

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 you consider that any of the side effects you see is serious, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

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 causes infections. It only acts 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 throw away 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

- infections of the testes
- infections of the female genital organs
- infections of the gastrointestinal tract and intrabdominal infections
- infections of the skin and soft tissue
- infections of the bones and joints
- treatment of infections in patients with a very low leukocyte count (neutropenia)
- prevention of infections in patients with a very low leukocyte 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 infections and bronchitis 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 or any of the other ingredients of **ciprofloxacin** (listed in section 6).
- If you are taking tizanidine (see section 2: Other medicines and ciprofloxacin).

Take special care with ciprofloxacin:

- What you need to know before you take **ciprofloxacin**: Tell your doctor:
 - if you have ever had kidney problems because your treatment will have to be adjusted.
 - if you suffer from epilepsy or other neurological conditions.
 - if you have a history of problems of the tendons during prior treatment with antibiotics like **ciprofloxacin**.
 - if you suffer from myasthenia gravis (a type of muscle weakness).
 - if you suffer from or have a family history of a long QT interval (detected in electrocardiograms, records of cardiac activity).
 - if you have a blood salt imbalance (especially if you have low potassium and magnesium levels).
 - if you have a very slow heart rate (called ‘bradycardia’).
 - if your heart is weakened (heart failure), or you have suffered a heart attack (myocardial infarction).
 - if you are a woman or elderly patient.
 - if you are taking other medicines that can cause changes in the electrocardiogram (see the section Other medicines and ciprofloxacin).
 - if you have been diagnosed with enlargement or a “bulge” in a large blood vessel (aortic aneurysm or aneurysm of a large peripheral vessel).
 - if you have had a previous episode of aortic dissection (tear in the wall of the aorta).
 - if you have a family history of aortic aneurysm or aortic dissection or other risk factors or predisposing disorders (e.g. connective tissue disorders like Marfan syndrome or Ehlers-

Danlos syndrome, or vascular disorders like Takayasu's arteritis, giant cell arteritis, Behçet's disease, arterial hypertension or known atherosclerosis).

- While taking **ciprofloxacin**:

Tell your doctor immediately if any of the following situations arise while taking **ciprofloxacin**. Your doctor will decide on the duration of your treatment with **ciprofloxacin**.

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: chest tightness, dizziness, nausea or fainting, or dizziness when standing up. If this happens, do not take any more **ciprofloxacin** and contact your doctor immediately.
- Sometimes **pain and swelling of the joints and tendinitis** may occur, especially if you are elderly and also receiving treatment with corticosteroids. At the first sign of pain or inflammation, stop taking **ciprofloxacin** 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 disorder**, such as ischaemia or ischaemic stroke, you may suffer adverse effects associated with the central nervous system. If this happens, stop taking **ciprofloxacin** and contact your doctor immediately.
- You may suffer **psychiatric reactions** the first time you take **ciprofloxacin**. If you suffer **depression** or **psychosis**, your symptoms can worsen with treatment with **ciprofloxacin**. If this happens, stop taking **ciprofloxacin** and contact your doctor immediately.
- You may experience symptoms of neuropathology such as pain, burning, tingling, numbness and/or weakness in the limbs. If this happens, stop taking **ciprofloxacin** and contact your doctor immediately.
- You may develop **diarrhoea** while taking antibiotics, including **ciprofloxacin**, or even several weeks after you stopped taking it. If the diarrhoea is intense or lasting, or if you notice that your stools contain blood or mucus, stop taking **ciprofloxacin** immediately, as this could endanger your life. Do not take medicinal products that stop or delay bowel movements and consult your doctor.
- While you are taking **ciprofloxacin**, tell your doctor or test laboratory staff if you need **blood or urine tests**.
- **Ciprofloxacin** can cause liver damage. If you notice symptoms such as loss of appetite, jaundice (yellowish colour of the skin), dark urine, itching or stomachache, stop taking **ciprofloxacin** immediately and consult your doctor straight away.

ciprofloxacin can cause a reduction in the white blood cell count and perhaps **decrease your resistance to infection**. 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 leukocytes (agranulocytosis). It is important to tell your doctor about your medicine.

