

Applicant: **AUROGEN SOUTH AFRICA (PTY) LTD**

Product Name: ZIMOZAR

Dosage form and strength: **POWDER FOR ORAL SUSPENSION 200 mg/5 mL**

## Patient Information Leaflet

### SCHEDULING STATUS

**S4**

### PATIENT INFORMATION LEAFLET

**ZIMOZAR** (powder for oral suspension)

Azithromycin dehydrate 200mg/5mL

Contains sugar 3887,95 mg sucrose

### Read all of this leaflet carefully before you start taking ZIMOZAR

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist, nurse or other healthcare provider.
- ZIMOZAR 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 ZIMOZAR is and what it is used for
2. What you need to know before you use ZIMOZAR
3. How to use ZIMOZAR
4. Possible side effects
5. How to store ZIMOZAR
6. Contents of the pack and other information

#### 1. What ZIMOZAR is and what it is used for

ZIMOZAR contain a medicine called azithromycin dihydrate. This belongs to one of the antibiotic medicines group called as macrolide.

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**For children under 45 kg:**

ZIMOZAR is used to treat inflammation of the tonsils, inflammation of the ear and sore throat caused by different type of bacterial organisms.

**For adults and children over 45 kg:**

Bronchial tubes membrane lining inflammation, uncomplicated skin and soft tissue infections and one of the paranasal sinuses inflammations.

**2. What you need to know before you take ZIMOZAR**

**Do not take ZIMOZAR:**

- If you are allergic to azithromycin, erythromycin or any of ZIMOZAR's ingredients.
- If you are allergic to any group of macrolide derivative medicines.
- If you are already taking medicines called ergot derivatives this may leads to ergotism (physiological state produced by a poison due to concurrent administration of ZIMOZAR with ergot derivatives).
- If you have any liver problems.

**Warnings and Precautions**

**Take special care with ZIMOZAR:**

Tell your doctor,

- If you develop any skin or allergic reactions.
- If you develop severe diarrhoea.
- If you have any problems with your kidney. You doctor will tell about cautions for how to take ZIMOZAR.
- If you have any liver problem (like jaundice - yellowing of the skin and the eyes).

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- If your baby is below 12 months of age.
- If you face cardiac dysrhythmia (an abnormal rate of muscle contractions in the heart) and torsade de pointes.
- If you suffer from an autoimmune neuromuscular disease called myasthenia gravis, your symptoms may become worse when taking ZIMOZAR.

**Taking other medicines with ZIMOZAR:**

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

ZIMOZAR may have an effect on other medicines or other medicines may have an effect on ZIMOZAR.

- Warfarin or any similar medicine used to prevent blood clots: use together can increase the risk of bleeding.
- Nelfinavir (an antiretroviral medicine that prevents human immunodeficiency virus (HIV) cells from multiplying in your body) levels may increase. Your doctor will check your blood levels and monitor you.
- Ergotamine, dihydroergotamine (used to treat migraine): ergotism (ie. itching in the limbs, muscle cramps and gangrene of hands and feet due to poor blood circulation) may occur. Use together is therefore not recommended.
- Digoxin (used for heart failure): digoxin levels may increase. Your doctor will check your blood levels.
- Atorvastatin (used to treat high blood cholesterol) taken with ZIMOZAR can result in the breakdown of muscle.
- Antacids (used for indigestion) can interact with ZIMOZAR. ZIMOZAR tablets should be taken at least 1 hour before or 2 hours after an antacid.
- Caution is advised if you are taking ZIMOZAR with ciclosporin (used to suppress the immune system to prevent and treat rejection of a transplanted organ or bone marrow).

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- Rifabutin (used to treat tuberculosis) and ZIMOZAR: when taken together this can result in decreased white blood cell count.

**Taking ZIMOZAR with food and drink:**

ZIMOZAR suspension should be taken with food.

**Pregnancy, breastfeeding and fertility**

Do not take ZIMOZAR if you are pregnant or breastfeeding your baby

ZIMOZAR passes into breastmilk.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking ZIMOZAR.

**Driving and using machinery:**

After taking ZIMOZAR you may get dizziness (a feeling that you are about to fall). Do not drive or operate any machinery for your safety.

