Approved Patient Information Leaflet for Medicines for Human Use:

AZITHROMYCIN 200 mg/5 mL AUSTELL

SCHEDULING STATUS: S4

AZITHROMYCIN 200 mg/5 mL AUSTELL powder for oral suspension

Azithromycin dihydrate

Contains sugar: sucrose 3,87 g per 5 mL

Read all of this leaflet carefully before you take AZITHROMYCIN 200 mg/5 mL AUSTELL

- 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 200 mg/5 mL AUSTELL 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 200 mg/5 mL AUSTELL is and what it is used for
2. What you need to know before you take AZITHROMYCIN 200 mg/5 mL AUSTELL
3. How to take AZITHROMYCIN 200 mg/5 mL AUSTELL
4. Possible side effects
5. How to store AZITHROMYCIN 200 mg/5 mL AUSTELL
6. Contents of the pack and other information

1. What AZITHROMYCIN 200 mg/5 mL AUSTELL is and what it is used for

AZITHROMYCIN 200 mg/5 mL AUSTELL contains azithromycin, which is an antibiotic, belonging to a class of antibiotics called macrolides.

AZITHROMYCIN 200 mg/5 mL AUSTELL is indicated to treat sore throat (pharyngitis/tonsillitis) and an ear infection (otitis media) in children 1 year and older.

It is also indicated in adults and children over 45 kg to treat mild to moderate:

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

2. What you need to know before you take AZITHROMYCIN 200 mg/5 mL AUSTELL

Do not take AZITHROMYCIN 200 mg/5 mL AUSTELL

- if you or your child is hypersensitive (allergic) to azithromycin or any other macrolide antibiotic such as erythromycin or any of the other ingredients of AZITHROMYCIN 200 mg/5 mL AUSTELL (listed in section 6)
- if you or your child is taking any ergot derivatives such as ergotamine which is used to treat migraines
- if you or your child has severe liver problems
- the safety and efficacy of AZITHROMYCIN 200 mg/5 mL AUSTELL in pregnancy and lactation have not been established (see Pregnancy, breastfeeding and fertility).

Warnings and precautions

Take special care with AZITHROMYCIN 200 mg/5 mL AUSTELL if you or your child:

- have previously experienced an allergic reaction after receiving azithromycin as included in AZITHROMYCIN 200 mg/5 mL AUSTELL, erythromycin or any other macrolide antibiotic. This allergic reaction can include a skin rash or wheezing
- have liver problems, your doctor may need to monitor your liver function or stop the treatment (see Do not take AZITHROMYCIN 200 mg/5 mL AUSTELL)
- are taking any ergot derivatives such as ergotamine (used to treat migraine) as these medicines

should not be taken together with AZITHROMYCIN 200 mg/5 mL AUSTELL

- have any heart conditions
- experience any symptoms of superinfection which may include high fever, black hairy tongue, loose stools or cough
- develop diarrhoea or loose stools during or after treatment. If this becomes severe or persistent or you notice that the stools contain blood or mucus, tell your doctor immediately. Do not take any medicine to treat your diarrhoea without first checking with your doctor.
- have kidney problems
- have myasthenia gravis (a condition that causes certain muscles to become weak)
- have diabetes
- if you are taking medicine chloroquine or hydroxychloroquine (used to treat malaria)

Children

- if your child is younger than 1 year, safety and efficacy of AZITHROMYCIN 200 mg/5 mL AUSTELL is not established in children less than 1 year old.
- if your child develops diarrhoea. If this becomes severe or persistent or you notice that the stools contain blood or mucus, consult your doctor immediately. In this situation, do not give the child any medicines which stop or slow bowel movement.
- if your child experiences symptoms of other infections such as fungal infections including candida (thrush).
- if your child complains of being able to feel their heartbeat, notices that their heartbeat does not feel or sound the same, gets dizzy or faints.
- if your child is less than 42 days old and vomits after feeding or is irritable during or after feeding.

