

Ruhsat sahibi:	"World Medicine İlaç San. ve Tic. A.Ş." Türkiye
Üretim yeri:	"World Medicine İlaç San. ve Tic. A.Ş." Türkiye (Güneşli)
Malzeme adı:	RW K.TAL ZIROMIN 200MG POW F.SUSP WM/GUR0
Tarih:	10.07.2024 (11:58) Ö
Farmakod:	IIIIIIII _____ ■
Print kodu / Malzeme kodu:	PM _____
Boyut:	150 x 270 mm (± 0.3 mm)
Renk:	■ PANTONE Process Black U
Kağıt cinsi:	1. Hamur 60 g/m ² ± %10
Su yolu:	Kısa kenara paralel
Versiyon:	00



ZIROMIN

PATIENT INFORMATION LEAFLET

ZIROMIN 200 mg/5 mL Powder for Oral Suspension For oral use.

- **Active substance:** Each 5 ml suspension contains 209.6 mg Azithromycin dihydrate equivalent to 200.00 mg Azithromycin.
- **Excipients:** Saccharose, Sodium phosphate tribasic, Sodium benzoate, Hydroxypropyl cellulose, Xanthan gum, Cherry flavor, Banana flavor.

Read all of this LEAFLET carefully before you start using this medicine because it includes special information for you.

- *Keep this leaflet. You may need to read it again.*
- *If you have any further questions, please 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 ZIROMIN is and what it is used for
2. Before you take ZIROMIN
3. How to take ZIROMIN
4. What are possible side effects?
5. How to store ZIROMIN

1. What ZIROMIN is and what it is used for

ZIROMIN powder for Oral Suspension is white colored, cherry scented, fluid, homogeneous, free from particles in pellet form granules which constitutes white or off-white suspension after reconstitution with water. It is presented in 60 ml of natural high density polyethylene (HDPE) bottles. Each 5 ml suspension contains 209.6 mg Azithromycin dihydrate equivalent to 200.00 mg Azithromycin.

ZIROMIN is in the group of antibiotics called macrolides. It is used in the treatment of infections -that the examples are given below- caused by some bacteria and other micro-organism:

- Chest, throat or nasal infections (such as bronchial inflammation, pneumonia, and sinusitis),
- Tonsillitis caused by Streptococcus pyogenes in presence of penicillin allergy in the sore throat (pharyngitis) treatment,
- Acute ear infections (acute otitis media),
- Skin and soft tissue infections (such as an abscess or boil),
- Sexually-transmitted diseases caused by an organism called chlamydia,
- Connected soft tissue ulcer caused by an organism called Haemophilus ducreyi and sexually-transmitted infections that no another accompanying infection is present caused by an organism called non multi-resistant Neisseria gonorrhoeae.

2. Before you take ZIROMIN

Do not take ZIROMIN in the conditions below.

- If you:
- are allergic to ZIROMIN or any other macrolide antibiotic such as erythromycin/ clarithromycin or any of the ingredients in the composition of ZIROMIN. An allergic reaction may cause skin rash or wheezing,
 - have liver problems,
 - are taking any ergot derivatives such as ergotamine (used to treat migraine).

Take special care with ZIROMIN in the following conditions

- If,
- you have kidney problems,
 - you have heart disease,
 - there are infection diseases in common occurred in a community,
 - passing of bacteria or bacteria toxins into blood is diagnosed or if there is a suspicion,
 - you are an in-patient,
 - you are old or too weak,
 - you have any other serious health problems (in cases of immune system insufficiency or congenital lack of spleen/ removal of spleen by surgery (asplenia), etc.),
 - you have liver disease,
 - as in other antibiotic drugs, the second infection risk in structure, which becomes weak with any infection related to insensitive organisms including fungus, should be observed by your doctor,
 - diarrhea problem occurs.

If any of these warnings applies or have been applied to you, even at a time in the past, please consult your doctor.

Taking ZIROMIN with food and drink

ZIROMIN is not affected by food or drink.

Pregnancy

Before using the drug, consult your doctor and pharmacist.

If you are pregnant, trying to become pregnant, you should not take ZIROMIN without consulting it with your doctor first.

ZIROMIN should only be used during pregnancy if necessary.

If you realize that you are pregnant during treatment, immediately consult your doctor or pharmacist.