- Tell your doctor if you or a relative suffer from a verified glucose-6-phosphate dehydrogenase (G6PD) deficiency, as this can present a risk of anaemia with ciprofloxacin.
- Your skin will become more **sensitive to sunlight or ultraviolet (UV) light** when you are taking **ciprofloxacin cifa**. Avoid exposure to intense sunlight or artificial ultraviolet light such as tanning booths.

Other medicines and ciprofloxacin:

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including non-prescription medicines.

Do not take ciprofloxacin cifa 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 **ciprofloxacin cifa**”).

The following medicinal products are known to interact in your body with **ciprofloxacin cifa**. If you take **ciprofloxacin cifa** 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 macrolide group) and some antipsychotics.

Ciprofloxacin cifa can increase the levels in blood of the following medicines:

- Pentoxifylline (for circulation disorders)
- Caffeine

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

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

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

Ciprofloxacin cinfa with food and drink:

If you take **ciprofloxacin cinfa** with the 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 cinfa** during pregnancy. Tell your doctor if you are planning to become pregnant.

Do not take **ciprofloxacin cinfa** during the breast-feeding period, as ciprofloxacin is excreted through maternal milk and may harm your baby.

Driving and using machines

Ciprofloxacin cinfa can reduce your state of alertness. It can cause some neurological effects. Therefore, ensure you know how you react to **ciprofloxacin cinfa** before driving vehicles or using machines. If you have any doubts, consult your doctor.

3. How to take ciprofloxacin cinfa

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

Your doctor will explain exactly how much **ciprofloxacin cinfa** 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 cinfa** 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 with or without food. The calcium you consume as part of a meal will not seriously affect the absorption of the medicine. Nevertheless, do not take **ciprofloxacin cinfa** 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 fluid when you take **ciprofloxacin cinfa**. **If you take more ciprofloxacin cinfa than you should**

If you take an amount greater 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 cinfa

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, wait for the next dose and take it at the usual time. Do not take a double dose to make up for a forgotten dose. Be sure to complete the treatment cycle.

If you stop taking ciprofloxacin cinfa

It is important that **you take the complete 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 could 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 cinfa** can cause side effects, although not everybody sees them.

If you consider that any of the side effects you see is serious, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

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

- nausea, diarrhoea
- joint pain in children

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

- 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 (transaminase and/or bilirubin)
- rash, itching or hives
- joint pain in adults
- impaired renal function
- pain in muscles and bones, feeling of malaise (asthenia) or fever
- increased alkaline phosphatase in the blood (a substance of the blood)

Rare side effects (may affect up to 1 in 1,000 people):

- inflammation of the intestines (colitis) linked to the use of antibiotics (may be fatal in very rare cases) (see section 2: Take special care with **ciprofloxacin cinfa**)
- changes in the white blood cell count (leukopenia, leukocytosis, neutropenia, anaemia), increase or reduction in the amounts of the blood coagulation factor (thrombocytes)
- allergic reaction, swelling (oedema) or quick swelling of the skin and mucous membranes (angioedema)
- increased sugar in the blood (hyperglycaemia)
- confusion, disorientation, reactions of anxiety, 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 cinfa) or dizziness
- visual problems
- tinnitus (humming in the ear), 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
- renal insufficiency, 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 (may affect up to 1 in 10,000 people):

- 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 cells and platelets (pancytopenia), with risk of death, and depression of bone marrow, also with risk of death (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 co-ordination, 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 exanthems (for example, the Stevens-Johnson syndrome with risk of death or toxic epidermic 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 severe myasthenia (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 rate abnormalities, irregular heart rate with risk of death, alterations in heart rate (called “prolonged QT interval” detected in electrocardiograms, record of heart activity).
- pustular rash
- syndrome related to poor water secretion and low sodium concentrations (SIADH).

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 cinfa

Do not store at a temperature above 25°C.
Keep this medicine out of the sight and reach of children.

Expiry

Do not use **ciprofloxacin cinfa** after the expiry date stated on the container after “EXP”. The expiry date refers to the last day of that month.

Do not discard 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 cinfa 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 norfloxacin cinfa looks like and contents of the pack

Ciprofloxacin cinfa 250 mg coated tablets are presented in tablet form. Each package contains 10 or 20 tablets.

