1.3.2 Patient Information Leaflet

SCHEDULING STATUS

S4

CLAMENTIN 1000 mg, film-coated tablet

Amoxicillin 875mg

Clavulanic acid 125 mg

Sugar free

Read all of this leaflet carefully before you start taking CLAMENTIN 1000 mg

Keep this leaflet. You may need to read it again.

If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.

CLAMENTIN 1000 mg 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 CLAMENTIN 1000 mg is and what it is used for.

2. What you need to know before you take CLAMENTIN 1000 mg.

3. How to take CLAMENTIN 1000 mg.

4. Possible side effects.

5. How to store CLAMENTIN 1000 mg.

6. Contents of the pack and other information.

1.What CLAMENTIN 1000 mg is and what it is used for

What CLAMENTIN 1000 mg is:

CLAMENTIN 1000 mg 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.

What it is used for:

CLAMENTIN 1000 mg is used to treat the following infections:

Infections of the upper airways:

- Recurrent tonsil infection
- Sinusitis
- Inner ear infection

Infection of the lower airways:

- Acute and chronic infection of the airways
- Infection of the lungs (pneumonia)

Infections of the genital and urinary tract:

- Infection of the bladder
- Infection of the urethra
- Infection of the kidney

Skin and soft tissue infections

2. What you need to know before you take CLAMENTIN 1000 mg

Do not take CLAMENTIN 1000 mg if you:

- if you are hypersensitive (allergic) to amoxicillin, clavulanic acid, any of the other beta-lactam medicines (e.g. penicillins, cephalosporins, carbapenem or monobactam) or to any of the other ingredients of CLAMENTIN 1000 mg (*listed 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);
- have a previous history of jaundice (yellowing of the skin) associated with penicillin;

- have ever had liver problems e.g. infection of the liver.

Warnings and precautions

Serious allergic reactions have been reported on penicillin therapy. If you experience a rash, swelling or difficulty in breathing, you should contact your healthcare provider immediately to receive treatment.

CLAMENTIN 1000 mg should be taken with special care in patients who:

- have a decrease in liver function (*see 'Do not take CLAMENTIN 1000 mg'*);
- are older than 60 years if they have a decrease in liver function;
- are being treated for kidney problems;
- are suffering from severe stomach flu as the tablet will not be absorbed and will possibly not work as well;
- suffer from severe allergies or asthma since such patients are more likely to respond with allergic reactions;
- have glandular fever or a sore throat, which may be glandular fever;
- have existing medical conditions such as severe diarrhoea, bleeding disorders, syphilis (a sexually transmitted disease) or lymphatic leukaemia (cancer of the blood and bone marrow);
- are not passing water regularly.

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 medicine.

Conditions you need to look out for:

- CLAMENTIN 1000 mg can make some existing conditions worse or cause serious side effects. These include allergic reactions, serious skin reactions, convulsions (fits) in patients with impaired renal function or in those receiving high doses and inflammation of the large intestine (presenting as stomach cramps, bloody stools, fever, watery diarrhoea).

- If you develop severe diarrhoea either while taking CLAMENTIN 1000 mg or within several weeks after treatment, tell your doctor as soon as possible.
- If you develop vomiting (1-4 hours after intake of CLAMENTIN 1000 mg) in the absence of allergic skin or respiratory symptoms, tell your doctor as soon as possible. This could be an allergic reaction known as Drug-induced enterocolitis syndrome (DIES). Further symptoms could be stomach pain, diarrhoea and low blood pressure.

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 healthcare provider know that you are taking CLAMENTIN 1000 mg. This is because CLAMENTIN 1000 mg can affect the results of these types of tests.

Maintenance of Adequate Fluid Intake:

Whilst taking CLAMENTIN 1000 mg, ensure you drink plenty of fluids to reduce the possibility of crystals forming in the urine.

Other medicines and CLAMENTIN 1000 mg

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

Tell your doctor if you are taking any of the following medicines:

- Other antibiotics e.g. tetracyclines (as they may interfere with the efficacy of CLAMENTIN 1000 mg).
- Medicine for gout (e.g. allopurinol and probenecid).
- Medicines for your heart (e.g. digoxin).

