from **epilepsy** or any other **neurological conditions**, such as cerebral ischaemia or stroke, you may suffer adverse effects associated with the central nervous system. If this happens, stop taking **ciprofloxacin cinfa** and contact your doctor immediately.
- You may suffer **psychiatric reactions** the first time you take **ciprofloxacin cinfa**. If you suffer **depression** or **psychosis**, your symptoms may worsen with treatment with

ciprofloxacino cinfra. If this happens, stop taking **ciprofloxacino cinfra** and contact your doctor immediately.

- On rare occasions, you may experience symptoms of nerve damage (neuropathy) such as pain, burning, tingling, numbness and/or weakness, especially in the feet and legs or the hands and arms. If this happens, stop taking ciprofloxacin and tell your doctor immediately to prevent the development of a potentially irreversible condition.
- You may develop **diarrhoea** while taking antibiotics, including **ciprofloxacino cinfra**, or even several weeks after having stopped taking them. If the diarrhoea becomes severe or persistent, or you notice that your stools contain blood or mucus, stop taking **ciprofloxacino cinfra** immediately, as this can be life-threatening. Do not take medicinal products that stop or slow down bowel movements and consult your doctor.
- If you have to take **blood or urine tests** while you are taking **ciprofloxacino cinfra**, tell your doctor or laboratory staff.
- **ciprofloxacino cinfra** may cause liver damage. If you notice symptoms such as loss of appetite, jaundice (yellowing of the skin), dark urine, itching or tenderness of the stomach, stop taking **ciprofloxacino cinfra** and consult your doctor immediately.
- **ciprofloxacino cinfra** may cause a reduction in the white blood cell count and perhaps **decrease your resistance to infections**. If you suffer an infection with symptoms such as fever and severe deterioration in your general state of health, or fever with symptoms of local infection such as pain in the throat/pharynx/mouth or problems urinating, consult your doctor immediately. You will undergo a blood test to check for a possible decrease in white blood cells (agranulocytosis). It is important to tell your doctor about your medicine.
- Tell your doctor if you or a relative is known to have a deficiency in glucose-6-phosphate dehydrogenase (G6PD), since this may present a risk of anaemia with ciprofloxacin.
- Your skin will become more **sensitive to sunlight or ultraviolet (UV) light** when you are taking **ciprofloxacino cinfra**. Avoid exposure to strong sunlight or artificial ultraviolet light such as tanning booths.

Other medicines:

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

Do not take ciprofloxacino cinfra at the same time as tizanidine, because this may cause adverse effects, such as low blood pressure and drowsiness (see section 2: “Do not take **ciprofloxacino cinfra**”).

The following medicinal products are known to interact in your body with **ciprofloxacino cinfra**. If you take **ciprofloxacino cinfra** at the same time as these medicines, it can influence the therapeutic effect of these medicines. It can also increase the likelihood of suffering adverse 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 respiratory problems)
- Tizanidine (for muscle spasticity in multiple sclerosis)

- Clozapine (an antipsychotic)
- Ropinirole (for Parkinson's disease)
- Phenytoin (for epilepsy)

Tell your doctor if you are taking other medicines that can alter your heart rate: medicines that belong to the group of antiarrhythmics (quinidine, hydroquinidine, disopyramide, amiodarone, sotalol, dofetilide, ibutilide) tricyclic antidepressants, some antibiotics (that belong to the macrolides group) and some antipsychotics.

ciprofloxacin may increase the levels in the blood of the following medicines:

- Pentoxifylline (for circulatory disorders)
- Caffeine

Some medicines **reduce** the effect of **ciprofloxacin**. Tell your doctor if you are taking or wish to take:

- Antacids
- Mineral supplements
- Sucralfate
- A polymeric phosphate binder (for example, sevelamer)
- Medicines or supplements containing calcium, magnesium, aluminium or iron

If these preparations are essential, take **ciprofloxacin** approximately **two** hours before or **four hours after** taking these formulations.