Marketing licence holder and manufacturer

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

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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 treatment or reduce the effectiveness of antibiotics if you do not comply with:

- the dose
- the programme
- the duration of the treatment

Consequently, to maintain the effectiveness of this medicine:

1. Use the antibiotics only when prescribed.
2. Follow the prescription strictly.
3. Do not reuse an antibiotic without a doctor's prescription, even if it is 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 you consider that any of the side effects you see is serious, talk to your doctor or pharmacist. This includes any side effects not listed in this leaflet.

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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 causes infections. It only acts 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

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
- infections of the testes
- infections of the female genital organs

- infections of the gastrointestinal tract and intrabdominal infections
- infections of the skin and soft tissue
- infections of the bones and joints
- treatment of infections in patients with a very low leukocyte count (neutropenia)
- prevention of infections in patients with a very low leukocyte 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 **ciprofloxacino cinfa**.

Children and adolescents:

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

- lung infections and bronchitis 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

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

2. What you need to know before you take ciprofloxacino cinfa:

- If you are allergic (hypersensitive) to the active substance or any of the other ingredients of **ciprofloxacino cinfa** (listed in section 6).
- If you are taking tizanidine (see section 2: Other medicines and ciprofloxacin).

Take special care with ciprofloxacino cinfa:

What you need to know before you take **ciprofloxacino cinfa**: Tell your doctor if:

- if you have ever had kidney problems because your treatment will have to be adjusted.
- if you suffer from epilepsy or other neurological conditions.
- if you have a history of problems of the tendons during prior treatment with antibiotics like **ciprofloxacino cinfa**.
- if you suffer from myasthenia gravis (a type of muscle weakness).
- if you suffer from or have a family history of a long QT interval (detected in electrocardiograms, records of cardiac activity).
- if you have a blood salt imbalance (specially if you have low potassium and magnesium levels).
- if you have a very slow heart rate (called ‘bradycardia’).
- if your heart is weakened (heart failure), or you have suffered a heart attack (myocardial infarction).
- if you are a woman or elderly patient.
- if you are taking other medicines that can cause changes in the electrocardiogram (see the section Other medicines and ciprofloxacin).
- if you have been diagnosed with enlargement or a “bulge” in a large blood vessel (aortic aneurysm or aneurysm of a large peripheral vessel).
- if you have had a previous episode of aortic dissection (tear in the wall of the aorta).
- if you have a family history of aortic aneurysm or aortic dissection or other risk factors or predisposing disorders (e.g. connective tissue disorders like Marfan syndrome or Ehlers-

Danlos syndrome, or vascular disorders like Takayasu's arteritis, giant cell arteritis, Behçet's disease, arterial hypertension or known atherosclerosis).

While taking ciprofloxacin:

Tell your doctor immediately if any of the following situations arise while taking **ciprofloxacin**. Your doctor will decide on the duration of your treatment with **ciprofloxacin**.

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: chest tightness, dizziness, nausea or fainting, or dizziness when standing up. If this happens, do not take any more **ciprofloxacin** and contact your doctor immediately.
- Sometimes **pain and swelling of the joints and tendinitis** may occur, especially if you are elderly and also receiving treatment with corticosteroids. At the first sign of pain or inflammation, stop taking **ciprofloxacin** 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 disorder**, such as ischaemia or ischaemic stroke, you may suffer adverse effects associated with the central nervous system. If this happens, stop taking **ciprofloxacin** and contact your doctor immediately.
- You may suffer **psychiatric reactions** the first time you take **ciprofloxacin**. If you suffer **depression** or **psychosis**, your symptoms can worsen with treatment with **ciprofloxacin**. If this happens, stop taking **ciprofloxacin** and contact your doctor immediately.
- You may experience symptoms of neuropathology such as pain, burning, tingling, numbness and/or weakness in the limbs. If this happens, stop taking **ciprofloxacin** and contact your doctor immediately.
- You may develop **diarrhoea** while taking antibiotics, including **ciprofloxacin**, or even several weeks after having stopped taking it. If the diarrhoea is intense or lasting, or if you notice that your stools contain blood or mucus, stop taking **ciprofloxacin** immediately, as this could endanger your life. Do not take medicinal products that stop or delay bowel movements and consult your doctor.
- While you are taking **ciprofloxacin**, tell your doctor or test laboratory staff if you have to take **blood or urine tests**.
- **Ciprofloxacin** can cause liver damage. If you notice symptoms such as loss of appetite, jaundice (yellowish colour of the skin), dark urine, itching or stomachache, stop taking **ciprofloxacin** immediately and consult your doctor straight away.
- **ciprofloxacin** can cause a reduction in the white blood cell count and perhaps **decrease your resistance to infection**. 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 leukocytes (agranulocytosis). It is important to tell your doctor about your medicine.

