

SCHEDULING STATUS

S4

CLAVUMED 375 – Film-coated Tablets

CLAVUMED 625 mg – Film-coated Tablets

Amoxicillin and Clavulanic acid

Sugar free

Read all of this leaflet carefully before you are given CLAVUMED 375 & CLAVUMED 625 mg

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or healthcare provider.
- CLAVUMED 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 is and what it is used for
2. What you need to know before you receive CLAVUMED
3. How to receive CLAVUMED
4. Possible side effects
5. How to store CLAVUMED
6. Contents of the pack and other information

1 WHAT CLAVUMED is and what it is used for

CLAVUMED Tablets contain antibiotics and works by killing bacteria that cause infections. It contains two different medicines called amoxicillin and clavulanic acid. CLAVUMED 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 tablets are used for the treatment of following:

- Upper respiratory tract infections (infections of nose, sinuses and pharynx)
- Lower respiratory tract infections (Infections of trachea, airways and lungs)
- Genito-urinary tract infections (infections of kidneys, ureters, bladder and reproductive organs)
- Skin and soft tissue (infections of the skin)

You may have been prescribed CLAVUMED for the treatment of infections caused by amoxicillin resistant organisms.

2 What you need to know before you take CLAVUMED

Do not take CLAVUMED if you:

If you are allergic (hypersensitive) to penicillins and cephalosporins or any other ingredients of CLAVUMED. See '*Contents of the pack and other information*' in section 6.

- If you have a severe allergic reaction to any other antibiotic (a allergic reaction may include rash, itching, swelling of face, lips, or hands/feet or breathing difficulties)
- If you have previous history of amoxicillin/clavulanic acid associated jaundice/hepatic dysfunction (disease of liver) when taking an antibiotic.

Warnings and precautions

Special care should be taken with CLAVUMED

Tell your doctor if you have any of the following medical conditions:

- if you have syphilis (sexually transmitted infection) as the use of the antibiotic in this condition can bring on an immune reaction which includes fever, chills, and worsening of rash
- if you have lymphatic leukaemia (cancer to white blood cells) since this condition can bring on skin rashes when used together with the antibiotic
- if you have impaired hepatic function (abnormal liver function)

- if you have infectious mononucleosis (increase in monocytes in the blood)
- if you have impaired renal function (abnormal kidney function)
- if you have a history of hypersensitivity (allergies) towards penicillins, other antibiotics or other allergens.
- if you have a sore throat or glandular fever
- if you have diarrhoea, abdominal cramps, pain or tenderness, nausea or fever after beginning or during treatment with the antibiotic
- if you start to have fits
- if you experience a skin reaction after beginning treatment with the antibiotic which includes itchy skin eruptions, headache and fever
- if you are breastfeeding
- if you are not passing urine or are passing a reduced amount of urine than is normal for you

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. This is because CLAVUMED can affect the results of these types of tests.

Other medicines and CLAVUMED

Always tell your healthcare provider if you are taking any other medicines. This includes all complementary or traditional medicines

- If you are taking probenecid (used to treat gout), your doctor may decide to adjust your dose of CLAVUMED.

- If you are taking oral contraceptives (the "pill", as CLAVUMED can interfere with the medicine's ability to work effectively).
- If you are taking allopurinol (used to treat gout) with CLAVUMED, it may be more likely that you will have an allergic skin reaction.
- Ampicillin (used to treat bacterial infection)
- Tetracyclines (used to treat bacterial infection)
- Bacteriostatic Medicines (used to treat infections)
- CLAVUMED can affect how methotrexate (a medicine to treat cancer or rheumatic diseases) works
- CLAVUMED may effect how mycophenolate mofetil (a medicine used to prevent the rejection of transplanted organs) works.

Clavumed might interfere with laboratory test used to treat the presence of glucose in urine. For this reason, enzymatic glucose oxidase method should be used.

