

Applicant: Aurogen South Africa (Pty) Ltd

Product Name: ZIMOZAR 500mg

Dosage form and strength: Film coated Tablet, Each film coated tablet contains Azithromycin Dihydrate Ph.Eur 500 mg.

MODULE 1

Date: 22.05.2020

1.3.2 Patient Information Leaflet

SCHEDULING STATUS

S4

PATIENT INFORMATION LEAFLET

ZIMOZAR (500 mg)

Azithromycin Dihydrate

Contains Sugar (Lactose Monohydrate 15.4 mg)

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, please 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.

What ZIMOZAR is and what it is used for

ZIMOZAR is an antibiotic which belongs to a group of antibiotics called macrolides. It is used to treat infections caused by bacteria and other micro-organisms.

ZIMOZAR is usually prescribed to treat respiratory tract infections such as inflammation of the bronchi, lung infection, tonsillitis, inflammation of the pharynx, sinusitis and ear infections, skin and soft tissue

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infections (such as abscess), or sexually transmitted diseases such as chancroid (painful sores on the genitalia) or those caused by an organism called *Chlamydia*.

1. What you need to know before you take ZIMOZAR

Do not take ZIMOZAR:

If you are hypersensitive (allergic) to azithromycin, erythromycin or any macrolide antibiotic or any of the other ingredients of ZIMOZAR.

If you are taking any ergot derivatives, which are used for the treatment of migraines and cluster headaches. These medicines, when taken with ZIMOZAR can cause a condition in the body called ergotism,

If you are suffering from or have ever suffered from liver disease.

Warnings and Special Precautions

Take special care with ZIMOZAR

Your doctor needs to know before you take ZIMOZAR if you have had any of the following:

- Liver problems: your doctor may need to monitor your liver function or stop the treatment
- If you are taking any ergot derivatives such as ergotamine (used to treat migraine) as these medicines should not be taken together with ZIMOZAR
- Kidney problems
- Heart conditions
- If you suffer from an autoimmune, neuromuscular disease called myasthenia gravis, your symptoms may become worse, when taking ZIMOZAR.

Tell your doctor immediately if you feel irregular heart beating in your chest or have an abnormal heartbeat when taking ZIMOZAR.

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, tell your doctor as soon as possible.

Tell your doctor if you develop skin serious reaction or new infections

Taking other medicines with ZIMOZAR:

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<p>Always tell your healthcare professional if you are taking any other medicine (this includes complementary or traditional medicines). See Do not take ZIMOZAR.</p>
<p>Tell your doctor before taking ZIMOZAR if you are taking any of the medicines listed below:</p> <ul style="list-style-type: none"> • Ergot or ergotamine (used to treat migraines) (see Take special care with ZIMOZAR) • Antacids (for indigestion) • Ciclosporin (used to suppress the immune system to prevent and treat rejection of a transplanted organ or bone marrow) • Digoxin (used to treat heart failure) • Warfarin or any similar medicine to prevent blood clots
<p>Pregnancy, breastfeeding and fertility</p>
<p>If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before ZIMOZAR is administered to you.</p>
<p>The safety and efficacy of ZIMOZAR in pregnancy and breastfeeding have not been established.</p>
<p>Driving and using machines</p> <p>ZIMOZAR may cause dizziness, convulsions, vertigo, increased sleepiness and temporary loss of consciousness, which may affect your ability to drive and operate machinery.</p>
<p>Important information about some of the ingredients of ZIMOZAR</p> <p>If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.</p> <p>Lactose may also have an effect on the control of your blood sugar if you have diabetes mellitus.</p>
<p>2. How to take ZIMOZAR</p>
<p>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.</p>
<p>Your doctor will tell you how long your treatment with ZIMOZAR will last.</p>

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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* or *Haemophilus ducreyi*, the dose is 1 g given as a single dose.

ZIMOZAR tablets should not be taken by children weighing less than 45 kg. For children weighing more than 45 kg the doses mentioned above are usually prescribed.

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

Taking ZIMOZAR with food and drink

ZIMOZAR tablets may be taken with or without food. They must be taken whole with a drink of water.

If you take more ZIMOZAR than you should

In the event of over dosage, consult your doctor or pharmacist without delay. If neither is available, contact the nearest hospital or poison control centre.

If you missed a dose of ZIMOZAR

It is important that you continue to take your medicine according to the instructions on the label and that you do not miss any doses. However, if you do miss a dose, take it as soon as you remember and take the next dose at the normal time. Do not take a double dose to make up for a forgotten dose.

3. 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 ZIMOZAR, please consult your doctor, pharmacist or other healthcare professional for advice.

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

- Swelling of the hands, feet, ankles, face, lips, and mouth or throat, which may cause difficulty in swallowing or breathing
- Rash or itching
- Diarrhoea (loose ,liquid or watery stools)

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- Abdominal pain

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- Abdominal discomfort (pain/ cramps), diarrhoea, nausea
- Palpitations (irregular heartbeats)
- Torsade de pointes (a form of faster heart rate)
- Neutropenia (shortness of breath, fatigue, muscle weakness, irregular heartbeat),

The following side effects occur less frequently or with an unknown frequency:

- Nervousness, aggressive reaction, agitation, anxiety
- Oral candidiasis (white, furry, sore tongue and mouth)
- Vaginal infection
- Dizziness (feeling if lightheaded or unbalanced)
- Syncope (fainting or light headedness)
- Convulsion (seizures)
- Paraesthesia (tingling)
- taste/smell perversion and/or loss
- Hypoaesthesia (increase in sensitivity to stimuli)
- deafness
- Tinnitus (ringing in the ears)
- Hypotension (low blood pressure)
- Abnormal vision
- Excessive gas, loose stools, vomiting
- Abnormal liver function
- Kidney inflammation
- Black or tarry faeces

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

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

4. How to store ZIMOZAR

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Store at or below 25 °C.

Keep in original packaging until required for use.

Do not store in a bathroom.

Do not use after the expiry date stated on the label.

Return all unused medicine to your pharmacist

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

5. Contents of the pack and other information

What ZIMOZAR contains

The active substance is Azithromycin Dihydrate

Calcium Hydrogen Phosphate, Anhydrous

Starch, Pregelatinised

Croscarmellose Sodium

Starch, Pregelatinised

Sodium Lauryl Sulfate

Magnesium Stearate

Opadry II 31K58902 white

Purified water

What ZIMOZAR looks like and contents of the pack

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White to off-white, oval shaped, film coated biconvex tablets, debossed with “6” & “7” on either side of the score-line on one side and “D” on other side

Clear PVC Film- Aluminium foil blister pack:

Azithromycin tablets 500 mg are packed in above blisters shall be further packed in preprinted cartons with package leaflet according to the approved pack size. The proposed labeling text for the primary and secondary pack.

For 500 mg:

3's: Printed cardboard carton containing 1 blister of 3 tablets each.

NAME, BUSINESS ADDRESS AND TELEPHONE NUMBER OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

AUROGEN SA (Pty) Ltd

Woodhill Office Park, Building 1, First Floor

53 Phillip Engelbrecht Avenue

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Johannesburg

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This leaflet was last revised in