- Tell your doctor if you or a relative suffer from a verified glucose-6-phosphate dehydrogenase (G6PD) deficiency, as this can present a risk of anaemia with ciprofloxacin.
- Your skin will become more **sensitive to sunlight or ultraviolet (UV) light** when you are taking **ciprofloxacin cifa**. Avoid exposure to intense 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 non-prescription medicines.

Do not take ciprofloxacin cifa 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 **ciprofloxacin cifa**”).

The following medicinal products are known to interact in your body with **ciprofloxacin cifa**. If you take **ciprofloxacin cifa** 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:

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- 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 macrolide group) and some antipsychotics.

Ciprofloxacin cifa can increase the levels in the blood of the following medicines:

- Pentoxifylline (for circulation disorders)
- Caffeine

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

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

Ciprofloxacin with food and drink:

If you take **ciprofloxacin** with the 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 period, as ciprofloxacin is excreted through maternal milk and may harm your baby.

Driving and using machines

Ciprofloxacin can reduce your state of alertness. It can cause some neurological effects. Therefore, ensure you know how you react to **ciprofloxacin** before driving vehicles or using 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 with or without food. 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 fluid when you take **ciprofloxacin**. **If you take more ciprofloxacin than you should:**

If you take an amount greater 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, wait for the next dose and take it at the usual time. Do not take a double dose to make up for a forgotten dose. Be sure to complete the treatment cycle.

If you stop taking ciprofloxacin cifa

It is important that **you take the complete 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 could 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 cifa** can cause side effects, although not everybody sees them.

If you consider that any of the side effects you see is serious, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

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

- nausea, diarrhoea
- joint pain in children

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

- 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 (transaminase and/or bilirubin)
- rash, itching or hives
- joint pain in adults
- impaired renal function
- pain in muscles and bones, feeling of malaise (asthenia) or fever
- increased alkaline phosphatase in the blood (a substance in the blood)

Rare side effects (may affect up to 1 in 1,000 people):

- inflammation of the intestines (colitis) linked to the use of antibiotics (may be fatal in very rare cases) (see section 2: Take special care with **ciprofloxacin cifa**)
- changes in white blood cell count (leukopenia, leukocytosis, neutropenia, anaemia), increase or reduction in the amounts of the blood coagulation factor (thrombocytes)
- allergic reaction, swelling (oedema) or quick swelling of the skin and mucous membranes (angioedema)
- increased sugar in the blood (hyperglycaemia)
- confusion, disorientation, reactions of anxiety, 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 cifa**) or dizziness
- visual problems
- tinnitus (humming in the ear), 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
- renal insufficiency, 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 (may affect up to 1 in 10,000 people):

- 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 cells and platelets (pancytopenia), with risk of death, and depression of bone marrow, also with risk of death (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 with risk of death or toxic epidermic 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 rate abnormalities, irregular heart rate with risk of death, alterations in heart rate (called “prolonged QT interval” detected in electrocardiograms, record of heart activity).
- pustular rash
- syndrome related to poor water secretion and low sodium concentrations (SIADH).

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 cinfa

Do not store at a temperature above 25°C.

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

Expiry

Do not use **ciprofloxacin cinfa** after the expiry date stated on the container after “EXP”. The expiry date refers to the last day of that month.

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

6. Contents of the pack and other information

What ciprofloxacin cinfa 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 cinfa 500 mg coated tablets are presented in tablet form. Each package contains 10 or 20 tablets.

Not all pack sizes may be available.

