

## Package leaflet: Information for the user

### Ziquin 500 mg film-coated tablets

#### Levofloxacin

#### **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 get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

#### **In this leaflet:**

1. What Ziquin is and what it is used for
2. Before you take Ziquin
3. How to take Ziquin
4. Possible side effects
5. How to store Ziquin
6. Further information

#### **1. What Ziquin tablets are and what they are used for**

##### **What this medicine is**

The active substance in your tablets is levofloxacin. This belongs to a group of medicines known as fluoroquinolone antibiotics, which kill bacteria.

##### **What this medicine does**

Ziquin tablets are used to treat infections caused by bacteria that are sensitive to levofloxacin. Your doctor will have decided if your infection can be treated with this medicine. Ziquin can be used to treat infections of the:

- Sinuses
- Lungs, in people with long-term breathing problems or pneumonia
- Urinary tract, including your kidneys or bladder
- Prostate gland, where you have a long lasting infection
- Skin and underneath the skin, including muscles. This is sometimes called ‘soft tissue’.

#### **2 Before you take Ziquin tablets**

##### **Do not use Ziquin tablets**

- if you are allergic (hypersensitive) to Levofloxacin or to other active substances that belong to the same group of antibiotics (i.e. quinolones) or to any of the other ingredients of the medicine.
- if you suffer from epilepsy. Otherwise, your risk of getting “fits” (convulsions) is increased.
- if you had ever had tendon problems (e.g. tendonitis) relating to treatment with an active substance that belongs to the same class of antibiotics (i.e. fluoroquinolones).
- if you are or planning to become pregnant or if you are breast feeding.
- if the tablets have been prescribed to children or growing teenagers. They could harm the cartilage of their growing bones. **The tablets are only intended for adults.**

Tell your doctor if you have had any problems with taking medicines in the past.

### **Take special care with Ziquin tablets**

- if you have experienced “fits” or brain damage in the past (such as stroke or severe brain injury). Make sure your doctor knows about your medical history, so he can give you appropriate advice.
- when you are exposed to sunlight or UV light. Do not stay out in strong sunlight for unnecessarily long periods and do not use a sun-lamp or solarium. Your skin may become more sensitive to light whilst using this medicine (may cause sunburn – like reactions).
- if you get pain or inflammation in your tendons, particularly if you are elderly or taking any medicines known as the corticosteroids (cortisone or similar medicines used as anti-inflammatory in many disorders such as asthma, allergic conditions/reactions and arthritis). If you experience any tendon complaints whilst or shortly after taking the tablets you should seek medical advice immediately and rest the affected limb to avoid tendon damage. Do not take the next dose of Ziquin unless your doctor tells you to.
- if you have severe, persistent and/or bloody diarrhoea during or after treatment with the tablets. This may be a sign of serious bowel inflammation (pseudomembranous colitis) which can occur following treatment with antibiotics. Tell your doctor immediately. It may be necessary to stop treatment and start specific therapy.
- if you have a family history of or have an actual defect in the liver enzyme called glucose-6-phosphate dehydrogenase (G6PD) (a rare hereditary disease). Patients with G6PD deficiency may be prone to destruction of red blood cells (haemolysis) when treated with quinolone antibacterial agents.
- if you suffer from kidney problems. Patients with reduced kidney activity (renal insufficiency) may need lower doses than patients with normal kidney activity.
- if you are taking any medicines which thin the blood (known as anti-coagulants e.g. warfarin).
- if you have ever had mental health problems. Tell your doctor immediately if your opinion and thoughts change (a psychotic reaction).
- if you have ever had symptoms due to nerve damage such as movement or sensory problems in hand and feet, that are more severe at night..
- if you have ever had heart problems.
- if you are diabetic and taking medicines by mouth that lowers blood glucose levels.
- if you have ever had liver problems. You should stop treatment and contact your doctor immediately if symptoms of liver disease develop such as reduced appetite, yellowing of the skin or whites of the eyes (jaundice), dark urine, itching or gastrointestinal disturbances.
- if you have allergic reactions to the medicine. In that case, you should stop treatment immediately and contact your doctor or an emergency doctor.

