PACKAGE LEAFLET: INFORMATION FOR THE USER

AZITRO 500 mg Lyophilized Powder for Solution for IV Infusion
For intravenous administration
Sterile

Active substance: Each vial contains 524.1 mg of azithromycin dihydrate equivalent to 500 mg of azithromycin, which after reconstitution results in a 100 mg/ml azithromycin solution (equivalent to 104.82 mg of azithromycin dihydrate).
Excipient(s): Citric acid monohydrate, sodium hydroxide, 30% sodium hydroxide solution (used for pH adjustment).

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 a white or off-white lyophilized particle-free powder in a transparent, colorless, glass vial, with a gray colored rubber stopper and a blue flip-off cap.

AZITRO contains azithromycin as active substance which belongs to a group of antibiotics called macrolides. Azithromycin exerts its effect by stopping or killing the bacteria that cause the infection. Azithromycin will not treat infections caused by viruses such as the common cold or flu.
AZITRO is used in the treatments of the following infections:
- chest, throat and nose infections [bronchitis, pneumonia, tonsillitis, sore throat (pharyngitis) and sinusitis]
- ear infections
- skin and soft tissue infections (abscess, boils)
- sexually transmitted diseases caused by a bacterium called chlamydia
- pelvic inflammatory disease (inflammation of the uterus and ovaries)

2. WHAT YOU NEED TO KNOW BEFORE YOU ARE GIVEN AZITRO

DO NOT TAKE AZITRO:
- If you are allergic to azithromycin, erythromycin, clarithromycin or to any other macrolide antibiotics or ketolid group antibiotics or any of the ingredients in AZITRO.
- If you have a history of liver problems or yellowing of the skin and eyes with any other forms of

azithromycin (e.g., tablet, suspension, injection).

Take special care with AZITRO
- If you have liver problems (AZITRO is not recommended for those with severe liver impairment)
- If you have kidney problems (those with severe kidney failure may need dose adjustment)
- If you have compensated (decompensated) heart failure or other heart disease (AZITRO may increase the risk of heart rhythm abnormalities)
- If you have had an abnormality in your heart rhythm, such as bradycardia (slowing of the heartbeat), QT syndrome that can lead to sudden death, or torsades de pointes (manifesting in electrocardiography (ECG)), or if you had such a condition in the past
- If you are using drugs that extend the QT interval: class 1A (quinidine, procainamide) and class III antiarrhythmics (dofetilide, amiodarone, sotalol)
- If your blood potassium or magnesium levels are low (hypokalemia, hypomagnesemia)
- If you are elderly
- If you have Myastenia gravis (a type of nerve-muscle disease that appears as muscle weakness and fatigue)

If you are taking any of the following medicines;
- Any ergot-derived drugs such as ergotamine (a drug used to treat migraine),
- Medicines used in heart rhythm disorder (class IA and III antiarrhythmics),
- Cisapride
- Terfenadine (see "Using with other medicines")

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

Taking AZITRO with food and drink
Since the drug is administered intravenously, it is not affected by food and drinks.

Pregnancy
Consult your doctor or pharmacist before taking this medicine.
AZITRO should not be used during pregnancy unless it is absolutely required.

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.
Since there is not enough information about whether azithromycin is excreted in human milk or not, it should not be used in breastfeeding mothers unless it is absolutely required.

Driving and using machines
AZITRO has no effect on the ability to drive and use machines.

Important information about some of the ingredients of AZITRO
Each vial of AZITRO contains approximately 4.42 mmol (or 101.54 mg) sodium. This should be considered for patients on controlled sodium diet.

Using with other medicines
Tell your doctor before taking AZITRO, if you are taking any of the medicines listed below:
- Warfarin (used to prevent blood clotting)
- Cyclosporine (a drug that suppresses the immune system, used to prevent tissue rejection in

organ or bone marrow transplants)
- Digoxin (used in heart failure)
- Ergot derivatives (used in migraine treatment)
- Theophylline (used to treat asthma)
- Terfenadine (used to treat allergies and hay fever)
- Zidovudine (used to treat AIDS patients).

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

3. HOW AZITRO IS GIVEN TO YOU

Instructions for proper use and dose/frequency of administration
Your doctor will decide how much and how long you will need AZITRO and will administer it to you.

The infusion dose of AZITRO is usually 500 mg intravenously for 2–5 days. Then, one 500 mg oral dose should be administered daily to complete a 7–10 day treatment cycle.

Method and route of administration
This medicine will be administered by healthcare professionals, do not administer on your own.
After diluting with a suitable solution, AZITRO is administered only intravenously.

Preparation of the solution for intravenous administration

Reconstitution
The initial solution of azithromycin is prepared by adding 4.8 ml of sterile water for injections to the 500 mg vial and shaking the vial until all the drug is dissolved. It is recommended that a standard 5 ml (non-automated) syringe be used to ensure that the exact volume of 4.8 ml of sterile water for injections is dispensed. Each ml of reconstituted solution contains azithromycin dihydrate equivalent to 100 mg azithromycin (100 mg/ml).

Parenteral administration drugs should be inspected visually for particulate in suspension prior to administration. If particulate in suspension is evident in reconstituted solution, the drug solution should be discarded.