Breast-feeding

It is not known whether ZIROMIN is excreted in breast milk or not. Do not take ZIROMIN suspension before asking your doctor.

Before taking the drug, consult your doctor or pharmacist.

Driving and using machines

ZIROMIN is not expected to affect your ability to drive or use machines.

Some important information about some excipients present in ZIROMIN content

This product contains saccharose. If you have been informed in the past by your doctor that you are intolerant to some sugars, contact your doctor before taking this medicinal product.

This product contains sodium. This should be considered for patients who are on a controlled sodium diet.

Taking with other medicines

Before taking ZIROMIN, tell your doctor whether you have taken one of the drugs listed below or not and share your questions and worries about ZIROMIN or other drugs with your doctor or pharmacist:

- Ergot or ergotamine,
- Warfarin or any similar medicine to prevent blood clots,
- Cyclosporine (used to suppress the immune system to prevent and treat rejection of a transplanted organ or bone marrow in organ or bone marrow transplantation),
- Digoxin (used for heart failure treatment),
- Theophylline (used for asthma treatment),
- Nelfinavir (used for HIV infection treatment).

If you take antacid for dyspepsia, you should take ZIROMIN one hour before or two hours after you take antacid.

A decrease in fragmented cell number in blood has been seen in patients taking rifabutin with ZIROMIN.

Please inform your doctor or pharmacist if you are taking at present or have recently taken any other medicines including medicines without a prescription.

3. How to take ZIROMIN

Instructions for proper using and dose/administration frequency:

ZIROMIN suspension is generally used for children under 45 kg. It may also be used in adults and older children who have difficulty swallowing capsules.

ZIROMIN should be taken as a single daily dose.

For treatment of sexually transmitted diseases due to *Chlamydia trachomatis*, *Haemophilus ducreyi* or susceptible *Neisseria gonorrhoeae*, the dose is 1000 mg in one single oral dose.

For treatment of pharyngitis/tonsillitis due to *S. pyogenes*, total dosage is given over a period of 5 days with 500 mg on the first day and then 250 mg on next days (2nd, 3rd, 4th and 5th day).

For all other indications the total dose is 1500 mg, to be taken as 500 mg per day during 3 days.

The adult dose is administered in children over 45 kg.

The normal dose in children under 45 kg is 10 mg per kg of body weight and it is given as single daily dose for 3 days.

Except treatment of Streptococcal pharyngitis, dose for children is 30 mg/kg in total, as a single dose of 10 mg/kg/day for 3 days or alternatively a single dose of 10 mg/kg for the first day and a single dose of 5 mg/kg for days 2 to 5 for 5 days.

Acute: As an alternative to doses above, a single dose of 30 mg/kg may be administered for treatment of ear infections (acute otitis media).

For pediatric streptococcal pharyngitis, it is shown that administration of Azithromycin as single daily dose of 10 mg/

70 mm

8 mm

8 mm

70 mm

kg or 20 mg/kg for 3 days is effective, however daily dose of 500 mg should not be exceeded. In some cases, your doctor may apply a therapy with different doses from mentioned doses above.

Administration route and method:
For oral use.

Preparation:
Shake the bottle containing powder. Then, take boiled and cooled water into the 5 ml syringe and add to bottle content 3 times and shake well. Powder in the bottle should be reconstituted with totally 15 ml boiled and cooled water. After reconstitution, 5 ml measuring cup contains 200 mg Azithromycin. Shake the bottle before every time you use.

Take suspension with 5 ml dose graduated syringe calibrated accordingly 0.10 ml intervals.

Different age groups:

Administration in pediatrics:
Information about use of ZIROMIN suspension in children is presented above.

It is not recommended to use Azithromycin on babies younger than 6 months.

Administration in elderly patients:

The same dose as in adult patients is used in the elderly patients.

Specific usage conditions

Renal failure:
No dose adjustment is necessary if you have mild and moderate level renal impairment. Caution should be exercised when Azithromycin is administered to patients with severe renal impairment.

Liver failure:
If you have mild and moderate level liver impairment, same dosage as in patients with normal liver function can be administered.

It should not be used in severe liver failure.

If you take impression about effect of ZIROMIN whether its effect stronger or weak, contact your doctor or pharmacist.