### **Heart problems**

Caution should be taken when using this kind of medicine, if you were born with or have family history of prolonged QT interval (seen on ECG, electrical recording of the heart), have salt imbalance in the blood (especially low level of potassium or magnesium in the blood), have a very slow heart rhythm (called 'bradycardia'), have a weak heart (heart failure), have a history of heart attack (myocardial infarction), you are female or elderly or you are taking other medicines that result in abnormal ECG changes (see section Taking other medicines)

If your eyesight becomes impaired or if your eyes seem to be otherwise affected, consult an eye specialist immediately.

### **Taking other medicines**

You must tell your doctor if you are taking other medicines that can alter your heart rhythm: medicines that belong to the group of anti-arrhythmics ) e.g. quinidine, hydroquinidine, disopyramide, amiodarone, sotalol, dofetilide, ibutilide), tricyclic antidepressants, some antimicrobials (that belong to the group of macrolides) some antipsychotics.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines you buy without a prescription, including herbal medicines.

Some medicines can interfere with your treatment or alter blood levels of those medicines you are currently taking, so make sure to check with your doctor or pharmacist before taking any other medications whether prescribed by a doctor or bought by you over the counter. In particular tell your doctor if you are taking any of the following:

- iron salts (used to treat anaemia), magnesium- or aluminium – containing antacids (medicines against heartburn and stomach pain) or medicines containing these salts. These drugs can reduce the absorption and efficacy of Ziquin tablets and as such they should be taken at least 2 hours before or after Ziquin tablets.
- sucralfate (used to protect the stomach wall). It may affect the absorption and reduce the efficacy of Ziquin tablets. It is best to take sucralfate 2 hours after Ziquin tablets.
- Vitamin K antagonists such as warfarin (used to prevent blood clots). In combination with Ziquin tablets may lead to an increase in bleeding.
- theophylline (used to treat asthma). The risk of getting “fits” may be increased.
- probenecid (used to prevent gout) or cimetidine (used to treat ulcers) reduce your kidneys ability to get rid of levofloxacin.
- ciclosporin (e.g. used to treat psoriasis, dermatitis, rheumatism). The effect of this medicine may be prolonged if used in combination with Ziquin tablets.
- corticosteroids, sometimes called steroids – used for inflammation. You may be more likely to have inflammation and/or breakage of your tendons.
- non-steroidal anti-inflammatory drugs (NSAIDS) – used for pain and inflammation such as aspirin, ibuprofen, fenbufen, ketoprofen and indomethacin. You are more likely to have a fit (seizure) if taken with Ziquin tablets.

### **Taking Ziquin tablets with food and drink**

Ziquin tablets may be taken during meals or at any time between meals. Swallow the tablets with a glass of water.

### **Pregnancy and Breast-feeding**

Do not take Ziquin tablets if you are pregnant or breast feeding a baby. It could harm your baby.

### **Driving and using machines**

Some side – effects like dizziness, drowsiness and visual disturbances may impair your ability to concentrate and react. Do not drive, operate dangerous machinery or have similar activities if you feel that your ability to concentrate and react is impaired.

## **3. How to take Ziquin tablets**

Always take Ziquin exactly as your doctor has told you.

You should check with your doctor or your pharmacist if you are not sure.

The duration of the treatment depends on the type and severity of your infection.

Your doctor will tell you how many tablets to take, at what time and for how long.

Most people need a dose of one or two tablets per day. Patients with reduced kidney activity may need lower doses.

### **Taking this medicine**

- Take this medicine by mouth
- Swallow the tablets whole with a glass of water
- The tablets may be taken during meals or at any time between meals

### **Protect your skin from sunlight**

Keep out of direct sunlight while taking this medicine. This is because your skin will become much more sensitive to the sun and may burn, tingle or severely blister if you do not take the following

precautions:

- Make sure you use high factor sun creams
- Always wear a hat and clothes which cover your arm and legs.
- Avoid sun beds.