- Medicine to make your blood thinner (e.g. warfarin). When taken with CLAMENTIN 1000 mg extra blood tests may be needed or the dose of the medicine adjusted.
- Medicine to help alcoholism (e.g. disulfiram).
- Oral contraceptives, as CLAMENTIN 1000 mg can make hormonal contraceptives less efficacious. You are advised to use supplementary non-hormonal contraceptive measures e.g. condoms.
- Methotrexate (a medicine used to treat cancer or rheumatic diseases). CLAMENTIN 1000 mg may reduce the excretion of methotrexate causing a potential increase in toxicity.
- Mycophenolate mofetil (a medicine used to prevent the rejection of transplanted organs).

CLAMENTIN 1000 mg with food and drink and alcohol

CLAMENTIN 1000 mg should be taken immediately before a meal, as this may decrease the incidence of gastrointestinal side effects such as nausea, vomiting and diarrhoea.

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 healthcare provider for advice before taking this medicine.

The safety of CLAMENTIN 1000 mg in pregnancy has not been established.

Amoxicillin is distributed into breast milk. If you are breastfeeding your baby while taking this medicine, your baby may experience some of the side effects associated with amoxicillin, such as diarrhoea, fungal infections or a skin rash.

CLAMENTIN 1000 mg can make hormonal contraceptives less efficacious. You are advised to use supplementary non-hormonal contraceptive measures e.g. condoms (*see 'Other medicines and CLAMENTIN 1000 mg'*).

Driving and using machines

It is not always possible to predict to what extent CLAMENTIN 1000 mg may interfere with the daily activities of a patient. CLAMENTIN 1000 mg can have side effects that may interfere with your daily activities (e.g. allergic reactions, dizziness, convulsions). Patients should ensure that they do not engage in the above activities until they are aware of the measure to which CLAMENTIN 1000 mg affects them (*see section 4 'Possible side effects'*).

3. How to take CLAMENTIN 1000 mg

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

Always take CLAMENTIN 1000 mg exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Your doctor will advise you on the correct dose for you.

The usual dose is:

- For severe infections and certain infections of the airways, the dose is one CLAMENTIN 1000 mg tablet every 12 hours.
- Take your tablets with a glass of water.
- Do not chew the tablet.
- Take the tablet at the start of a meal to prevent stomach problems.
- Do not stop treatment early. Finish all your tablets, even if you feel better.
- Your doctor will tell you how long your treatment with CLAMENTIN 1000 mg will last.
- Your doctor may tell you to take a lower dose than normal if you have a kidney problem.
- If you have liver problems, you may have more frequent blood tests to check how your liver is working.

- If you have the impression that the effect of CLAMENTIN 1000 mg is too strong or too weak, tell your doctor or pharmacist.

If you take more CLAMENTIN 1000 mg than you should

In the event of an overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

Show the pack to the doctor.

If you take too much CLAMENTIN, signs might include an upset stomach (feeling sick, being sick or diarrhoea) or convulsions.

If you forget to take CLAMENTIN 1000 mg

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

If you stop taking CLAMENTIN 1000 mg

Do not stop treatment early. Finish all your tablets, even if you feel better.

4. Possible side effects

CLAMENTIN 1000 mg can have side effects.

Not all side effects reported for CLAMENTIN 1000 mg are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking CLAMENTIN 1000 mg, please consult your healthcare provider for advice.

If any of the following happens, stop taking CLAMENTIN 1000 mg and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing;
- rash (hives) or itching;
- fainting;
- inflammation of the protective membrane surrounding the brain (aseptic meningitis);
- chest pain in the context of allergic reactions, which may be a symptom of allergy triggered cardiac infarction (Kounis syndrome).

Serious skin reactions:

- a widespread rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals (*Stevens-Johnson syndrome*), and a more severe form, causing extensive peeling of the skin (more than 30 % of the body surface - *toxic epidermal necrolysis*);
- a widespread red skin rash with small pus-containing blisters (*bullous exfoliative dermatitis*);
- a red, scaly rash with bumps under the skin and blisters (*exanthemous pustulosis*);
- 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*));
- 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 – *erythema multiforme*);
- a red rash commonly seen on both sides of buttocks, upper inner thighs, armpits and neck (known as *symmetrical drug-related intertriginous and flexural exanthema (SDRIFE) or baboon syndrome*);
- rash with blisters arranged in a circle with central crusting or like a string of pearls (linear IgA disease).