If you take more ZIROMIN than they should:

If you take too much ZIROMIN, you may feel unwell. In this case, tell your doctor or go to emergency department of the nearest hospital. Take any remaining medicine with you.

If you take more ZIROMIN than you should do, 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 your next dose at the right time.

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

Effects that may occur when treatment with ZIROMIN is terminated:

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

Take ZIROMIN as long as your doctor recommends, even if you begin to feel better. Do not stop taking ZIROMIN without talking to your doctor.

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

4. What are possible side effects?

Like all medicines, ZIROMIN can cause side effects to patients, who are sensitive to the substances in its content.

Tell your doctor immediately if you experience any of the following symptoms after taking this medicine. The symptoms may be severe although they are rare.

- Irregular heartbeat, asphyxia, dizziness or fainting,
- Fulminant wheeziness,
- Difficulty in breathing,
- Swelling of eyelids,
- Swelling of face or lips,
- Rash or itching (especially if it is affecting the whole body).

The most common side effects that occur while taking ZIROMIN are listed below. These may go away during treatment as your body adjusts to the medicine. Tell your doctor if any of these side effects continue to bother you:

Side effects are shown as listed in the categories below:
Very Common :It may be seen at least 1 in 10 patients.

Common :It may be seen less than 1 in 10 patients, but more than 1 in 100 patients.
Uncommon :It may be seen less than 1 in 100 patients, but more than 1 in 1000 patients.
Rare :It may be seen less than 1 in 1000 patients.
Very Rare :It may be seen less than 1 in 10000 patients.
Not known :It cannot be estimated with the available data.

Very Common:

- Diarrhea,
- Stomachache,
- Nausea,
- Gas.

Common:

- Headache, dizziness,
- Pins and needles, prickling sensation or numbness on skin,
- Abnormal taste disorder, loss of appetite,
- Visual disorders, sensory loss,
- Vomiting, dyspepsia,
- Rash, itching,
- Joint pain,
- Low numbers of lymphocytes (a white blood cell type), higher number of eosinophils (a white blood cell type),
- Low blood bicarbonate,
- Tiredness.

Uncommon:

- Fungal infections of the mouth and vagina (thrush),
- Low numbers of leukocytes (a white blood cell type), low number of neutrophils (a white blood cell type),
- Allergic reactions of various severity,
- Common rash and desquamation,
- Severe skin reactions due to exposure to light or sunlight,
- Rash,
- Aggression,
- Reduced sense of touch,
- Sleepiness,
- Sleeplessness,
- Ringing in the ears, loss of hearing (irreversible),
- Irregular heartbeat,
- Constipation,
- Liver Inflammation,
- Chest pain,
- General loss of strength,
- Swelling,
- General discomfort,
- Abnormal laboratory test values (i.e. Blood and liver tests),
- Vomiting accompanied by stomach-ache (bloody or non -bloody).

Rare:

- Anxiety,
- Dizziness (vertigo),
- Abnormal liver functions.

Additional side effects obtained post-marketing:

Unknown:

- Aggression, anxiety, convulsion, hyperactivity, fainting,
- Loss of smell or altered sense of smell, loss of taste,
- Cardiac dysrhythmia, fast heart rhythms, irregular heartbeat,
- Low blood pressure,
- Inflammation of the pancreas, color change on tongue, severe skin reactions,
- Liver failure, loss of liver function, jaundice, redness on skin,
- Renal failure, inflammation of the kidney,
- Abnormal electrocardiogram (ECG),
- Stomach ache accompanied by fever and diarrhea,
- Easily bruising or bleeding,
- Tiredness accompanied by dark urine,
- Regional muscle weakness.

Please inform your doctor or pharmacist if you experience any side effect that is not included in this patient information 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. It can be stored for 5 days at the room temperature after reconstitution.

Use in accordance with expiry date.

Do not use ZIROMIN after the expiry date on the package.

Marketing Authorization Holder:

World Medicine İlaç San. ve Tic. A.Ş.
Bağcılar / İstanbul / TURKEY

Manufacturing Site:

World Medicine İlaç San. ve Tic. A.Ş.
15 Temmuz Mahallesi, Cami Yolu Caddesi No:50
Güneşli / Bağcılar / İstanbul / TURKEY

70 mm

8 mm

8 mm

70 mm