

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S4

AZITHROMYCIN UNICORN 500 film coated tablets

500 mg azithromycin dihydrate equivalent to 500 mg azithromycin

Contains sugar: 10,80 mg lactose monohydrate

Read all of this leaflet carefully before you start taking **AZITHROMYCIN UNICORN 500**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- **AZITHROMYCIN UNICORN 500** 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 UNICORN 500** is and what it is used for
2. What you need to know before you take **AZITHROMYCIN UNICORN 500**
3. How to take **AZITHROMYCIN UNICORN 500**
4. Possible side effects
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6. Contents of the pack and other information

1. What **AZITHROMYCIN UNICORN 500** is and what it is used for

AZITHROMYCIN UNICORN 500 is an antibiotic that belongs to a group of antibiotics called macrolides. It is used to treat infections caused by bacteria and other microorganisms.

AZITHROMYCIN UNICORN 500 is used to treat lower respiratory tract infection including bronchitis,

pneumonia (infection in the lungs), skin infections and infections in the genital area in adults.

In children, **AZITHROMYCIN UNICORN 500** is prescribed in the treatment of ear and tonsil infections.

2. What you need to know before you take **AZITHROMYCIN UNICORN 500**

Do not take **AZITHROMYCIN UNICORN 500**:

- If you are hypersensitive (allergic) to azithromycin, erythromycin, any of the macrolide or ketolide antibiotics or any other ingredient of **AZITHROMYCIN UNICORN 500** (see section 6).
- If you are taking medication containing ergotamine (usually in migraine medication).
- If you suffer from any liver disease.
- If you are pregnant, trying to become pregnant or breastfeeding your baby (see section 2).

Warnings and precautions

Take special care with **AZITHROMYCIN UNICORN 500**:

- If you develop a severe allergic reaction (hives, difficulty breathing, swelling of your face, lips, tongue, or throat) to **AZITHROMYCIN UNICORN 500**, this reaction can reoccur even after you have stopped the treatment.
- If you have syphilis.
- have known or suspected bacteremia (bacterial infection in the blood)
- If your liver is not functioning normally (which is characterised by yellowing of the skin and eyes, dark urine, bleeding easily) contact your doctor immediately and stop taking **AZITHROMYCIN UNICORN 500**.
- If you have any heart disorders (QT prolongation, currently receiving any medicines to treat an irregular heartbeat).
- If you have any electrolyte disturbance (low levels of potassium or magnesium in your blood).
- If you have a slow, irregular heartbeat (bradycardia) or severe heart failure in which your heart is unable to pump enough blood throughout your body.
- If you have any signs or symptoms of secondary infection (including a fungal infection).
- If you develop diarrhoea during the treatment with **AZITHROMYCIN UNICORN 500**, please inform your doctor immediately.

- If you suffer from myasthenia gravis (muscle weakness).
- If you have a kidney disorder.

Children and adolescents

AZITHROMYCIN UNICORN 500 should not be given to children under 1 year of age or weighing less than 45 kg.

Other medicines and AZITHROMYCIN UNICORN 500

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

Tell your doctor or pharmacist if you are currently using the following medicines:

- Nelfinavir (treats HIV)
- Hay fever tablets (non-sedating).
- Phenytoin (for seizures)
- Cimetidine (used for ulcers of the stomach and intestines)
- Ciclosporin (immunosuppressant medication).
- Digoxin (heart medication).
- Aluminium or magnesium containing antacids (used for heartburn).
- Migraine medication containing ergotamine.
- Blood thinning tablets (e.g. warfarin).
- Oral contraceptive tablets (used to prevent unwanted pregnancies).

AZITHROMYCIN UNICORN 500 with food and drink

AZITHROMYCIN UNICORN 500 can be taken, orally with or without food.

Pregnancy and breastfeeding and fertility

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

AZITHROMYCIN UNICORN 500. It is not yet known if **AZITHROMYCIN UNICORN 500** is safe for your baby or unborn child. The safety and efficacy of **AZITHROMYCIN UNICORN 500** in breastfeeding has

not been established. The effect of **AZITHROMYCIN UNICORN 500** on fertility is not yet available.

Driving and using machines

It is not always possible to predict to what extent **AZITHROMYCIN UNICORN 500** may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which **AZITHROMYCIN UNICORN 500** affects them.

AZITHROMYCIN UNICORN 500 may cause dizziness and visual disturbances. Take care if you feel dizzy, tired or drowsy while taking **AZITHROMYCIN UNICORN 500**.

AZITHROMYCIN UNICORN 500 contains lactose, which is a type of sugar. If you have been told by your doctor that you cannot tolerate or digest some sugars (you have an intolerance to some sugars), talk to your doctor before taking **AZITHROMYCIN UNICORN 500**.

3. How to take AZITHROMYCIN UNICORN 500

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

Always take **AZITHROMYCIN UNICORN 500** exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

AZITHROMYCIN UNICORN 500 tablets should be taken whole as a single dose with or without food.

Your doctor will tell you how long your treatment with **AZITHROMYCIN UNICORN 500** will last. If you have the impression that the effect of **AZITHROMYCIN UNICORN 500** is too strong or too weak, talk to your doctor or pharmacist.

Do not stop taking your medicine before you have consulted with your doctor. This is an antibiotic and you should complete the course. **AZITHROMYCIN UNICORN 500** is usually taken as a single daily dose for 3 days.

The dosage remains the same for elderly people as well as children with a body weight over 45 kg.

If you take more AZITHROMYCIN UNICORN 500 than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre. Take this leaflet and any remaining tablets with you, so that the doctor knows what you have taken.

