

ZITRO® 500 mg, film-coated tablet
Azithromycine

Read all of this leaflet carefully before you start taking 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 only. Do not pass it on to others, even if their signs of illness are the same as yours, it may harm them.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet ?

1. What is ZITRO 500 mg film-coated tablets and in which case is it used ?
2. What you need to know before you take ZITRO 500 mg film-coated tablets?
3. How to take ZITRO 500 mg film-coated tablets?
4. Possible side effects?
5. How to store ZITRO 500 mg film-coated tablets?
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1. WHAT IS ZITRO 500 mg FILM-COATED TABLETS AND IN WHICH CASE IS IT USED ?

pharmacotherapeutic Class - ATC code: J01FA10

This medicine is an antibacterial antibiotic that belongs to the macrolides family. It is indicated in the treatment of certain bacterial infections with sensitive germs.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE ZITRO 500 mg FILM-COATED TABLETS

Never take ZITRO 500 mg film-coated tablets if

- you are allergic to azithromycine, erythromycine, to any other macrolide antibiotic, to ketolide or any of the other ingredients of this medicine (listed in section 6).
- in combination with dihydroergotamine and ergotamine (anti-migraine drugs)
- in combination with cisapride (anti-reflux medication),
- in combination with colchicine (treatment of gout),
- severe hepatic impairment.

Warnings and precautions

Talk to your doctor or pharmacist before taking ZITRO 500 mg film-coated tablets.

Take special care with ZITRO 500 mg film-coated tablets :

If you have swelling of the face or neck (edema) or a severe skin rash with blisters on the skin, sores in the mouth, or inflammation of the eyes,

YOU SHOULD STOP THE TREATMENT AND CONTACT YOUR DOCTOR IMMEDIATELY because these effects can threaten your life or lead to death.

If you notice on your skin a rash-related symptom even without any other associated effect, a yellow skin color, dark urine, a tendency to bleed, a change in your state of consciousness or behavior, the occurrence of severe diarrhea, myasthenia gravis (muscle autoimmune disease that mainly results in muscle weakness) or heart problems, tell your doctor immediately, to tell you whether you should stop your treatment and replace it by another antibiotic.

Before taking this treatment, tell your doctor if you have had an urticaria or other rash, itching, angioedema (abrupt swelling of the face and neck of allergic origin).

Before taking this treatment, inform your doctor in case of :

- kidney disease,
- severe liver disease,
- prolonged QT interval (abnormality observed on the electrocardiogram),
- hypokalemia, hypomagnesemia (low potassium or magnesium in the blood),
- bradycardia, cardiac arrhythmia, severe heart failure,
- concomitant treatment with QT prolonging treatments : in particular certain antiarrhythmic medications (eg quinidine, amiodarone, sotalol), antipsychotics (eg phenothiazines, pimozide), tricyclic antidepressants (eg citalopram) or other antibiotics (ex : cloxacillin, levofloxacin).

Children

Not applicable.

Other medicines and ZITRO 500 mg film coated tablets

This medicine is contraindicated in combination with dihydroergotamine, ergotamine, cisapride and colchicine (see "Do not take ZITRO, film-coated tablets").

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines :

- Bromocriptine (medicine against the inflow of milk, against Parkinson's disease)
- Cabergoline (medicine against excess prolactin-hormone causing lactation)
- Pergolide (medicine indicated in the treatment of Parkinson's disease)
- Lisuride (medicine used in Parkinson's disease or against excess prolactin-hormone causing lactation)
- Atorvastatin and simvastatin (medicines to lower cholesterol)
- Ciclosporin (immunosuppressants)
- Digoxine (medicine used in some heart disorders)
- Colchicine (used in the treatment of gout and familial Mediterranean fever)
- Medicines that may cause torsades de pointes (heart rhythm disorder)
- Antivitamin K (medicine preventing blood clotting)

ZITRO 500 mg film-coated tablets with food and drinks

Not applicable.

Pregnancy and breastfeeding

It is better not to use this medicine for the first three months of pregnancy. Starting from the beginning of the 4th month of pregnancy, this medicine will only be used on the advice of your doctor.

If you discover that you are pregnant during treatment, only your doctor can judge the need to continue.

