

**Approved Patient Information Leaflet for Medicines for Human Use:**

**MYCIBACT IV**

**SCHEDULING STATUS:** S4

**MYCIBACT IV, 500mg powder for Solution for injection**

**Azithromycin dihydrate**

**Sugar Free**

**Read all of this leaflet carefully before you start taking MYCIBACT IV**

- 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.

**What is in this leaflet**

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

**1. What MYCIBACT IV is and what it is used for**

MYCIBACT IV belongs to a group of antibiotics called macrolides. It is used to treat localised infections caused by bacteria. It is indicated for the treatment of serious infections or when oral treatment cannot be used. It is used for treatment of pneumonia (lung infection), caused by susceptible microorganisms.

## **2. What you need to know before you receive MYCIBACT IV**

### **MYCIBACT IV should not be administered to you**

- if you are hypersensitive (allergic) to azithromycin or any of the other ingredients of MYCIBACT IV (listed in section 6)
- If you are taking any ergot derivative such as ergotamine used to treat migraine
- if you have a liver problem.

### **Warnings and precautions**

Tell your doctor or health care provider before being given MYCIBACT IV:

- if you have an allergic reaction such as red or white spots on the skin, itching and skin irritation, swelling of the skin, larynx (throat) or tongue, and difficulty in breathing, in which case you should stop treatment with MYCIBACT IV
- if you have or have had kidney problems
- if you have or have had liver problems: your doctor may need to monitor your liver function or stop the treatment
- if you have or have had an abnormal heart rhythm in particular problems such as long QT syndrome (shown on an electro-cardiogram or ECG machine)
- if you feel heart palpitations or have an abnormal heartbeat or get dizzy or faint when taking MYCIBACT IV, in which case you should inform your doctor immediately
- if you develop diarrhoea or loose stools during or after treatment. In some cases, there is the possibility of developing a serious intestinal

inflammation known as pseudomembranous colitis. Do not take any medicine to treat your diarrhoea without first checking with your doctor.

Other important precautions:

- fungal infections may occur while you take MYCIBACT IV
- medicines known as ergot derivatives e.g. ergotamine or dihydroergotamine (medicines used for migraines or reducing blood flow) should not be taken together with MYCIBACT IV
- Worsening of symptoms has been observed in patients with myasthenia gravis receiving azithromycin.

### **Children and adolescents**

The safety and efficacy of MYCIBACT IV for the treatment of infections in children has not been established.

### **Other medicines and MYCIBACT IV**

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 such as ergotamine used to treat migraine
- digoxin used to treat heart failure
- colchicine used for gout.
- warfarin or any similar medicine to prevent blood clots
- ciclosporin 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

- nelfinavir used for the treatment of HIV infection (AIDS)
- zidovudine, for HIV. MYCIBACT IV may reduce the blood levels of zidovudine and should therefore be taken at least 1-2 hours before or after Zidovudine.
- rifabutin for HIV or tuberculosis (TB)
- theophylline for breathing problems.

### **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**

MYCIBACT IV may cause side effects such as dizziness and visual impairment. It is not always possible to predict to what extent MYCIBACT IV 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 MYCIBACT IV affects them.

### **MYCIBACT IV contains sodium**

MYCIBACT IV contains 114 mg (4,96 mmol) sodium (main component of cooking/table salt) in each 500 mg vial. This is equivalent to 5,7 % of the recommended maximum daily dietary intake of sodium for an adult.

## **3. How to receive MYCIBACT IV**

Carefully follow all instructions given to you by your doctor, nurse or pharmacist.

MYCIBACT IV will be given to you as an infusion into a large vein.

You will not be expected to give yourself MYCIBACT IV. It will be given to you by a person who is qualified to do so.

### **Pneumonia**

500 mg administered as a single intravenous daily dose for at least two days, followed by oral administration of azithromycin. The appropriate timing of the switch to oral therapy will be done at the discretion of your doctor.

### **Method of administration**

MYCIBACT IV is intended to be administered by intravenous infusion.

MYCIBACT IV will be reconstituted and diluted according to the instructions by a health care professional and should be administered as an intravenous infusion over at least 60 minutes.

### **Duration of administration**

The duration of your treatment will depend on the severity of your infection.

Your doctor will inform you.

### **If you are administered more MYCIBACT IV than you should**

Since a health care provider will administer MYCIBACT IV, he / she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

### **If MYCIBACT IV is not administered to you**

Since a health care provider will administer MYCIBACT IV, it is unlikely that the dose will be missed.