Marketing licence holder and manufacturer

Laboratorios Cinfa, S.A.

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

This leaflet was last reviewed in: January 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:

- the dose
- the programme
- the duration of the treatment

Consequently, to maintain the effectiveness of this medicine:

1. Use the antibiotics only when prescribed.
2. Follow the prescription strictly.
3. Do not reuse an antibiotic without a doctor's prescription, even if it is 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 you consider that any of the side effects you see is serious, talk to your doctor or pharmacist. This includes any side effects not listed in this leaflet.

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 causes infections. It only acts 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
- infections of the testes
- infections of the female genital organs
- infections of the gastrointestinal tract and intrabdominal infections

- infections of the skin and soft tissue
- infections of the bones and joints
- treatment of infections in patients with a very low leukocyte count (neutropenia)
- prevention of infections in patients with a very low leukocyte 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 cifa**.

Children and adolescents:

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

- lung infections and bronchitis 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 cifa 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 cifa:

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

Take special care with ciprofloxacin cifa:

What you need to know before you take **ciprofloxacin cifa**: Tell your doctor if:

- if you have ever had kidney problems because your treatment will have to be adjusted.
- if you suffer from epilepsy or other neurological conditions.
- if you have a history of problems of the tendons during prior treatment with antibiotics like **ciprofloxacin cifa**.
- if you suffer from myasthenia gravis (a type of muscle weakness).
- if you suffer from or have a family history of a long QT interval (detected in electrocardiograms, records of cardiac activity).
- if you have a blood salt imbalance (specially if you have low potassium and magnesium levels).
- if you have a very slow heart rate (called ‘bradycardia’).
- if your heart is weakened (heart failure), or you have suffered a heart attack (myocardial infarction).
- if you are a woman or elderly patient.
- if you are taking other medicines that can cause changes in the electrocardiogram (*see the section Other medicines and ciprofloxacin*).
- if you have been diagnosed with enlargement or a “bulge” in a large blood vessel (aortic aneurysm or aneurysm of a large peripheral vessel).
- if you have had a previous episode of aortic dissection (tear in the wall of the aorta).
- if you have a family history of aortic aneurysm or aortic dissection or other risk factors or predisposing disorders (e.g. connective tissue disorders like Marfan syndrome or Ehlers-Danlos syndrome, or vascular disorders like Takayasu’s arteritis, giant cell arteritis, Behçet’s disease, arterial hypertension or known atherosclerosis).

While taking ciprofloxacin cinfa:

Tell your doctor immediately if any of the following situations arise while taking **ciprofloxacin cinfa**. Your doctor will decide on the duration of your treatment with **ciprofloxacin cinfa**.

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: chest tightness, dizziness, nausea or fainting, or dizziness when standing up. If this happens, do not take any more **ciprofloxacin cinfa** and contact your doctor immediately.
- Sometimes **pain and swelling of the joints and tendinitis** may occur, especially if you are elderly and also receiving treatment with corticosteroids. At the first sign of pain or inflammation, stop taking **ciprofloxacin cinfa** 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 disorder**, such as ischaemia or ischaemic 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 can worsen with treatment with **ciprofloxacin cinfa**. If this happens, stop taking **ciprofloxacin cinfa** and contact your doctor immediately.
- You may experience symptoms of neuropathology such as pain, burning, tingling, numbness and/or weakness in the limbs. If this happens, stop taking **ciprofloxacin cinfa** and contact your doctor immediately.
- You may develop **diarrhoea** while taking antibiotics, including **ciprofloxacin cinfa**, or even several weeks after having stopped taking it. If the diarrhoea is intense or lasting, or if you notice that your stools contain blood or mucus, stop taking **ciprofloxacin cinfa** immediately, as this could endanger your life. Do not take medicinal products that stop or delay bowel movements and consult your doctor.
- While you are taking **ciprofloxacin cinfa**, tell your doctor or test laboratory staff if you have to take **blood or urine tests**.
- **Ciprofloxacin cinfa** can cause liver damage. If you notice symptoms such as loss of appetite, jaundice (yellowish colour of the skin), dark urine, itching or stomachache, stop taking **ciprofloxacin cinfa** immediately and consult your doctor straight away.
- **ciprofloxacin cinfa** can cause a reduction in the white blood cell count and perhaps **decrease your resistance to infection**. 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 leukocytes (agranulocytosis). It is important to tell your doctor about your medicine.

