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English

PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

AZITRINE®

Azithromycin 250 mg / 500 mg
Tablet

Please read this leaflet carefully before taking this medication, as it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have other questions, ask your doctor, pharmacist or nurse.
- This medication has been personally prescribed. Do not give it to other people. It could be harmful, even if the signs of illness are identical to yours.
- If you experience any side effects, talk to your doctor, pharmacist or nurse. This also applies to any undesirable effect that is not mentioned in this leaflet. See section 4

What is in this leaflet?

1. What did AZITRINE® film coated tablet and in which cases is it used?
Pharmacotherapeutic class: Antibacterials for systemic use - code ATC: J01FA10
This drug is an antibacterial family of macrolide antibiotic.
It is indicated in the treatment of some bacterial infections to sensitive germs.

2 What are the information to know before taking AZITRINE®, film coated tablet ?
If your doctor has informed (e) an intolerance to some sugars, contact them before taking this medication.
Do not take AZITRINE® film coated tablet :
- If you are allergic to azithromycin, erythromycin, to any macrolide antibiotic, to the ketolide or one of the other components contained in this drug, mentioned in section 6,
- If the association with dihydroergotamine, ergotamine (migraine medicines),
- If the association with cisapride (anti-reflux medication),
- If the association with colchicine (treatment of gout),
- in case of severe liver failure.

Warnings and precautions
Ask your doctor, pharmacist or nurse before taking AZITRINE® film coated tablet.
If you experience 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 need to stop treatment and contact your doctor immediately because these effects can put your life in danger, or result in death.
If you notice on your skin a symptom for a rash even without other associated effect, a yellow coloring of the skin, dark urinalysis, a tendency to bleeding, a change in your state of consciousness or your behavior, the occurrence of severe diarrhoea, of myasthenia gravis (autoimmune disease mainly resulting in muscle weakness) or even heart problems, tell your doctor immediately, so that it tells you if you need to stop your treatment and replace it with a different antibiotic.
The use of this drug is not recommended in patients with intolerance to galactose, Lapp lactase deficiency or a syndrome of malabsorption of glucose or galactose (rare hereditary diseases).
Before taking this treatment, tell your doctor if during a previous antibiotic treatment you have had a rash or other skin rashes, itching, angioedema (sudden swelling of the face and neck of origin Allergic).
Before taking this treatment, tell your doctor if:
- kidney disease,
- severe liver disease,
- prolongation of the Qt (anomaly observed on the ECG),
- hypokalemia, hypomagnesemia (decrease of potassium or magnesium in the blood),
- bradycardia, cardiac arrhythmia, severe heart failure,
- concomitant treatment with treatments lengthening the QT interval: including anti-arrhythmic medications (ex: quinidine, amiodarone, sotalol), antipsychotics (ex: phenothiazines, pimozide), tricyclic antidepressants (ex:) citalopram) or other antibiotiques (ex: moxifloxacin, levofloxacin),
- Reactive to food or vomiting of your newborn.

Children
Not applicable.
Other drugs and AZITRINE®, film coated tablet
This medication is contraindicated in association with dihydroergotamine, ergotamine, cisapride, and colchicine (see 'do not take AZITRINE®').
In order to avoid possible interactions with several drugs, including bromocriptine (drug against milk, against Parkinson's disease), cabergoline (excess prolactin-hormone medication causing the) lactation), pergolide (indicated medication in the treatment of Parkinson's disease), the buride (medicine used in Parkinson's disease or against excess prolactin-hormone causing lactation), atorvastatin and simvastatin) drugs to lower cholesterol levels), Cyclosporine (immunosuppressant drug), digoxin (medicine used in certain disorders of the heart), drugs that can cause torsades tip (heart rhythm disorder) and the antivitamines K (medication prevent blood clotting), it should be noted systematically any ongoing treatment to your doctor or your pharmacist.
Tell your doctor or pharmacist if you take, have recently taken or could take any other medication.
AZITRINE® film coated tablet with food and beverage
Not applicable
Pregnancy and breastfeeding
It is best not to use this medication for the first three months of pregnancy. From the beginning of the 4th month of pregnancy, this drug will be used on the advice of your doctor.
If you discover you are pregnant during treatment, consult your doctor, because only he can judge the need to continue.
If you are pregnant or breastfeeding, if you think you are pregnant or planning a pregnancy, ask your doctor or pharmacist before taking this medication.
Driving and using machines
You can introduce undesirable effects, such as a dizzying sensation, drowsiness, Visual or auditory disorders during treatment with azithromycin. You must take precautions during certain activities such as driving vehicles, and use tools or machines. If you feel tired, you should avoid potentially dangerous tasks, including driving vehicles or use tools and machines.