The reconstituted solution must be further diluted prior to administration as instructed below.

Dilution
To obtain a azithromycin concentration of 1.0-2.0 mg/ml, transfer 5 ml of the 100 mg/ml azithromycin solution to the appropriate amount of any of the diluents listed below.
- 0.9 % sodium chloride
- 0.45 % sodium chloride
- 5% dextrose in water
- Lactated Ringer's solution
- 20m Eq KCI Solution with 0.45% Sodium Chloride with 5% Dextrose
- 5% Dextrose in Lactated Ringer's Solution
- 5% dextrose in 0.3% sodium chloride
- 5% dextrose in 0.45% sodium chloride

Final infusion solution concentration (mg/ml)	Amount of diluent (ml)

1.0 mg/ml	500 ml
2.0 mg/ml	250 ml

It is recommended that a 500 mg dose of AZITRO, diluted according to the instructions above, be administered as an intravenous infusion over at least 60 minutes.

No other drugs should be added to the AZITRO solution and simultaneous infusion should not be administered from the same intravenous line.

Different age groups
ONLY FOR ADULTS

Use in children
In controlled clinical trials, azithromycin was given orally to children aged 6 months to 16 years. The safety and efficacy of intravenous azithromycin in children younger than 16 years has not been determined.

Use in elderly
Dose adjustment is not required in 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
It should be used with caution in patients with 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 are given more AZITRO than you should
Since this drug will be administered by healthcare professionals, it is unlikely that you will be given more or less medication than necessary.
In case of overdose, you may experience more side effects. Your doctor will give you the appropriate treatment for these side effects.

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

If you forget to take AZITRO
Since AZITRO will be administered by healthcare professionals, necessary measures will be taken to prevent this.
Do not take a double dose to make up for a forgotten dose.

If you stop taking AZITRO
When the treatment is terminated without your doctor's consent, not all of the bacteria causing the infection may die. Thus, the infection is not completely treated or can recur.

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.
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.

If you get any of the followings, stop using AZITRO and contact your doctor or go to your nearest hospital emergency department IMMEDIATELY:
Common:

- Rash, itching, hives on the skin,
- Diarrhea (usually bloody and slimy), stomach pain and fever.

Uncommon:

- Swelling on the face, lips, tongue, or anywhere on the body; shortness of breath; wheezing or difficult breathing.
- Yellowing of the eyes and skin (jaundice).
- Chest pain.
- Fainting.
- Fits (seizures).

These are all very serious side effects. If you have any of these, it means that you have serious allergy to AZITRO. You may need urgent medical attention or hospitalization.

Inform your doctor STRAIGHT AWAY or go to the nearest hospital emergency department if you notice any of the following side effects:

Common

- Severe persistent diarrhea
- Itching
- Hives, itching or skin rash

Uncommon

- Fast or irregular heartbeat
- Loss of sensitivity or sensation, especially on the skin
- Increased bowel movements or blood in urine
- Frequent and uncomfortable signs of infection, such as fever, severe tremors, sore throat or mouth ulcers
- Aggressive reactions, irritability, restlessness or anxiety
- Severe (upper) stomach pains, often with nausea and vomiting

Rare

- Sunburn symptoms that occur in less time than usual, such as redness, swelling, or blisters
- Easier bleeding or bruising than usual, reddish or purplish spots under the skin

These are all serious side effects. You may need urgent medical attention.

If you notice any of the following side effects, tell your doctor:

Common
- Pain and inflammation on the local injection site and pain during infusion
- Vaginal infection (thrush) - sore and itchy vagina and/or white discharge
- Nausea (feeling sick), vomiting, stomach pain
- Skin rash

Uncommon
- Thrush in the mouth - white, hairy, sore tongue and mouth
- Loss of taste, indigestion, flatulence, increased bowel movements
- Dizziness/vertigo (dizziness caused by inner ear disorders), headache
- Fatigue, drowsiness, exhaustion
- Muscle or joint pain
- Hearing loss or tinnitus
- Change in taste and smell

These are all mild side effects of AZITRO.

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 in its original package.
Before reconstitution, store the vial at room temperature below 30°C in its original package.

AZITRO, after dilution to 1 mg/ml or 2 mg/ml according to the instructions with solutions given below, is chemically and physically stable for 24 hours, when stored below 30°C and for 7 days when stored between 2-8°C.

- 0.9 % sodium chloride
- 0.45 % sodium chloride
- 5% dextrose in water
- Lactated Ringer's solution
- 20m Eq KCI Solution with 0.45% Sodium Chloride with 5% Dextrose
- 5% Dextrose in Lactated Ringer's Solution
- 5% dextrose in 0.3% sodium chloride
- 5% dextrose in 0.45% sodium chloride

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

If you notice any defects on product and/or its package, do not use AZITRO.

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.
Dumlupınar Mahallesi. Ankara Caddesi No: 2
Kartepe - KOCAELI/TURKEY

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THE FOLLOWING INFORMATION IS INTENDED FOR HEALTHCARE PROFESSIONALS ONLY

AZITRO should not be given as bolus injection or intramuscular injection.

Preparation of the solution for intravenous administration

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