

Amoxicillin trihydrate
equivalent to amoxicillin 875 mg *Clavulanate*
potassium
equivalent to clavulanic acid 125 mg

Patient information leaflet

SCHEDULING STATUS:

S4

CLAVUMED 1 g film coated tablets

**(Amoxycillin trihydrate equivalent to 875 mg amoxicillin + Potassium clavulanate and
microcrystalline cellulose (1:1) equivalent to 125 mg clavulanic acid)**

Clavumed 1 g is sugar free.

Read all of this leaflet carefully before you start taking CLAVUMED 1 g.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **Clavumed 1 g** 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 **Clavumed 1 g** is and what it is used for
2. What you need to know before you take **Clavumed 1 g**
3. How to take **Clavumed 1 g**



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4. Possible side effects
5. How to store **Clavumed 1 g**
6. Contents of the pack and other information

1. What CLAVUMED 1 g is and what it is used for

Clavumed 1 g contains 875 mg amoxicillin + 125 mg clavulanic acid.

Clavumed 1 g is an antibiotic and works by killing bacteria that cause infections. It contains two different medicines called amoxicillin and clavulanic acid. Amoxicillin belongs to a group of medicines called “penicillins” that can sometimes be stopped from working (made inactive). The other active component (clavulanic acid) stops this from happening.

Clavumed 1 g is used for the treatment of a wide range of bacterial infections. These infections are:

- Chest infections such as bronchitis and pneumonia;
- Infections of sinuses (sinusitis), tonsils (tonsillitis) and the ear (otitis media);
- Skin infections and soft tissue infection
- Urinary tract infections (cystitis, urethritis, pyelonephritis)

2. What you need to know before you take CLAVUMED 1 g

Clavumed 1 g is only available with a doctor's prescription.

Do not take CLAVUMED 1 g:

- If you have or previously had an allergic reaction to amoxicillin, or to other beta lactam antibiotics (e.g., penicillin, ampicillin, or cephalosporin such as cephalexin, cefadroxil)

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or to clavulanic acid or to any of the other tablet ingredients listed above. (Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin).

- If you have had liver problems (yellowing of skin and whites of eyes) with amoxicillin/ clavulanate combination at any time in the past.

If you are not sure, talk to your doctor or pharmacist before taking **Clavumed 1 g**.

Warnings and precautions

Take special care with CLAVUMED 1 g:

- If you have had skin rashes after taking any medicine
- If you have a condition commonly known as glandular fever (also called infectious mononucleosis)
- If you have clotting problems
- If you have problems with your kidney(s) and/ or liver
- If you have been diagnosed to have lymphatic leukaemia (a type of blood cancer)
- If you are suffering from syphilis

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before taking **Clavumed 1 g**.

In some cases, your doctor may investigate the type of bacteria that is causing your infection. Depending on the results, you may be given a different strength of **Clavumed** or a different

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medicine.

With long-term use of amoxicillin and clavulanate potassium, a more serious form of diarrhoea (pseudomembranous colitis) may occur. Consult your doctor immediately and do not use medicines to stop the diarrhoea . e.g. loperamide

Fits may occur, if you have kidney problems or have taken high doses of **Clavumed** consult your doctor or pharmacist.

Prolonged use of **Clavumed** may occasionally result in an overgrowth of non-susceptible organisms or yeast and patients should be observed carefully for superinfections.

A red scaly rash with bumps under the skin and blisters may occur at the time of initiation of treatment. Do not take **Clavumed** and consult your doctor or pharmacist.

Other medicines and CLAVUMED 1 g:

Always tell your healthcare professional if you are taking any other medicine (This includes complementary or traditional medicines).

Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist each time you get a new medicine.

