Ziquin 500 mg film-coated tablets

Levofloxacin

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any queries, consult 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 symptoms are the same as yours.
- If you experience any adverse reactions, talk to your doctor or pharmacist. This includes any possible reactions not listed in this leaflet.

What is in this leaflet

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1. What Ziquin is and what it is used for

Ziquin contains a medication known as levofloxacin, which is an antibiotic belonging to the fluoroquinonlone group.

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

Following the instructions regarding dosing, intake and treatment length given to you by your doctor is important. Do not save or reuse this medication. If, upon completion of treatment, you have antibiotics left over, return it to the pharmacy in order for it to be appropriately destroyed. The medication should not be thrown down the drain or in the rubbish.

This medication is used to treat the following bacterial infections: Acute bacterial sinusitis

- Exacerbation of chronic bronchitis.
 Community-acquired pneumonia.
- Complicated urinary tract infections, including pyelonephritis (including kidney infections).
- Chronic bacterial prostatitis. Skin and soft tissue infections.

2. What you need to know before taking Ziquin

Do not take Ziquin if

- You are allergic to levofloxacin or any of the other compounds that form this medication (see section 6) or other similar antibiotics such as ciprofloxacin or ofloxacin.
- You suffer from epilepsy. You have previously had problems with your tendons (tendo-nitis) when taking levofloxacin or any other similar medication. You are a child or are under the age of 18.
- You are pregnant, trying to become pregnant or breastfeeding.

Warnings and precautions Consult your doctor before taking Ziquin if:

- You have previously suffered from epilepsy or have suffered a brain injury in the past (such as a stroke), since it may increase the possibility of suffering seizures (attacks). Make sure you inform your doctor of your complete medical history. You have the rare hereditary G-6-phosphate dehydrogenase deficiency, since taking levofloxacin may increase the proba-
- bility of suffering blood problems.
- You suffer from renal disease/injury, as your doctor may
- decide to give you a lower dose of levofloxacin. You are taking medication to avoid blood clotting (such as warfarin), as your doctor will want to monitor your blood coagulation while you take levofloxacin.
- You are diabetic and receive concomitant treatment with oral hypoglucaemiants.
- You have a history of psychiatric disorders.
 You have a history of psychiatric disorders.
 You have heart problems: care must be taken when using this type of medication if you were born with or there is a family history of long QT interval (seen in an ECG, a recording of the second se of the heart's electrical activity), suffer from blood salt imbalances (especially low blood potassium or magnesium levels), have a slow heart rate (called "bradycardia"), have a weak heart (cardiac failure), have a history of heart attacks (myocardial infarction), are female, elderly or are taking medication that causes changes in ECG (see "Use of other medication" section).

Other warnings

- Levofloxacin may, on rare occasions, cause pain in and inflammation of the tendons. This is most likely to occur if you are an elderly patient or are taking steroid-based medication (such as cortisone or hydrocortisone). If you experience any tendon problems while taking or shortly after taking levofloxacin, seek medical care immediately and rest the affected limb (leg or arm). Do not take the following dose of levofloxacin unless your doctor advises you to do so. In these cases you will experience swelling or pain in the area of the affected tendon. Suspending treatment may be necessary.
- If you start to experience severe, persistent and/or bloody

your doctor immediately. It may mean that you are suffering from severe intestinal inflammation (pseudomembranous colitis), which may sometimes occur after antibiotic treatment. You may need to discontinue treatment with levofloxacin and

- be prescribed a different medication by your doctor. Not exposing oneself to strong sunlight and refraining from the use of UV lamps while taking levofloxacin is recommended. Your skin may become a lot more sensitive to the sun and experience sunburn.
- Treatment with levofloxacin must be discontinued if the patient experiences symptoms such as burning, tingling, pain or numbness. These may be signs of "neuropathy". Treatment with levofloxacin is not considered the best
- treatment for the majority of serious cases of pneumococcal pneumonia.
- Nosocomial infections caused by P. aeruginosa may require combined treatment.
- Levofloxacin is not effective against infections caused by MRSA.In suspected MRSA infections, levofloxacin must be combined with a medication that is intended to treat MRSA infections.
- If you present liver damage symptoms this may be considered a risk to your life, primarily if you suffer from any basic disease (for example, widespread infection-sepsis), or other liver disease symptoms, such as anorexia, jaundice and/or mucous, dark urine, itchiness or soft abdomen. In these cases treatment must be discontinued and consult your doctor.

