PACKAGE LEAFLET: INFORMATION FOR THE USER

AZITRO 500 mg Film Coated Tablets
Taken by mouth.

Active substance: Each tablet contains 524.032 mg azithromycin dihydrate equivalent to 500 mg azithromycin.
Excipient(s): Anhydrous dibasic calcium phosphate, sodium carboxymethyl cellulose 150 (Nymcel-ZSB16), microcrystalline cellulose PH 102, sodium lauryl sulphate, magnesium stearate
Film coating (Opadry OY-D-7233 white): Hypromellose, titanium dioxide, talc, polyethylene glycol/macrogol, sodium lauryl sulphate

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 500 mg is a film coated tablet. It is supplied in 3 tablet blister packages; each tablet contains 524.032 mg azithromycin dihydrate equivalent to 500 mg azithromycin. AZITRO is a white, oblong, homogenous, odorless, film coated tablet with "AZITRO" engraved on one side.

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* (tonsilitis), in treatment of sore throat (pharyngytis) 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 TAKE AZITRO

DO NOT TAKE 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 an acquired infection from the community
- 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.

Taking AZITRO with food and drink
You should take AZITRO either 1 hour before or 2 hours after meals.

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.

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
AZITRO does not contain any excipient requiring any warning.

Taking 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 1 hour before or 2 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 TAKE AZITRO

Instructions for proper use and dose/frequency of administration
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.

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

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.

Method and route of administration
The tablets should be swallowed whole.

Different age groups

Use in children
For pediatric patients weighing over 45 kg, adult doses are administered. For indications except tonsillitis/pharyngitis, the recommended total dosage is 1500 mg. The dosage for treatment of tonsillitis/pharyngitis is 500 mg on day 1 and 250 mg daily on days 2 through 5, the duration of therapy is 5 days.

Oral suspension forms are available for pediatric patients weighing less than 45 kg.

Efficacy and safety of azithromycin have not been established for infants younger than 6 months of age, therefore its use is not recommended for infants younger than 6 months of age.

Use in elderly
Adult doses are administered in the elderly patients.
Special conditions

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

Liver failure
Same doses may be administered to patients with 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 too many AZITRO tablets 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 the 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 feeling faint 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

Not known:
- 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.

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:
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