Tell your doctor:

- If you are taking probenecid (medicine for treating joint problems and along with

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certain other antibiotics for treating severe infections), your doctor may decide to adjust your dose of **Clavumed 1 g**

- If you are taking allopurinol (medicine for treating joint problems), it may be more likely that you will have allergic skin reactions
- If you are taking hormonal contraceptives (oral pills). This medicine may reduce the effect of contraceptive pill
- If blood thinning medicines or anticoagulants are taken (e.g. warfarin, acenocoumarol), then extra blood tests may be needed
- Methotrexate (a medicine used to treat cancer or rheumatic diseases)
- Mycophenolate mofetil (a medicine used to prevent the rejection of transplanted organs).
- Tetracyclines (medicines used to treat wide range infections)

Blood and urine tests

If you are having blood tests (such as red blood cell status tests or liver function tests) or urine tests (for glucose), let the doctor or nurse know that you are taking **Clavumed 1 g**. This is because **Clavumed 1 g** can affect the results of these types of tests.

Clavumed 1 g with food and alcohol:

Clavumed 1 g with food

CLAVUMED 1 g should be taken at the start of a meal.

Clavumed 1 g with alcohol

No information available.

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Pregnancy and breast-feeding

Do not take **Clavumed 1 g** if you are pregnant, or if you think you might be pregnant. Take special care if you are breast-feeding.

If you are pregnant or breast-feeding your baby, please consult your doctor, pharmacist or other health care professional for advice before taking **Clavumed 1 g**.

Driving and using machinery

No studies on the effects on the ability to drive and use machines have been performed. However, undesirable effects may occur (e.g. allergic reactions, dizziness, convulsions), which may influence your ability to drive and use machines.

3. How to take CLAVUMED 1 g

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

Always take **Clavumed 1 g** exactly as your doctor has instructed you. Check with your doctor or pharmacist if you are not sure.

The usual dose is one **Clavumed 1 g** tablet taken twice daily.

Swallow the tablet(s) whole with a glass of water. For best results, you may take **Clavumed 1 g** at the start of a meal.

Your dose may be different in case you have kidney and/or liver problems.

Take your medicine as directed and for as long as directed; do not stop them, even if you feel better.

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If you have the impression that the effect of **Clavumed 1 g** is too strong or too weak, talk to your doctor or pharmacist.

If you take more CLAVUMED 1 g than you should

If you take too much **Clavumed 1 g**, signs might include an upset stomach (feeling sick, being sick or diarrhoea) or convulsions. **In the event of over-dosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre immediately.** Take this leaflet or some medicine with you so your doctor will know what you have taken.

If you forget to take CLAVUMED 1 g

If you forget to take a dose take it as soon as you remember.

However, if it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule. Do not take a double dose to make up for forgotten individual doses.

If you stop taking CLAVUMED 1 g

Continue taking **Clavumed 1 g** until the course is finished or for as long as your doctor tells you.

Do not stop taking **Clavumed 1 g** just because you feel better as the infection can return.

If you have any further questions on the use of **Clavumed 1 g**, ask your doctor or pharmacist.

4. Possible side effects

Clavumed 1 g can have side effects.

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Not all side effects reported for **Clavumed 1 g** are included in this leaflet. Should your general health get worse or if you experience any untoward effects while taking this medication, please consult your doctor, pharmacist or other healthcare professional for advice.

- Sudden signs of allergy such as rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing (anaphylactic reaction, angioedema)
- A red, scaly rash with bumps under the skin and blisters (exanthemous pustulosis)
- Inflammation of blood vessels which may be visible as red spots on the skin (hypersensitivity vasculitis)
- Widespread red skin rash with small pus-containing blisters (bullous exfoliative dermatitis)
- Rare skin condition with severe blisters and bleeding in the lips, eyes, mouth, nose and genitals (Steven Johnson syndrome) and a more severe form, causing extensive peeling of the skin (toxic epidermal necrolysis)
- Severe condition of the skin that may affect the mouth and other parts of the body (erythema multiforme)
- Fever, swelling, skin rash, enlargement of the lymph nodes (serum sickness like syndrome)
- Flu-like symptoms with a rash, fever, swollen glands, and abnormal blood test results (including increased white blood cells (eosinophilia) and liver enzymes) (Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS)).