If you are pregnant or breastfeeding, think you may be pregnant or are planning pregnancy, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

You may experience side effects such as dizziness, drowsiness, certain visual or auditory disturbances during treatment with azithromycine. You must take precautions when carrying out certain activities such as driving vehicles, and using tools or machinery. If you feel tired, you should avoid performing potentially dangerous tasks, such as driving vehicles or using tools or machines.

3. HOW TO TAKE ZITRO 500 mg FILM-COATED TABLETS?

This medicine has been prescribed only for you in a specific situation:

- it cannot be adapted to another case;
- do not use it again without medical advice;
- do not advise it to another person.

Dosage

Follow these instructions unless your doctor has given you further instructions. Do not forget to take your medicine.

Your doctor will define the duration of your treatment with ZITRO 500 mg film-coated tablets. Do not suspend treatment before its term since there is a risk of disease relapse.

Method of Administration

Tablets can be taken with or without food, once a day.

Duration of treatment

The duration of treatment is:

- 3 days for the treatment of certain throat infections and oral infections,
- 5 days for bronchitis treatment.

To be effective, this antibiotic should be used regularly at the prescribed doses, and as long as your doctor has advised you.

The disappearance of fever, or any other symptom, does not mean that you are completely cured.

The possible impression of fatigue is not due to antibiotic treatment but to the infection itself. Reducing or suspending your treatment would have no effect on this infection and delay your healing.

If you have taken more ZITRO 500 mg film-coated tablets than you should

Consult your doctor or pharmacist immediately.

If you forget to take ZITRO 500 mg film-coated tablets

Do not take a double dose to make up for the dose you forgot to take.

If you stop taking ZITRO 500 mg film-coated tablets

Not applicable.

If you have any further questions about the use of this medicine, ask your doctor or pharmacist for more information.

4. Possible side effects?

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Common side effects (may affect more than 1 in 10 patients)

Diarrhea.

Common side effects (may affect from 1 to 10 patients in 100)

headaches, vomiting, abdominal pain, nausea, decreased lymphocytes (white blood cells) in the blood, increased blood levels of eosinophils, basophils, monocytes, neutrophils (white blood cells), decreased bicarbonate in the blood.

Uncommon side effects (may affect from 1 to 10 patients in 1000)

Infection due to microscopic fungi especially in the mouth, pneumonia, infection due to bacteria, pharyngitis, gastroenteritis, respiratory disorder, rhinitis, drop in the number of white blood cells in the blood (leucocytes, neutrophils, eosinophils), allergy, nervousness, insomnia, dizziness, drowsiness, taste disturbance, tingling sensation, sight disturbance, hearing impairment, loss of appetite, palpitations, flushing, difficulty breathing, nosebleeds, constipation, flatulence, abdominal discomfort, difficult digestion, difficulty swallowing, abdominal distension, dry mouth, rash, mouth ulcer, salivary hypersecretion, rash, itching, urticaria, skin inflammation, dry skin, excessive sweating, osteoarthritis, muscle pain, back pain, neck pain, difficulty in passing urine, pain in the kidneys, vaginal bleeding (between periods), testicular problem, fatigue, malaise, swelling (including edema of the face, angioedema), chest pain, fever, pain, swelling of the limbs and extremities

increased blood levels of liver enzymes (aspartate aminotransferases, alanine aminotransferases), bilirubin, urea, creatinine, alkaline phosphatase, chlorides, glucose, platelets, bicarbonates,

decreased blood levels of red blood cells, abnormal blood levels of potassium, sodium, post-procedure complication.

Rare side effects (may affect up to 1 and 10 in 1000patients)

Agitation, liver disorder, cholestatic hepatitis (liver condition characterized by fever and pain), photosensitivity (skin reaction when exposed to sunlight or UV light).

Side effects of unknown frequency

Severe diarrhea (pseudomembranous colitis), decreased levels of platelets in the blood (important elements of coagulation), hemolytic anemia (destruction of red blood cells in the blood), generalized allergic reaction, aggressive behavior, anxiety, delirium, hallucination, syncope, convulsions, decreased skin sensitivity, hyperactivity, loss of smell or taste, gum disease, myasthenia (muscular autoimmune disease), hearing impairment including deafness and / or ringing, heart rhythm disorders (torsade de pointe, arrhythmia, prolonging of the visible QT interval on the electrocardiogram, low blood pressure, inflammation of the pancreas, discoloration of the tongue, liver damage that can rarely affect the patient's life, fulminant hepatitis (severe acute hepatitis), hepatic necrosis, skin detachment can quickly spread to the whole body including mucous membranes (Stevens-Johnson syndrome and toxic epidermal necrosis), erythema multiforme, joint pain, acute renal failure, interstitial nephritis (kidney inflammation).