Taking ciprofloxacin with food and drink

If you take **ciprofloxacin** with meals, you must not eat or drink dairy products (such as milk or yoghurt) or drinks with added calcium when you take the tablets, as this can affect the absorption of the active substance.

Pregnancy and breast-feeding

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

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

Do not take **ciprofloxacin** during the breast-feeding because ciprofloxacin is excreted in breast milk and may harm your baby.

Driving and using machines

ciprofloxacin can reduce your state of alertness. Some neurological effects may occur. Therefore, ensure you know how you react to **ciprofloxacin** before driving vehicles or operating machines. If you have any doubts, consult your doctor.

3. How to take ciprofloxacin

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

Your doctor will explain exactly how much **ciprofloxacin** you must take, how often and for how long. This will depend on the type of infection you have and its severity.

Tell your doctor if you have kidney problems because it may be necessary to adjust your dose.

Treatment generally lasts from 5 to 21 days, but can last longer for more severe infections. Take the tablets exactly as your doctor has indicated. If you have any doubts about how many **ciprofloxacin** tablets to take and how to take them, ask your doctor or pharmacist how many tablets you must take and how you must take them.

- Swallow the tablets with plenty of fluid. Do not chew the tablets because they do not taste nice.
- Try to take the tablets at the same time each day.
- You can take the tablets at mealtimes or between meals. The calcium you consume as part of a meal will not seriously affect the absorption of the medicine. Nevertheless, do not take **ciprofloxacin** tablets with dairy products such as milk or yoghurt, or mineral-enriched fruit juices (for example, orange juice enriched with calcium).

Remember to drink plenty of fluids while you are taking **ciprofloxacin**.

If you take more ciprofloxacin than you should

If you take more than the prescribed dose, seek medical attention immediately. If possible, take the tablets or the box to show to the doctor.

If you forget to take ciprofloxacin

Take the normal dose as soon as possible and then continue the treatment as has been prescribed for you. However, if it is almost time for the 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 the course of treatment.

If you stop taking ciprofloxacin

It is important that you **complete the course of treatment**, even if you start to feel better after a few days. If you stop taking this medicine too soon, your infection may not have been cured completely and the symptoms may worsen. You might also develop resistance to the antibiotic.

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

4. Possible side effects

Like all medicines, **ciprofloxacin** 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 tell your doctor or pharmacist.

Common side effects (between 1 and 10 in every 100 people are likely to get these):

- nausea, diarrhoea
- joint pain in children

Uncommon side effects (between 1 and 10 in every 1,000 people are likely to get these):

- mycotic superinfections (fungal)
- a high concentration of eosinophils, a type of white blood cell
- loss of appetite (anorexia)
- hyperactivity or agitation
- headache, dizziness, sleep problems or taste disorders
- vomiting, abdominal pain, gastrointestinal problems such as slow digestion (indigestion/acidity) or flatulence
- increase in the amount of certain substances in the blood (transaminases and/or bilirubin)

- rash, itching or hives
- joint pain in adults
- impaired kidney function
- pain in muscles and bones, feeling unwell (asthenia) or fever
- increase in blood alkaline phosphatase (a certain substance in the blood)

Rare side effects (between 1 and 10 in every 10,000 people are likely to get these):