3., How take AZITRINE®?
Make sure to always take this medication exactly following the directions of your doctor or pharmacist. Check with your doctor or pharmacist if you doubt.
This drug was personally prescribed to you in a specific situation:
- It can be adapted to another one;
- do not reuse it without medical advice;
- do not recommend it to another person.

Dosage
AZITRINE® 250 film coated tablets:
As an indication, the usual dosage is in adults:
•for the treatment of oral infections and some angina: 2 tablets of 250 mg in a single dose daily for 3 days;
•for the treatment of bronchitis: 2 tablets of 250 mg in one take 1st day, then 1 tablet per day 4 days.
•for the treatment of the urethres and cervicites: 4 tablets in one take
To strictly comply with your doctor's prescription.
AZITRINE® 500, film coated tablets:
As an indication, the usual dosage is in adults:
•for the treatment of oral infections and some angina: 1 tablet in a single dose daily for 3 days;
•for the treatment of bronchitis: 1 tablet in a single taken 1st day, then 1 tablet AZITRINE® 250 mg per day 4 days.
•for the treatment of the urethres and cervicites: 2 tablets in one take.
To strictly comply with your doctor's prescription.
If you have the impression that the effect of AZITRINE®, film coated tablet is too strong or too weak, talk to your doctor or pharmacist.

Mode of administration
The tablets can be taken with or without food, in one take per day.
Duration of treatment
The duration of the treatment is:
- 3 days for the treatment of oral infections and some angina
- 5 days for the treatment of bronchitis.

To be effective, this antibiotic should be used regularly at the prescribed doses, and as long as your doctor you will be advised.
The disappearance of fever or any other symptoms, does not mean that you are completely healed.
Printing possible fatigue, is not due to antibiotic treatment but the infection itself. The fact to reduce or suspend your treatment would have no effect on this impression and delay your recovery.
If you take more AZITRINE® than you should
See your doctor or your pharmacist immediately.
If you forget to take AZITRINE®
Do not double dose to make up for the dose that you forgot to take.
If you stop taking AZITRINE®
Without object.
If you have other questions about the use of this medicine, ask your doctor, pharmacist or nurse.