Reporting side effects

If you get any side effects, talk to your doctor or pharmacist. This also applies to any side effects that are not mentioned in this leaflet. You can also report side effects directly via the national reporting system. By reporting side effects you can help provide more information on the safety of the medicine.

5. HOW TO STORE ZITRO 500 mg film-coated tablet ?

Keep this medicine out of sight and reach of children.

Do not use this medicine after the expiry date which is stated on the box. The expiry date refers to the last day of this month.

No special storage conditions.

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

6. PACKAGING CONTENTS AND OTHER INFORMATION

What ZITRO 500 mg film-coated tablet contains

	ZITRO 500
Active substance :	
Azithromycin (azithromycin dihydrate)	500 mg (524.1mg)
Excipients :	
Cellulose microcrystalline, Sodium Croscarmellose, Sodium lauryl sulfate, magnesium stearate, Coating with Yellow Opadry, Polyvinyle Alcohol, titanium dioxide, polyethylene glycol/ Macrogol, Talc, Iron Oxide Yellow non irradiated.	

What is ZITRO 500 mg film-coated tablet and contents of the outer packaging

This medicine comes in the form of a film-coated tablet in PVC/Aluminium Blister, Box of 3 tablets.

Supply and prescription conditions:

List I

Holder of the marketing authorization and Manufacturer

LES LABORATOIRES MEDIS

Road of Tunisie - KM 7 - BP 206 - 8000 Nabeul - Tunisia

Tel : (216) 72 23 50 06. Fax: (216) 72 23 50 16.

E-mail : contact@labomedis.com

Marketing Authorization Number:

The last date of revision: 12/2019

This is a Medicine
- A medicine is a product but not like any others product.
- A medicine is a product that affects your health. If it's not used properly, it can be health threatening.
- Strictly adhere to the prescription of your Doctor and the use instructions prescribed, follow your pharmacist advice.
- Your doctor and your pharmacist know the medicine, its use and side effect.
- Don't stop the use of the treatment on your own during the prescribed time.
- Don't think, don't increase the doses without doctor's advice.
Keep all medicine out of reach of children

What to know about antibiotics

Antibiotics are effective in fighting infections caused by bacteria. They are not effective against virus infections

Also, your doctor has decided to prescribe this antibiotic because it is precisely right for you and your current illness.

Bacteria have the ability to survive or reproduce despite the action of an antibiotic. This phenomenon is called resistance: it makes some antibiotic treatments inactive.

Resistance increases through the misuse or inappropriate use of antibiotics.

You may promote the appearance of resistant bacteria and thus delay your recovery or even inactivate this medicine, if you do not respect:

- the dose to take,
 - the moments of taking,
 - and the duration of treatment.
- Consequently, to preserve the effectiveness of this medicine:
- Use antibiotics only when prescribed by your doctor.
 - Strictly follow your prescription.
 - Do not reuse an antibiotic without medical prescription even if you think you are fighting a seemingly similar illness.
 - Never give your antibiotic to another person, it may not be suitable for his/her illness.
 - Once your treatment is finished, return to your pharmacist any unfinished boxes for a proper destruction.



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26, Av. de l'Indépendance
Résidence Meriem
Bordj Boisson 3080 Ariana
Alg. A App. Alg.

Melleur Qualité

2019

Client : MEDIS
Contact: Walid KHALFALLAH
Désignation : ZITRO 500MG
Format : 15 x23 cm
Impression : 1 couleur recto verso
logiciel : Indesign CS4, Illustrator CS4,
Opérateur : MARWA KARRA
Grammage de papier : 60g

Date : 15-01-2020
Code article : NO0194
Version : 00
Couleur : Bleu 293C
Police : times
Corps : 5,4
Interligne : 5,1
Prelié sans Bande

Signature client

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