These all are very serious side effects. If you have them you may have had a serious allergic

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reaction or other type of reaction to **Clavumed 1 g**. 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:

Frequent adverse effects:

- Infection of the skin, nails, and mucous membranes (mucocutaneous candidiasis, mucocutaneous candidosis)
- Severe diarrhoea (which may contain blood or mucous) along with stomach cramps

Less frequent or unknown frequency adverse effects

- Convulsions
- Liver disease having symptoms of nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and eyes, light coloured bowel motions, dark coloured urine (hepatitis, cholestatic jaundice)
- Unusual bleeding or bruising under the skin (thrombocytopenic purpura)
- Frequent infections, a condition in which there is a decreased number of red blood cells (anaemia, haemolytic anaemia)
- Kidney disease (interstitial nephritis)
- Inflammation of the protective membrane surrounding the brain (aseptic meningitis)

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

If any of the following happens stop taking **Clavumed 1 g** and tell your doctor immediately or

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go to the casualty department of your nearest hospital:

Tell your doctor if you notice any of the following:

Frequent adverse effects:

- Unusually active (Hyperactivity), headache and dizziness
- Nausea (feeling sick), vomiting (being sick), indigestion, abnormal taste, stomach ache, diarrhoea, sore tongue and mouth (stomatitis, glossitis), black discolouration of tongue, discolouration of teeth
- Itching, skin rashes
- Vaginal discharge and itching
- A fungal infection caused by Candida in the vagina
- Tiredness, hot flushes

Less frequent adverse effects:

- Inflammation of stomach (gastritis)
- Crystals in urine (crystalluria)

There may be changes in the results of certain laboratory tests

- Abnormal liver function tests
- Abnormal numbers of platelets (thrombocytopenia, thrombocytosis)
- Abnormal prothrombin time
- Abnormal white blood cells in blood (agranulocytosis, eosinophilia, neutropenia, leucopenia)

If you notice any side effects not mentioned in this leaflet, please inform your doctor or

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pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. 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 CLAVUMED 1 g.

5. How to store CLAVUMED 1 g

Store all medicines out of reach of children.

- Store at or below 25 °C, in the original package, protected from light and moisture.
- KEEP ALL MEDICINES OUT OF THE REACH AND SIGHT OF CHILDREN.
- Do not use after the expiry date stated on the carton or label.
- Return all unused medicines to your pharmacist.
- Do not dispose of unused medicines in drains or sewerage systems.

6. Contents of the pack and other information

What CLAVUMED 1 g contains

The active substances are amoxicillin 875 mg + clavulanic acid 125 mg.

Each film coated tablet contains Amoxycillin trihydrate equivalent to 875 mg amoxicillin + Potassium clavulanate and microcrystalline cellulose (1:1) equivalent to 125 mg clavulanic

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acid.

The other ingredients are:

For the core tablet: colloidal anhydrous silica, Eudragit E 100 (basic butylated methacrylate copolymer), magnesium stearate, microcrystalline cellulose (PH 112), povidone (K30) and sodium starch glycolate (Type A).

For the coating: Opadry 03B58965 white consisting of hypromellose, macrogol/ PEG 400, talc and titanium dioxide.

What CLAVUMED 1 g looks like and Contents of the pack

Clavumed 1 g are white to off-white film coated capsule shaped tablets debossed with “**RX509**” on one side and a score line on the other side.

Carton contains 10 tablets packed in PVC/PVdC blister pack in pouch.

Holder of Certificate of Registration

RANBAXY PHARMACEUTICALS (PTY) LTD
14 Lautre Road, Stormill, Ext.1,
Roodepoort, 1724
South Africa

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Ranbaxy Pharmaceuticals (Pty) Ltd
CLAVUMED 1 g

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Registration numbers

50/20.1.1/0228

Access to the corresponding professional information

