Approved Patient Information Leaflet for Medicines for Human Use:

AUSTELL CO-AMOXICLAV 375/625 mg Tablets

SCHEDULING STATUS: S4

Austell Co-Amoxiclav 375/625 mg Tablets

Amoxicillin trihydrate and potassium clavulanate

Sugar free

Austell Co-Amoxiclav 375 mg Tablets

Each tablet contains amoxicillin trihydrate equivalent to 250 mg amoxicillin and potassium clavulanate equivalent to 125 mg clavulanic acid.

Austell Co-Amoxiclav 625 mg Tablets

Each tablet contains amoxicillin trihydrate equivalent to 500 mg amoxicillin and potassium clavulanate equivalent to 125 mg clavulanic acid.

Read all of this leaflet carefully before you start using Austell Co-Amoxiclav

- 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.
- Austell Co-Amoxiclav 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 Austell Co-Amoxiclav is and what it is used for
2. What you need to know before you take Austell Co-Amoxiclav
3. How to take Austell Co-Amoxiclav
4. Possible side effects

5. How to store Austell Co-Amoxiclav

6. Contents of the pack and other information

1. What Austell Co-Amoxiclav is and what it is used for

Austell Co-Amoxiclav contains the active substance called Amoxicillin trihydrate equivalent to amoxicillin 250 mg and amoxicillin 500 mg and potassium clavulanate equivalent to clavulanic acid 125 mg which belongs to the group of medicines called penicillins.

Austell Co-Amoxiclav Tablets are used for the treatment of infections caused by amoxicillin resistant organisms producing beta-lactamases sensitive to clavulanic acid:
Upper respiratory tract infections, such as sinusitis, recurrent otitis media (middle ear infection), tonsillitis.

Lower respiratory tract infections, such as bronchitis and bronchopneumonia.
Genito-urinary tract infections, such as cystitis, urethritis, pyelonephritis.
Skin and soft tissue infections.

Austell Co-Amoxiclav Tablets will also be effective in the treatment of infections caused by amoxicillin sensitive organisms at the appropriate amoxicillin dosage since in this situation the clavulanic acid component does not contribute to the therapeutic effect.

2. What you need to know before you take Austell Co-Amoxiclav

Do not take Austell Co-Amoxiclav

- if you are hypersensitive (allergic) to Amoxicillin trihydrate and potassium clavulanate or any of the other ingredients of Austell Co-Amoxiclav (listed in section 6).
- if you have a previous history of amoxicillin/clavulanic –associated jaundice/hepatic dysfunction.

- if you suffer from infectious mononucleosis

Warnings and precautions

Take special care with Austell-Co-Amoxiclav:

- If you have a history of allergy to drugs
- If you suffer from renal impairment
- If you suffer from lymphatic leukaemia or HIV infection

Pregnancy and breast feeding:

If you are pregnant or breast feeding your baby while taking the medicine please consult your doctor, pharmacist or other health care professional for advice.

Other medicines and Austell-Co-Amoxiclav

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

Taking other medicines with Austell-Co-Amoxiclav may cause undesirable interactions. Please consult your doctor or a pharmacist if you are taking any of the following:

- Probenecid decreases the renal tubular secretion of amoxicillin but does not affect clavulanic acid excretion. Concurrent use with Austell Co- Amoxiclav Tablets may result in increased and prolonged blood levels of amoxicillin, but not of clavulanic acid.
- Austell Co- Amoxiclav Tablets may reduce the efficacy of oral contraceptives and the patients should be warned accordingly.
- The concomitant administration of allopurinol and ampicillin substantially increases the incidence of skin rashes in patients receiving both agents as compared to patients receiving ampicillin alone.

- Tetracyclines and other bacteriostatic drugs may interfere with the bactericidal effects of amoxicillin.

Interaction with Laboratory tests:

It is recommended that when testing for the presence of glucose in urine during Austell Co- Amoxiclav Tablets treatment, enzymatic glucose oxidase methods should be used. Due to the high urinary concentrations of amoxicillin, false positive readings are common with chemical methods.

