Approved Patient Information Leaflet for Medicines for Human Use:

CLARITHROMYCIN 250 mg / 500 mg AUSTELL tablets

SCHEDULING STATUS: S4

CLARITHROMYCIN 250 mg AUSTELL film-coated tablets

CLARITHROMYCIN 500 mg AUSTELL film-coated tablets

Clarithromycin

Preservative: Sorbic acid 0,063 % *m/m*

Sugar free

Read all of this leaflet carefully before you start taking CLARITHROMYCIN AUSTELL tablets

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

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

CLARITHROMYCIN AUSTELL tablets contain the active substance called clarithromycin which belongs to the group of medicines called macrolide antibiotics.

CLARITHROMYCIN AUSTELL tablets works by killing or stopping the growth of bacteria that may cause certain infections.

CLARITHROMYCIN AUSTELL tablet is used for:

- throat infections such as tonsillitis
- lower respiratory tract infections, e.g. bronchitis, pneumonia
- upper respiratory tract infections, e.g. pharyngitis, sinusitis
- skin infections such as impetigo and cellulitis
- soft tissue infections, e.g. folliculitis, erysipelas
- mild to moderately severe acute otitis media (infection of your middle ear)
- It is also used in combination with other medications to kill *H. Pylori*, a bacteria known to cause duodenal ulcers in the digestive tract
- Clarithromycin has been used in treatment regimens which include clarithromycin plus amoxicillin and omeprazole; clarithromycin plus tinidazole and omeprazole; and clarithromycin plus tetracycline and bismuth subsalicylate.

There is some evidence that disseminated and localized infections in HIV-positive adults, due to *Mycobacterium avium* or *Mycobacterium intracellulare* respond to clarithromycin.
Based on bacteriological results, clarithromycin should be used in conjunction with other antimycobacterials.
To a lesser extent localised infections due to *Mycobacterium chelonae* and *Mycobacterium kansasii* have responded to clarithromycin.

Your doctor may choose to use a medication for conditions other than the ones listed in this information leaflet. If you're unsure why you are taking this medication, contact your doctor.

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

Do not take CLARITHROMYCIN AUSTELL tablets

- If you are hypersensitive (allergic) to clarithromycin, erythromycin, other macrolide antibiotics, or to any of the other ingredients of CLARITHROMYCIN AUSTELL tablets (listed in section 6).

- If you are taking astemizole, terfenadine, cisapride, or pimozide.
- If you or someone in your family has a history of heart rhythm disorders (ventricular cardiac arrhythmia, including torsade de pointes) or abnormality of electrocardiogram (ECG, electrical recording of the heart) called “long QT syndrome”.
- If you suffer from porphyria.
- If you are pregnant.
- If you are taking ergotamine or dihydroergotamine commonly used to treat migraine as the combination with CLARITHROMYCIN AUSTELL tablets may cause constriction of blood vessels resulting in a decrease of oxygen supply to the brain and hands and feet ultimately causing tissue damage.
- If you are taking statins e.g. simvastatin and lovastatin, medicines used to treat high cholesterol, as it may increase the risk of rhabdomyolysis which is the breakdown of damaged muscle.
- If you are taking colchicine, a medicine used to treat gout.
- If you are taking oral midazolam (a sedative).
- If you are taking a medicine containing lomitapide.
- If you are taking medicines called ticagrelor or ranolazine (for heart attack, chest pain or angina).
- If you have abnormally low levels of potassium or magnesium in your blood (hypokalaemia or hypomagnesaemia).
- If you have severe liver disease with kidney disease.
- If you are taking certain antipsychotic medicines, such as quetiapine, cariprazine, and aripiprazole (for mental problems), it can make the levels of these antipsychotic medicines in your blood go up. This can lead to severe side effects (see section ‘Other medicines and CLARITHROMYCIN AUSTELL tablets).

Warnings and precautions

Special care should be taken with CLARITHROMYCIN AUSTELL tablets.

- Allergy: Clarithromycin should be taken with caution by anyone who has had some form of medicine allergy. It should not be taken by anyone who is allergic to similar medicines (e.g., azithromycin, erythromycin). If an allergic reaction to clarithromycin occurs, stop taking the drug and contact a doctor.
- Kidney disease: People with kidney disease should be cautious while taking clarithromycin. The

elimination of CLARITHROMYCIN AUSTELL tablets is reduced in patients with renal function impairment, especially those with a creatinine clearance of < 30 mL/min.

