Proposed Clean Patient Information Leaflet

SCHEDULING STATUS

S4

Azithromycin 500 Biotech, 500 mg, film-coated tablets

Azithromycin dihydrate equivalent to 500 mg azithromycin base

Azithromycin 500 Biotech contains sugar, 14,4 mg lactose monohydrate

Read all of this leaflet carefully before using AZITHROMYCIN 500 BIOTECH

- Keep this leaflet. You may need to read it again.
- If you have any further question, please ask your doctor, pharmacist, nurse or other health care provider.
- Azithromycin 500 Biotech has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What Azithromycin 500 Biotech is and what it is used for
2. What you need to know before you use Azithromycin 500 Biotech
3. How to use Azithromycin 500 Biotech
4. Possible side effects
5. How to store Azithromycin 500 Biotech
6. Contents of the pack and other information

1. WHAT AZITHROMYCIN 500 BIOTECH IS AND WHAT IT IS USED FOR

Each Azithromycin 500 Biotech film-coated tablet contains azithromycin dihydrate equivalent to 500 mg azithromycin base.

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Azithromycin belongs to a group of medicines called macrolide antibiotics. Antibiotics are used to treat infections caused by micro-organisms like bacteria.

Adults:

Azithromycin 500 Biotech is used for the treatment of certain infections caused by bacteria that are sensitive to it, such as:

- lower respiratory tract infections (such as bronchitis, sinusitis and pneumonia),
- as an alternative to first line therapy of pharyngitis/tonsillitis,
- uncomplicated skin and soft tissue infections,
- uncomplicated genital infections caused by *Chlamydia trachomatis* in men and women.

Children: 1 year and over

Azithromycin 500 Biotech are indicated for pharyngitis/tonsillitis and otitis media caused by susceptible organisms in children over 45 kg. (Azithromycin suspension is recommended in children under 45 kg)

2. WHAT YOU NEED TO KNOW BEFORE YOU USE AZITHROMYCIN 500 BIOTECH

Do not use AZITHROMYCIN 500 BIOTECH:

- if you are hypersensitive (allergic) to azithromycin dehydrate or any of the other ingredients of Azithromycin 500 Biotech (listed in section 6).
- if you are using ergot derivates (e.g. ergotamine).
- if you have liver problems.
- if you are pregnant or breastfeeding your baby.

Warnings and precautions

Take special care with Azithromycin 500 Biotech:

- if you have ever had a serious allergic reaction causing swelling of the face and throat, possibly with breathing problems, rash, fever or swollen glands.

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- if you have ever had Stevens Johnson Syndrome, toxic epidermal necrolysis (TEN) or Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) after the use of Azithromycin 500 Biotech.
- if you develop severe or persistent diarrhoea during or after treatment.
- if you experience any liver or kidney problems.
- when your newborn starts to vomit or is irritable during feeds, please inform your doctor.
- if you have severe heart problems or problems with your heartbeat such as long QT syndrome (shown on an electro-cardiogram or ECG machine) or use any other medicines that prolong QT-intervals.
- if you have a certain type of muscle weakness called myasthenia gravis.

Children

The safety and efficacy of Azithromycin 500 Biotech in children less than 1 year have not been established.

Other medicines and Azithromycin 500 Biotech

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Tell your doctor if you are taking any of the following medicines:

- Ergot derivatives (e.g. ergotamine to treat migraines).
- Antacid (to treat heartburn or indigestion). Azithromycin 500 Biotech should be taken at least 1 hour before or 2 hours after the antacid.
- Cyclosporin (immunosuppressant).
- Digoxin (to treat various heart conditions) and colchicine (to treat gout).
- Phenytoin (medicine used to treat epilepsy).
- Warfarin (to treat blood clots).
- Terfenadine (to treat allergic conditions).
- Astemizole (antihistamine) and alfentanil (opioid used during surgery)

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- Atorvastatin (used to treat cholesterol).
- Cisapride (increases gastric motility).
- Nelfinavir (used to treat HIV).
- Rifabutin (medicine used to treat tuberculosis).

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

Driving and using machines

There are no data available about the influence of Azithromycin 500 Biotech on the ability to drive or operate machines. However, Azithromycin 500 Biotech may cause dizziness and seizures so make sure you are not affected before driving or operating machinery.

Azithromycin 500 Biotech contains lactose monohydrate and sodium

Azithromycin 500 Biotech contains lactose monohydrate. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Azithromycin 500 Biotech contains less than 1 mmol (23 mg) of sodium per tablet, that is to say it is essentially 'sodium-free.'

3. HOW TO TAKE AZITHROMYCIN 500 BIOTECH

Do not share medicines prescribed for you with any other person.

Always take Azithromycin 500 Biotech exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Azithromycin 500 Biotech should be administered as a single daily dose with or without food. Azithromycin 500 Biotech should be taken whole.

Adults:

For all indications other than sexually transmitted diseases, the total dose is 1,5 g which should be given as 500 mg daily for 3 days.

For sexually transmitted diseases caused by Chlamydia trachomatis the dose is 1 g given as a single dose.

Use in the elderly:

Normal adult dosage is recommended.

Use in children:

Children over 45 kg - dose as per adults.

This formulation is not suitable for children under 45 kg.