Other medicines and AZITHROMYCIN 200 mg/5 mL AUSTELL

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

If you or your child are taking any of the following medicines, consult your doctor, pharmacist or other health care provider as these medicines may interact with AZITHROMYCIN 200 mg/5 mL AUSTELL

- antacids (medicine for indigestion) can interact with AZITHROMYCIN 200 mg/5 mL AUSTELL. AZITHROMYCIN 200 mg/5 mL AUSTELL should be taken at least 1 hour before or 2 hours after the antacid
- ergot derivatives such as ergotamine (used to treat migraines), see Warnings and Precautions
- digoxin (medicine used to treat heart problems)
- colchicine (used for gout)
- cimetidine given 2 hours before AZITHROMYCIN 200 mg/5 mL AUSTELL administration won't have an effect on AZITHROMYCIN 200 mg/5 mL AUSTELL
- warfarin medicine used to "thin" blood and prevent blood clots
- ciclosporin (used to suppress the immune system to prevent and treat rejection of a transplanted organ or bone marrow)
- atorvastatin (used to treat high blood cholesterol)
- zidovudine and nelfinavir (an antiretroviral to treat HIV)
- terfenadine (for hay fever or a skin allergy)
- hydroxychloroquine or chloroquine (used to treat conditions 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.

AZITHROMYCIN 200 mg/5 mL AUSTELL with food and drink

AZITHROMYCIN 200 mg/5 mL AUSTELL can be taken with food.

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 AZITHROMYCIN 200 mg/5 mL AUSTELL.

The safety and efficacy of AZITHROMYCIN 200 mg/5 mL AUSTELL in pregnancy and breastfeeding have not been established.

Driving and using machines

After taking AZITHROMYCIN 200 mg/5 mL AUSTELL, you may get dizziness (a feeling that you are about to fall). Do not drive or operate any machinery for your safety.

It is not always possible to predict to what extent AZITHROMYCIN 200 mg/5 mL AUSTELL 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 200 mg/5 mL AUSTELL affects them.

AZITHROMYCIN 200 mg/5 mL AUSTELL contains sucrose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking AZITHROMYCIN 200 mg/5 mL AUSTELL.
Patients with rare hereditary problems of fructose intolerance glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

3. How to take AZITHROMYCIN 200 mg/5 mL AUSTELL

Do not share medicines prescribed for you or your child with any other person.
Always take or give AZITHROMYCIN 200 mg/5 mL AUSTELL exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are unsure.

AZITHROMYCIN 200 mg/5 mL AUSTELL is supplied as powder for suspension. Your pharmacist or doctor will reconstitute it before dispensing it to you.

AZITHROMYCIN 200 mg/5 mL AUSTELL is usually used for children under 45 kg. It may also be used in adults and older children who have difficulty swallowing tablets or capsules.

Children aged 1 year and older (under 45 kg)

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.

Weight	Dosage
< 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 (refer to AUSTELL AZITHROMYCIN 500 mg Tablets PI).

Your doctor will decide on the dose to be given. Your doctor or pharmacist will explain to you how much to give your child.

Duration of administration

Your doctor will tell you how long your treatment with AZITHROMYCIN 200 mg/5 mL AUSTELL will last. Do not stop treatment early, as this may lead to a recurrence of your condition. If you have the impression that AUSTELL AZITHROMYCIN 200 mg/5 ml AZITHROMYCIN 200 mg/5 mL AUSTELL is too strong or too weak, tell your doctor or pharmacist.

Do not stop taking or giving AZITHROMYCIN 200 mg/5 mL AUSTELL without discussing it with your doctor even if you or your child feels better.

Method of administration

Take or give AZITHROMYCIN 200 mg/5 mL AUSTELL once a day with food.

AZITHROMYCIN 200 mg/5 mL AUSTELL suspension should be given to your child using the 5 mL oral dosing syringe or the spoon provided.

If you or your child take more AZITHROMYCIN 200 mg/5 mL AUSTELL than you should:

If you or your child have taken too much AZITHROMYCIN 200 mg/5 mL AUSTELL, your child or you may feel sick (nausea), be sick (vomit) or have diarrhoea.

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

If you forget to take or give your child a dose of AZITHROMYCIN 200 mg/5 mL AUSTELL

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

If you stop taking or giving AZITHROMYCIN 200 mg/5 mL AUSTELL

If you stop taking or giving AZITHROMYCIN 200 mg/5 mL AUSTELL, the infection may come back. Take or give AZITHROMYCIN 200 mg/5 mL AUSTELL for the full treatment time as prescribed by your doctor**.**

4. Possible side effects

AZITHROMYCIN 200 mg/5 mL AUSTELL can have side effects.

Not all side effects reported for AZITHROMYCIN 200 mg/5 mL AUSTELL are included in this leaflet. Should yours or your child's general health worsen or if you or he or she experience any untoward effects while taking AZITHROMYCIN 200 mg/5 mL AUSTELL, please consult your health care provider for advice.