- Liver disease: People with liver disease should be cautious while taking clarithromycin. If you experience yellowing of skin and white of the eyes, abdominal pain and tenderness, dark urine and severe itchy skin you should stop taking CLARITHROMYCIN AUSTELL tablets immediately.
- If you experience severe diarrhoea, you may be suffering from pseudomembranous colitis due to CLARITHROMYCIN AUSTELL tablets.
- If you are taking colchicine (usually taken for gout). Do not take clarithromycin and colchicine together as it is contraindicated.
- If you are taking benzodiazepines e.g. midazolam or medicines used as muscle relaxants and to treat anxiety. Do not take clarithromycin and oral midazolam together as its contraindicated.
- if you have heart problems (e.g. heart disease, heart failure, an unusually slow heart rate)
- if you have abnormally low levels of potassium or magnesium in your blood (hypokalaemia or hypomagnesaemia)
- If you are taking blood glucose lowering medicines such as insulin as it may cause hypoglycaemia, where your glucose level drops too much.
- If you are taking anticoagulants (medicines that help prevent blood clots)
- If you have, or are prone to, fungal infections (e.g. thrush)
- If you are taking rifabutin and/or rifampicin as the combination will cause a decrease of CLARITHROMYCIN AUSTELL tablets in your blood. Co-administration has been reported to cause a higher incidence of uveitis, an inflammation of part of the eye compared to when rifabutin is taken alone.
- If you are taking theophylline, a medicine used to open your airways to help you breath better.

Children

CLARITHROMYCIN AUSTELL tablets are not suitable for use in children under 12 years of age.

Other medicines and CLARITHROMYCIN AUSTELL tablets

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

or traditional medicines.)

The following medication may interact with clarithromycin and therefore you should notify your doctor or healthcare professional if you are taking medicines that contains any of the following before taking CLARITHROMYCIN AUSTELL:

- digoxin, quinidine or disopyramide (for heart problems)
- ibrutinib (for cancer treatment)
- warfarin, or any other anticoagulant e.g. dabigatran, rivaroxaban, apixaban (for blood thinning)
- carbamazepine, divalproex, valproate, phenobarbital or phenytoin (for epilepsy)
- nateglinide, pioglitazone, repaglinide, rosiglitazone or insulin (used to lower blood glucose levels)
- gliclazide or glimepiride (sulphonylureas used in the treatment of type II diabetes)
- aminophylline, theophylline, oxitriphylline (used in patients with breathing difficulties such as asthma)
- triazolam, alprazolam or intravenous or oromucosal-midazolam (sedatives)
- cilostazol (for poor circulation)
- methadone (used in the treatment of opioid addiction)
- methylprednisolone (a corticosteroid)
- vinblastine (for treatment of cancer)
- cyclosporin, sirolimus and tacrolimus (immune suppressants)
- etravirine, efavirenz, nevirapine, ritonavir, indinavir, zidovudine, atazanavir, saquinavir (anti-viral drugs used in the treatment of HIV)
- rifabutin, rifampicin, fluconazole, itraconazole (used in the treatment of certain bacterial infections)
- tolterodine (for overactive bladder)
- verapamil, amlodipine, diltiazem (for high blood pressure)
- 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)
- hydroxychloroquine or chloroquine (used to treat conditions including rheumatoid arthritis, or to treat or prevent malaria). Taking these medicines at the same time as clarithromycin may increase the chance

of you getting side effects that affect your heart.

- cimetidine, omeprazole, lansoprazole
- bromocriptine
- buspirone
- SSRIs (e.g., fluoxetine, paroxetine, sertraline)
- Please tell your doctor if you are taking oral contraceptive pills and diarrhoea or vomiting occurs, as you may need to take extra contraceptive precautions such as using a condom.

