Approved Patient Information Leaflet for Medicines for Human Use:

VARIMAX

SCHEDULING STATUS: S4

VARIMAX 250 mg capsule

Azithromycin dihydrate

Methylparaben 0,14 % *m/m* (preservative)

Propylparaben 0,04 % *m/m* (preservative)

Contains sugar: lactose

Each capsule contains 144,90 mg lactose.

Read all of this leaflet carefully before you start taking VARIMAX

- 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.
- VARIMAX 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 VARIMAX is and what it is used for
2. What you need to know before you take VARIMAX
3. How to take VARIMAX
4. Possible side effects
5. How to store VARIMAX
6. Contents of the pack and other information

1. What VARIMAX is and what it is used for

VARIMAX contains the active substance called azithromycin dihydrate which belongs to the group of antibiotics called macrolides.

VARIMAX is used in adults and children over 45 kg for the treatment of:

- chest, throat or nasal infections [such as bronchitis, pneumonia, tonsillitis, sore throat (pharyngitis) and sinusitis]
- ear infections
- skin and soft tissue infections (such as an abscess or boil)

VARIMAX is also used in uncomplicated genital infections in men and women with sexually transmitted diseases.

2. What you need to know before you take VARIMAX

Do not take VARIMAX:

- if you are hypersensitive (allergic) to azithromycin dihydrate, other macrolide antibiotics such as erythromycin or clarithromycin or any of the other ingredients of VARIMAX (listed in section 6).
- if you are taking ergot derivatives such as ergotamine (used to treat migraines)
- if you have liver problems
- if you are pregnant or breastfeeding.

Warnings and precautions

Talk to your doctor or pharmacist before taking VARIMAX if you have or have had any of the following conditions:

- liver problems: your doctor may need to monitor your liver function or stop the treatment
- heart conditions
- kidney problems
- myasthenia gravis (a condition that causes certain muscles to become weak).

Take special care with VARIMAX

- Serious allergic reactions (such as anaphylaxis, angioedema, fever, eosinophilia, and skin eruptions) have been reported with the use of VARIMAX.
- If you are taking any ergot derivatives such as ergotamine (used to treat migraine) as these medicines should not be taken together with VARIMAX.
- Tell your doctor immediately if you feel your heart beating in your chest or have an abnormal heartbeat or get dizzy or faint or suffer from any muscle weakness when taking VARIMAX.
- If you experience any symptoms of superinfection which may include high fever or respiratory distress.
- If you develop diarrhoea or loose stools during or after treatment, tell your doctor at once. Do not take any medicine to treat your diarrhoea without first checking with your doctor. If your diarrhoea continues, please inform your doctor.
- if you are taking medicine chlororquine or hydroxychloroquine (used to treat malaria)
- if your child is younger than 1 year as safety and efficacy of VARIMAX has not established in children less than 1 year old.

Children

Do not give VARIMAX to children younger than 1 year as safety and efficacy of VARIMAX has not established.

Other medicines and VARIMAX

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

VARIMAX may interact with the medicines listed below:

- antacids (for indigestion), VARIMAX should be taken one hour before or two hours after antacids. Antacids may decrease the amount of azithromycin in the blood, which may decrease its effects.
- digoxin (used to treat heart failure)
- colchicine (used for gout and familial Mediterranean fever)
- ergot or ergotamine – see ‘Warnings and precautions’ section

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- warfarin or any similar medicine to prevent blood clots
- cyclosporin (used to suppress the immune system to prevent and treat rejection of a transplanted organ or bone marrow)
- terfenadine (for hay fever or a skin allergy)
- hydroxychloroquine or chloroquine (used to treat autoimmune diseases including rheumatoid arthritis, or to treat or prevent malaria): Taking these medicines at the same time as azithromycin may increase the chance of you getting side effects that affect your heart.

VARIMAX with food

You should take VARIMAX either 1 hour before a meal or 2 hours after a meal.

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 VARIMAX.
Azithromycin has not been studied in pregnant women and it is not known whether azithromycin passes into breast milk.
VARIMAX must not be used during pregnancy or when breastfeeding.

Driving and using machines

It is not always possible to predict to what extent VARIMAX may interfere with the daily activities of a patient.
However, the possibility of side effects like dizziness, sleepiness, tiredness, fits or fainting should be considered when performing these activities.
Patients should ensure that they do not engage in the above activities until they are aware of the measure to which VARIMAX affects them.

VARIMAX contains lactose

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If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Information on sodium content

Zithromax contains less than 1 mmol sodium (23 mg) per capsule, that is to say essentially ‘sodium free’.

3. How to take VARIMAX

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

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

Take the recommended dose at least 1 hour before, or 2 hours after a meal.

For sexually transmitted diseases caused by *Chlamydia trachomatis*:

- A single dose of 1 g (4 capsules) azithromycin.

Other infections:

- Adults and children over 45 kg: A total dose of 1,5 g which should be given as 500 mg (2 capsules) daily for 3 days or alternatively an initial single oral dose of 500 mg on day 1, then 250 mg as a single daily dose for 4 days.

