Cardiac dysrhythmia, tachyarrhythmia, arrhythmia
Low blood pressure
Pancreatitis, tongue discoloration, severe skin reactions
Liver failure, liver dysfunction, jaundice, redness of the skin
Renal failure, renal inflammation
Abnormal electrocardiogram (ECG)
Abdominal pain associated with fever and diarrhea
Easy bruising or bleeding
Tiredness associated with dark-colored urine
Local muscle weakness

Reporting of side effects
Talk with your doctor, pharmacist or nurse if you experience any side effect that is included or not included in this patient information leaflet. Also, report the side effects you have encountered, to Turkish Pharmacovigilance Center (TUFAM) via clicking "Drug Side Effect Report" icon on www.titck.gov.tr or via calling the side effect report line on 0800 314 00 08. By reporting experienced side effects, you will be contributing in obtaining more information regarding the safety of your drug.

If you encounter any side effect that is not included in this patient information leaflet, inform your doctor or pharmacist.

5. How to store ZITRO
Store ZITRO by keeping out of the reach and sight of children in its original package. Store at room temperature below 25°C.

Use in line with the expiry date.
Do not use ZITRO after the expiry date on the package. Do not use ZITRO if you notice any failure/defect in the product and/or packaging.

Do not throw away drugs that have expired or are not being used! Give them to the collection system determined by the Ministry of Environment and Urbanism.

This patient information leaflet was approved on 11.06.2014.

PATIENT INFORMATION LEAFLET

ZITRO 250 mg film coated tablet
It is taken orally.

• **Active ingredient:** Each tablet contains 262.05 mg azithromycin dihydrate equivalent to 250 mg azithromycin.
• **Excipients:** Starch, pregelatinised, low substituted hydroxypropyl cellulose (LHPC 21) (E463), calcium hydrogen phosphate dihydrate, sodium lauril sulfate, croscarmellose sodium (ac-di-sol), lactose, anhydrous (obtained from bovine milk), colloidal anhydrous silica (E551), magnesium stearate (E572), hydroxypropyl methyl cellulose 2910/hypromellose 5cp (E464), macrogol/polyethylene glycol 400 (E1521) and titanium dioxide (E171).

Read all of this 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, please ask your doctor or pharmacist.*
• *This medicine has been prescribed for you only. Do not give it to others.*
• *In the course of use, when you visit a doctor or a hospital, tell your doctor that you use this drug.*
• *Follow the directives of this leaflet strictly. Do not use* ***higher or lower*** *doses than your recommended dose.*

In this patient information leaflet:

Topics are included.
1. What ZITRO is and what it is used for
ZITRO is 250 mg film coated tablet. It is presented in blister packaging containing 6 tablets, each tablet contains 250 mg azithromycin. ZITRO is a white colored, oblong, scored on both sides, biconvex, film coated tablet. The purpose of score is only for facilitating breaking the tablet for swallowing, it is not for dividing the tablet into equal doses. Tablet contains lactose obtained from bovine milk.

ZITRO belongs to a group of antibiotics called macrolides. 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)
• In the treatment of pharyngitis and tonsillitis caused by *Streptococcus pyogenes* in presence of penicillin allergy
• Ear infections
• Skin and soft tissue infections (such as an abscess or boil)
• Sexually-transmitted diseases caused by an organism called *Chlamydia*
• Soft tissue ulcers caused by a micro-organism called *Haemophilus ducreyi* and sexually transmitted infections caused by a non multidrug-resistant micro-organism called *Neisseria gonorrhoeae* without any accompanying infections

2. What you need to know before you use ZITRO
Do not use ZITRO in the following conditions
If,
• You are allergic to ZITRO or any other macrolide antibiotics such as erythromycin or clarithromycin or any of the ingredients of ZITRO. An allergic reaction may cause skin rash or wheezing.
• You have liver problems.
• You are taking any ergot derivatives such as ergotamine (used to treat migraine).

Use ZITRO with special care in the following conditions
• If you have kidney problems.
• If you have heart diseases.
• If you have an infectious disease which is shared in a community.
• If there is diagnosis or suspicion of septicemia.
• If you are an in-patient.
• If you are elderly or extremely weak.
• If you have other serious health problems (immune system deficiency or congenital asplenia/surgical asplenia conditions etc.).
• If you have liver disease.
• As with other antibiotic medicines, a risk of a secondary infection should be observed by your doctor in the weakened body due to any kind of infection caused by insusceptible organisms including fungi.
• If you develop diarrhea.

If these cautions apply to you, even for any previous period, please consult to your doctor.

Using ZITRO with food and drink
Use ZITRO 1 hour before or 2 hours after meals.

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Pregnancy
Ask your doctor or pharmacist for advice before taking this medicine.
If you are pregnant or trying to become pregnant, you should not take ZITRO without discussing it with your doctor first.
ZITRO should only be used during pregnancy if necessary.
Consult to your doctor immediately if you notice that you are pregnant during your treatment.

Breast-feeding
It is not known whether azithromycin is eliminated with human breast milk.
Ask your doctor or pharmacist before taking this medicine.

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

Important information about some of the ingredients of ZITRO
This drug product contains lactose. If you are sensitive to some sugars, inform your doctor before using the drug.