**ZIMOZAR contains sucrose:**

ZIMOZAR contains sucrose, which is a type of sugar. So before taking ZIMOZAR, please consult your doctor for advice if you have intolerance to some sugars.

**3. How to take ZIMOZAR**

Do not share medicines prescribed for you with any other person. Always take ZIMOZAR exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

ZIMOZAR powder should be reconstituted with required quantity of water as given below:

Amount of water to be added	Total deliverable volume (azithromycin content)	Azithromycin concentration after reconstitution

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9 mL	15 mL (600 mg)	200 mg/5 mL
15 mL	30 mL (1 200 mg)	200 mg/5 mL

ZIMOZAR should be administered as a single daily dose (i.e., 200 mg/5 mL).

Shake well before each use

**Use in children: 1 year and older.**

The total dose in children is 30 mg/kg which should be given as a single daily dose of 10 mg/kg for 3 days according to the following guidance:

- < 15 kg : 10 mg/kg once daily on days 1 - 3.
- 15 - 25 kg : 200 mg (5 mL) once daily on days 1 - 3.
- 26 - 35 kg : 300 mg (7,5 mL) once daily on days 1 - 3.
- 36- 45 kg : 400 mg (10 mL) once daily on days 1 - 3.
- > 45 kg : Dose as per adults

Always take ZIMOZAR exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

If you have the impression that the effect of ZIMOZAR is too strong or too weak, tell your doctor or pharmacist.

Your doctor will tell you how long your treatment with ZIMOZAR will last. Do not stop treatment early because this may reoccurrence of your condition. If you have the impression that the effect of ZIMOZAR is too strong or too weak, tell your doctor or pharmacist.

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**If you take more ZIMOZAR than you should**

Symptoms of overdose are loss of hearing, severe nausea, vomiting and diarrhoea (frequent and watery bowel movements).

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

**If you forget to take ZIMOZAR**

If you forgot to take a dose, take it as soon as you remember unless it is nearly time for your next dose.

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

**4. Possible side effects**

ZIMOZAR can have side effects:

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

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

- difficulty in breathing, swelling of eyelids, face, mouth, throat or lips, rash or itching (especially affecting the whole body).
- severe or prolonged diarrhoea, which may have blood or mucus in it, during or after treatment with ZIMOZAR as this may be a sign of serious bowel inflammation
- severe skin rash causing redness and flaking
- rapid or irregular heartbeat
- low blood pressure

These are all very serious side effects. If you have them, you may have a serious reaction to ZIMOZAR.

You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

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- Acute generalised exanthematous pustulosis (AGEP) (skin reaction),
- Stevens-Johnson syndrome (A rare, serious disorder of the skin and mucous membranes,
- a range of conditions affecting blood cells (Leukopenia, Neutropenia, Eosinophilia, Thrombocytopenia, Haemolytic anaemia), which are characterised by fatigue, shortness of breath, muscle weakness and irregular heartbeat
- Palpitations (A sensation that the heart is racing, pounding, fluttering or skipping a beat, often bothersome, but hardly ever a sign of heart disease)
- Hepatic function abnormal, Jaundice cholestatic (which are characterised by yellowing of the skin and eyes, abdominal pain and swelling, pale stools and dark urine

Frequent side effects:

- headache
- Diarrhoea, vomiting, abdominal pain, nausea
- Lymphocyte count decreased, Eosinophil count increased, Blood bicarbonate decreased, Basophils increased, Monocytes increased, Neutrophils increased (which are detectable through laboratory tests).

Less frequent side effects:

- yeast infections of the mouth and vagina (thrush)
- Hypersensitivity and anaphylactic reaction (a severe, potentially life-threatening allergic reaction)
- Anorexia (An eating disorder causing people to obsess about weight and what they eat)
- Nervousness, Insomnia, Agitation
- Aggression, Anxiety,
- Delirium (serious disturbance in mental abilities that results in confused thinking and reduced awareness of surroundings), Hallucination
- Dizziness, Somnolence (Strong desire for sleep and feeling of drowsiness,
- Dysgeusia (an altered or impaired sense of taste)

