

## 1.3.2 Patient Information Leaflet

**SCHEDULING STATUS**

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**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:**

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CLAMENTIN 1000 mg is an antibiotic and works by killing bacteria that cause infections. It contains two different medicines called amoxicillin and clavulanic acid.

CLAMENTIN 1000 mg 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:**

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- are hypersensitive (allergic) to penicillin and cephalosporin or any of the other ingredients of CLAMENTIN 1000 mg (*listed in section 6*).
- 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**

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

**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.**

- 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 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;
- have lymphatic blood cancer;
- are not passing water regularly;

CLAMENTIN 1000 mg can make some existing conditions worse, or cause serious side effects e.g. convulsions (fits) in patients with impaired renal function or in those receiving high doses (*see section 4 'Possible side effects'*).

#### **Blood and urine tests:**

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

#### **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.
- Medicine for gout (e.g. allopurinol and probenecid).
- Medicines for your heart (e.g. digoxin).
- Medicine to make your blood thinner (e.g. coumarin).
- Medicine to help alcoholism (e.g. disulfiram).
- Oral contraceptives- CLAMENTIN 1000 mg can make hormonal contraceptives less efficacious. You are advised to take supplementary non-hormonal contraceptive measures e.g. condoms.
- Methotrexate (a medicine used to treat cancer or rheumatic diseases).
- 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.

#### **Pregnancy and breastfeeding and fertility**

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The safety of CLAMENTIN 1000 mg during pregnancy and whilst breastfeeding has not been established.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking CLAMENTIN 1000 mg.

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

#### **Driving and using machinery**

It is not always possible to predict to what extent CLAMENTIN 1000 mg 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 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.

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- 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 complaint.
- 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 stop taking CLAMENTIN 1000 mg**

Do not stop treatment early.

Finish all your tablets, even if you feel better.

#### **If you take more CLAMENTIN 1000 mg than you should**

In the event of an overdose, consult your doctor or pharmacist. If neither is available, rush the patient to the nearest hospital or poison control centre. Show the pack to the doctor.

#### **If you forget to take CLAMENTIN 1000 mg**

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

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#### 4. Possible 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 doctor, pharmacist or other 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)*);

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- 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*);
- 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;
- inflammation of the large intestine, causing watery diarrhoea usually with blood and mucus, stomach pain and/or fever;

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.
- 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;

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- 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.

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;
- easy bruising, bleeding and pinpoint-sized reddish-purple spots on the lower legs;
- inflammation of the lining of the stomach;
- painful swelling and sores inside the mouth;
- soreness of the tongue.

The following side effects have been reported less frequently:

- increase in some substances (enzymes) produced by the liver;
- dizziness;
- headache;
- upper abdominal discomfort with symptoms such as as burning sensation, bloating or gassiness, nausea or feeling full too quickly after starting to eat;

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- severe reduction in the number of white blood cells.

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

- tooth discolouration;
- inflammation of tubes in the kidney;
- low number of red blood cells (haemolytic anaemia);
- crystals in urine leading to acute kidney injury;
- hyperactivity;
- low number of cells involved in blood clotting.

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.

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare providers are asked to report any suspected adverse reactions to SAHPRA via the “**6.04 Adverse Drug Reactions 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 CLAMENTIN 1000 mg.

### 5. How to store CLAMENTIN 1000 mg

Store all medicine out of reach of children.

Store at or below 25 °C.

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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:*

Talc, povidone, microcrystalline cellulose, magnesium stearate, croscarmellose cellulose, purified water and silicon dioxide colloidal.

##### *Tablet film-coat consisting of:*

Triethyl citrate, ethyl cellulose aqueous dispersion, hypromellose, talc, titanium dioxide and purified water.

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

#### What CLAMENTIN 1000 mg looks like:

White to pale yellow, oblong, scored on both sides. Approximately 10 x 22mm.

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#### **Contents of the pack:**

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

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

#### **REGISTRATION NUMBER**

A40/20.1.2/0088

#### **Holder of Certificate of Registration and Manufacturer**

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#### **Access to the corresponding Professional Information**

Can be obtained on the SAHPRA website.