

PATIENT INFORMATION LEAFLET

ZIROMIN 500 mg Film-coated Tablets

Taken orally.

- **Active Substance:** Azithromycin dihydrate equivalent to 500 mg Azithromycin.
- **Excipients:** Pregelatinized starch, hydroxypropyl cellulose, calcium hydrogen phosphate dihydrate, sodium lauryl sulphate, croscarmellose sodium, anhydrous lactose (originating from cow's milk), colloidal anhydrous silica, magnesium stearate, film coating Opadry® white Y-1-7000 (Hypromellose 2910 5cp, Polyethylene glycol 400 and Titanium dioxide (E171)).

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

- *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. Do not pass it on to others.*
- *If you go to doctor or hospital at the time of using this medicine, please tell your doctor.*
- *Please follow the instructions exactly. Do not use another **high or low doses** out of recommended.*

In this leaflet:

- 1. What is ZIROMIN and what it is used for?***
- 2. Before you take ZIROMIN.***
- 3. How to take ZIROMIN?***
- 4. Possible side effects***
- 5. How to store ZIROMIN?***

1. WHAT IS ZIROMIN AND WHAT IT IS USED FOR?

ZIROMIN is a 500 mg film coated tablets. It is presented in blister packages of 3 tablets, each tablet contains 500 mg azithromycin. ZIROMIN is a white coloured, one side notched, one side flat, oblong film-coated tablet.

ZIROMIN belongs to group of antibiotics called macrolide. It is used to treat infections caused by certain bacteria and other micro-organisms, which include:

- Chest, throat or nasal infections (such as bronchitis, pneumonia and sinusitis)
- Tonsillitis caused by *Streptococcus pyogenes*, in presence of penicillin allergy in treatment of sore throat (pharyngitis)
- Ear infections
- Skin and soft tissue infections (such as abscess or boil)
- Sexually transmitted diseases caused by an organism called *Chlamydia*
- Connected soft tissue ulcer caused by a microorganism called *Haemophilus ducreyi* and sexually transmitted infections without other concomitant infection caused by a microorganism called *Neisseria gonorrhoeae*, which is not multi-resistant

2. BEFORE YOU TAKE ZIROMIN

DO NOT USE ZIROMIN in following situations

If;

- You are allergic to ZIROMIN or other macrolide antibiotics such as erythromycin / clarithromycin or any of ingredients of ZIROMIN. An allergic reaction may cause skin rash or wheezing.
- You have hepatic problems.
- You are using one of the ergot derivatives such as ergotamine (used for migraine treatment)

Take ZIROMIN carefully in following situations

If;

- You have renal problems
- You have heart disease
- There are infectious diseases that have occurred jointly in a community
- You are diagnosed or have suspected bacteria or bacterial toxins in the blood
- You are an inpatient
- You are elderly or extremely weakness

- You have other severe health problems (immune system insufficiency or congenital absence of spleen/removal of the spleen by surgical intervention (asplenia) etc.)
- You have hepatic problems
- As with other antibiotic medicines, risk of a second infection in the body weakened by any infection due to non-susceptible organisms, including fungi, should be observed by your doctor.
- Diarrhoea problem occurs

If these warnings are valid for you, even at any time in the past, please consult your doctor.

Using of ZIROMIN with food and drink

Take ZIROMIN either 1 hour before a meal or 2 hours after a meal.

Pregnancy

Consult your doctor or pharmacist before using the drug.

You should not take ZIROMIN if you are pregnant or trying to get pregnant, unless consult your doctor.

ZIROMIN should be used during pregnancy, only when required.

Consult your doctor or pharmacist immediately if you realize you are pregnant during treatment.

Breast-feeding

It is not known that a ZIROMIN is excreted with mother's milk or not.

Consult your doctor or pharmacist before using the drug.

Driving and using machines

It is not expected that ZIROMIN has an effect on the ability to drive or use machines.