- inflammation of the intestines (colitis) linked to the use of antibiotics (can be fatal in very rare cases) (see section 2: Take special care with **ciprofloxacin**)
- changes in the blood cell count (leukopenia, leukocytosis, neutropenia, anaemia), increased or decreased amounts of a blood coagulation factor (thrombocytes)
- allergic reaction, swelling (oedema) or rapid swelling of the skin and mucous membranes (angioedema)
- increased sugar in the blood (hyperglycaemia)
- confusion, disorientation, anxiety reactions, strange dreams, depression or hallucinations.
- tingling sensation and numbness, unusual sensitivity to sensory stimuli, reduced skin sensitivity, tremors, seizures (see section 2: Take special care with **ciprofloxacin**) or dizziness
- eyesight problems
- tinnitus (ringing in the ears), loss of hearing, deterioration of hearing
- increased heart rate (tachycardia)
- expansion of the blood vessels (vasodilatation), drop in arterial blood pressure or fainting
- shortness of breath including symptoms of asthma
- liver disorders, jaundice (cholestatic jaundice), hepatitis
- sensitivity to light (see section 2: Take special care with **ciprofloxacin**)
- muscle pain, inflammation of the joints, increased muscle tone or cramps
- kidney failure, blood or crystals in the urine (see section 2: Take special care with **ciprofloxacin**), inflammation of the urinary tract
- fluid retention or excessive perspiration
- abnormal coagulation factor levels (prothrombin) or increased concentrations of the enzyme amylase

Very rare side effects (less than 1 in every 10,000 people are likely to get these):

- a particular type of reduction of the white blood cell count (haemolytic anaemia), a dangerous reduction of a type of white blood cell (agranulocytosis), a reduction of the amount of white and red 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 **ciprofloxacin**)
- serious allergic reactions (anaphylactic reaction or anaphylactic shock, with risk of death - serum sickness) (see section 2: Take special care with **ciprofloxacin**)
- mental disorders (psychotic reactions) (see section 2: Take special care with ciprofloxacin)
- migraine, impaired coordination, instability when walking (abnormal gait), impaired sense of smell (olfactory disorders); pressure in the brain (intracranial pressure)
- visual distortions of colours
- inflammation of the blood vessel walls (vasculitis)
- pancreatitis
- death of liver cells (hepatic necrosis), which very rarely leads to liver failure with risk of death
- small localised bleeds under the skin (petechiae), diverse skin rashes or exanthema (for example, Stevens-Johnson syndrome which can be fatal or toxic epidermal necrolysis).
- muscle weakness, inflammation of the tendons, rupture of the tendons –especially the long tendon at the rear of the ankle (Achilles tendon) (see section 2: Take special care with

ciprofloxacin), worsening of symptoms of myasthenia gravis (see section 2: Take special care with **ciprofloxacin**)

Frequency unknown (frequency cannot be estimated from the available data):

- problems related to the nervous system such as pain, burning, tingling, numbness and/or weakness in the limbs
- severe heart rhythm abnormalities, life-threatening irregular heart rate, altered heart rate (called "prolongation of the QT interval" detected in electrocardiograms, recording of heart activity).
- pustular rash
- syndrome related to poor water secretion and low sodium concentrations (SIADH).
- Loss of consciousness due to severe decrease in blood sugar levels (hypoglycaemic coma). See Section 2.

The administration of antibiotics containing quinolones and fluoroquinolones has been linked to very rare cases of long lasting (up to months or years) or permanent adverse drug reactions, such as inflammation of tendons, tendon rupture, joint pain, pain in the limbs, difficulty 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, taste and smell, in some cases regardless the presence of pre-existing risk factors.

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 ciprofloxacin

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

Do not store at a temperature above 25°C

Expiry

Do not use **ciprofloxacin** after the expiry date stated on the package 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 you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What ciprofloxacin 500 mg coated tablets contains

- The active substance is ciprofloxacin.
- The other ingredients are: croscarmellose sodium, microcrystalline cellulose (E-460), anhydrous colloidal silica, cornstarch, sodium lauryl sulphate, magnesium stearate (E-470b), talc (E-553b), hypromellose (E-464), titanium dioxide (E-171), macrogol 400.

What ciprofloxacin looks like and contents of the pack

ciprofloxacin 500 mg coated tablets are presented in the form of scored tablets.

Each package contains 14 tablets.