#### **4. Possible side effects**

MYCIBACT IV can have side effects.

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

If any of the following happens, stop receiving MYCIBACT IV and tell your health care provider immediately or go to the casualty department at your nearest hospital:

- serious allergic reactions which may cause sudden wheeziness, difficulty in breathing, swelling of eyelids, face 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 MYCIBACT IV as this may be a sign of serious bowel inflammation “colitis”
- rapid or irregular heartbeat, fainting, low blood pressure
- severe skin rash causing redness and flaking
- serious skin reactions:
  - fever and sore throat with a rash, that develops quickly, and possibly blistering of the skin, mouth, genitals and anal regions.  
The eyes may also be affected and may be red and swollen

(these could be signs of a serious skin reaction called Stevens Johnson Syndrome)

- blistering of the skin, severe skin reaction (toxic epidermal necrolysis (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 MYCIBACT IV. You may need urgent medical attention or hospitalisation.

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

- changes in the ability to see
- changes in ability to hear, including loss of hearing, convulsions (“fits”)
- dark urine, yellowing of the skin or the whites of the eyes (these may be signs of a problem with the liver)
- difficulty in urinating, urinating excessively or noticing that urine has changed colour (these may be signs of a problem with the kidneys)
- chest pain
- noticing blood in the stools

- severe pain in the stomach region together with nausea (feeling sick) and vomiting (being sick) (these may be signs of a problem with the pancreas)
- fungal infections of the mouth or vagina
- noticing that it takes longer for blood to clot after an injury.

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

Tell your health care provider if you notice any of the following:

*Frequent side effects*

- stomach cramps, feeling sick, diarrhoea, wind
- dizziness, headache
- numbness or pins and needles
- being sick, indigestion
- loss of appetite, taste disturbance
- visual disturbances, deafness
- changes in liver function
- itching, rash, inflammation
- joint pain
- local injection site reactions (inflammation/pain)
- 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)

- skin rashes or itching, hives, skin more sensitive to sunlight than normal
- feeling nervous, easily agitated
- reduced sense of touch or sensation (hypoesthesia)
- sleepiness or sleeplessness (insomnia)
- poor hearing or ringing in the ears
- heart palpitations, chest pain
- constipation, stomach pain associated with diarrhoea and fever
- inflammation of the liver (hepatitis), changes in liver enzymes
- general loss of strength
- swelling
- general discomfort
- abnormal laboratory test values (e.g. blood or liver tests)
- agitation
- sudden spinning feeling often triggered by moving your head too quickly (vertigo).

*Side effects with frequency unknown*

- fits or fainting
- aggression or anxiety
- 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

- bruising or prolonged bleeding after injury
- abnormal electrocardiogram (ECG)
- reduction in red blood cells which can make the skin pale and cause weakness or breathlessness
- Local injection site reactions (inflammation/pain).

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 MYCIBACT IV.

### **5. How to store MYCIBACT IV**

- Store all medicines out of reach of children
- Unopened container: Store at or below 30 °C, store in the original packaging until required for use.
- After reconstitution the final infusion solutions of Azithromycin lyophilized powder for infusion 500mg/vial, are stable for 24 hours when stored at room temperature (below 30 °C) and for 72 hours when stored at refrigerator (2 to 8 °C).
- Do not use after the expiry date stated on the label

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

Your doctor, pharmacist or healthcare professional knows how to store MYCIBACT IV. The doctor or nurse who is administering MYCIBACT IV to you, will make sure that the medicine is not used after the expiry date printed on the vial.

They will also reconstitute MYCIBACT IV and visually inspect the solution before giving it to you. Only clear solution without particles will be used.

## **6. Contents of the pack and other information**

### **What MYCIBACT IV contains**

The active substance is azithromycin (as dihydrate). Each vial contains 500 mg of azithromycin (as azithromycin dihydrate).

The other ingredients are citric acid and sodium hydroxide.

### **What MYCIBACT IV looks like and contents of the pack**

MYCIBACT IV is a white powder for solution for infusion. It is supplied in an uncoloured glass type I single dose vial with a rubber stopper and sealed with an aluminium/plastic flip-off cap.

Each vial is packaged in a cardboard box.

### **Holder of Certificate of Registration**

Austell Laboratories (Pty) Ltd

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JOHANNESBURG

Austell Pharmaceuticals, 530193, MYCIBACT IV 500 mg Powder for solution for infusion

2193

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**Registration number**

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