Usage with the other medicines

Inform your doctor whether you are taking the medicines listed below, before take ZIROMIN and share your questions or concerns about ZIROMIN or other medicines to your doctor or pharmacist:

- Antacids - used for heartburn and indigestion. Azithromycin should be taken at least 1 hour before or 2 hours after the antacid
- Ergotamine -dihydroergotamine (used for migraine) should not be taken at the same time as serious side effects may develop (ergotism - i.e. itching in the limbs, muscle cramps and gangrene of hands and feet due to poor blood circulation)
- Cholesterol lowering medicines (statins)
- Hydroxychloroquine (used to treat rheumatic diseases or malaria): heart problems may occur
- Warfarin or a similar medicine to prevent blood clots
- Cisapride - (used to treat stomach problems), or terfenadine (used to treat hay fever): should not be taken at the same time as this may cause severe heart problems (shown on an electrocardiogram or ECG machine)
- Zidovudine or nelfinavir - used to treat HIV infections. Taking nelfinavir with Azithromycin may mean that you get more of the side effects listed in this leaflet
- Cyclosporin (used to suppress the immune system to prevent and treat rejection of a transplanted organ or bone marrow)
- Rifabutin - used to treat tuberculosis (TB)
- Quinidine - used to treat heart rhythm problems (called antiarrhythmics)

If you are taking antacid for indigestion, you should take ZIROMIN either one hour before taking antacid or two hours after taking antacid.

A decrease in number of fragmented cells in blood has been observed in patients taking rifabutin with ZIROMIN.

Please inform your doctor or pharmacist about prescribed or non-prescribed medicines you use or have used recently.

3. HOW TO TAKE ZIROMIN

Instructions for appropriate usage and dosage/frequency of administration:

ZIROMIN should be taken as a single daily dose.

For the treatment of sexually transmitted diseases caused by *Chlamydia trachomatis*, *Haemophilus ducreyi* or susceptible *Neisseria gonorrhoeae*, the dose is 1000 mg taken orally once.

For all the other indications, the total dose is 1500 mg, taken as 500 mg daily for 3 days.

In the treatment of *S. pyogenes* tonsillitis/pharyngitis, the total dose is administered in a period of 5 days, 500 mg on the first day and 250 mg on following days (2nd, 3rd, 4th and 5th day).

Method of administration:

It should be swallowed whole by orally.

Use in various age groups

Use in children:

Adult dose is administrated in children over 45 kg. The maximum recommended total dose for any treatment other than tonsillitis / pharyngitis in children is 1500 mg. In the treatment of *S. pyogenes* tonsillitis/pharyngitis, the total dose (1500 mg) is administered in a period of 5 days, 500 mg on the first day and 250 mg daily on following days (2nd, 3rd, 4th and 5th day).

Oral suspension forms are available for children under 45 kg body weight.

Since efficacy and safety of azithromycin has not shown in infants under 6 months yet, administration is not recommended.

Use in elderly:

For elderly the same dosage as for adults uses.

Special usage conditions:

Renal Impairment:

If you have mild to moderate renal impairment, no dose adjustment is required. If you have severe renal impairment, caution should be taken when administering of azithromycin.

Hepatic Impairment:

If you have mild to moderate hepatic impairment, same dose can be administered as in patients with normal hepatic function.

It should not be used in severe hepatic impairment.

If have an impression about that effect of ZIROMIN is too strong of too weak, consult your doctor or pharmacist.

If you take more ZIROMIN than you should

If you take too much ZIROMIN, you may feel uncomfortable. In such case, talk to your doctor or go to the emergency department of the nearest hospital. Take the remainder of the medicine along with yourself.

If you use more ZIROMIN than you should, please talk to your doctor or pharmacist.

If you forget to take ZIROMIN

If you forget to take ZIROMIN, take it as soon as you can. Take next dose at the right time.

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

If you stop taking ZIROMIN

If you stop taking ZIROMIN too soon, the infection may occur again.