Marketing authorisation holder and manufacturer:

Laboratorios Cinfa, S.A.
Carretera Olaz-Chipi, 10. Polígono Industrial Areta,
31620, Huarte (Navarre) Spain

This leaflet was last revised in: April 2019

Advice/medical guidance

Antibiotics are used to treat bacterial infections. They are not effective against viral infections. If your doctor has prescribed you antibiotics, you need them specifically for your current illness. Despite the antibiotics, some bacteria can survive or grow. This phenomenon is known as resistance: some treatments with antibiotics are becoming ineffective.

Improper use of antibiotics increases resistance. You may even help the bacteria to become more resistant and, therefore, delay your cure or reduce the effectiveness of antibiotics if you do not comply with:

- dosage
- the schedule
- the duration of the treatment

Consequently, to maintain the effectiveness of this medicine:

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 antibiotics to another person; they might not be suitable for their illness.
5. When you finish your treatment, return all unused medicines to the chemist, to ensure they are disposed of correctly.

Package leaflet: information for the user

ciprofloxacin cinfa 750 mg coated tablets
ciprofloxacin

Read all of this leaflet carefully before you start taking 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 tell your doctor or pharmacist. See section 4.

What is in this leaflet:

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

1. What ciprofloxacin cinfa is and what it is used for

ciprofloxacin cinfa is an antibiotic that belongs to the fluoroquinolone family. The active substance is ciprofloxacin. Ciprofloxacin acts by eliminating the bacteria that cause infections. It only works with specific strains of bacteria.

Antibiotics are used to treat bacterial infections. They are not effective in the treatment of viral infections, such as flu or colds.

Please follow your doctor's instructions with regard to dose, times and duration of treatment carefully.

Do not keep this medicine or use it to treat other conditions. If you have any antibiotic remaining at the end of your course of treatment, please return it to your pharmacist, who will dispose of it properly. Do not dispose of any medicines via wastewater or household waste.

Adults:

ciprofloxacin cinfa is used in adults to treat the following bacterial infections:

- infections of the respiratory tract
- recurrent or long-lasting infections of the ear or sinuses
- urinary tract infections
- genital tract infections in men and women
- infections of the gastrointestinal tract and intra-abdominal infections
- infections of the skin and soft tissue
- infections of the bones and joints
- treatment of infections in patients with a very low white blood cell count (neutropenia)
- prevention of infections in patients with a very low white blood cell count (neutropenia)
- prevention of infections caused by the bacterium *Neisseria meningitidis*

- exposure to anthrax by inhalation

If you suffer a severe infection, or if the infection is caused by more than one type of bacterium, it is possible that you will be administered an additional antibiotic treatment, in addition to **ciprofloxacin**.

Children and adolescents:

ciprofloxacin is used in children and adolescents, under specialised medical supervision, to treat the following bacterial infections:

- lung and bronchial infections in children and adolescents suffering from cystic fibrosis
- complicated infections of the urinary tract, including infections that have reached the kidneys (pyelonephritis)
- exposure to anthrax by inhalation

ciprofloxacin can also be used to treat severe infections in children and adolescents when deemed necessary.

2. What you need to know before you take ciprofloxacin

- If you are allergic (hypersensitive) to the active substance, to other quinolone drugs, or to any of the other ingredients of **ciprofloxacin** (see section 6).
- If you are taking tizanidine (see section 2: Taking other medicines).

Take special care with ciprofloxacin: Before taking this medicinal product

Do not take antibacterial medicinal products containing fluoroquinolones or quinolones, including ciprofloxacin, if you have previously experienced any serious adverse reaction when taking a quinolone or fluoroquinolone. If you have, you must inform your doctor as soon as possible.

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.