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- Paraesthesia (tingling or prickling, “pins-and-needles” sensation)
- Syncope (fainting or a sudden temporary loss of consciousness)
- Convulsion (a sudden, violent, irregular movement of the body)
- Hypoesthesia (a decreased sense of touch or sensation)
- Psychomotor hyperactivity (which include excessive unnecessary pacing, tapping your toes or rapid talking).
- Anosmia (partial or complete loss of the sense of smell),
- Visual impairment, blurred vision
- Ear disorder, Vertigo (a sudden internal or external spinning sensation, often triggered by moving your head too quickly),
- Hearing impairment including deafness and/or tinnitus (ringing sensation in ear),
- Rash, itchiness, Urticaria, Dermatitis, Dry skin,
- Hyperhidrosis (abnormally excessive sweating involving the extremities, underarms and face, usually unrelated to body temperature or exercise),
- Sensitivity to light reaction,
- Hot flush
- Hypotension
- Dyspnoea (Difficult or laboured breathing)
- Nose bleeds
- Constipation, Flatulence, Dyspepsia (stomach discomfort), Gastritis dysphagia (chronic stomach reflux) , Abdominal distension, Dry mouth, Eructation (excess wind in stomach), Mouth ulceration,
- Salivary hypersecretion
- Pancreatitis (inflammation of the pancreas),
- Tongue discolouration
- Liver failure (which has rarely resulted in death)

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- Osteoarthritis, Myalgia (pain in a muscle or group of muscles), Back pain, Neck pain
- Arthralgia (physical discomfort where two or more bones meet to form a joint, ranging from mild to disabling),
- Dysuria (Discomfort, pain or burning when urinating),
- Renal failure acute, Nephritis interstitial (characterised by increase in urination, blood in your urine or dark urine, nausea or vomiting or swelling in any area of your body).
- abnormal bleeding from the womb
- Testicular disorder
- Oedema (swelling), Asthenia (abnormal physical weakness or lack of energy), Malaise (a general feeling of discomfort, illness, or unease whose exact cause is difficult to identify), tiredness, Face swelling, Chest pain, fever, Pain,

Side effects detectable through laboratory tests

- Aspartate aminotransferase increased, Alanine aminotransferase increased, blood bilirubin increased, blood urea increased,
- Blood creatinine increased, blood potassium abnormal, blood alkaline phosphatase increased
- Chloride increased, glucose increased, platelets increased, Haematocrit decreased, Bicarbonate increased, abnormal sodium.

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. This includes any possible side effects not listed in this leaflet. You can also report side effects via

[https://www.sahpra.org.za/documents/86422f1b6.04\\_ARF1\\_Jul16\\_v4.pdf](https://www.sahpra.org.za/documents/86422f1b6.04_ARF1_Jul16_v4.pdf). By reporting side effects, you can help provide more information on the safety of this medicine.

### **5. How to store ZIMOZAR**

**For dry powder:** Store at or below 25 °C

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**For reconstitution suspension:** The reconstitution suspension should be stored at or below 25 °C and any unused suspension should be discarded after 10 days. No refrigeration required.

Keep the bottle in the carton until required for use.

Keep HDPE bottles tightly close.

**STORE ALL MEDICINES 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 ZIMOZAR contains**

The other ingredients of ZIMOZAR are art cherry flavour, art ripe banana flavour, FD&C red No. 40, hydroxypropyl cellulose, sucrose (60/200), sucrose (200), tribasic sodium phosphate anhydrous and xanthan gum.

### **What ZIMOZAR looks like and contents of the pack**

White to off-white, granular powder, forming a pale to dark pink flavoured suspension on constituted with water.

#### **HDPE bottle:**

##### **15 mL:**

ZIMOZAR is a dry powder filled in 30 mL white opaque round heavy weight HDPE bottle closed with 28 mm white opaque polypropylene child resistant closure with peelable aluminium induction sealing liner. (15 mL after reconstitution).

##### **30 mL:**

ZIMOZAR is a dry powder filled in 60 mL white opaque round heavy weight HDPE bottle closed with 28 mm white opaque polypropylene child resistant closure with peelable aluminium induction sealing liner.

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(30 mL after reconstitution).

The outer carton also contains a 10 mL plastic syringe with 0,2 mL graduation.

**Pack size:** 15 mL and 30 mL.

**HOLDER OF THE CERTIFICATE OF REGISTRATION**

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