

Approved Patient Information Leaflet for Medicines for Human Use:

AUSTELL CLARITHROMYCIN IV

SCHEDULING STATUS: S4

AUSTELL CLARITHROMYCIN IV 500 mg Lyophilised powder for solution for injection

Clarithromycin

Sugar free

Read all of this leaflet carefully before you are given AUSTELL CLARITHROMYCIN IV

Keep this leaflet. You may need to read it again.

If you have further questions, please ask your doctor or your pharmacist.

What is in this leaflet

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

1. What AUSTELL CLARITHROMYCIN IV is and what it is used for

AUSTELL CLARITHROMYCIN IV contains clarithromycin, as the active ingredient, which is an antibiotic of the macrolides group that works by stopping the growth of certain bacteria which cause infections.

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It is used treat various types of bacterial infections such as:

1. Chest infections such as bronchitis and pneumonia
2. Throat and sinus infections
3. Skin and tissue infections

2. What you need to know before you take AUSTELL CLARITHROMYCIN IV

AUSTELL CLARITHROMYCIN IV should not be administered to you

- if you are hypersensitive (allergic) to clarithromycin, other macrolide antibiotics such as erythromycin or azithromycin [7] or any of the other ingredients of AUSTELL CLARITHROMYCIN IV (listed in section 6).
- if you are taking medicines called ergot alkaloid tablets (e.g. ergotamine or dihydroergotamine) or use ergotamine inhalers (used to treat a migraine type headache)
- if you are taking midazolam tablets (used for sleeplessness)
- if you are taking astemizole and terfenadine anti-histamine medicines taken for hay fever and allergies,
- if you are taking cisapride (a medicine that was used to treat reflux) or pimozide (a medicine for psychosis) as combining these medicines with AUSTELL CLARITHROMYCIN IV can sometimes cause serious disturbances in heart rhythm. Consult your doctor for advice on alternative medicines
- if you or someone in your family has a history of heart rhythm disorders (ventricular cardiac arrhythmia, including torsades de pointes) or abnormality of electrocardiogram (ECG, electrical recording of the heart) called “long QT syndrome”
- if you are taking ticagrelor (a medicine used to prevent blood clotting) or ranolazine (a medicine used for heart attack, chest pain or angina)
- if you are taking lovastatin or simvastatin commonly known as statins (used to lower levels of cholesterol (a type of fat) in the blood). Statins can cause rhabdomyolysis (a condition

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which causes the breakdown of muscle tissue which can result in kidney damage) and myopathy (muscle pain or muscle weakness)

- if you are taking colchicine (a medicine used to treat gout)
- if you have low levels of potassium in your blood (hypokalaemia)
- if you have severe liver disease and kidney disease

Warnings and precautions

Tell your doctor or health care provider before being given AUSTELL CLARITHROMYCIN IV injection

- if you are pregnant or breastfeeding
- if you have or have had any liver or kidney problems
- if you have heart problems (e.g. heart disease, heart failure, an unusually slow heart rate, or abnormally low levels of magnesium in the blood (hypomagnesaemia))
- if you have, or are prone to, fungal infections (e.g. thrush)
- if you are taking colchicine (a medicine used to treat gout)
- if you are taking certain medicines called benzodiazepines (e.g. midazolam, triazolam) used as sedatives and calmatives
- if you are taking certain medicines called statins (used to lower levels of cholesterol (a type of fat) in the blood)
- if you are taking certain medicines to lower blood sugar
- if you are taking certain medicines (e.g. warfarin) to prevent blood clotting

Tell your doctor immediately if during treatment you suffer from

- diarrhoea while taking or after taking antibiotics, including AUSTELL CLARITHROMYCIN IV If this becomes severe or persistent or you notice that your stools contain blood or mucus, consult your doctor or healthcare professional immediately. In this situation, you should not take medicines that stop or slow bowel movement.
- if you have fungal infections (e.g. thrush).

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- If you have heart problems (e.g. heart disease, heart failure, an unusually slow heart rate, or abnormally low levels of magnesium in the blood (hypomagnesaemia))
- If you have any liver or kidney problems
- If you are pregnant or breast feeding

Children and adolescents

AUSTELL CLARITHROMYCIN IV is not suitable for use in children under 12 years of age.