- Talk to your doctor before taking ciprofloxacin if you:

- have ever had kidney problems because your treatment will have to be adjusted
- suffer from epilepsy or other neurological conditions
- have a history of tendon problems during previous treatment with antibiotics like ciprofloxacin
- suffer from myasthenia gravis (a type of muscle weakness)
- suffer from or have a family history of prolongation of the QT interval (detected in electrocardiograms, recording of heart activity)
- have a salt imbalance in the blood (especially if you have low levels of potassium and magnesium)
- have a very slow heart rate (called ‘bradycardia’)
- have a weak heart (heart failure), or you have suffered a heart attack (myocardial infarction)
- are a female or elderly patient
- are taking other medicines that can cause changes in the electrocardiogram (*see the section Taking other medicines*)

- have been diagnosed with enlargement or a “bulge” in a large blood vessel (aortic aneurysm or large vessel peripheral aneurysm)
- have experienced a previous episode of aortic dissection (tear in the wall of the aorta)
- have a family history of aortic aneurysm or aortic dissection or other risk factors or predisposing conditions (e.g. connective tissue disorders like Marfan syndrome or vascular Ehlers-Danlos syndrome, or vascular disorders such as Takayasu’s arteritis, giant cell arteritis, Behçet’s disease, arterial hypertension or known atherosclerosis).

- **During treatment with this medicinal product:**

Tell your doctor immediately if any of the following situations arise while taking **ciprofloxacin cinfa**. Your doctor will decide if the treatment with **ciprofloxacin cinfa** needs to be stopped

If you feel a sudden sharp pain in your abdomen or back, seek emergency medical attention immediately.

Consult an ophthalmologist immediately if you experience impaired vision or any problem with your eyes.

- **Sudden severe allergic reactions** (anaphylactic shock or reaction, angioedema). There is a small possibility that, even with the first dose, 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, do not take any more **ciprofloxacin cinfa** and contact your doctor immediately.

Serious, disabling, long-lasting, and potentially irreversible adverse reactions

Antibacterial medicines containing fluoroquinolones or quinolones, including ciprofloxacin, have been associated with very rare but serious adverse effects, some of which were long-lasting (persisting for months or years), disabling or potentially irreversible. This includes pain in the tendons, muscles and joints of the upper and lower limbs, difficulty in walking, abnormal sensations such as sharp pains, tingling, tickling, numbness or a burning sensation (paraesthesia), disorders of the senses such as impaired vision, taste, smell and hearing, depression, memory impairment, intense fatigue and severe sleep disorders.

If you experience any of these adverse effects after taking ciprofloxacin cinfa[®], contact your doctor immediately, before continuing with the treatment. You and your doctor will decide whether to continue the treatment or not, also considering the use of a different class of antibiotic.

- On rare occasions, pain and swelling in the joints and inflammation or rupture of the tendons may occur. The risk is greater if you are elderly (over 60 years of age), have received an organ transplant, have kidney problems or are being treated with corticosteroids. Inflammation and rupture of tendons can occur within the first 48 hours of treatment and even up to several months after stopping treatment with ciprofloxacin. At the first sign of pain or inflammation of a tendon (for example, in the ankle, wrist, elbow, shoulder or knee), stop taking ciprofloxacin cinfa, contact your doctor and rest the painful area. Avoid any unnecessary exercise, as this could increase the risk of tendon rupture.
- If you suffer from **epilepsy** or any other **neurological conditions**, such as cerebral ischaemia or stroke, you may suffer adverse effects associated with the central nervous system. If this happens, stop taking **ciprofloxacin cinfa** and contact your doctor immediately.
- You may suffer **psychiatric reactions** the first time you take **ciprofloxacin cinfa**. If you suffer **depression** or **psychosis**, your symptoms may worsen with treatment with

ciprofloxacino cinsa. If this happens, stop taking **ciprofloxacino cinsa** and contact your doctor immediately.