- Tell your doctor if you or a relative suffer from a verified glucose-6-phosphate dehydrogenase (G6PD) deficiency, as this can present a risk of anaemia with ciprofloxacin.
- Your skin will become more **sensitive to sunlight or ultraviolet (UV) light** when you are taking **ciprofloxacin cifa**. Avoid exposure to intense 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 non-prescription medicines.

Do not take ciprofloxacin cifa 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 **ciprofloxacin cifa**”).

The following medicinal products are known to interact in your body with **ciprofloxacin cifa**. If you take **ciprofloxacin cifa** 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 macrolide group) and some antipsychotics.

Ciprofloxacin cifa can increase the levels in the blood of the following medicines:

- Pentoxifylline (for circulation disorders)
- Caffeine

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

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

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

Ciprofloxacin cina with food and drink:

If you take **ciprofloxacin cina** with the 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 cina** during pregnancy. Tell your doctor if you are planning to become pregnant.

Do not take **ciprofloxacin cina** during the breast-feeding period, as ciprofloxacin is excreted through maternal milk and may harm your baby.

Driving and using machines

Ciprofloxacin cina can reduce your state of alertness. It can cause some neurological effects. Therefore, ensure you know how you react to **ciprofloxacin cina** before driving vehicles or using machines. If you have any doubts, consult your doctor.

3. How to take ciprofloxacin cina

Always take **ciprofloxacin cina** 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 cina** 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 cina** 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 with or without food. The calcium you consume as part of a meal will not seriously affect the absorption of the medicine. Nevertheless, do not take **ciprofloxacin cina** 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 fluid when you take **ciprofloxacin cina**. **If you take more ciprofloxacin cina than you should:**

If you take an amount greater 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 cina:

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, wait for the next dose and take it at the usual time. Do not take a double dose to make up for a forgotten dose. Be sure to complete the treatment cycle.

If you stop taking ciprofloxacin

It is important that **you take the complete 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 could 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 sees them.

If you consider that any of the side effects you see is serious, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

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

- nausea, diarrhoea
- joint pain in children

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

- 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 (transaminase and/or bilirubin)
- rash, itching or hives
- joint pain in adults
- impaired renal function
- pain in muscles and bones, feeling of malaise (asthenia) or fever
- increased alkaline phosphatase in the blood (a substance in the blood)

Rare side effects (may affect up to 1 in 1,000 people):

- inflammation of the intestines (colitis) linked to the use of antibiotics (may be fatal in very rare cases) (see section 2: Take special care with **ciprofloxacin**)
- changes in white blood cell count (leukopenia, leukocytosis, neutropenia, anaemia), increase or reduction in the amounts of the blood coagulation factor (thrombocytes)
- allergic reaction, swelling (oedema) or quick swelling of the skin and mucous membranes (angioedema)
- increased sugar in the blood (hyperglycaemia)
- confusion, disorientation, reactions of anxiety, 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
- visual problems
- tinnitus (humming in the ear), 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
- renal insufficiency, 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 (may affect up to 1 in 10,000 people):

- 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 cells and platelets (pancytopenia), with risk of death, and depression of bone marrow, also with risk of death (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 with risk of death or toxic epidermic 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 rate abnormalities, irregular heart rate with risk of death, alterations in heart rate (called “prolonged QT interval” detected in electrocardiograms, record of heart activity).
- pustular rash
- syndrome related to poor water secretion and low sodium concentrations (SIADH).

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 cinfa

Do not store at a temperature above 25°C.

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

Expiry

Do not use **ciprofloxacin cinfa** after the expiry date stated on the container after “EXP”. The expiry date refers to the last day of that month.

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What ciprofloxacin cinfa 750 mg coated tablets contains

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- 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.

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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:

- the dose
- the programme
- the duration of the treatment

Consequently, to maintain the effectiveness of this medicine:

1. Use the antibiotics only when prescribed.
2. Follow the prescription strictly.
3. Do not reuse an antibiotic without a doctor's prescription, even if it is 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.