PACKAGE LEAFLET: INFORMATION FOR THE USER

AZITRO 200 mg/5 ml Powder for Oral Suspension
Taken by mouth.

Active substance: Each 5 ml of reconstituted oral suspension contains azithromycin dihydrate equivalent to 200 mg azithromycin.
Excipient(s): Sodium phosphate, tribasic; sodium benzoate; sodium saccharin; colloidal silicon dioxyde; hydroxypropyl methylcellulose; xanthan gum; banana flavor; sucrose

Read all of this PACKAGE LEAFLET carefully before you start using this medicine because 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.*
- *During the period when you take this medicine, tell your doctor that you take this drug when you go to doctor or hospital.*
- *Exactly comply with what is written in this leaflet. Do not take either a* ***higher*** *or* ***lower*** *dose other than recommended to you for this medicine.*

In this leaflet:

1. WHAT AZITRO IS AND WHAT IT IS USED FOR

AZITRO is white to off white granular powder, which forms a creamy-white, homogeneous suspension when reconstituted with a characteristic odor. It is presented in semi opaque plastic bottles of 15 ml or 30 ml. Each measuring spoon (5 ml) contains Azithromycin Dihydrate equivalent to 200 mg Azithromycin.

AZITRO belongs to a group of antibiotics called macrolides. It is used to treat infections caused by certain bacteria and other microorganisms, some examples of these infections are listed below:
- Chest, throat and nasal infections (inflammation of bronchi, lungs and sinusitis etc.)
- Infections of tonsils caused by *Streptococcus pyogenes* (tonsillitis), in treatment of sore throat (pharyngitis) in presence of penicillin allergy
- Acute ear infections (acute otitis media)
- Skin and soft tissue infections (abscesses or boils etc.)
- Sexually transmitted diseases caused by a microorganism called *Chlamydia*
- Soft tissue ulcers caused by a microorganism called *Haemophilus ducreyi* and uncomplicated genital infections caused by a non-multi resistant microorganism called *Neisseria gonorrhoeae*, when there are no other accompanying infections

2. BEFORE YOU USE AZITRO

DO NOT USE AZITRO
- If you are allergic to AZITRO or any other macrolide antibiotic such as erythromycin or clarithromycin or any of the ingredients in AZITRO. An allergic reaction may cause skin rash or wheezing.
- If you have liver problems.
- If you are using any ergot derivatives such as ergotamine (used to treat migraine).

Take special care with AZITRO
- If you have kidney problems.
- If you have heart disease.
- If there is a community-acquired infection
- If you have been diagnosed or suspected that bacteria or bacterial toxins are present in blood.
- If you are bedridden.
- If you are old or very weak.
- If you have other serious health problems (immunodeficiency, or absence of a spleen at birth/ spleen was removed by surgery (asplenia), etc.)
- If you have a liver disease.
- As with other antibiotics, there is risk of a secondary infection caused by non-susceptible organisms including fungi when your body has already been weakened by an existing infection, therefore you should be monitored by your doctor against this risk.
- If you develop diarrhea.

Please consult your doctor, even if these warnings were applicable to you at any time in the past.

Using AZITRO with food and drink
AZITRO is not affected by food or drink.

Pregnancy
Consult your doctor or pharmacist before taking this medicine.
If you are pregnant or planning to get pregnant, you should consult your doctor before taking AZITRO.
AZITRO should not be used during pregnancy unless it is clearly needed.

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

Breast-feeding
Consult your doctor or pharmacist before taking this medicine.
It is not known whether AZITRO is excreted in human milk. You should not take AZITRO without discussing it with your doctor first.

Driving and using machines
AZITRO is not expected to affect your ability to drive or use machines.

Important information about some of the ingredients of AZITRO
This medicine contains sucrose. If you have been told by your doctor that you have an intolerance to some sugars contact your doctor before taking AZITRO.

This medicine contains than 1.2 mmol sodium (27.58 mg); to be taken into consideration by patients on a controlled sodium diet.

Using other medicines
Tell your doctor before taking AZITRO, if you are taking any of the medicines listed below and consult your doctor or pharmacist if you have any further questions about AZITRO and other drugs:
- 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)
- Digoxin (used to treat heart failure)
- Theophylline (used to treat asthma)
- Nelfinavir (used to treat HIV infection)

If you are using antacids for indigestion, you should take AZITRO one hour before or two hours after taking antacids.

Low number of neutrophils was observed in subjects receiving concomitant treatment of AZITRO and rifabutin

If you are taking or have recently taken any other medicines, including medicines obtained without prescription, please tell your doctor or pharmacist.

3. HOW TO USE AZITRO

Instructions for proper use and dose/frequency of administration:
AZITRO suspension is generally used for children under 45 kg. It may also be used in adults and older children who have difficulty swallowing capsules.

AZITRO should be taken as a single daily dose.

The dosage for treatment of sexually transmitted diseases due to *Chlamydia trachomatis*, *Haemophilus ducreyi* or susceptible *Neisseria gonorrhoeae* is 1000 mg as a single oral dose.

The dosage for treatment of tonsillitis/pharyngitis due to *S. pyogenes,* is 500 mg on day 1 and 250 mg daily on days 2 through 5, the duration of therapy is 5 days.

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

For pediatric patients weighing over 45 kg, adult doses are administered.

The usual dose in children less than 45 kg is 10 mg/kg of bodyweight, given as a single daily dose for 3 days.

Except for the treatment of Streptococcal pharyngitis, in children total dose of 30 mg/kg given as 10 mg/kg once daily for 3 days or 10 mg/kg as a single dose on the first day followed by 5 mg/kg/day on days 2-5.