- On rare occasions, you may experience symptoms of nerve damage (neuropathy) such as pain, burning, tingling, numbness and/or weakness, especially in the feet and legs or the hands and arms. If this happens, stop taking ciprofloxacin and tell your doctor immediately to prevent the development of a potentially irreversible condition.
- You may develop **diarrhoea** while taking antibiotics, including **ciprofloxacino cinsa**, or even several weeks after having stopped taking them. If the diarrhoea becomes severe or persistent, or you notice that your stools contain blood or mucus, stop taking **ciprofloxacino cinsa** immediately, as this can be life-threatening. Do not take medicinal products that stop or slow down bowel movements and consult your doctor.
- If you have to take **blood or urine tests** while you are taking **ciprofloxacino cinsa**, tell your doctor or laboratory staff.
- **ciprofloxacino cinsa** may cause liver damage. If you notice symptoms such as loss of appetite, jaundice (yellowing of the skin), dark urine, itching or tenderness of the stomach, stop taking **ciprofloxacino cinsa** and consult your doctor immediately.
- **ciprofloxacino cinsa** may cause a reduction in the white blood cell count and perhaps **decrease your resistance to infections**. If you suffer an infection with symptoms such as fever and severe deterioration in your general state of health, or fever with symptoms of local infection such as pain in the throat/pharynx/mouth or problems urinating, consult your doctor immediately. You will undergo a blood test to check for a possible decrease in white blood cells (agranulocytosis). It is important to tell your doctor about your medicine.
- Tell your doctor if you or a relative is known to have a deficiency in glucose-6-phosphate dehydrogenase (G6PD), since this may present a risk of anaemia with ciprofloxacin.
- Your skin will become more **sensitive to sunlight or ultraviolet (UV) light** when you are taking **ciprofloxacino cinsa**. Avoid exposure to strong sunlight or artificial ultraviolet light such as tanning booths.

Other medicines:

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

Do not take ciprofloxacino cinsa at the same time as tizanidine, because this may cause adverse effects, such as low blood pressure and drowsiness (see section 2: “Do not take **ciprofloxacino cinsa**”).

The following medicinal products are known to interact in your body with **ciprofloxacino cinsa**. If you take **ciprofloxacino cinsa** at the same time as these medicines, it can influence the therapeutic effect of these medicines. It can also increase the likelihood of suffering adverse 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 respiratory problems)
- Tizanidine (for muscle spasticity in multiple sclerosis)

- Clozapine (an antipsychotic)
- Ropinirole (for Parkinson's disease)
- Phenytoin (for epilepsy)

Tell your doctor if you are taking other medicines that can alter your heart rate: medicines that belong to the group of antiarrhythmics (quinidine, hydroquinidine, disopyramide, amiodarone, sotalol, dofetilide, ibutilide) tricyclic antidepressants, some antibiotics (that belong to the macrolides group) and some antipsychotics.

ciprofloxacin may increase the levels in the blood of the following medicines:

- Pentoxifylline (for circulatory disorders)
- Caffeine

Some medicines **reduce** the effect of **ciprofloxacin**. Tell your doctor if you are taking or wish to take:

- Antacids
- Mineral supplements
- Sucralfate
- A polymeric phosphate binder (for example, sevelamer)
- Medicines or supplements containing calcium, magnesium, aluminium or iron

If these preparations are essential, take **ciprofloxacin** approximately **two** hours before or **four hours after** taking these formulations.

Taking ciprofloxacin with food and drink:

If you take **ciprofloxacin** with meals, you must not eat or drink dairy products (such as milk or yoghurt) or drinks with added calcium when you take the tablets, as this can affect the absorption of the active substance.

Pregnancy and breast-feeding

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

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

Do not take **ciprofloxacin** during the breast-feeding because ciprofloxacin is excreted in breast milk and may harm your baby.

Driving and using machines

ciprofloxacin can reduce your state of alertness. Some neurological effects may occur. Therefore, ensure you know how you react to **ciprofloxacin** before driving vehicles or operating machines. If you have any doubts, consult your doctor.

3. How to take ciprofloxacin

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

Your doctor will explain exactly how much **ciprofloxacin** you must take, how often and for how long. This will depend on the type of infection you have and its severity.

Tell your doctor if you have kidney problems because it may be necessary to adjust your dose.

