

# 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

1. What Ziquin is and what it is used for
2. What you need to know before taking Ziquin
3. How to take Ziquin
4. Possible side effects
5. How to store Ziquin
6. Contents of the package and additional information

### 1. What Ziquin is and what it is used for

Ziquin contains a medication known as levofloxacin, which is an antibiotic belonging to the fluoroquinolone 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 (tendonitis) 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 probability 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 hypoglycaemics.
- 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 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 diarrhoea, during or after treatment with levofloxacin, inform

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.

– 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 that belong to the antiarrhythmic drug group (such as quinidine, hydroquinidine, disopyramide, amiodarone, sotalol, dofetilide, ibutilide), tricyclic antidepressants, some antibiotics (belonging to the macrolide group) and some antipsychotic drugs.

– Theophylline, since it increases the risk of seizures (attacks).

– Probenecid and cimetidine may reduce renal elimination of levofloxacin.

– Sucralfate 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. Sucralfate 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.

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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 than 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 tendon)
- 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