4. WHAT ARE THE POTENTIAL ADVERSE EFFECTS?
Like all drugs, this medication can cause side effects, but they occur systematically in all.
Very common side effects (may affect more than 1 in 10)
Diarrhea.
Common side effects (may affect up to 1 in 10 patients in 100)
Headache, 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 up to 1 in 10 out of 1000 patients)
Infection due to microscopic fungi in the mouth, pneumonia, infection due to bacteria, pharyngitis, gastroenteritis, troubled breathing, rhinitis, decline in the number of white cells in the blood (white blood cells, neutrophils, Eosinophilic), allergy, nervousness, insomnia, vertiginous sensation, drowsiness, disorder of taste, tingling sensation, disorder of the view, trouble hearing, dizziness, loss of appetite, palpitations, puff of heat, respiratory difficulty, bleeding from the nose, constipation, flatulence, abdominal discomfort, difficult digestion, difficulty swallowing, abdominal distension, dry mouth, red, ulceration of the mouth, salivary hypersecretion, skin rash, itching, urticaria, inflammation of the skin, dry skin, excessive sweating, osteoarthritis, muscle pain, back pain, pain in the neck, difficulty urinating, pain in the kidneys, vaginal bleeding (in the rules), testicular problem, fatigue, discomfort, swelling (edema especially at the level of the face, angioedema), pain in the chest, fever, pain, swelling of the members and ends, increase in blood levels of liver enzymes (aspartate aminotransferases, alanine) aminotransferases), bilirubin, urea, creatinine, alkaline phosphatases, chlorides, glucose, platelets, reduction in blood levels of red blood cells, abnormal blood level of potassium, bicarbonate, sodium, post-procedure complications.
Rare side effects (may affect up to 1 to 10 users in 10,000)
Agitation, disorder of the liver, hepatitis cholestatique (liver disease characterized by fever and pain), photosensitivity (skin reactions during exposure to sunlight or UV), rash on the skin that can be accompanied by fever., occurring suddenly and beginner to the face or the folds and can spread (widespread acute fever pustulose).
Very rare side effects (may affect up to 1 to 10 patients on 100000)
Allergic reaction with increase in the number of eosinophils (a type of white blood cell) and systemic symptoms (DRESS Syndrome).
Side effects, the frequency is not known
Severe diarrhea (pseudomembranous colitis), decreased platelet levels in the blood (important elements of coagulation), hemolytic anemia (red blood cell destruction), generalized allergic reaction, aggressive behavior, Anxiety, delirium, hallucination, syncope, convulsion, decreased skin sensitivity, hyperactivity, loss of smell or taste, gum disease, myasthenia gravis (muscle autoimmune disease), hearing disorder including deafness and/or Ringing, heart rhythm disorders (high-speed cables, arrhythmia, prolonging of the QT interval visible to the electrocardiogram), lower tension, inflammation of the pancreas, discoloration of the tongue, hepatic impairments that can rarely Putting into play the life of the patient, ranting hepatitis (severe acute hepatitis), hepatic necrosis, skin detachment that can rapidly extend to the whole body including mucous membranes (Stevens-Johnson syndrome and Toxic epidermal necrosis), erythema Multifaceted, joint pain, acute renal failure, interstitial nephritis (inflammation of the kidney).
Reporting Side effects
If you experience any side effects, talk to your doctor or pharmacist. This also applies to any adverse effects that would not be mentioned in this manual. By reporting adverse reactions, you are helping to provide more information about the safety of the drug.
5. How to store AZITRINE® film coated tablet?
Store below 30°C. Protect from light and moisture.
Keep out of reach and sight of children.
Do not use this medication after the expiration date shown on the box.

Do not throw any medication at the sewage or with the household waste. Ask your pharmacist to remove any medications you no longer use. These measures will help to protect the environment.

6. Contents of the package and other information
What contains AZITRINE®, film coated tablet
AZITRINE® film coated tablet:
Each film coated tablet contains:
Azithromycin dihydrate
equivalent to Azithromycin Anhydrous 250 mg
Excipients q.s.

Excipients with known Effects: Sodium Benzoate.
Other excipients: Microcrystalline cellulose, Maize starch, Sodium starch glycolate, , purified talc, magnesium stearate, isopropyl alcohol, Dichloromethane, wincoat WT-1001 White.

AZITRINE® 500, coated tablets:
Each film coated tablet contains:
Azithromycin dihydrate
equivalent to Azithromycin Anhydrous 500 mg
Excipients q.s.
Excipients with known Effects: Sodium Benzoate.
Other excipients: Microcrystalline cellulose, Maize starch, Sodium starch glycolate, , purified talc, magnesium stearate, isopropyl alcohol, Dichloromethane, wincoat WT-1001 White.

What is AZITRINE® film coated tablets and outer packaging content
AZITRINE® film coated tablet:
This medicine is in the form of a coated tablet. Box of 6 tablets.
AZITRINE 500®, film coated tablet:
This medicine is in the form of a coated tablet. Box of 3 tablets.

This leaflet was last updated in 10/2021

If you have any questions about this product or would like to report an adverse reaction contact us by phone : +225 27 21 25 52 38

MA Holder & operator: **IMEX PHARMA**
Rose Belle Building, Unit 3, Rose Belle Business Park, Mauritius.

Manufacturer:
BLISS GVS PHARMA LTD,
Dewan Udyog Nagar, Ajiyali, Palghar, Maharashtra- 401 404, INDIA.