Using Ziquin with other medication

Inform your doctor or pharmacist if you are taking, have recently taken or may have to take any other medication, including OTC medications or plant-based medicines. It is especially important that you mention:

- Sucraffate or medications that contain iron, magnesium or aluminium salts since these medications may interfere with levofloxacin absorption and should not be taken at the same time. Sucraffate must be taken two hours after taking levofloxacin and two hours before or after medications that contain iron, aluminium or magnesium.
- Non-steroidal based anti-inflammatory medication such as fenbufen, ibuprofen, naproxen, which are often used to treat joint pain and problems.
- Theophylline, since it increases the risk of seizures (attacks). Probenecid and cimetidine may reduce renal elimination of levofloxacin.
- Cyclosporine, since levofloxacin may make the effect of
- cyclosporine last longer. Vitamin K antagonists (such as warfarin) since haemorrhages are more likely. Your doctor may require regular monitoring of your clotting tests in order to check your blood coagulation.
- Medications that may alter heart rate. Including medications had belong to the antiarhythmic drug group (such as quinidine, hydroquinidine, dispyramide, amiodarone, sotalol, dofetilide, ibutilide), tricyclic antidepressants, some antibiotics (belonging to the macrolide group) and some antipsychotic drugs.

Opiate urine analysis

Urine tests may yield false positive results for strong analgesics known as opiates when levofloxacin is taken. If you are taking levofloxacin, inform your doctor before having your blood tested.

Taking Ziquin with food and drink

Levofloxacin can be taken with or without food. Take it with water or a drink that contains plenty of water. Taking this product with orange juice may cause a reduction of quinolone plasma levels.

Pregnancy and breast-feeding

Do not take levofloxacin if you are pregnant, trying to become pregnant or are breastfeeding.

If you are pregnant or breastfeeding, or think you might be pregnant or are attempting to become pregnant, check with your doctor before taking any form of medication.

Driving and using machines

Levofloxacin may cause dizziness, drowsiness, visual disturbances and confusion.

If you experience any of these symptoms, do not drive, operate machinery or perform any potentially dangerous activity.

3. How to take Ziguin

Follow the administration instructions for this medication provided by your doctor. If in doubt, consult your doctor or pharmacist. Swallow the tablets whole with a glass of water. They can be

taken with or without food.

The recommended dose is one or two tablets a day. The length of treatment depends on the type and severity of the infection. If you have a kidney disorder you may need a lower dose.

If you take more Ziquin that you should

If you accidentally take one tablet too many, it is unlikely that anything will happen. If you accidentally take several tablets too many, inform your doctor or attend your closest Accident and Emergency service. If possible, take the packaging with you to show the doctor. If you take too many tablets, you may experience confusion, dizziness, loss of consciousness, seizures (attacks), and heart disorders (irregular heartbeats).

In the event of an overdose or accidental ingestion, immediately consult your doctor or pharmacist or ring the Toxicological Information Service, indicating the medication and the quantity ingested.

If you forget to take Ziquin

If you forget to take a dose of this medication, take it as soon as you remember. However, if it is almost time for the following dose, omit the forgotten dose. Do not take a double dose in order to compensate for the forgotten dose.

If you stop taking Ziquin

Completing the treatment cycle is important. Do not stop taking levofloxacin just because you feel better. If you stop taking the tablets too soon, the infection may reappear or worsen. If you feel you need to stop taking the tablets due to a secondary effect, talk with your doctor before taking the following dose.

If you have any other doubt regarding the use of this medication, ask your doctor or pharmacist.

4. Possible side effects

As with all other medications, Ziquin may produce side effects, although not all people suffer them.

Contact your doctor immediately if you experience any of the following rare side effects:

- Sudden wheezing, difficulty breathing or dizziness, swelling of the eyelids, face, lips, tongue or throat, flaking of and blisters on skin, the mouth, eyes and genitals, dermatitis affecting the entire body,
- bloody diarrhoea (this may be a sign of a more serious disease, pseudomembranous colitis) (see section 2),
- pain in and inflammation of the tendons (tendonitis).

Contact your doctor immediately if you experience any of the following side effects, if they worsen or if you experience any other side effects:

Common (may affect up to 1 in 10 people)

- diarrhoea, - nausea.
- increased hepatic enzymes in blood test results.