Elderly persons: The normal adult dosage is recommended.

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

Duration of administration

Your doctor will tell you how long your treatment with VARIMAX will last. If you have the impression that the effect of VARIMAX is too strong or too weak, tell your doctor or pharmacist.

Method of administration

VARIMAX is for oral administration.

If you take more VARIMAX than you should

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

Symptoms of overdose include hearing loss, severe nausea, vomiting and diarrhoea.

If you forget to take VARIMAX

If you forget to take VARIMAX take it as soon as you can. Take you next dose at the right time. Do not take a double dose to make up for a forgotten individual dose.

If you stop taking VARIMAX

If you stop taking VARIMAX too soon, the infection may return. Take the capsules for the full time of the treatment, even when you begin to feel better.

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

4. Possible side effects

VARIMAX can have side effects.

Not all side effects reported for VARIMAX are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking VARIMAX, please consult your health care provider for advice.

If any of the following happens, stop taking VARIMAX 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

- severe or prolonged diarrhoea, which may have blood or mucus in it, during or after treatment with Varimax as this may be a sign of serious bowel inflammation
- rapid or irregular heartbeat
- low blood pressure
- serious skin reactions:
  - blistering of the skin, mouth, eyes, and genitals (Stevens-Johnson Syndrome (SJS))
  - blistering of the skin, severe skin reaction (Toxic Epidermal Necrosis (TEN))
  - skin rash accompanied by other symptoms such as fever, swollen glands, and an increase of eosinophils (a type of white blood cell). A rash appears as small, itchy red bumps (Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS))
  - skin eruption that is characterised by the rapid appearance of areas of red skin studded with small pustules (small blisters filled with white/yellow fluid) (Acute Generalized Exanthematous Pustulosis (AGEP)).

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- dizziness, headache
- numbness or pins and needles
- loss of appetite, taste disturbance
- visual disturbances, deafness
- stomach cramps, feeling sick, diarrhoea, wind
- being sick, indigestion
- skin rash and /or itching
- joint pain
- tiredness or weakness

- low numbers of lymphocytes (a type of white blood cell), higher number of eosinophils (a type of white blood cell)
- low blood bicarbonate

Less frequent side effects:

- yeast infections of the mouth and vagina (thrush)
- low numbers of leukocytes (a type of white blood cell), low number of neutrophils (a type of white blood cell)
- allergic reactions of various severity
- skin more sensitive to sunlight than normal
- feeling nervous and agitation
- reduced sense of touch or sensation (hypoesthesia)
- sleepiness or sleeplessness (insomnia)
- poor hearing or ringing in the ears
- vertigo
- heart palpitations, chest pain
- constipation, stomach pain associated with diarrhoea and fever
- inflammation of the liver (hepatitis), changes in liver enzymes
- abnormal laboratory test values (e.g. blood or liver tests)
- changes in liver function.

Side effects with frequency unknown:

- aggression or anxiety
- fits or fainting
- feeling hyperactive
- localised muscle weakness
- loss of smell or altered sense of smell, loss of taste

- tongue discolouration
- inflammation of the pancreas (pancreatitis)
- inflammation of the kidney or kidney failure
- yellowing of the skin or eyes (jaundice) or liver failure (rarely life-threatening)
- abnormal electrocardiogram (ECG)
- reduction in red blood cells which can make the skin pale and cause weakness or breathlessness.

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. By reporting side effects, you can help provide more information on the safety of VARIMAX**.**

Suspected side effects can also be reported directly to the Holder of the Certificate of Registration via medsafety@austell.co.za.

5. How to store VARIMAX

Store all medicines out of reach of children.

Store at or below 25 °C.

Do not use after the expiry date stated on the label/carton/bottle.

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 VARIMAX contains

The active substance Is azithromycin dihydrate.

Shanur Healthcare (Pty) Ltd, 36/20.1.1/0164, Varimax, capsules, 250 mg

Each capsule contains azithromycin dihydrate equivalent to 250 mg azithromycin base.

Methylparaben 0,14 % *m/m* (preservative).

Propylparaben 0,04 % *m/m* (preservative).

Contains sugar: lactose 144,90 mg.

The other ingredients are anhydrous lactose, maize starch (dried), magnesium stearate, colloidal anhydrous silica and sodium lauryl sulphate.

The gelatin capsule contains iron oxide (red), titanium dioxide, methylparaben, propylparaben, sodium lauryl sulphate, water and gelatin.

What VARIMAX looks like and contents of the pack

Brown/white coloured, size '0", hard gelatin capsules containing a white to off-white powder.

VARIMAX is supplied in blister packs (composed of transparent PVC and aluminium foil backing) of 3 or 6 capsules in a carton.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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This leaflet was last revised in

Shanur Healthcare (Pty) Ltd, 36/20.1.1/0164, Varimax, capsules, 250 mg

Registration number

36/20.1.1/0164