Do not take CLARITHROMYCIN AUSTELL with the following medications as its contraindicated:

- lovastatin, atorvastatin, rosuvastatin (HMG-CoA reductase inhibitors, commonly known as statins, and used to lower levels of cholesterol (a type of fat) in the blood). Statins can cause rhabdomyolysis (a condition which causes the breakdown of muscle tissue which can result in kidney damage) and signs of myopathy (muscle pain or muscle weakness) should be monitored.
- quetiapine, cariprazine, and aripiprazole or other antipsychotic medicines
- other macrolide medicines, lincomycin and clindamycin (lincosamides – a type of antibiotic)
- astemizole, terfenadine, cisapride, or pimozide
- ergotamine, dihydroergotamine, methysergide (used to treat migraines)
- colchicine (a medicine used for gout)
- oral midazolam (sedative)
- ticagrelor or ranolazine (for heart attack, chest pain or angina).

CLARITHROMYCIN AUSTELL tablets with food and drink

CLARITHROMYCIN AUSTELL tablets may be taken with or without meals.

Pregnancy and breastfeeding

If you are pregnant, breastfeeding, or think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care professional for advice before taking

CLARITHROMYCIN AUSTELL tablets.

Pregnancy: Safety and effectiveness in pregnancy has not been established.

Breast-feeding: Clarithromycin passes into breast milk. The safety of this medication for use while nursing has not been established.

Driving and using machines

It is not always possible to predict to what extent CLARITHROMYCIN AUSTELL tablets 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 CLARITHROMYCIN AUSTELL tablets affects them.
Clarithromycin may make you feel dizzy or drowsy. If they affect you in this way do not drive, operate machinery or do anything that requires you to be alert.

CLARITHROMYCIN AUSTELL tablets contain sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially ‘sodium-free’.

3. How to take CLARITHROMYCIN AUSTELL tablets

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

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

Adults and children over 12 years: The recommended adult dose of clarithromycin is 250 mg to 500 mg twice daily, taken with or without meals.

Duration of administration

Your doctor will tell you how long your treatment with CLARITHROMYCIN AUSTELL tablets will last. The

usual duration of treatment for most conditions is 7 to 14 days.

Method of administration

You can take CLARITHROMYCIN AUSTELL tablets with meals or independently of meals.

This medication may cause less stomach upset if taken with food.

Many things can affect the dose of medication that a person needs, such as body weight, other medical conditions, and other medications. If your doctor has recommended a dose different from the ones listed here, do not change the way that you are taking the medication without consulting your doctor.

If you take more CLARITHRMYCIN AUSTELL tablets than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre. Overdose of this medicine is likely to cause vomiting and stomach pains.

If you forget to take AUSTELL CLARITHROMYCIN tablets

If you miss a dose, take it as soon as possible and continue on with your regular schedule. If it is almost time for your next dose, skip the missed dose and continue on with your regular dosing schedule. Do not double doses.

If you stop taking CLARITHROMYCIN AUSTELL tablets

It is very important that this medication be taken exactly as prescribed by your doctor. Finish all this medication, even if you start to feel better.

4. Possible side effects

CLARITHROMYCIN AUSTELL tablets can have side effects.

Not all side effects reported for CLARITHROMYCIN AUSTELL tablets are included in this leaflet. If your general state of health worsens or if you experience any untoward effects while taking CLARITHROMYCIN

AUSTELL tablets, please consult your health care provider for advice.

The side effects listed below are not experienced by everyone who takes this medication. If you are concerned about side effects, discuss the risks and benefits of this medication with your doctor. Your health professional may be able to help you to deal with some of the effects.
The following side effects may go away as your body becomes used to the medicine; check with your doctor if they continue or become bothersome.

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

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing
- skin rash or itching
- fainting.

These are very serious side effects. If you have them, you may have had a serious reaction to CLARITHROMYCIN AUSTELL tablets. You 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:

- fever
- shortness of breath
- yellow eyes or skin
- watery and severe diarrhoea, which may also be bloody
- muscle pain or weakness known as rhabdomyolysis (a condition which causes the breakdown of muscle tissue which can result in kidney damage
- severe skin reactions such as painful blistering of the skin, mouth, lips, eyes and genitals (symptoms of a rare allergic reaction called Stevens-Johnson syndrome/toxic epidermal necrolysis).

- red, scaly rash with bumps under the skin and blisters (symptoms of exanthematous pustulosis). The frequency of this side effect is not known (cannot be estimated from the available data).
- rare 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).