Pregnancy and breast-feeding and fertility

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

CLAVUMED may interfere with the effectiveness of your oral contraceptive, hence you should use an alternative or additional method of contraception while taking this medicine (such as condom). The safety of CLAVUMED in pregnancy has not been established.

Both of the medicines found in CLAVUMED are excreted into breast milk. Although significant problems in humans have not yet been discovered, the use of CLAVUMED by breastfeeding mothers may lead to the baby becoming sensitive, developing diarrhoea, thrush (Candidiasis) and skin rash, hence you should consult with your doctor before commencing or the possibility of stopping treatment.

Driving and using machines

Clavumed may cause dizziness or tiredness. It is not always possible to predict to what extent CLAVUMED may interfere with the daily activities of the patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which CLAVUMED affects them. If this happens to you, do not drive, use machines, or perform other tasks that need full attention unless you are feeling well.

3. How to take CLAVUMED

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

Always use CLAVUMED exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

Your doctor may decide the right dose and duration of treatment for you.

The usual dose is one CLAVUMED 375 tablet every 8 hours at the start of meal. For more severe infections and infection of the respiratory tract, the dose should be one CLAVUMED 625 tablet every eight hours at the start of a meal. CLAVUMED may be taken or given at the start of a meal or slightly before. Swallow the tablets whole immediately with a full glass of water before meal.

Patients with kidney problems

If you have kidney problems the dosages may vary from those stated above depending on whether you have a problem with your kidney(s) and/or amoxicillin sensitive or resistant organisms.

Your doctor will tell you how long your treatment with CLAVUMED will last. If you have the impression that the effect of CLAVUMED is too strong or too weak, tell your doctor or pharmacist.

If you take more CLAVUMED than you should

If you have too much CLAVUMED signs might include an upset stomach (feeling sick, being sick or diarrhoea) or convulsions. If you suffer from kidney disease, and notice anything unusual with your urine (intense burning, or red blood cells in your urine) get medical help immediately.

In the event of overdose, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control centre. Remember to take this leaflet and/or the package with you to show the doctor what you have taken.

Overdose may cause gastro-intestinal effects such as nausea, vomiting, diarrhoea, crystalluria and symptoms of water and electrolyte imbalance.

If you forget to take or missed a dose of CLAVUMED

If you forget to take a dose, take it as soon as you remember, unless it is really time to take the next one. Do not take a double dose to make up for forgotten individual doses.

If you stop taking CLAVUMED

Keep taking or giving **CLAVUMED** until the course of treatment is finished, even if you feel better.

You need every dose to help fight the infection. If some bacteria survive they can cause the infection to come back and make the medicine less effective due to resistance.

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

4. Possible side effects

CLAVUMED can have side-effects.

Not all side-effects reported for CLAVUMED are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking CLAVUMED, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of these symptoms occur, stop taking CLAVUMED and tell your doctor immediately or go to the casualty department at your nearest hospital.

- skin rash, itching or hives on the skin,
- swelling of the hands, feet, ankles, face, lips, tongue mouth and throat or other parts of the body, shortness of breath, wheezing or trouble breathing.
- Dizziness or collapse
- Inflammation of the large intestine, causing watery diarrhoea usually with blood and mucus, stomach pain and/or fever
- Less urine than is normal to you
- Yellowing of the skin and eyes, dark urine, and tiredness which may be symptoms of liver problems
- Inflammation of the protective membrane surrounding the brain (aseptic meningitis)
- Chest pain in the context of allergic reaction, which may be a symptom to allergy triggered infarction (Kounis syndrome).

