

PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

(AZILEX) Azithromycin 250 mg capsule

Azithromycin Dihydrate

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your health care provider.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects becomes serious, or if you notice any side effects not listed in this leaflet, please tell your health care provider.

In this leaflet:

1. What AZILEX is and what it is used for
2. What you need to know before you take AZILEX
3. How to take AZILEX
4. Possible side effects
5. How to store AZILEX
6. Further information

1. WHAT AZILEX IS AND WHAT IT IS USED FOR

Each AZILEX capsule contains Azithromycin 250mg as the active ingredient. Azithromycin belongs to a group of medicines called macrolide antibiotics and is used to treat bacterial infections.

AZILEX is used to treat the following infections and is a suitable alternative to penicillins in hypersensitive patients: Throat infections e.g. tonsillitis, pharyngitis and sinus infections, chest infections, such as bronchitis and pneumonia, ear infections, skin and soft tissue infections, Sexually transmitted diseases caused by an organism called Chlamydia.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE CIPROLEX

Do not take AZILEX if;

- you are allergic (hypersensitive) to azithromycin dihydrate or any other macrolide antibiotic such as erythromycin or clarithromycin or any of the other ingredients in this medicine. An allergic reaction may cause skin rash or wheezing.
- you suffer from serious liver problems or if you are taking any ergot derivatives such as ergotamine (used to treat migraine).

Cautions before you take AZILEX

AZILEX is suitable for most people. Ask yourself the following questions to check whether this product is suitable for you:

- Are you pregnant or breastfeeding?
- Are you sensitive to any of the active or inactive ingredients or any similar medicine?
- Do you suffer from liver problems or heart problems?
- Do you suffer from Myasthenia Gravis?

If the answer to any of the above questions is YES, then consult your doctor or pharmacist before taking this medicine.

Interactions with other medicines

The action of Azithromycin can also be affected by, or have an effect on, other types of medication. You should talk to your doctor or pharmacist before taking AZILEX if you are taking any of the following:

- Ergot or ergotamine
- Warfarin or any similar medicine to prevent blood clots
- Ciclosporin (used to suppress the immune system)
- Digoxin (used to treat heart failure)
- Theophylline (used to treat asthma)
- Terfenadine (for hay fever or a skin allergy)
- If you are taking antacids (for indigestion), AZILEX should be taken one hour before or two hours after antacids.

Taking AZILEX with food and drink

The capsules should be taken either 1 hour before a meal or 2 hours after a meal or on an empty stomach.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking AZILEX.

Driving and using machines

AZILEX is not expected to affect your ability to drive or use machines.

3. HOW TO TAKE AZILEX

Always take AZILEX exactly as your health care provider has told you. You should check with your health care provider if you are not sure. The usual doses are:

The capsules should be swallowed whole and taken either 1 hour before a meal or 2 hours after a meal or on an empty stomach.

The usual dose in adults and children over 7 stones (45 kg) is 500mg (2 capsules), once a day, for 3 days.

For some diseases such as Chlamydia the dose is 1g (4 capsules) taken all together for one day only.

AZILEX capsules should not be taken by children weighing less than 45kg.

Your doctor may prescribe different doses to the above. Always follow your doctors' instructions

If you take more AZILEX than you should

If you accidentally take more than the recommended dose, go to your nearest hospital casualty department or contact your doctor immediately. Always take the product packaging with you so you can be treated appropriately.

If you forget to take AZILEX

If you forget a dose, take it as soon as you remember unless it is time for the next dose. Do not take two doses at the same time. Do not take a double dose to make up for a forgotten tablet. If

you have to skip a dose, still take all of your capsules. This means that you will finish your course a day later.

If you have any further questions on the use of this product, ask your health care provider.

4. POSSIBLE SIDE EFFECTS

Like all medicines, AZILEX can cause side effects, although not everybody gets them. However tell your doctor immediately if you experience any of the following symptoms after taking this medicine: Sudden wheeziness, difficulty in breathing, swelling eyelids, face or lips, rash or itching (especially affecting the whole body), severe or prolonged diarrhea, which may have blood or mucus in it, during or after treatment with AZILEX as this maybe a sign of serious bowel inflammation, severe skin rash causing redness and flaking, rapid or irregular heartbeat and low blood pressure.

The most common side effects of this medicine are feeling or being sick, diarrhea and/or stomach ache.

Side effects that are not as common are listed below:

Uncommon (occurs in less than 1 in 100 users)

Dizziness, fits, headache, fainting, changes in taste and smell, flatulence, poor appetite, indigestion, painful joints, vaginal inflammation, drowsiness, rashes, itchy rash.

Rare (occurs in less than 1 in 1,000 users)

Thrush (candidiasis), increase in nosebleeds, bruising, sore throat or infections, aggression, restlessness, hyperactivity, anxiety, difficulty sleeping, nervousness, pins and needles, poor hearing, tinnitus, deafness, palpitations, irregular or racing heart beat, low blood pressure, constipation, tongue discolouration, feeling tired or unwell, weakness or loss of strength, sensitivity to sunlight, pancreatitis. Inflammation of the lining of large intestine – this could be a sign of pseudomembranous colitis (symptoms of this are diarrhea, stomach cramps, fever, blood in the stools).

Changes in liver function or jaundice (yellowing of the skin or whites of the eye), liver damage, failure or inflammation (fatigue, weakness, loss of appetite, weight loss, abdominal pain, fever).

Severe but rare skin conditions such as erythema multiforme (raised, red patches on the skin which may blister), Stevens Johnson Syndrome (more severe form of erythema multiforme) or toxic epidermal necrolysis (red painful rash that looks like a scald and may cause peeling of the skin). Kidney failure or inflammation (increased need to urinate at night, muscle twitching and cramps, loss of appetite, feeling or being sick, unpleasant taste in mouth).

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your health care.

5. HOW TO STORE AZILEX

Keep out of the reach and sight of children. Store below 25 °C. Store in the original carton and away from light. Do not use AZILEX after the expiry date which is stated on the carton after 'Exp'. AZILEX should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What AZILEX contains:

The active pharmaceutical ingredient is Azithromycin Dihydrahte.

The other ingredients (excipients) are Starch Maize, Colloidal Silicon Dioxide, Methyl Paraben, Propyl Paraben, Lactose, Magnesium Stearate, Polypasdone XL and Sodium starch Glycolate.

What AZILEX looks like and contents of the pack:

AZILEX is a hard gelatin cream coloured capsule of size “0”. It is imprinted in black ink with “Luex” on cap and “AZL250” on the body, containing white to off white granular powder. 6 capsules are packed in PVC/aluminum foil blisters and these blisters are packed in printed inner cartons along with an insert.

Manufacturer

UNICHEM INDUSTRIES LTD.

Parcel No. 167, Block 1, Section 44

Near Abgon Street, Kaneshie

Telephone: 030-222 7722

Telefax: 030-223 3529

E-mail: unichem3@africaonline.com.gh

This leaflet was last approved on 10/2019.