If any of the following happens, stop taking or giving AZITHROMYCIN 200 mg/5 mL AUSTELL and tell your doctor immediately or go to the casualty department at your nearest hospital:

- sudden wheeziness, difficulty in breathing, swelling of eyelids, tongue, throat, face or lips, rash or itching (especially affecting the whole body) - these could be signs of a serious allergic reaction
- severe or prolonged diarrhoea, which may have blood or mucus in it, during or after treatment with

AZITHROMYCIN 200 mg/5 mL AUSTELL as this may be a sign of serious bowel inflammation "colitis"

- rapid or irregular heartbeat, fainting, low blood pressure
- dark urine, yellowing of the skin or the whites of the eyes (these may be signs of a problem with liver
- fever (high temperature) and sore throat with a rash, that develops quickly, with itching and peeling or flaking of the skin and possibly blistering of the mouth and the genital and anal regions. The eyes may also be affected and may be red and swollen (these could be signs of a severe allergic rash called Stevens Johnson Syndrome)
- other serious skin reaction:
    - 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. You or your child 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:

Frequents:

- deafness
- changes in the ability to see "vision"
- nausea (feeling sick), diarrhoea, pain in the stomach (abdomen), passing wind, vomiting, loss of appetite, taste disturbance
- skin rashes or itching

- tingling sensation or numbness in the skin
- joint pain
- dizziness, headache
- noticed on a blood test: changes in the levels of certain blood cells, decreased amounts of bicarbonate in the blood.

Less frequent:

- changes in ability to hear
- chest pain
- fungal infections of the mouth or vagina
- a ringing sound in the ears
- sensitivity of skin to light, hives
- constipation
- feeling nervous, easily agitated
- sleepiness or inability to sleep
- reduced sensation in the skin
- tiredness or weakness
- swelling, especially of the arms and legs
- noticed on a blood test: changes in liver enzymes, changes in levels of bilirubin, urea, creatinine or potassium.

Frequency not known:

- convulsions (“fits”)
- difficulty in urinating, urinating excessively or noticing that urine has changed colour (these may be signs of a problem with the kidneys)
- 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
- noticing that it takes longer for blood to clot after an injury

- paleness of the skin and feeling very weak or breathless, could be a sign of a decrease in red blood cells (haemolytic anaemia)
- feeling hyperactive, anxious or aggressive
- loss of smell or altered sense of smell, loss of taste, tongue discoloration
- localised muscle weakness
- abnormal electrocardiogram (ECG).

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 Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of AZITHROMYCIN 200 mg/5 mL AUSTELL.

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 AZITHROMYCIN 200 mg/5 mL AUSTELL

Store all medicines out of reach of children.

Store in the original packaging until required for use.

Powder and reconstituted suspension should be stored at or below 25 °C.

Refrigeration is not required. Discard any unused suspension after 10 days.

After reconstitution: shake the bottle well before each dose. Keep the bottle tightly closed.

Do not use AZITHROMYCIN 200 mg/5 mL AUSTELL after the expiry date printed on the label, container or outer carton.

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 AZITHROMYCIN 200 mg/5 mL AUSTELL contains

- The active substance is azithromycin dihydrate
- The other ingredients are banana flavour, hydroxypropylcellulose strawberry flavour, sucrose, trisodium phosphate (anhydrous) and xanthan gum.

What AZITHROMYCIN 200 mg/5 mL AUSTELL looks like and contents of the pack

Reconstituted solution:

Before reconstitution: fine, off-white powder with banana—strawberry odour.

After reconstitution: A whitish liquid with banana-strawberry odour and flavour.

AZITHROMYCIN 200 mg/5 mL AUSTELL is supplied in transparent amber glass bottles (Type III), with a polyethylene sealing disc and a white polyethylene cap in pack sizes of 15 and 30 ml. The bottles are further packed into cardboard boxes together with a dosing syringe.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

Austell Pharmaceuticals (Pty) Ltd

1 Sherborne Road

Parktown

Johannesburg, 2193

Tel: +2711 611 1400 or +27 860 287 835

This leaflet was last revised in

19 March 2026

Registration number

50/20.1.1/0567

Access to the corresponding Afrikaans Patient Information Leaflet and latest Professional Information

Access to the corresponding Afrikaans Patient Information Leaflet and latest Professional Information for this medicine is available on the following URL: https://austell.co.za/product-info/

Austell Pharmaceuticals (Pty) Ltd

Tel: +27 11 611 1400 or +27 860 287 835