As alternative to the above dosing, 30 mg/kg may be given as a single dose for the treatment of acute ear infections (acute otitis media).

For pediatric Streptococcal pharyngitis, azithromycin was effective as a single daily dose of 10 mg/kg or 20 mg/kg for 3 days, but daily doses of 500 mg should not be exceeded.

Your doctor may prescribe different doses to the above stated.

Method and route of administration:
Taken by mouth.

Reconstitution
Shake the dry powder in bottle.
Afterwards, pour boiled and then cooled water up to the mark on the supplied measuring device, add into the contents of bottle and shake well. 5 ml of the reconstituted suspension contains 200 mg of azithromycin. Shake the bottle before each use.

Using the measuring spoon:
Suspension is administered with double sided (2.5-5ml) measuring spoon.

Different age groups

Use in children
Information regarding the use of AZITRO suspension in children is given above.

Its use is not recommended for infants younger than 6 months of age.

Use in elderly
The same dosage as in adult patients is used in the elderly patients.

Special conditions

Kidney failure:
No dosage adjustment is recommended in mild to moderate kidney failure. Caution should be exercised when azithromycin is administered in severe kidney failure.

Liver failure
Same doses may be administered in mild to moderate liver failure as is with normal liver function.
It should not be used in case of severe liver failure.

If you have the impression that the effect of AZITRO is too strong or too weak, talk to your doctor or pharmacist.

If you take more AZITRO than you should
If you take more AZITRO than you should, you may feel unwell. In such a case, tell your doctor or contact nearest hospital emergency department immediately. Take the remaining medicine with you.

If you think you have taken more AZITRO than you should, consult your doctor or pharmacist.

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

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

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

Take AZITRO for the full time of treatment recommended by your doctor, even when you begin to feel better. Do not stop using AZITRO without consulting your doctor.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, AZITRO may cause side effects in people sensitive to ingredients.

Tell your doctor immediately if you experience any of the following symptoms after taking this medicine. Although they are very rare, the symptoms can be severe.
- Irregular heartbeat, shortness of breath, dizziness or fainting while using AZITRO
- Sudden wheezing
- Difficulty breathing
- Swelling of eyelids
- Swelling of face or lips
- Rash or itching (especially affecting the whole body).

The most common side effects that occur when taking AZITRO 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 classified in the following frequencies:
Very common : affects at least 1 in 10 patients
Common : affects 1 to 10 patients in 100
Uncommon : affects 1 to 10 patients in 1000
Rare : affects 1 to 10 patients in 10.000
Very rare : affects less than 1 patient in 10,000
Unknown : cannot be estimated from the available data.

Very common
- Diarrhea
- Stomach cramps
- Feeling sick
- Flatulence

Common
- Headache, drowsiness
- Pins and needles or numbness
- Taste disturbance, loss of appetite
- Visual disturbances, deafness
- Being sick, indigestion
- Rash, itching

- Joint pain
- Low number of lymphocytes (type of white blood cells), higher number of eosinophils (type of white blood cell) counts
- Low blood bicarbonate
- Tiredness

Uncommon
- Yeast infections of the mouth and vagina (thrush)
- Low number of leukocytes (type of white blood cells) and low number of neutrophils (type of white blood cells)
- Allergic reactions various severity
- Widespread skin rash and blistering of the skin
- Severe skin reactions due to exposure to light or sunlight
- Hives
- Feeling nervous
- Reduced sense of touch
- Sleepiness
- Sleeplessness
- Poor hearing or ringing in the ears (irreversible)
- Irregular heartbeat
- Constipation
- Inflammation of the liver
- Chest pain
- General loss of strength
- Swelling
- General discomfort
- Abnormal laboratory test values (e.g. blood or liver tests)
- Vomiting associated with abdominal pain (which may be bloody)

Rare
- Agitation
- Dizziness (vertigo)
- Abnormal liver functions

Other side effects in post-marketing experience

Unknown
- Aggression, anxiety, fits, hyperactivity, fainting
- Loss of smell or altered sense of smell, loss of taste
- Disorder of heart rhythm, fast heart beat, irregular heart beat
- Low blood pressure
- Inflammation of the pancreas, tongue discoloration, severe skin reactions
- Liver failure, liver dysfunction, jaundice, skin redness
- Kidney failure, inflammation of kidney
- Abnormal electrocardiogram (ECG)
- Stomach pain associated with diarrhea and fever
- Easily bruising or bleeding

- Tiredness associated with dark urine
- Local muscle weakness

Reporting of side effects
If you get any side effects including any possible side effects not listed in this leaflet, talk to your doctor, pharmacist or nurse. You can also report side effects directly to Turkey Pharmacovigilance Center (TÜFAM) via clicking on the icon of 'Side Effect Reporting for Medicines' at www.titck.gov.tr or calling +90 800 314 00 08 as the line of side effect reporting.
By reporting side effects you can help provide more information on the safety of this medicine.

If you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE AZITRO

Keep AZITRO out of reach and sight of children. Store in the original package.

Store at room temperature below 25°C. After reconstitution, it is stable at room temperature below 25 °C for 5 days.

Use in line with the expiry date.
Do not use AZITRO after the expiry date which is stated on the package.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

Marketing Authorization Holder:
DEVA Holding A.Ş.
Halkalı Merkez Mah. Basın Ekspres Cad. No: 1
34303 Küçükçekmece - ISTANBUL/TURKEY

Manufacturing site:
DEVA Holding A.Ş.
Çerkezköy Organize Sanayi Bölgesi
Karaağaç Mah. Atatürk Cad., No: 32
Kapaklı - TEKIRDAG/TURKEY

This leaflet was last revised on 17.10.2017