Other medicines and AUSTELL CLARITHROMYCIN IV

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

You should not be given AUSTELL CLARITHROMYCIN IV if you are taking any of the medicines listed in the section above “You should not be given AUSTELL CLARITHROMYCIN IV if:”

AUSTELL CLARITHROMYCIN IV may interact with other medicines. Make sure your doctor knows if you are taking any of the following because you may need to change your treatment or you may need to have regular tests performed.

Tell your doctor if you are taking the following medicines.

- digoxin, quinidine or disopyramide (for heart problems)
- warfarin, or any other anticoagulant (for blood thinning). Your doctor might want to test your blood clotting time (prothrombin times) more often
- ibrutinib (for cancer treatment)
- carbamazepine, valproate, phenobarbital or phenytoin (for epilepsy)
- fluvastatin, pravastatin and rosuvastatin (HMG-CoA reductase inhibitors, commonly known as statins, and used to lower levels of cholesterol (a type of fat) in the blood (e.g.)). Statins can cause rhabdomyolysis (a condition which causes the breakdown of muscle tissue which can result in kidney damage) and myopathy (muscle pain or muscle weakness) and the signs thereof should be monitored

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- diabetes medicine (used to lower blood glucose levels) such as certain tablets (e.g. nateglinide, pioglitazone, repaglinide, rosiglitazone) or insulin
- gliclazide or glimepiride (sulphonylureas used in the treatment of type II diabetes)
- theophylline (used in patients with breathing difficulties such as asthma)
- triazolam, alprazolam or intravenous or oromucosal midazolam (sedatives)
- cilostazol (for poor circulation)
- methylprednisolone (a corticosteroid)
- vinblastine (for treatment of cancer)
- ciclosporin, sirolimus and tacrolimus (immune suppressants used after an organ transplant)
- etravirine, efavirenz, nevirapine, ritonavir, zidovudine, atazanavir, saquinavir (antiretroviral medicines used in the treatment of HIV)
- rifabutin, rifampicin, rifapentine (used in the treatment of certain bacterial infections)
- fluconazole, itraconazole (used in the treatment of certain fungal infections)
- tolterodine (for overactive bladder)
- verapamil, amlodipine, diltiazem (for high blood pressure)
- omeprazole (used to treat stomach ulcers)
- sildenafil, vardenafil and tadalafil (for impotence in adult males or for use in pulmonary arterial hypertension (high blood pressure in the blood vessels of the lung))
- St John's Wort (a herbal product used to treat depression)
- quetiapine or other antipsychotic medicines
- other macrolide medicines (e.g. erythromycin and azithromycin) used to treat bacterial infections
- lincomycin and clindamycin (lincosamides – a type of antibiotic)
- if you are taking oral contraceptive pills and diarrhoea or vomiting occurs, inform your doctor as you may need to take extra contraceptive precautions such as using a condom.

AUSTELL CLARITHROMYCIN IV with food and drink

Your doctor or a nurse will administer AUSTELL CLARITHROMYCIN IV to you.

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AUSTELL CLARITHROMYCIN IV can be given to you either before or after a meal.

Pregnancy and breastfeeding

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 being given AUSTELL CLARITHROMYCIN IV.

The effect of AUSTELL CLARITHROMYCIN IV in pregnant women and women breastfeeding their baby is not known. Tell your doctor if you are pregnant, think you may be pregnant or are trying to become pregnant.

Driving and using machines

It is not known how AUSTELL CLARITHROMYCIN IV will affect your driving or ability to use machines. AUSTELL CLARITHROMYCIN IV may make you feel dizzy, light-headed, confused or disorientated. Do not drive or operate machinery until you know how AUSTELL CLARITHROMYCIN IV affects you. If you are affected you in this way do not drive, operate machinery or do anything that requires you to be alert.

3. How to take AUSTELL CLARITHROMYCIN IV

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

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

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

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

- This medicine will be given to you through a drip (by infusion into a vein) by a doctor or health care professional.
- The usual dose of AUSTELL CLARITHROMYCIN IV for adults is 1 000 mg divided into two equal doses and given directly into the blood stream (intravenously) by a drip over a period of 60 minutes.
- You will be treated for up to two to five days. As soon as you are well enough to take medicine orally, you will no longer be given this medicine via drip.

If you have the impression that the effect of AUSTELL CLARITHROMYCIN IV is too strong or too weak, you should talk to your doctor or pharmacist.

