

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S4**

CO-AMOXICLAV 375 UNIMED Film-coated Tablets

CO-AMOXICLAV 625 UNIMED Film-coated Tablets

CO-AMOXICLAV 1000 UNIMED Film-coated Tablets

Amoxicillin and Clavulanic Acid

Sugar free

Read all of this leaflet carefully before you start taking CO-AMOXICLAV UNIMED

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

1. What CO-AMOXICLAV UNIMED is and what it is used for

CO-AMOXICLAV UNIMED 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.

CO-AMOXICLAV UNIMED is used in adults and children to treat the following infections:

- respiratory tract infections
- urinary tract infections
- skin and soft tissue infections

2. What you need to know before you take CO-AMOXICLAV UNIMED

Do not take CO-AMOXICLAV UNIMED if you:

- if you are hypersensitive (allergic) to amoxicillin, clavulanic acid, penicillin or any of the other ingredients of CO-AMOXICLAV UNIMED. See ‘*Contents of the pack and other information*’ in section 6.
- if you have ever had a severe allergic reaction to any other antibiotic. This can include a skin rash or swelling of the face or throat.
- if you have ever had liver problems or jaundice (yellowing of the skin) when taking an antibiotic.

Warnings and precautions

Special care should be taken with CO-AMOXICLAV UNIMED:

- 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 have or are being treated for liver or kidney problems
- if you have syphilis 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 since this condition can bring on skin rashes when used together with the antibiotic
- if you are breastfeeding
- if you are not passing urine regularly 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 CO-AMOXICLAV UNIMED. This is because CO-AMOXICLAV UNIMED can affect the results of these types of tests.

Other medicines and CO-AMOXICLAV UNIMED

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 for gout), your doctor may decide to adjust your dose of CO-AMOXICLAV UNIMED.
- If you are taking oral contraceptives (the “pill”), as CO-AMOXICLAV UNIMED can interfere with the medicine’s ability to work effectively.
- If you are taking allopurinol (used for gout) with CO-AMOXICLAV UNIMED, it may be more likely that you will have an allergic skin reaction.
- If you are taking any other antibiotics (such as doxycycline) as these can interfere with the effectiveness of CO-AMOXICLAV UNIMED
- If medicines to help stop blood clots (such as warfarin) are taken with CO-AMOXICLAV UNIMED then extra blood tests and adjusting your dose may be needed

- CO-AMOXICLAV UNIMED can affect how methotrexate (a medicine used to treat cancer or rheumatic diseases) works
- CO-AMOXICLAV UNIMED may affect how mycophenolate mofetil (a medicine used to prevent the rejection of transplanted organs) works

Pregnancy and 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 this medicine.

CO-AMOXICLAV UNIMED 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 condoms).

The safety of CO-AMOXICLAV UNIMED in pregnancy has not been established.

Both of the medicines found in CO-AMOXICLAV UNIMED are excreted into breast milk. Although significant problems in humans have not been discovered, the use of CO-AMOXICLAV UNIMED 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

It is not always possible to predict to what extent CO-AMOXICLAV UNIMED 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 CO-AMOXICLAV UNIMED affects them.

CO-AMOXICLAV UNIMED can have side effects and the symptoms may affect your ability to drive.

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

3. How to take CO-AMOXICLAV UNIMED

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

Always take CO-AMOXICLAV UNIMED exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose for CO-AMOXICLAV 375 UNIMED or CO-AMOXICLAV 625 UNIMED is 1 tablet three times a day.

The usual dose for CO-AMOXICLAV 1000 UNIMED is 1 tablet twice a day.

Take tablet immediately before a meal.

Swallow the tablets whole with a glass of water.

Patients with kidney problems

If you have kidney problems the dose might be changed and chosen by your doctor based on your kidney function.

Your doctor will tell you how long your treatment with of CO-AMOXICLAV UNIMED will last.