Uncommon (may affect up to 1 in 100 people)

- other fungal or bacterial infections that cannot be treated with levofloxacin
- decrease or increase in the number of white blood cells, anorexia,
- drowsiness or insomnia, restlessness,
- headaches, feeling of dizziness, vertigo,
- loss of appetite, discomfort, vomiting,
- stomach pain, indigestion,
- constipation.
- change in blood analysis results due to liver or kidney damage, dermatitis.
- itchiness,
- general weakness,
 flatulence.

Rare (may affect up to 1 in 1,000 people) – tendency to suffer haematomas and to bleed easily due to a

- decrease in platelets in the blood.
- severe decrease in white blood cells, mental problems, such as hallucinations (seeing or hearing things that aren't there) and/or delirium (unwavering belief in something that is false),
- anxiety, depression,
- agitation, confusion,
- seizures (epileptic-like fits),
- tremors.
- tingling in the hands and feet,
 rapid heartbeat,
- low arterial pressure,
- difficulty breathing that may become serious (dyspnea/bronchospasms)
- bloody diarrhoea,
- itchy dermatitis, urticaria
 pain in and inflammation of the tendons (tendonitis) (for example, in the Achilles tendor

- hallucinations (seeing or hearing things that do not exist),
- changes in sense of taste or smell.
- numbness in limbs, movement disorders including difficulty walking.
- vision and hearing disorders
- allergic reactions in the lungs,
- hepatitis (inflammation of the liver),
- swelling of the face, lips, tongue or throat and difficulty swallowing and/or breathing (angiooedema)
- increase in photosensitivity,
- ruptured tendons,
- muscle weakness,
- severe renal disorders (including renal failure), fever.

Unknown (cannot be estimated from the available data)

- decrease in red blood cells (anaemia) or in the number of all blood cells
- ringing, buzzing in the ears (tinnitus), abnormally rapid heart rate, irregular heart rate that may be life-threatening, alterations in heart rate (called "long QT interval", seen in ECG, the heart's electrical activity), jaundice and serious hepatic injury including cases of acute heartie follow, primarily in patients with serious underlying
- hepatic failure, primarily in patients with serious underlying conditions,
- formation of severe blisters and destructive reactions in the skin and mucous membranes (lining of the mouth or intestine), muscle damage (rhabdomyolysis),
- pain (chest and back pain, hand and leg pain),
- hypersensitivity.

The following side effects have been reported with antibiotics that are similar to levofloxacin:

- coordination problems,
- swelling of small blood vessels due to an allergic reaction, - porphyria attacks (in patients with porphyria).

If you believe any of the side effects you are experiencing is severe, or if you notice any side effects not mentioned in this leaflet, inform your doctor or pharmacist.

5. How to store Ziquin

Keep this medication out of the sight and reach of children. Do not store at a temperature above 30°C.

Do not use this medication after the expiry date that appears on the packaging, after the abbreviation EXP. The expiry date is the last day of the month indicated.

6. Contents of the package and additional information What Ziquin contains

The active substance is levofloxacin. Each film-coated tablet contains 500 mg of levofloxacin (as levofloxacin hemyhydrate).

The other compounds are:

- Core of the tablet: hydroxypropyl methylcellulose, crospovidone,microcrystalline cellulose, colloidal anhydrous silica, prege-latinised cornstarch and sodium stearyl fumarate.
- Tablet coating: Opadry Y-1-7000 and red ferric oxide (E-172).

Product appearance and contents of the package

Ziquin is available as pink, film-coated tablets (tablets) with a score line. The tablet can be divided in equal halves.

Each pack contains 7,10 or 200 tablets.

Marketing Authorisation Holder and Manufacturer

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

This is a Medicament

- Medicament is a product which affects your health and its
- consumption contrary to instructions is dangerous for you. Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medi-
- cament. The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of reach of children.

Council of Arab Health Ministers Union of Arab Pharmacists

- muscle and joint pain.

Very rare (may affect up to 1 in 10,000 people)

- severe decrease in white blood cells, which leads to symptoms such as fever, sore throat and feeling increasingly sick, sudden drop in arterial pressure or collapse (shock),
- decrease in blood sugar level (especially in diabetic patients), psychotic reactions with self-harming behaviours, including suicidal ideas or acts.

This leaflet was last revised in: March 2012