XXXXXXXX

French

NOTICE: INFORMATION DE L'UTILISATEUR

AZITRINE®

Azithromycine 250 mg / 500 mg
Comprimé

Veuillez lire attentivement cette notice avant de prendre ce médicament car elle contient des informations importantes pour vous.
- **Gardez cette notice. Vous pourriez avoir besoin de la relire.**
- Si vous avez d'autres questions, interrogez votre médecin, votre pharmacien ou votre infirmier/ère.
- Ce médicament vous a été personnellement prescrit. Ne le donnez pas à d'autres personnes. Il pourrait leur être nocif, même si les signes de leur maladie sont identiques aux vôtres.
- Si vous ressentez un quelconque effet indésirable, parlez-en à votre médecin, votre pharmacien ou votre infirmier/ère. Ceci s'applique aussi à tout effet indésirable qui ne serait pas mentionné dans cette notice. Voir rubrique 4.

Que contient cette notice ?

1. QU'EST-CE QUE AZITRINE®, comprimé pelliculé ET DANS QUELS CAS EST-IL UTILISÉ?
Classe pharmacothérapeutique : Antibactériens à usage systémique - code ATC : J01FA10
Ce médicament est un antibiotique antibactérien de la famille des macrolides.
Il est indiqué dans le traitement de certaines infections bactériennes à germes sensibles.

2. QUELLES SONT LES INFORMATIONS À CONNAÎTRE AVANT DE PRENDRE AZITRINE®, comprimé pelliculé ?
Si votre médecin vous a informé(e) d'une intolérance à certains sucres, contactez-le avant de prendre ce médicament.
Ne prenez jamais AZITRINE® comprimé pelliculé :
- si vous êtes allergique à l'azithromycine, à l'érythromycine, à tout autre antibiotique macrolide, au kétolide ou à l'un des autres composants contenus dans ce médicament, mentionnés dans la rubrique 6.
- on cas d'association avec la dihydroergotamine et l'ergotamine (médicaments antimigraineux),
- en cas d'association avec le cisapride (médicament anti-reflux),
- en cas d'association avec la colchicine (traitement de la goutte),
- en cas d'insuffisance hépatique sévère.

Avertissements et précautions
Adressez-vous à votre médecin, pharmacien ou votre infirmier/ère avant de prendre AZITRINE®, comprimé pelliculé.
Si vous présentez un gonflement du visage ou du cou (œdème) ou une éruption cutanée sévère accompagnée de cloques sur la peau, de plaies dans la bouche, ou d'une inflammation des yeux, VOUS DEVEZ ARRÊTER LE TRAITEMENT ET CONTACTER VOTRE MEDECIN IMMEDIATEMENT car ces effets peuvent mettre votre vie en danger ou entraîner le décès.
Si vous remarquez sur votre peau un symptôme correspondant à une éruption cutanée même sans autre effet associé, une coloration jaune de la peau, des urines foncées, une tendance aux saignements, une modification de votre état de conscience ou de votre comportement, la survenue de diarrhées sévères, de myasthénie (maladie auto-immune musculaire qui se traduit principalement par une faiblesse musculaire) ou encore des troubles cardiaques, prévenez votre médecin immédiatement, afin qu'il vous indique si vous devez arrêter votre traitement et le remplacer par un autre antibiotique.
L'utilisation de ce médicament est déconseillée chez les patients présentant une intolérance au galactose, un déficit en lactase de Lapp ou un syndrome de malabsorption du glucose ou du galactose (maladies héréditaires rares).
Avant de prendre ce traitement, prévenez votre médecin si à l'occasion d'un traitement antibiotique antérieur vous avez présenté une urticaire ou autres éruptions cutanées, démangeaison, oedème de Quincke (brusque gonflement du visage et du cou d'origine allergique).
Avant de prendre ce traitement, prévenez votre médecin en cas de :
- maladie rénale,
- maladie du foie sévère,
- allongement de l'intervalle QT (anomalie observée sur l'électrocardiogramme),
- hypokaliémie, hypomagnésémie (baisse du potassium ou du magnésium dans le sang),
- bradycardie, arythmie cardiaque, insuffisance cardiaque grave,
- traitement concomitant avec des traitements allongeant l'intervalle QT : notamment certains médicaments antiarythmiques (ex : quinidine, amiodarone, sotalol), les antipsychotiques (ex : phénothiazines, pimozide), les antidépresseurs tricycliques (ex : citalopram) ou encore d'autres antibiotiques (ex : moxifloxacine, lévofloxacine),
- Hyper-réactivité à la nourriture ou vomissements de votre nouveau-né.

