

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 further questions, please ask your doctor or your pharmacist.

– This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.

In this leaflet:

1. What **ciprodyne 500 mg coated tablets** is and what it is used for.
2. Before you take **ciprodyne 500 mg coated tablets**.
3. How to take **ciprodyne 500 mg coated tablets**.
4. Possible side effects.
5. Storing **ciprodyne 500 mg coated tablets**.

ciprodyne 500 mg coated tablets

The active ingredient is ciprofloxacin.

Each coated tablet contains:

ciprofloxacin (INN) (hydrochloride) 500 mg

The excipients are: sodium croscarmellose, microcrystalline cellulose, anhydrous colloidal silica, maize starch, sodium lauryl sulphate, magnesium stearate, talc, hypromellose, titanium dioxide, macrogol 400.

Holder and responsible for manufacture:

Laboratorios Cinfa, S.A. C/ Olaz-Chipi, 10 - Poligono Industrial Areta. 31620 Huarte-Pamplona (Navarre)-Spain

1. WHAT **ciprodyne 500 mg coated tablets** IS AND WHAT IT IS USED FOR

ciprodyne 500 mg coated tablets is supplied in tablets. Each package contains 10 tablets.

ciprodyne 500 mg coated tablets belongs to a group of antibiotics called quinolones.

ciprodyne 500 mg coated tablets is indicated in the treatment of infections caused by pathogens susceptible to ciprofloxacin located at:

- Airways (including cystic fibrosis and anthrax).
- Ears and throat.
- Urinary and genital system (genitourinary).
- Abdomen (including anthrax).
- Blood (systemic).
- Bone and joints (osteoarticular).
- Skin and soft tissues.
- Gallbladder.

ciprodyne is also indicated in the prevention of infection by anthrax.

2. BEFORE YOU TAKE **ciprodyne 500 mg coated tablets**

Do not take **ciprodyne 500 mg coated tablets**:

– If you are allergic to ciprofloxacin or other quinolones or any other ingredient of this medicine.

– If you have pain or inflammation of any type at the calf, particularly the Achilles tendon. If this occurs, discontinue the treatment, rest completely and immediately notify your doctor.

– If you have any renal dysfunction, since your doctor must adjust the dose of ciprofloxacin.

Take special care with **ciprodyne 500 mg coated tablets**:

– If you have current or previous epileptic episodes and/or seizures: blood flow disorders or previous thrombosis and/or brain haemorrhage.

– If you are over 65 years old and you are taking a treatment with anti-inflammatory drugs (corticosteroids), quinolones can cause the inflammation and breakage of the tendons.

When the first sign of pain or inflammation occurs, discontinue the treatment and rest the extremities involved.

– If you have evident severe or persistent diarrhoea during or after treatment with **ciprodyne 500 mg coated tablets**, since it may be due to a special type of colitis called pseudomembranous colitis, that can be serious. In this case, contact your doctor immediately.

– If you have a past medical or family history of deficit of glucose-6-phosphate dehydrogenase (congenital or acquired metabolic disorder).

– During the treatment with this medicine, you are recommended to avoid exposure to UV radiation and not to expose excessively to sunlight; otherwise, protect your skin adequately.

– If you suffer myasthenia gravis, since in this case **ciprodyne 500 mg coated tablets** should be used with caution.

Contact your doctor if any of the above occur.

Pregnancy and breast-feeding

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

The use of **ciprodyne 500 mg coated tablets** is not recommended during pregnancy or breast-feeding.

Driving and using machines

The treatment with **ciprodyne 500 mg coated tablets** can affect your ability to drive or use machines. The risk increases during the first days of treatment, if alcohol drinks are taken and if the dose of the medicine is increased; therefore, do not drive or use dangerous machines if any of the above occur.

Taking other medicines

Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines, even those not prescribed.

Some medicines can affect the action of ciprofloxacin, including:

- Antacids, iron, sucralose and calcium, didanosine, oral nutritional solutions and dairy products: the concomitant use of these medicines with ciprofloxacin can cause a reduction in the effect of ciprofloxacin; therefore, it is recommended to take ciprofloxacin 3 hours before or 4 hours after taking these products.
- Theophylline, caffeine or pentoxifylline: the blood levels of these medicines increase when they are taken concomitantly with ciprofloxacin; therefore, the risk of occurrence of side effects due to these medicines also increases.
- Non-steroidal anti-inflammatory drugs (NSAIDs): the use of these medicines (except for acetylsalicylic acid) concomitantly with quinolones at very high doses can cause seizures.
- Cyclosporine (a medicine that can prevent transplantation rejection): when taken concomitantly with ciprofloxacin it can cause renal dysfunction.
- Warfarin (a medicine used to fluidify blood and prevent the formation of clots), glibenclamide (a medicine for the treatment of diabetes), phenytoin (a medicine used in the treatment of epilepsy), ropinirole (a medicine used in the treatment of Parkinson's disease): when taken concomitantly with ciprofloxacin, the effect of these drugs can increase.
- Probenecid (a medicine used in the treatment of gout), metoclopramide, (a medicine used in the treatment of nausea and vomiting): when taken concomitantly with ciprofloxacin, they can increase ciprofloxacin blood levels and, therefore, increase the effects of this medicine.
- Opioid premedication (medicines used for pre-operative sedation): when used concomitantly with ciprofloxacin, they can reduce ciprofloxacin blood levels and, therefore, reduce the effects of this medicine.