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

The side effects frequently encountered are:

- Mucocutaneous candidiasis (thrush – yeast infection of the vagina, mouth or skin folds)
- Serum sickness-like syndrome, anaphylactic (hypersensitivity) reaction stomatitis, black hairy tongue, enterocolitis, antibiotic-associated colitis (including pseudomembranous colitis and haemorrhagic colitis)
- Urticaria, pruritus, skin rashes
- Vaginitis, genital moniliasis
- Hot flushes
- hepatitis (abdominal pain, nausea and vomiting)
- yellowing of the skin or whites of the eyes (jaundice)

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

Less frequent side effects:

- Dizziness, Headache, Tiredness
- Oral candidiasis (yeast infection of the mouth)
- Bullous exfoliative dermatitis, hives, itching, erythema multiforme (a skin rash, which may blister, and looks like small targets – central dark spots surrounded by a paler area, with a dark ring around the edge)

The following side effects can be expected but the frequency is unknown:

- Overgrowth of non-susceptible organisms
- Tooth discolouration
- Haemolytic anaemia (low number of red blood cells) reversible thrombocytopenia, thrombocytopenic purpura, eosinophilia (increase in the number of white blood cells) reversible (including neutropenia), agranulocytosis, platelet dysfunction.
- Hypersensitivity vasculitis (inflammation of blood vessels which may be visible as red or purple raised spots on the skin, but can affect other parts of the body), angioedema
- Clostridium difficile colitis, glossitis
- Elevated liver enzyme values Hepatitis (inflammation of liver), cholestatic jaundice, liver dysfunction

- Stevens-Johnson syndrome (a widespread rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals), acute generalised exanthematous pustulosis (a red, scaly rash with bumps under the skin and blisters), toxic epidermal necrolysis (extensive peeling of the skin – more 30 % of the body surface).
- Interstitial nephritis (inflammation of tubes in the kidney), crystalluria (crystals in the urine leading to acute kidney injury), dysuria or urinary retention, proteinuria
- Chest pain, oedema, chills, fatigue, malaise, epistaxis
- Acute inflammation of the pancreas (acute pancreatitis). If you have severe and on-going pain in the stomach area this could be a sign of acute pancreatitis
- Drug-induced enterocolitis syndrome (DIES) has been reported mainly in children receiving amoxicillin/clavulanate. It is a certain kind of allergic reaction with the leading symptom of repetitive vomiting (1-4 hours after medicine intake). Further symptoms could comprise abdominal pain, lethargy, diarrhoea and low blood pressure.
- Rash with blisters arranged in a circle with central crusting or like string of pearls (linear IgA disease).

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 CLAVUMED.

5. How to store CLAVUMED

Store at or below 25 °C, protected from light and moisture.

KEEP OUT OF REACH OF CHILDREN.

This medicinal product does not require any special storage conditions

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets)

What CLAVUMED contains

CLAVUMED 375

The active substances are Amoxicillin 250 mg (as amoxicillin trihydrate 289.017) and Clavulanic acid 125 mg (as potassium 154.76).

CLAVUMED 625

The active substances are Amoxicillin 500 mg (as amoxicillin trihydrate 578.03) and Clavulanic acid 125 mg (as potassium 154.76) as the active ingredients.

CLAVUMED tablets also contain the following inactive ingredients: Butylhydroxytoluene (as antioxidant), colloidal anhydrous silica, croscarmellose sodium, hydroxypropyl methylcellulose, hypromellose, macrogol 400, magnesium stearate, microcrystalline.

What CLAVUMED looks like and contents of the pack

Clavumed 375: White to off-white oval shaped biconvex, film coated tablets

Imprinted with 'R375' in black ink on one side.

Clavumed 625: White to off-white oval shaped biconvex, film coated tablets

Imprinted with 'R625' in black ink on one side.

Clavumed 375

Aluminium strip pack containing 15 and 100 tablets in a carton.

Clavumed 625

Aluminium strip pack containing 15 tablets in a carton.

Holder of Certificate of Registration

Unimed Healthcare (Pty) Ltd

Cnr Birch Road and Bluegum Avenue

Anchorville

Lenasia

1827

South Africa

Tel: +27 11 056 6999

This leaflet was last revised in

28 November 2024

Registration numbers

Clavumed 375: 33/20.1.2/0461

Clavumed 625: 33/20.1.2/0462