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to CLAMENTIN 1000 mg. 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:

- inflammation of blood vessels (vasculitis) which may be visible as red or purple raised spots on the skin, but can affect other parts of the body;
- fever, joint pain, swollen glands in the neck, armpit or groin (symptoms of glandular fever);
- inflammation of the large intestine, causing watery diarrhoea usually with blood and mucus, stomach pain and/or fever (symptoms of antibiotic-associated colitis);
- jaundice, caused by increases in the blood of bilirubin (a substance produced in the liver) which may make your skin and whites of the eyes appear yellow;
- inflammation of the liver (hepatitis);
- convulsions (in people taking high doses of CLAMENTIN 1000 mg or who have kidney problems);
- black tongue which looks hairy.

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):

- 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.

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

Tell your doctor if you notice any of the following:

The following side effects have been reported frequently:

- nausea;
- vomiting;
- diarrhoea;
- thrush (*Candida* - a yeast infection of the vagina, mouth or skin folds);
- indigestion (upper abdominal discomfort with symptoms such as a burning sensation, bloating or gassiness, nausea or feeling full too quickly after starting to eat);
- easy bruising, bleeding and pinpoint-sized reddish-purple spots on the lower legs (signs of a condition called thrombocytopenic purpura);
- inflammation of the lining of the stomach;
- painful swelling and sores inside the mouth (stomatitis);
- soreness of the tongue (signs of a condition called glossitis).

The following side effects have been reported less frequently:

- thrombocytosis (a disorder in which your body produces too many platelets);
- thrombocytopenia (low number of cells involved in blood clotting);
- agitation, anxiety, behavioural changes, confusion, insomnia (difficulty falling or staying asleep);
- a state of excessive restlessness (hyperactivity);
- increase in some substances (enzymes) produced by the liver;
- dizziness;
- headache;
- haematuria (blood in your urine);
- interstitial nephritis is a kidney disorder in which the spaces between the kidney tubules become swollen (inflamed);
- decrease in the number of leukocytes which is a type of white blood cells.

The following side effects have been reported but the frequency is unknown:

- tooth discolouration;
- severe reduction in the number of white blood cells (agranulocytosis);
- low number of red blood cells (haemolytic anaemia);
- angioneurotic oedema which is a painless swelling under the skin, triggered by an allergy;
- serum sickness-like syndrome (skin rash accompanied by joint and muscle pain and frequently fever);
- crystals in urine leading to acute kidney 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, 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 CLAMENTIN 1000 mg.

5. How to store CLAMENTIN 1000 mg

Store all medicine out of reach of children.

Store at or below 25 ºC.

Store in a cool place.

Protect from light and moisture.

Store in the original package/container.

Do not store in a bathroom.

Do not use after the expiry date stated on the label / carton / bottle.

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 CLAMENTIN 1000 mg contains:

The active substances are:

Amoxicillin trihydrate equivalent to amoxicillin 875mg and potassium clavulanate equivalent to clavulanic acid 125 mg.

The other ingredients are:

Tablet core:

Croscarmellose cellulose, magnesium stearate, microcrystalline cellulose,

povidone, silicon dioxide colloidal, talc.

Tablet film-coat consisting of:

Ethyl cellulose aqueous dispersion, hypromellose, talc, titanium dioxide, triethyl citrate.

What CLAMENTIN 1000 mg looks like and contents of the pack:

What CLAMENTIN 1000 mg looks like:

White to light yellow, oblong, biconvex tablet, scored on both sides. Approximately 10 x 22 mm.

Contents of the pack:

The tablets are packed in aluminium foil, soft, 30 μm, with PE coating, printed for sealing package.

10, 15, 16, 21, 30, 50, 90, 100 or 500 tablets will be packed in a cardboard box.

Holder of Certificate of Registration

Viatris Healthcare (Pty) Ltd

4 Brewery Street

Isando, 1609

Gauteng

Republic of South Africa

Tel: +27 (0) 11 451 1300

This leaflet was last revised in

29 May 2025

REGISTRATION NUMBER

A40/20.1.2/0088