Take ZIROMIN even if you start to feel better, until the treatment of your doctor recommend is completed. Do not stop taking ZIROMIN, without talking to your doctor.

If you have any further questions about the use of this medicine, consult your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, side effects may occur in people who are hypersensitivity to excipients of ZIROMIN.

If you have any of the following symptoms after taking this medicine **inform your doctor immediately**. Symptoms may be severe, although they are rare.

- Irregular heartbeat, shortness of breath, dizziness or fainting during use of ZIROMIN,
- Sudden wheezing,
- Difficulty in breathing,
- Swelling of eyelids,

- Swelling of face or lips,
- Rash or itching (especially if it effects the whole body).

The most common side effects are listed below during use of ZIROMIN. These may disappear during treatment as your body gets used to the medicine. If one of these side effects continue disturbing you, inform your doctor.

Side effects are listed as shown in categories below.

Very common	: May seen in more than 1 in 10 patients
Common	: May seen in less than 1 in 10, but more than 1 in 100 patients
Uncommon	: May seen in less than 1 in 100, but more than 1 in 1000 patients
Rare	: May seen in less than 1 in 1000, but more than 1 in 10000 patients
Very rare	: May seen in less than 1 in 10000 patients
Not known	: Cannot estimated with obtained data

Very common

- Diarrhoea
- Abdominal pain
- Nausea
- Flatulence

Common:

- Headache, feeling dizzy
- Sensation of pins and needles or numbness in skin
- Abnormal taste disturbance, loss of appetite
- Visual impairment, loss of sense
- Vomiting, indigestion
- Skin rashes and itching
- Joint pain
- Low number of lymphocytes (a type of white blood cell), high number of eosinophil (a type of white blood cell)

- Low level of bicarbonate in the blood
- Fatigue

Uncommon:

- Fungal inflammation inside mouth and vagina (candidiasis)
- Low numbers of leukocyte (a type of white blood cell), neutrophil (a type of white blood cell)
- Allergic reactions at various levels
- Disseminated rash and skin exfoliation
- Severe skin reactions due to exposure to light or sunlight
- Urticaria
- Nervousness
- Reduced sense of touch
- Feeling drowsy
- Sleeping difficulty
- Ringing in the ears or hearing loss (irreversible)
- Irregular heartbeat
- Constipation
- Hepatic Inflammation
- Chest pain
- Weakness
- Swelling
- General discomfort
- Abnormal laboratory test values (i.g. Blood or hepatic tests)
- Vomiting accompanied by abdominal pain (with or without blood)

Rare:

- Anxiety
- Spinning sensation (vertigo)
- Abnormal hepatic function

Additional side effects obtained after post-marketing

Not known:

Aggression, anxiety, convulsion, hyperactivity, fainting

Loss of smell or change in sense of smell, loss of taste

Cardiac arrhythmia, too fast heartbeat, irregular heartbeat

Low blood pressure

Pancreatic inflammation, discoloration of the tongue, severe skin reactions

Hepatic impairment, dysfunction of the hepatic, jaundice, skin rash

Renal impairment, kidney inflammation

Abnormal electrocardiogram (EKG)

Abdominal pain with fever and diarrhea

Easily bruising or bleeding

Tiredness accompanied by dark coloured urine

Local muscle weakness

Inform your doctor or pharmacist if you meet any other side effect which is not written in this leaflet.

5. HOW TO STORE ZIROMIN

Keep ZIROMIN out of the reach and sight of children and in its package.

Do not store above 30°C.

Use in accordance with expiry date.

Do not use ZIROMIN after the expiry date on package.

Do not use ZIROMIN if you notice deficiencies on product and/or package.

Marketing Authorisation Holder

World Medicine İlaç San. ve Tic. A.Ş.

Bağcılar / İstanbul /TURKEY

Manufacturer site

World Medicine İlaç San. ve Tic. A.Ş.

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