If you are taking medicines on a regular basis, using the medicine at the same time with another medicine may cause undesirable interactions. Please consult your doctor, pharmacist or other health care professional for advice.

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 Austell Co- Amoxiclav.

Driving and using machines

It is not always possible to predict to what extent Austell Co- Amoxiclav 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 Austell Co- Amoxiclav affects them.

Austell Co- Amoxiclav can have side effects and the symptoms may make you unfit to drive.

Do not drive or operate machinery unless you are feeling well.

Austell Co- Amoxiclav contains Sodium

The sodium content must be taken into account in patients on a sodium restricted diet if the administration of high doses is necessary.

3. How to take Austell Co- Amoxiclav

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

Always take Austell-Co-Amoxiclav exactly as your doctor instructed you. You should check with your doctor or pharmacist if you are not sure.

Adult:

The adult dose for Austell Co- Amoxiclav Tablets is one Austell Co- Amoxiclav 375 mg tablet every eight hours at the start of a meal. For more severe infections and infection of the respiratory tract, the dose should be one Austell Co- Amoxiclav 625 mg tablet every eight hours at the start of a meal.

Since Austell Co- Amoxiclav 375 mg and 625 mg tablets contain the same amount of clavulanic acid (125 mg as the potassium salt), two Austell Co- Amoxiclav 375 mg tablets are not equivalent to one Austell Co- Amoxiclav 625 mg tablet.

Therefore, two Austell Co- Amoxiclav 375 mg tablets should not be substituted for one Austell Co- Amoxiclav 625 mg tablet.

Impaired renal function:

The dose may need to be reduced in impaired kidney function. Dosage adjustments are based on the maximum recommended level of amoxicillin.

The following schedule is proposed:

Austell Co-Amoxiclav 375 mg and 625 mg Tablets :

Mild impairment (creatinine clearance greater than 30 ml/minute) : no change in dosage.

Moderate impairment (creatinine clearance 10 to 30 ml/minute) : 1 tablet every twelve hours.

Severe impairment (creatinine clearance less than 10 ml/minute): half a tablet every twelve hours.

Haemodialysis decreases serum concentrations of both amoxicillin and clavulanic acid and an additional dose should be administered at the end of dialysis.

Dosage Guide:

Amoxicillin-Sensitive Organisms

Product	**Upper Respiratory Tract Infection**	**Lower Respiratory Tract Infection**	**Urinary Tract infection**	**Skin and soft Tissue Infections**
Austell-Co Amoxiclav 375 mg Tablets	1 tablet 8 hourly	----	1 tablet 8 hourly	1 tablet 8 hourly
Austell-Co Amoxiclav 625 mg Tablets	1 tablet 8 hourly	1 tablet 8 hourly	1 tablet 8 hourly	1 tablet 8 hourly

Amoxicillin-Resistant Organisms

Product	**Upper Respiratory Tract Infection (otitis media)**	**Lower Respiratory Tract Infection (bronchitis)**	**Urinary Tract infection**	**Skin and soft Tissue Infections**
Austell-Co Amoxiclav 375 mg Tablets	------	-------	1 tablet 8 hourly	1 tablet 8 hourly
Austell-Co Amoxiclav 625 mg Tablets	1 tablet 8 hourly	1 tablet 8 hourly	1 tablet 8 hourly	1 tablet 8 hourly

Children: The dose of Austell Co- Amoxiclav Tablets in children is 25-50 mg/kg/day of the 4 parts amoxicillin, 1 part clavulanic acid preparations (which corresponds to a daily dosage of the equivalent of 20-40 mg/kg of amoxicillin and 5–10 mg/kg of clavulanic acid) to be taken in divided doses every eight hours, at the start of a meal.

Duration of administration

Your doctor will tell you how long your treatment with Austell-Co-Amoxiclav will last. Do not stop treatment early because … If you have the impression that the effect of Austell-Co-Amoxiclav is too strong or too weak, talk to your doctor or pharmacist.

Method of administration

Tablets should be taken immediately before a meal.

If you take more Austell-Co-Amoxiclav than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control center.