**If you are already taking iron tablets, antacids or sulcralfate**

- Do not take this medicine at the same time as Ziquin film-coated tablets. Take your dose of these medicines at least 2 hours before or after Ziquin film-coated tablets.

**How much to take**

- Your doctor will decide on how many Ziquin film-coated tablets you should take.
- The dose will depend on the type of infection you have and where the infection is in your body.
- The length of your treatment will depend on how serious your infection is
- If you feel the effect of your medicine is too weak or strong, do not change the dose yourself, but ask your doctor.

**Adults and the elderly.**

**Infections of sinuses**

One tablet of Ziquin 500 mg, once each day.

**Infection of the lungs, in people with long term breathing problems.**

½ tablet or one tablet Ziquin 500 mg , once each day

**Pneumonia**

One tablet of Ziquin 500mg , once or twice each day.

**Infection of the urinary track, including your kidneys or bladder.**

½ tablet of Ziquin 500 mg ,each day

**Infection of the prostate gland, where you have a long lasting infection**

One tablet of Ziquin 500 mg, once each day.

**Infection of the skin and underneath the skin, including muscles**

½ tablet or one tablet Ziquin 500 mg , once or twice each day

Adults with kidney problems

Your doctor may need to give you a lower dose

Children and teenagers

**The medicine must not be given to children and teenagers.**

**If you take more Ziquin tablets than you should**

If you accidentally take one tablet too many, nothing is likely to happen. If you accidentally take several tablets too many, contact your doctor or get other medical advice. If possible, take your tablets or the box with you to show the doctor. The signs of an overdose include symptoms such as confusion, dizziness, impairment of consciousness, (convulsive) fits and heart disorder, possibly leading to abnormal heart rhythm.

**If you forget to take Ziquin tablets**

If you forget to take a dose, take it as soon as you remember, unless it is nearly time for you to take your next dose. Then go on as before. Do not take a double dose to make up for a missed dose.

**If you stop taking Ziquin tablets**

It is important to finish your course of tablets as prescribed by your doctor. Do not stop, even if you

begin to feel better before you have finished them all. If you stop the tablets too soon your condition may get worse. If you feel you have to stop of a side effect, tell a doctor immediately to get advice before taking the next dose.

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

#### **4. Possible side effects**

Like all other medicines Ziquin can cause side effects although not everybody gets them. The side effects in this section are given with an estimation of the frequency with which they may occur. If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

*Severe allergic reactions can occur very rarely. These can happen after the first dose or even after treatment has stopped. **If you get any of these side effects while having your medicine, stop having Ziquin immediately and tell your doctor or go to the nearest hospital casualty department.** Signs of an allergic reaction are:*

- fast heart rate, low blood pressure, fever, breathing problems, shock,
- swelling of the face, tongue and throat, skin reactions such as swelling and redness, blood problems, ulcers in the mouth, eyes, gut and genital organs,
- severe liver problems can develop in some people. Signs of liver problems include yellow skin, dark urine, stomach tenderness and loss of appetite.
- unaccountable muscle pain, muscle weakness muscle cramps.
- Bloody diarrhoea, fever, and mild to moderate stomach cramps (symptoms of pseudomembranous colitis).
- tendon rupture (e.g.: Achilles tendon), which may occur within 48 hours after starting treatment and may be bilateral, muscular weakness, which may be of special importance in patients with myasthenia gravis (a rare disease of the nervous system)

***Ziquin may cause a reduction in the number of white blood cells and your resistance to infection may be decreased. If you experience an infection with symptoms such as fever and serious deterioration of your general condition, or fever with local infection symptoms such as sore throat/pharynx/mouth or urinary problems you should see your doctor immediately. A blood test will be taken to check possible reduction of white blood cells (agranulocytosis). It is important to inform your doctor about your medicine.***