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:

- nausea and vomiting
- severe abdominal or stomach cramps and pain
- abdominal tenderness
- unusual bleeding or bruising
- change in sense of taste
- headache
- difficulty sleeping
- widening of blood vessels
- increased sweating

Less frequent side effects:

- high temperature
- swelling, redness or itchiness of the skin
- oral or vaginal ‘thrush’ (a fungal infection)
- inflammation of the stomach and intestines
- decrease of the levels of blood platelets (blood platelets help stop bleeding)
- decrease in white blood cells (leukopenia)
- decrease in neutrophils (neutropenia)

- stiffness
- chills
- increase of eosinophils (white blood cells involved in immunity)
- exaggerated immune response to a foreign agent
- lack or loss of appetite
- anxiety, nervousness
- drowsiness, tiredness, dizziness or shaking
- involuntary muscle movements
- vertigo
- ringing in the ears or hearing loss
- chest pain or changes in heart rhythm such as palpitations or an irregular heartbeat
- asthma (lung disease associated with tightening of air passages, making breathing difficult)
- nosebleed
- blood clot that causes sudden blockage in a lung artery (pulmonary embolism)
- inflammation of the lining of the gullet (oesophagus) and lining of the stomach
- anal pain
- bloating, constipation, wind, burping
- dry mouth
- situation where the bile (fluid made by the liver and stored in the gallbladder) cannot flow from the gallbladder to the duodenum (cholestasis)
- inflammation of the skin characterized by the presence of the bullae which are filled with fluid, itchy and painful rash
- muscle spasms, muscle pain or loss of muscle tissue. If your child suffers from myasthenia gravis (a condition in which the muscles become weak and tire easily), clarithromycin may worsen these symptoms.
- raised abnormal kidney and liver function blood test and raised blood tests
- feeling weak, tired and having no energy.

Side effects with frequency unknown:

- inflammation of the 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)
- 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)
- convulsion (fits)
- paraesthesia, more commonly known as 'pins and needles'
- loss of taste or smell or inability to smell properly
- type of heart rhythm disorder (Torsade de pointes, ventricular tachycardia)
- loss of blood (haemorrhage)
- inflammation of the pancreas
- discolouration of the tongue or teeth
- acne
- 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).

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 AUSTELL CLARITHROMYCIN tablets**.**

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 tablets

- Store in well closed container at or below 25 °C.
- Protect from light.
- 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 AUSTELL CLARITHROMYCIN tablets contains

- The active substance is clarithromycin.
- The other ingredients are microcrystalline cellulose, colloidal anhydrous silica, croscarmellose sodium, povidone, stearic acid, purified talc, magnesium stearate, hypromellose, propylene glycol, sorbitan monooleate, vanilla dry flavour, titanium dioxide, quinoline yellow lake, hydroxypropyl cellulose and sorbic acid.

CLARITHROMYCIN 250 mg AUSTELL tablets:

Each tablet contains 257 mg clarithromycin (6-0 methyl erythromycin A) equivalent to 250 mg anhydrous clarithromycin.

Preservative: Sorbic acid 0,063 % *m/m.*

Sugar free.

CLARITHROMYCIN 500 mg AUSTELL tablets:

Each tablet contains 515,5 mg clarithromycin (6-0 methyl erythromycin A) equivalent to 500 mg anhydrous

clarithromycin.

Preservative: Sorbic acid 0,063 % *m/m.*

Sugar free.

What CLARITHROMYCIN AUSTELL tablets looks like and contents of the pack

CLARITHROMYCIN 250 mg AUSTELL film-coated tablets

Yellow, oval-shaped, convex tablets, scored on one side, film coated, 14 x 8 mm.

CLARITHROMYCIN 500 mg AUSTELL film-coated tablets

Yellow, oval-shaped, convex tablets, scored on one side, film coated, 19 x 10 mm.

CLARITHROMYCIN 250 mg AUSTELL tablets is packed in PVC/PVDC Aluminium blister packs of 10 or 14 tablets.

CLARITHROMYCIN 500 mg AUSTELL tablets is packed in PVC/PVDC Aluminium blister packs of 10 or 14 tablets.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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CLARITHROMYCIN 250 mg AUSTELL tablets: A38/20.1.1/0475

CLARITHROMYCIN 500 mg AUSTELL tablets: A38/20.1.1/0476

Access to the corresponding Professional Information

Professional Information for this medicine is available on the following URL: https://austell.co.za/product-info/

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