If you forget to take Austell-Co-Amoxiclav:

Do not take a double dose to make up for forgotten individual doses

4. Possible side effects

Austell-Co-Amoxiclav can have side effects.

Not all side effects reported for Austell-Co-Amoxiclav are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking Austell-Co-Amoxiclav, please consult your health care provider for advice.

If any of the following happens, stop taking Austell-Co-Amoxiclav 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
- rash or itching
- fainting.

These are very serious side effects. If you have them, you may have had a serious reaction to Austell-Co-Amoxiclav. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent side effects:

- mucocutaneous candidosis
- diarrhoea

- nausea
- vomiting

Less frequent side effects:

- reversible leucopenia (including neutropenia)
- thrombocytopenia
- dizziness
- headache
- indigestion
- rises in AST and/or ALT
- skin rash
- pruritus
- urticaria
- erythema multiforme

Side effects with frequency unknown:

- overgrowth of non-susceptible organisms
- reversible agranulocytosis
- haemolytic anaemia
- prolongation of bleeding time and prothrombin time
- angioneurotic oedema
- anaphylaxis
- serum sickness-like syndrome
- hypersensitivity vasculitis
- Hypersensitivity reaction that affects your arteries that pump blood away from your heart, this may cause a heart attack or other heart problems.
- reversible hyperactivity
- convulsions

- aseptic meningitis
- antibiotic-associated colitis
- drug-induced enterocolitis syndrome
- pancreatitis acute
- black hairy tongue
- hepatitis
- cholestatic jaundice
- stevens-Johnson syndrome
- toxic epidermal necrolysis
- bullous exfoliative-dermatitis
- acute generalised exanthemous pustulosis (AGEP)
- drug reaction with eosinophilia and systemic symptoms (DRESS)
- hypersensitivity reaction that causes blisters in the skin (in the mouth, genitals or eyes).
- interstitial nephritis
- crystalluria (including acute renal injury)

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-Co-Amoxiclav.

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-Co-Amoxiclav

Store all medicines out of reach of children.

Store at or below 25 °C. Protect from light.

Keep strip packs in carton until required for use.

Keep all medicines out of the reach and sight of children.

Return all unused medicines 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-Co-Amoxiclav contains

- The active substance are Amoxicillin trihydrate equivalent to amoxicillin 250 mg and amoxicillin 500 mg and potassium clavulanate equivalent to clavulanic acid 125 mg.
- The other ingredients are Colloidal silicon dioxide, croscarmellose sodium, microcrystalline cellulose, magnesium stearate, hydroxypropyl methyl cellulose, dibutyl phthalate, purified talc, titanium dioxide, isopropyl alcohol and methylene chloride.

Austell Co-Amoxiclav 375 mg Tablets

Each tablet contains amoxicillin trihydrate equivalent to 250 mg amoxicillin and potassium clavulanate equivalent to 125 mg clavulanic acid.

Austell Co-Amoxiclav 625 mg Tablets

Each tablet contains amoxicillin trihydrate equivalent to 500 mg amoxicillin and potassium clavulanate equivalent to 125 mg clavulanic acid.

What Austell-Co-Amoxiclav looks like and contents of the pack

Austell Co-Amoxiclav 375 mg Tablets

Austell Pharmaceuticals (Pty) Ltd, A390488 - 9, Austell Co- Amoxiclav, Tablets and 375/625 mg

White to off-white oval shaped film coated tablets with ‘R375’ embossing on one side.

Austell Co-Amoxiclav 625 mg Tablets

White to off-white oval shaped film coated tablets with ‘R625’ embossing on one side.

Austell Co-Amoxiclav 375 mg Tablets is supplied in Aluminium strip pack of 5X3’s

Austell Co-Amoxiclav 625 mg Tablets is supplied in Aluminium strip pack of 5X3’s

Holder of Certificate of Registration

Austell Pharmaceuticals (Pty) Ltd

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Registration numbers

Austell Co-Amoxiclav 375 mg Tablets: A39/20.1.2/0488

Austell Co-Amoxiclav 625 mg Tablets: A39/20.1.2/0489

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/

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