Other side effects include

##### Common affects 1 to 10 users in 100

- Nausea, diarrhoea
- Increase in blood levels of liver enzymes

##### Uncommon affects 1 to 10 users in 1000

- Itching and rash
- Loss of appetite, stomach upset (dyspepsia), vomiting or pain in the abdominal region
- Headache, dizziness, drowsiness, sleeping problems
- Increase or decrease in the number of white blood cells
- General weakness. Any antibacterial treatment that kills certain germs may lead to a disturbance of the micro-organisms (bacteria / fungi) that are normally found in humans. Consequently, the number of other bacteria or fungi may increase, which in rare cases requires treatment

##### Rare affects 1 to 10 users in 10,000

- General allergic reactions (anaphylactic / anaphylactoid reactions) (which may sometimes occur even after the first dose and which may develop fast within minutes or hours of intake) with symptoms such

as eheals (urticaria), cramping of the bronchi and possibly severe breathing problems, as well as in very rare cases swelling of the skin and mucous membranes (e.g. in the face and throat)

- Feeling like tingling, e.g. in the hands (paraesthesia), trembling, “fits” (convulsions) and confusion
- Anxiety, depression, psychotic reactions, restlessness (agitation)
- Abnormally rapid beating of the heart, abnormally low blood pressure
- Tendon pain and inflammation (tendonitis), joint pain or muscle pain
- Decrease in the number of blood platelets leading to tendency to bruise and bleed easily

Very rare affects less than 1 user in 10,000

- Sudden drop in blood pressure or collapse (shock), mild skin reactions, increased sensitivity of the skin to sun and ultraviolet light
- Decrease in blood sugar to a too low level (hypoglycaemia) which may be of special importance in patients treated for diabetes, attacks of porphyria in patients with porphyria (a very rare metabolic disease)
- Vision and hearing disorders, disturbances of taste and smell, numbness, disorders of movement, including walking difficulties.
- Hallucinations, psychotic reactions with risk of suicidal thoughts or actions.
- Circulatory collapse (anaphylactic like shock).
- Severe decrease in the number of white blood cells (agranulocytosis) leading to symptoms such as recurrence or persistence of fever, sore throat and feeling more ill again
- Inflammation of the liver; disturbances of kidney function and occasional kidney failure due to allergic kidney reactions (interstitial nephritis).
- Fever, allergic inflammation of small blood vessels or allergic lung reactions.

Not known frequency cannot be estimated from the available data.

- Severe blistering reactions of the skin and mucous membranes (Steven’s Johnson syndrome), toxic epidermal necrolysis (Lyells’ syndrome) and erythema exsudativum multiforme.
- Decrease in red blood cells (anaemia) due to blood cell damage, decrease in the number of all types of blood cells.

#### Heart problems

Not known: Abnormal fast heart rhythm, life-threatening irregular heart rhythm 'alteration of the heart rhythm (called 'prolongation of QT interval', seen on ECG, electrical activity of the heart.

### **5. How to store Ziquin tablets**

Keep out of the reach and sight of children.

Do not use this medicine after the expiry date which is shown on the packaging. The expiry date refers to the last day of the month.

Do not store at a temperature above 30°C.

Keep the blister in the outer carton in order to protect from light.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

### **6. Further information**

#### **What Ziquin contains**

The active ingredient is levofloxacin.

Each tablet of Ziquin 500 mg tablets contains 500 mg of levofloxacin hemihydrates equivalent to 500 mg of levofloxacin.

The other ingredients are:

Tablet core: hydroxypropyl methylcellulose, crospovidone, microcrystalline cellulose, colloidal

anhydrous silica, pregelatinized corn starch and sodium stearyl fumarate.  
Film coating: Opadry Y-1-7000 and red iron oxide (E-172).

**What Ziquin looks like and contents of the pack**

Ziquin 500 mg film-coated tablets are biconvex pink color film coated oblong tablets, scored and with “L” engraved on one side. The tablet can be divided into equal halves.

Each pack contains 5 tablets (one blister of 5 tablets), 7 tablets (one blister of 7 tablets) or 10 tablets (one blister of 10 tablets).

**Marketing Authorisation Holder and Manufacturer**

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

**This leaflet was last revised in May 2015**

**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 medicament.
- 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**