3. HOW TO TAKE **ciprodyne 500 mg coated tablets**

The tablet is generally swallowed whole with the aid of some liquid (for instance, a glass of water) and preferably two hours before or after meals.

We recommend you to drink plenty of fluids during the treatment with this medicine.

Follow these directions unless your doctor gives you others.

Remember to take your medicine.

Your doctor will tell you the dose and duration of your treatment with **ciprodyne 500 mg coated tablets**. Do not discontinue the treatment earlier, since the infection could not be fully cured.

The standard adult dose is 1 tablet every 12 hours. In the case of treatment or prevention of infection by anthrax, the standard dose is 500 mg every 12 hours by oral route.

The standard treatment period for acute infections is 5 to 10 days. However, the treatment should be continued for three days after the signs and symptoms subside.

In the case of treatment or prevention of infection by anthrax, the common duration of treatment is 60 days.

Elderly: The dose is equivalent to that used in adults. It will be only adjusted in the case of renal dysfunction.

Children and adolescents (5-17 years): The recommended dose is 20 mg/kg every 12 hours po, and the maximum daily dose is 1,500 mg. In the case of treatment or prevention of infection by anthrax, the recommended dose is 10-15 mg/kg every 12 hours po.

Renal dysfunction: In case of any renal dysfunction, notify your doctor, since a dose adjustment will be required.

Impaired liver function: In adults, no dose adjustment is needed.

If you take more **ciprodyne 500 mg coated tablets than you should:** The symptoms that you can suffer include: light-headedness, tremor, headache, fatigue and confusion and also stomach and intestinal disorders and renal and liver function abnormalities.

Immediately ask your doctor or pharmacist, or go to the nearest hospital.

If you forget to take **ciprodyne 500 mg coated tablets:** In case you forgot to take a dose, you must take the tablet as soon as possible continuing the treatment as prescribed. However, when it is close to the next dose, you should rather not take the missed tablet and take the next at the scheduled time.

Do not take a double dose to make up for forgotten individual doses.

4. POSSIBLE SIDE EFFECTS

Like all medicines, **ciprodyne 500 mg coated tablets** can have side effects.

The most common ones occur in the stomach and bowel, the central nervous system and the skin. The following side effects have been described.

Stomach and bowel: Common: nausea, vomiting, abdominal pain, flatulence and diarrhoea. Rare: pseudomembranous colitis.

Central nervous system disorders: Common: light-headedness, headache, fatigue, restlessness and confusion.

Other reactions such as insomnia, anxiety or sweating can occur very rarely.

Special sense disorders: Very rare: taste, smell and visual disturbances.

Skin and allergy: Common: Skin reactions such as itching and rash.

Skin spots can occur very rarely. Also other allergic reactions such as swelling, breathlessness, circulatory shock and renal and/or liver function complications.

Cardiovascular disorders: Uncommon: palpitations.

Very rare: swelling, flushing, headache, fainting, tachycardia.

Locomotor disorders: Uncommon: joint pain and inflammation.

Very rare: muscle pain. In isolated cases: tendinitis (for instance, of the Achilles tendon). Worsening of the symptoms of myasthenia.

Blood disorders: Uncommon: abnormalities of the blood formula (eosinophilia, leukopenia, anaemia, thrombocytopenia).

Very rare: other abnormalities of the blood formula (leukocytosis, thrombocytosis, haemolytic anaemia, pancytopenia, agranulocytosis), abnormal prothrombin values, high blood sugar levels, crystals in urine or blood in urine.

Other side effects: The prolonged, repeated use of ciprofloxacin has been associated with the development of overinfection by resistant bacteria or fungi.

Whenever any of these side effects occurs, you should contact your doctor, who will evaluate the appropriateness of discontinuing the medicine.

If you notice any other side effect not above described, ask your doctor or pharmacist.

5. STORING **ciprodyne 500 mg coated tablets**

No special storage conditions are required.

KEEP THIS MEDICINE OUT OF THE REACH AND SIGHT OF CHILDREN.

Shelf life: This medicine must not be used beyond the shelf life shown in the package.

This leaflet has been approved in September, 2002.



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