Enfants
Sans objet.
Autres médicaments et AZITRINE®, comprimé pelliculé
Ce médicament est contre-indiqué en association avec la dihydroergotamine, l'ergotamine, le cisapride et la colchicine (voir « Ne pas prendre AZITRINE® »).
Afin d'éviter d'éventuelles interactions avec plusieurs médicaments, et notamment la bromocriptine (médicament contre la montée de lait, contre la maladie de Parkinson), la cabergoline (médicament contre l'excès de prolactine-hormone provoquant la lactation), le pergolide (médicament indiqué dans le traitement de la maladie de Parkinson), le buride (médicament utilisé dans la maladie de Parkinson ou contre l'excès de prolactine-hormone provoquant la lactation), l'atorvastatine et la simvastatine (médicaments pour baisser le taux de cholestérol), la ciclosporine (médicament immunosuppresseur), la digoxine (médicament utilisé dans certains troubles du cœur), les médicaments pouvant provoquer des torsades de pointe (trouble du rythme cardiaque) et les antivitamines K (médicament empêchant la coagulation du sang), il faut signaler systématiquement tout autre traitement en cours à votre médecin ou à votre pharmacien.
Informez votre médecin ou pharmacien si vous prenez, avez récemment pris ou pourriez prendre tout autre médicament.
AZITRINE®, comprimé pelliculé avec des aliments et boissons
Sans objet.
Grossesse et allaitement
Il est préférable de ne pas utiliser ce médicament pendant les trois premiers mois de la grossesse. A partir du début du 4ème mois de la grossesse, ce médicament ne sera utilisé que sur les conseils de votre médecin.
Si vous découvrez que vous êtes enceinte pendant le traitement, consultez votre médecin car lui seul peut juger de la nécessité de poursuivre.
Si vous êtes enceinte ou que vous allaitez, si vous pensez être enceinte ou planifiez une grossesse, demandez conseil à votre médecin ou pharmacien avant de prendre ce médicament.
Conduite de véhicules et utilisation de machines
Vous pouvez présenter des effets indésirables, tels qu'une sensation vertigineuse, somnolence, certains troubles visuels ou auditifs au cours du traitement par azithromycine. Vous devez prendre des précautions pendant la réalisation de certaines activités telles que conduire des véhicules, et utiliser des outils ou des machines. Si vous ressentez une fatigue, vous devez éviter d'effectuer des tâches potentiellement dangereuses, notamment conduire des véhicules ou utiliser des outils et des machines.
3. COMMENT PRENDRE AZITRINE® comprimé pelliculé ?
Veillez à toujours prendre ce médicament en suivant exactement les indications de votre médecin ou pharmacien. Vérifiez auprès de votre médecin ou pharmacien en cas de doute.
Ce médicament vous a été personnellement prescrit dans une situation précise :
- il ne peut être adapté à un autre cas ;
- ne pas le réutiliser sans avis médical ;
- ne pas le conseiller à une autre personne.

Posologie
AZITRINE®, 250 comprimé pelliculé:
A titre indicatif, la posologie usuelle est, chez l'adulte :
- pour le traitement de certaines angines et des infections bucco-dentaires : 2 comprimés de 250 mg en une seule prise par jour pendant 3 jours ;
- pour le traitement des bronchites : 2 comprimés de 250 mg en une seule prise le 1er jour, puis 1 comprimé par jour les 4 jours suivants.
- pour le traitement des urétrites et cervicites : 4 comprimés en une prise

Se conformer strictement à l'ordonnance de votre médecin.