If you have the impression that the effect of CO-AMOXICLAV UNIMED is too strong or too weak, tell your doctor or pharmacist.

If you take more CO-AMOXICLAV UNIMED than you should

If you have too much CO-AMOXICLAV UNIMED, 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 over dosage, consult your doctor or pharmacist. If neither is available contact the nearest hospital or poison control centre.

If you forget to take CO-AMOXICLAV UNIMED

If you forgot to take your medicine, take it as soon as you remember.

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

If you stop taking CO-AMOXICLAV UNIMED

Keep taking CO-AMOXICLAV UNIMED until the 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.

4. Possible side effects

CO-AMOXICLAV UNIMED can have side effects.

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

If any of the following happens, stop taking CO-AMOXICLAV UNIMED 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
- 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 of allergy

triggered cardiac infarction (Kounis syndrome)

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

The side effects frequently encountered are:

- Mucocutaneous candidiasis
- Serum sickness-like syndrome, anaphylactic (hypersensitivity) reaction
- Diarrhoea, nausea, vomiting, indigestion, abdominal pain, abnormal taste, gastritis, stomatitis, black hairy tongue, enterocolitis, antibiotic-associated colitis (including pseudomembranous colitis and haemorrhagic colitis)
- Urticaria, pruritus, skin rashes
- Vaginitis, genital moniliasis
- Hot flushes

Less frequent side effects are:

- 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)
- Vaginal candidiasis (yeast infection of the vagina)

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

- Overgrowth of non-susceptible organisms
- 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
- Hepatitis (inflammation of liver), cholestatic jaundice, hepatic 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 “**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 CO-AMOXICLAV UNIMED.

5. How to store CO-AMOXICLAV UNIMED

Store all medicines out of reach of children.

Store at or below 30°C

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).

6. Contents of the pack and other information

What CO-AMOXICLAV UNIMED contains

CO-AMOXICLAV 375 UNIMED:

The active substances are Amoxicillin 250 mg (as amoxicillin trihydrate 286.70 mg) and Clavulanic acid 125 mg (as potassium clavulanate 277.77 mg).

CO-AMOXICLAV 625 UNIMED:

The active substances are Amoxicillin 500 mg (as amoxicillin trihydrate 573.40 mg) and Clavulanic acid 125 mg (as potassium clavulanate 277.77 mg).

CO-AMOXICLAV 1000 UNIMED:

The active substances are Amoxicillin 875 mg (as amoxicillin trihydrate 1033.44 mg) and Clavulanic acid 125 mg (as potassium clavulanate 277.77 mg).

The other ingredients are microcrystalline cellulose, purified water, sodium starch glycolate, colloidal silicon dioxide, magnesium stearate, opadry white, isopropyl alcohol and methylene chloride.

What CO-AMOXICLAV UNIMED looks like and contents of the pack

CO-AMOXICLAV 375 UNIMED:

White oval shaped film coated tablets, debossed with 'A' on one side and '63' on other side.

CO-AMOXICLAV 625 UNIMED:

White oval shaped film coated tablets, debossed with "A" on one side and "64" on the other side.

CO-AMOXICLAV 1000 UNIMED:

White coloured, capsule shaped, film coated tablets debossed with "A" on one side and with a score line in between "6" and "5" on the other side.

CO-AMOXICLAV UNIMED is marketed in a triple laminated aluminium foil blister packs, enclosed in a pre-printed carton containing 2 blister strips of 5 tablets each.

Holder of Certificate of Registration

UNIMED HEALTHCARE (PTY) LTD

Birch Road & Bluegum Avenue,

Anchorville,

Lenasia, 1827

South Africa

Tel: +27 11 056 6999

This leaflet was last revised in

22 November 2024

Registration numbers

CO-AMOXICLAV 375 UNIMED: 50/20.1.2/0975

CO-AMOXICLAV 625 UNIMED: 50/20.1.2/0976

CO-AMOXICLAV 1000 UNIMED: 50/20.1.2/0977