Your doctor will tell you how long your treatment with Azithromycin 500 Biotech will last. Do not stop treatment early because resistance to antibiotics may occur. If you have the impression that the effect of Azithromycin 500 Biotech is too strong or too weak, tell your doctor or pharmacist.

If you take more Azithromycin 500 Biotech than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take Azithromycin 500 Biotech

Do not take a double dose to make up for forgotten individual doses.

4. POSSIBLE SIDE EFFECTS

Azithromycin 500 Biotech can have side effects.

Not all side effects reported for Azithromycin 500 Biotech are included in this leaflet. Should your general

health worsen or if you experience any untoward effects while taking Azithromycin 500 Biotech, please consult your health care provider for advice.

If any of the following happens, stop taking Azithromycin 500 Biotech and tell your doctor immediately or go to the casualty department at your nearest hospital:

- 'swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing',
- 'rash or itching',
- 'fainting'

These are all very serious side effects. If you have them, you may have had a serious reaction to Azithromycin 500 Biotech. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

Frequent:

- paraesthesia (pins-and-needles in your arms, hand, legs and feet),
- deafness, hearing loss.

Less frequent:

- allergic reaction,
- leukopenia (a low level of white blood cells),
- thrombocytopenia (low number of platelets in the blood),
- neutropenia (low number of neutrophils in the blood),
- convulsion (epilepsy),
- palpitations (sensation that you heart is racing, pounding or skipping a beat),
- chest pain,
- dysrhythmia including ventricular tachycardia,

- electro-cardiogram QT prolonged,
- Torsades de pointes (type of abnormal heart rhythm),
- hepatitis (inflammation of the liver),
- liver function abnormal,
- cholestatic jaundice (condition where the flow of bile from the liver stops or slow down),
- hepatic necrosis,
- liver failure,
- photosensitivity reaction (sometimes referred to as sun allergy),
- urticaria (skin rash),
- serious skin reactions including Stevens-Johnson syndrome, toxic epidermal necrolysis and erythema multiforme,
- acute kidney failure,
- interstitial nephritis (when the spaces between the small tubes in the kidney become inflamed and this reduces the kidneys' ability to filter properly),
- nephritis (inflammation of the kidneys),
- asthenia (decreased muscle strength),
- anaemia in children (lack of blood),
- hyperkinesia (increase in muscular activity).

Side effects with unknown frequency:

- pseudomembranous colitis (inflammation of the colon caused by bacteria),
- pancreatitis (inflammation of the pancreas),
- pyloric stenosis (a condition where the opening between the stomach and small intestine thickens),
- DRESS (Drug reaction with eosinophilia and systemic symptoms).

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

Tell your doctor if you notice any of the following:

Frequent:

- anorexia
- headache,
- dizziness,
- dysgeusia (an altered or impaired sense of taste),
- somnolence (strong desire for sleep and feeling of drowsiness),
- diarrhoea (rarely resulting in dehydration),
- abdominal discomfort (pain/cramps),
- nausea and vomiting (less frequently resulting in dehydration),
- arthralgia (joint pain),
- fatigue.

Less frequent:

- moniliasis (fungal infection),
- nervousness,
- aggression reaction,
- agitation,
- anxiety,
- abnormal vision,
- vertigo (sensation of spinning),
- tinnitus (ringing in the ears),
- low blood pressure,
- constipation (infrequent bowel movements, and small, hard-to-pass stool),
- dyspepsia (indigestion),
- flatulence,
- loose stools,

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- melaena (dark tarry stool with or without visible blood),
- vaginitis,
- malaise (general sense of being unwell),
- insomnia in children (inability to fall asleep and stay asleep),
- paediatric conjunctivitis (inflammation of the eye),
- cough in children,
- pharyngitis in children,
- pleural effusion in children (build-up of fluid in the lungs),
- rhinitis in children (irritation and swelling of the mucous membranes),
- enteritis in children (inflammation of the small intestine),
- gastritis in children (inflammation of the stomach lining),
- oral moniliasis in children (fungal infection in the mouth),
- paediatric eczema,
- fever.

Side effects with unknown frequency:

- hyperactivity,
- anosmia (partial or complete loss of smell),
- tongue discoloration,
- oral candidiasis,
- sweating (in children).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications:

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https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of Azithromycin 500 Biotech.

5. HOW TO STORE AZITHROMYCIN 500 BIOTECH

Store at or below 25 °C.

Do not remove the blisters from the outer carton until required for use.

STORE ALL MEDICINE OUT OF REACH OF CHILDREN.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Azithromycin 500 Biotech contains

The active substance is azithromycin dihydrate equivalent to 500 mg azithromycin base.

The other ingredients are:

Tablet core – magnesium stearate, maize starch, microcrystalline cellulose, silica colloidal anhydrous, sodium lauryl sulphate, sodium starch glycollate.

Coating (Opadry white) - hydroxypropyl methylcellulose, lactose monohydrate, macrogol 4000, purified water, titanium dioxide.

What Azithromycin 500 Biotech looks like and contents of the pack

Azithromycin 500 Biotech is presented as white to off-white, oval film-coated tablet with a breaking notch on one side. One-sided embossment "A500".

Azithromycin 500 Biotech are packed into white, opaque PVC/Aluminium blisters of 2, 3 or 10 tablets each.

HOLDER OF CERTIFICATE OF REGISTRATION

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