Treatment generally lasts from 5 to 21 days, but can last longer for more severe infections. Take the tablets exactly as your doctor has indicated. If you have any doubts about how many **ciprofloxacin** tablets to take and how to take them, ask your doctor or pharmacist how many tablets you must take and how you must take them.

- Swallow the tablets with plenty of fluid. Do not chew the tablets because they do not taste nice.
- Try to take the tablets at the same time each day.
- You can take the tablets at mealtimes or between meals. The calcium you consume as part of a meal will not seriously affect the absorption of the medicine. Nevertheless, do not take **ciprofloxacin** tablets with dairy products such as milk or yoghurt, or mineral-enriched fruit juices (for example, orange juice enriched with calcium).

Remember to drink plenty of fluids while you are taking **ciprofloxacin**.

If you take more ciprofloxacin than you should:

If you take more than the prescribed dose, seek medical attention immediately. If possible, take the tablets or the box to show to the doctor.

If you forget to take ciprofloxacin:

Take the normal dose as soon as possible and then continue the treatment as has been prescribed for you. However, if it is almost time for the 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 the course of treatment.

If you stop taking ciprofloxacin

It is important that you **complete the course of treatment**, even if you start to feel better after a few days. If you stop taking this medicine too soon, your infection may not have been cured completely and the symptoms may worsen. You might also develop resistance to the antibiotic.

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

4. Possible side effects

Like all medicines, **ciprofloxacin** 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 tell your doctor or pharmacist.

Common side effects (between 1 and 10 in every 100 people are likely to get these):

- nausea, diarrhoea
- joint pain in children

Uncommon side effects (between 1 and 10 in every 1,000 people are likely to get these):

- mycotic superinfections (fungal)
- a high concentration of eosinophils, a type of white blood cell
- loss of appetite (anorexia)
- hyperactivity or agitation
- headache, dizziness, sleep problems or taste disorders
- vomiting, abdominal pain, gastrointestinal problems such as slow digestion (indigestion/acidity) or flatulence
- increase in the amount of certain substances in the blood (transaminases and/or bilirubin)

- rash, itching or hives
- joint pain in adults
- impaired kidney function
- pain in muscles and bones, feeling unwell (asthenia) or fever
- increase in blood alkaline phosphatase (a certain substance in the blood)

Rare side effects (between 1 and 10 in every 10,000 people are likely to get these):

- inflammation of the intestines (colitis) linked to the use of antibiotics (can be fatal in very rare cases) (see section 2: Take special care with **ciprofloxacin**)
- changes in the blood cell count (leukopenia, leukocytosis, neutropenia, anaemia), increased or decreased amounts of a blood coagulation factor (thrombocytes)
- allergic reaction, swelling (oedema) or rapid swelling of the skin and mucous membranes (angioedema)
- increased sugar in the blood (hyperglycaemia)
- confusion, disorientation, anxiety reactions, strange dreams, depression or hallucinations.
- tingling sensation and numbness, unusual sensitivity to sensory stimuli, reduced skin sensitivity, tremors, seizures (see section 2: Take special care with **ciprofloxacin**) or dizziness
- eyesight problems
- tinnitus (ringing in the ears), loss of hearing, deterioration of hearing
- increased heart rate (tachycardia)
- expansion of the blood vessels (vasodilatation), drop in arterial blood pressure or fainting
- shortness of breath including symptoms of asthma
- liver disorders, jaundice (cholestatic jaundice), hepatitis
- sensitivity to light (see section 2: Take special care with **ciprofloxacin**)
- muscle pain, inflammation of the joints, increased muscle tone or cramps
- kidney failure, blood or crystals in the urine (see section 2: Take special care with **ciprofloxacin**), inflammation of the urinary tract
- fluid retention or excessive perspiration
- abnormal coagulation factor levels (prothrombin) or increased concentrations of the enzyme amylase