If you are given more AUSTELL CLARITHROMYCIN IV than you should

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

Treatment of over-dosage is usually symptomatic:

You will be treated in hospital and your progress will be monitored.

If you forget to take AUSTELL CLARITHROMYCIN IV

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

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

If you stop taking AUSTELL CLARITHROMYCIN IV

If your treatment with AUSTELL CLARITHROMYCIN IV is stopped too soon, the infection may come back or your condition may worsen.

4. Possible side effects

AUSTELL CLARITHROMYCIN IV can have side effects.

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

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

- having difficulty breathing, fainting, with or without swelling of the throat, face, tongue, lips and eyes and severe rash and/or itching of the skin (these could be signs of an allergic reaction)
- severe and quick-developing skin reactions, such as painful blistering of the skin, mouth, lips, eyes, genitals and anus with itching and peeling or flaking of your skin, fever (high temperature) and sore throat (symptoms of a rare allergic reaction called Stevens-Johnson syndrome/toxic epidermal necrolysis)
- a red, scaly rash with bumps under the skin and blisters (symptoms of exanthematous pustulosis)
- allergic skin reactions which cause severe illness with ulceration of the mouth, lips and skin which causes severe illness with rash, fever and inflammation of internal organs (DRESS)
- severe or prolonged diarrhoea, which may contain blood and/or mucus in it (this could be antibiotic associated colitis including pseudomembranous colitis). Diarrhoea may occur over two months after treatment with clarithromycin, in which case you should still contact your doctor

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- noticing changes in heart rate, being able to feel your heart beat together with dizziness or fainting (these may be signs of a problem with the rhythm of your heart)
- yellowing of the skin or the whites of your eyes (jaundice), skin irritation, pale stools, dark urine, tender abdomen or loss of appetite together with nausea (feeling sick) and vomiting (being sick). These are signs that your liver may have inflammation and not be working properly
- muscle pain or weakness known as rhabdomyolysis (a condition which causes the breakdown of muscle tissue which can result in kidney damage).

These are very serious side effects. If you have them, you may have had a serious reaction to AUSTELL CLARITHROMYCIN IV You may need urgent medical attention.

Less frequent

- if you are getting sick more often (colds), these may be signs of a decrease in your white blood cells (leukopenia)
- signs of infection, such as high temperature, chills, shivering, headaches, sweating, flu-like symptoms or weakness, bruising, pale skin and/or breathlessness. This may be the result of a blood disorders (such as and neutropenia)
- coughing, wheezing, shortness of breath, a high temperature and a general ill feeling associated with an increase of white blood cells (eosinophilia)
- tightening of air passages, making breathing difficult due to a lung disease (asthma)
- sudden shortness of breath with a sharp, stabbing chest pain that may get worse with deep breath, a rapid heart rate, unexplained cough, sometimes with bloody mucus. These are signs of a blood clot that causes sudden blockage in a lung artery (pulmonary embolism)
- situation where the bile (fluid made by the liver and stored in the gallbladder) cannot flow from the gallbladder to the duodenum (cholestasis) causing clay-coloured or white stools, dark urine, inability to digest certain foods, itching, nausea or vomiting, pain in the right upper part of the abdomen and/or yellow skin or eyes

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- abdominal pain, nausea and vomiting, dark-coloured urine, itching and rash, fatigue, loss of appetite with yellowing of skin and eyes (hepatitis)

Frequency unknown

- large, raised red patches on the skin, especially that of the face and legs, with fever and severe general illness which can sometimes recur and is caused by a bacterial infection (erysipelas)
- noticing that it takes longer for your blood to clot after an injury, these may be a sign of a decrease in your platelets (thrombocytopenia)
- Large swelling around the eyelids and lips, swelling of hands, feet, throat, lesions on the face, trunk, genitals, and extremities, abdominal pain and a rash that is not itchy (angioedema)
- convulsions (“fits”)
- hearing loss
- blood loss through damaged blood vessels, organs or skin (haemorrhage)
- severe upper abdominal pain (that radiates to your back and feels worse after eating), together with fever, nausea (feeling sick), vomiting (being sick) and tenderness when touching the abdomen. These could be signs of inflammation of your pancreas (acute pancreatitis)
- fatigue, dark urine, joint and muscle pain, loss of appetite, fever, abdominal discomfort, weakness and yellowing of the whites of the eyes (sclera) and skin and inside of the mouth. These could be signs and symptoms of hepatic jaundice caused by a dysfunctional liver
- muscle pain and/or muscle weakness (myopathy)
- change in the levels of products produced by the kidney with tiredness, swelling or puffiness in the face, abdomen, thighs or ankles or problems with urination. This can be caused by inflammation of the kidney (nephritis) or an inability of the kidney to function properly (renal failure)