If you forget to take AZITHROMYCIN UNICORN 500

If you forget to take a dose, take it as soon as you remember. Do not take a double or larger dose to make up for the forgotten individual doses. Continue to take the next tablet at the usual time.

4. Possible side effects

AZITHROMYCIN UNICORN 500 can have side effects.

Not all side effects reported for **AZITHROMYCIN UNICORN 500** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

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

- Hives; difficulty in swallowing or breathing; swelling of your hands, feet, ankles, face, lips, tongue, or throat, hoarseness
- Rash or itching.
- Fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to **AZITHROMYCIN UNICORN 500**. 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:

Less frequently occurring side effects:

- Fast or irregular heartbeats (palpitations).

Side effects occurring with frequency unknown:

- Convulsions (fits/seizures).
- Changes of the heart rhythm seen on an electrocardiogram (QT prolongation and torsade de pointes).

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

Tell your doctor as soon as possible if you notice any of the following:

Frequently occurring side effects:

- Lack of appetite (anorexia).

- Dizziness, headache, sensation of pins and needles or numbness (paraesthesia), changes in your sense of taste.
- Visual impairment.
- Deafness.
- Diarrhoea (loose stools), stomach pain, feeling sick (nausea), wind, being sick (vomiting), indigestion, constipation.
- Joint pain (arthralgia).
- Unusual tiredness.
- Change in the quantity of white blood cells and the concentration of bicarbonate in the blood.

Less frequently occurring side effects:

- Reduction in the number of white blood cells.
- Thrush (candidiasis), oral thrush, vaginal infection, pneumonia, fungal infection, bacterial infection, inflammation of the throat (pharyngitis), stomach flu (gastroenteritis), breathlessness, chest pain, wheezing and cough (respiratory disorder), inflammation of the mucous membrane inside the nose (rhinitis).
- Build-up of fluid in tissues that line the lungs and the chest.
- Nervousness, feeling agitated or restless.
- Reduced sense of touch (hypoesthesia).
- Hearing loss or ringing in your ears, ear disorder, 'spinning' sensation (vertigo).
- Hot flushes.
- Nosebleed (epistaxis).
- Inflammation of the stomach lining (gastritis), difficulty swallowing, swollen abdomen, dry mouth, belching, mouth ulcer, increased salivary flow.
- Inflammation of the liver (hepatitis) causing yellowing of the skin or eyes or tiredness.
- Stevens-Johnson syndrome (more severe form of erythema multiforme), sensitivity to sunlight, itchy skin rash, pale or red irregular raised patches with severe itching (urticaria), inflammation of the skin (dermatitis), dry skin, excessive sweating.
- Swelling and reduced motion in your joints (osteoarthritis), muscle pain, back pain, neck pain.
- Painful urination, pain in your kidneys.
- Spotting, testicular disorder.

- Face swelling, chest pain, fever, nerve pain, swelling (oedema), general feeling of being unwell, weakness.
- Change in liver enzyme levels and blood levels, post procedural complications.

Side effects occurring with frequency unknown:

- Reduction of red blood cells due to destruction (haemolytic anaemia), reduction in number of platelets (thrombocytopenia).
- Dark tarry stool with or without visible blood.
- Aggression, anxiety, sleepiness (somnolence), sleeplessness (insomnia), confusion, hallucinations.
- Difficulty chewing or swallowing and slurred speech (myasthenia gravis), fainting (syncope), muscle spasms, changes in smell and taste.
- Low blood pressure (hypotension).
- Inflammation of the lining of the large intestine (pseudomembranous colitis, you might get diarrhoea, stomach cramps, fever, blood in the stools), taste disturbances, inflammation of the pancreas causing pain and tenderness in the abdomen and back, discolouration of the tongue.
- Liver not functioning normally, cholestatic jaundice (a complication of cholestasis, in which bile is unable to flow through the liver normally).
- Toxic epidermal necrolysis (red painful rash that looks like a scald and may cause peeling of the skin), erythema multiforme (raised red patches on the skin which may blister)

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 or 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: <https://www.sahpra.org.za/Publications/Index/8>. Reporting can also be done directly to Unicorn Pharmaceuticals at: vigilance@unicornpharma.co.za . By reporting side effects, you can help provide more information on the safety of **AZITHROMYCIN UNICORN 500**.

5. How to store AZITHROMYCIN UNICORN 500

- Store at or below 25 °C.

- Keep blister strip in outer carton until required for use.
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Do not use after the expiry date printed on the label or carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What AZITHROMYCIN UNICORN 500 contains

Active ingredient:

AZITHROMYCIN UNICORN 500: Each film coated tablet contains azithromycin dihydrate equivalent to 500 mg azithromycin base.

Inactive ingredients:

Calcium hydrogen phosphate anhydrous, croscarmellose sodium, hypromellose, magnesium stearate, Opadry White (containing hypromellose, lactose monohydrate, titanium dioxide, triacetin), pregelatinised starch, sodium lauryl sulphate.

Contains sugar 10,80 mg: lactose monohydrate.

What AZITHROMYCIN UNICORN 500 looks like and contents of the pack

White to off-white capsule shaped, film coated tablets, debossed with "AZ" and "500" on either side of the score line on one side and plain on the other side of the tablet.

Hard tempered silver aluminium foil blister pack (PVC/PVdC) with heat sealable lacquer and white opaque PVC film coated with PVdC, containing 2, 3 or 10 tablets per blister strip.

One blister strip is placed in an outer cardboard carton.

Holder of Certificate of Registration

Unicorn Pharmaceuticals (Pty) Ltd.

Corner Searle & Pontac Streets,

Woodstock,

Cape Town, 8001

South Africa

enquiries@unicornpharma.co.za

This leaflet was revised in

16 November 2023

Registration number

45/20.1.1/1076