Using with other medications
Tell your doctor before taking ZITRO if you are taking any of the medicines listed below, and share your questions and concerns about ZITRO or other medicines 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)
- 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 ZITRO one hour before taking antacids, or two hours after taking antacids.
A decrease in the segmented cell count in the blood is observed in patients who are taken ZITRO and rifabutin concomitantly.
Please tell your doctor or pharmacist if you are using or have recently used any prescribed or non-prescribed medicine.

3. How to use ZITRO
Instructions for proper use and dose/administration frequency:
ZITRO should be taken as a single daily dose.
In the treatment of *Chlamydia trachomatis, Haemophilus ducreyi* or sensitive *Neisseria gonorrhoeae* originated sexually transmitted diseases, the dosage is 1000 mg in one single oral dose.
For all other indications total dose is 1500 mg, to be administered as 500 mg per day for 3 consecutive days.
In the treatment of *S. pyogenes* originated tonsillitis/pharyngitis, total dosage is used for 5 days as 500 mg for day 1 and as 250 mg for the days after (day 2, 3, 4 and 5).

Administration route and method:
It should be taken from oral route as a whole.

Various age groups:
Pediatric use:
Adult dose is administered for children over 45 kg.
With the exception of tonsillitis/pharyngitis, the maximum recommended total dose is 1500 mg in children for any kind of treatment. In the treatment of tonsillitis/pharyngitis, total dose is used for 5 days, as 500 mg in the 1st day and as 250 mg the days after that (2^{nd}, 3^{rd}, 4^{th}, and 5^{th} days).
Oral suspension forms are available for children below 45 kg.
Since the efficacy and safety of azithromycin was not shown yet for infants under the age of 6 months, its use is not recommended.
Geriatric use:
The same dose used for adult patients is used in the elderly.

Special administration conditions:
Renal failure:
No dose adjustment is necessary if you have mild to moderate renal impairment. If you have severe renal impairment, azithromycin should be used with caution.
Hepatic failure:
If you have mild to moderate impaired liver function, the same dose which is used for the patients with normal liver function can be used.
It should not be used in severe hepatic failure.
If you have any impression that the effect of ZITRO is too strong or too weak, consult to your doctor or pharmacist.

If you used more ZITRO than you should:
You may feel unwell if you use too much ZITRO. In such case, talk to your doctor or apply to nearest emergency service. Take the rest of the medicine with you.
If you used more ZITRO than you should, talk to a doctor or pharmacist.

If you forget to use ZITRO:
If you forget to take ZITRO, take it as soon as possible. Take the next dose at the right time.
Do not use double doses to balance the forgotten doses.

Possible effects of discontinuation of ZITRO treatment:
If you stop taking ZITRO very early, the infection may recur.
Take ZITRO as recommended by your doctor, even if you begin to feel better. Do not stop using ZITRO before talking to your doctor first.
If you have any further questions about the use of this product, ask your doctor or pharmacist for advice.

4. Possible side effects
As with all medicines, there may be side effects in the individuals who are sensitive to any of the ingredients of ZITRO.
Tell your doctor immediately if you experience any of the following symptoms after taking this medicine. These are rare symptoms but can be severe.
- While taking ZITRO: Irregular heartbeat, gasping, dizziness, or fainting,
- Sudden wheeziness,
- Difficulty in 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 ZITRO, 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 by category as shown below:

Very Common	: Observed in at least one of 10 patients.
Common	: Less than one in 10 patients, but may be observed in more than one in 100 patients.
Uncommon	: Less than one in 100 patients, but may be observed in more than one in 1000 patients.
Rare	: Less than one in 1000 patients, but may be observed in more than one in 10000 patients.
Very rare	: May be observed in less than one in 10000 patients.
Not known	: It cannot be estimated from the available data.

Very Common:
Diarrhea
Abdominal pain
Nausea
Flatulence

Common:
Headache, stupor
Pins and needles or numbness
Abnormal taste disturbance, loss of appetite
Visual disturbance, loss of sense
Vomiting, indigestion
Rash, itching
Joint pain
Low lymphocyte (a type of white blood cells) count, high eosinophil (a type of white blood cells) count
Low blood bicarbonate
Fatigue

Uncommon:
Yeast infection of the mouth and vagina (thrush)
Low leukocyte (a type of white blood cells) and low neutrophil (a type of white blood cells) count
Allergic reactions at various severities
Generalized rash and peeling of the skin
Severe skin reactions originating from exposure to light or sun
Urticaria
Nervousness
Reduced sense of touch
Sleepiness
Insomnia
Tinnitus, hearing impairment (irreversible)
Irregular heartbeat
Constipation
Liver inflammation
Chest pain
General loss of strength
Swelling
General discomfort
Abnormal laboratory test values (e.g. Blood or liver tests)
Vomiting (bloody or without blood) accompanied by abdominal pain

Rare:
Anxiety
Dizziness (vertigo)
Abnormal liver functions

Additional side effects experienced in post-marketing period

Not known:
Aggression, anxiety, convulsion, hyperactivity, fainting
Loss of smell or altered sense of smell, loss of taste