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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:

- difficulty sleeping
- changes in sense of taste
- headache
- widening of blood vessels
- stomach problems such as diarrhoea, vomiting, feeling sick (nausea), indigestion, stomach pain
- abnormal liver function test
- rash
- increased sweating
- feeling pain or tender at the site of injection, or inflammation at the vein

Less frequent side effects:

- high temperature
- swelling, redness or itchiness of the skin
- oral or vaginal 'thrush' (a fungal infection)

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- inflammation of the stomach and intestines
- lack or loss of appetite
- anxiety, nervousness
- drowsiness, tiredness, dizziness or shaking
- involuntary muscle movements
- a sensation of whirling and loss of balance, with dizziness or light-headedness (vertigo)
- ringing in the ears and difficulty in hearing
- nose bleed
- inflammation of the lining of the gullet (oesophagus) and lining of the stomach
- anal pain
- pain, tenderness and swelling of the mouth and/or tongue
- bloating, constipation, wind, burping
- dry mouth
- raised abnormal kidney and liver function blood test and raised blood tests
- inflammation of the skin characterised by the presence of the bumps which are filled with fluid, itchy and painful rash
- muscle spasms, muscle stiffness and muscle pain
- feeling weak, tired and having no energy
- chest pain
- chills
- stiffness
- decrease of the levels of blood platelets
- increase in eosinophil
- exaggerated immune response to a foreign agent
- asthma: lung disease associated with tightening of air passages, making breathing difficult
- blood clot that causes sudden blockage in a lung artery (pulmonary embolism)

Side effects with frequency unknown:

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- psychiatric problems such confusion, loss of bearings, hallucinations (seeing things), change in sense of reality or panicking, depression, abnormal dreams or nightmares and mania (feeling of elation or over-excitement)
- loss of taste or smell or inability to smell properly
- paraesthesia, more commonly known as 'pins and needles'
- discolouration of the tongue or teeth
- acne
- abnormal urine colour
- inflammation of colon
- bacterial infection of the outer layers of the skin
- reduction in the level of certain blood cells (which can make infections more likely or increase the risk of bruising or bleeding)
- convulsion (fits)
- type of heart rhythm disorder (Torsade de pointes, ventricular tachycardia)
- inflammation of the pancreas
- change in the levels of products produced by the kidney, inflammation of the kidney or an inability of the kidney to function properly (you may notice tiredness, swelling or puffiness in the face, abdomen, thighs or ankles or problems with urination)

In patients with AIDS or other immunocompromised conditions who are treated for long periods of time, it is often difficult to distinguish between side effects and underlying signs of HIV or other illnesses.

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

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publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of AUSTELL CLARITHROMYCIN IV.

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 AUSTELL CLARITHROMYCIN IV

Store all medicines out of reach of children

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

Store at or below 25 °C.

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

The reconstituted product can be stored at 25 °C for 6 hours or at 2-8 °C for 48 hours.

6. Contents of the pack and other information

What AUSTELL CLARITHROMYCIN IV contains

- The active substance is clarithromycin
- The other ingredients are lactobionic acid, water for injection

AUSTELL CLARITHROMYCIN IV 500 mg lyophilised powder for solution for injection

Each vial contains clarithromycin 500 mg and lactobionic acid as a solubilising agent.

What AUSTELL CLARITHROMYCIN IV looks like and contents of the pack

AUSTELL CLARITHROMYCIN IV: A homogenous uniform white-coloured freeze-dried powder which on reconstitution with water for injection produces a clear, colourless solution free of particulate matter

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Reconstituted solution:

The solution is clear colourless solution free of particulate matter.

AUSTELL CLARITHROMYCIN IV is supplied in 20 mL transparent type I glass vials with grey chlorobutyl cap and green flip-off aluminium capsule.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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