Very rare side effects (less than 1 in every 10,000 people are likely to get these):

- a particular type of reduction of the white blood cell count (haemolytic anaemia), a dangerous reduction of a type of white blood cell (agranulocytosis), a reduction of the amount of white and red 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 **ciprofloxacin**)
- serious allergic reactions (anaphylactic reaction or anaphylactic shock, with risk of death - serum sickness) (see section 2: Take special care with **ciprofloxacin**)
- mental disorders (psychotic reactions) (see section 2: Take special care with ciprofloxacin)
- migraine, impaired coordination, instability when walking (abnormal gait), impaired sense of smell (olfactory disorders); pressure in the brain (intracranial pressure)
- visual distortions of colours
- inflammation of the blood vessel walls (vasculitis)
- pancreatitis
- death of liver cells (hepatic necrosis), which very rarely leads to liver failure with risk of death
- small localised bleeds under the skin (petechiae), diverse skin rashes or exanthema (for example, Stevens-Johnson syndrome which can be fatal or toxic epidermal necrolysis).
- muscle weakness, inflammation of the tendons, rupture of the tendons –especially the long tendon at the rear of the ankle (Achilles tendon) (see section 2: Take special care with

ciprofloxacin), worsening of symptoms of myasthenia gravis (see section 2: Take special care with **ciprofloxacin**)

Frequency unknown (frequency cannot be estimated from the available data):

- problems related to the nervous system such as pain, burning, tingling, numbness and/or weakness in the limbs
- severe heart rhythm abnormalities, life-threatening irregular heart rate, altered heart rate (called "prolongation of the QT interval" detected in electrocardiograms, recording of heart activity).
- pustular rash
- syndrome related to poor water secretion and low sodium concentrations (SIADH).
- Loss of consciousness due to severe decrease in blood sugar levels (hypoglycaemic coma). See Section 2.

The administration of antibiotics containing quinolones and fluoroquinolones has been linked to very rare cases of long lasting (up to months or years) or permanent adverse drug reactions, such as inflammation of tendons, tendon rupture, joint pain, pain in the limbs, difficulty 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, taste and smell, in some cases regardless the presence of pre-existing risk factors.

Reporting of side effects

If you see any side effects, talk to your doctor or pharmacist. This includes any 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 ciprofloxacin

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

Do not store at a temperature above 25°C.

Expiry

Do not use **ciprofloxacin** after the expiry date stated on the package 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 you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What ciprofloxacin 750 mg coated tablets contains

- The active substance is ciprofloxacin.
- The other ingredients are: croscarmellose sodium, microcrystalline cellulose (E-460), anhydrous colloidal silica, cornstarch, sodium lauryl sulphate, magnesium stearate (E-470b), talc (E-553b), hypromellose (E-464), titanium dioxide (E-171), macrogol 400.

What ciprofloxacin looks like and contents of the pack

ciprofloxacin 750 mg coated tablets are presented in the form of scored tablets.

Each package contains 14 tablets.

Marketing authorisation holder and manufacturer:

Laboratorios Cinfa, S.A.
Carretera Olaz-Chipi, 10. Polígono Industrial Areta,
31620, Huarte (Navarre) Spain

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Advice/medical guidance

Antibiotics are used to treat bacterial infections. They are not effective against viral infections. If your doctor has prescribed you antibiotics, you need them specifically for your current illness. Despite the antibiotics, some bacteria can survive or grow. This phenomenon is known as resistance: some treatments with antibiotics are becoming ineffective.

Improper use of antibiotics increases resistance. You may even help the bacteria to become more resistant and, therefore, delay your cure or reduce the effectiveness of antibiotics if you do not comply with:

- dosage
- the schedule
- the duration of the treatment

Consequently, to maintain the effectiveness of this medicine:

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 antibiotics to another person; they might not be suitable for their illness.
5. When you finish your treatment, return all unused medicines to the chemist, to ensure they are disposed of correctly.