1.3.2 Patient Information Leaflet

SCHEDULING STATUS

S4

CLAMENTIN S (125/31,25 mg, powder for suspension)

CLAMENTIN SF (250/62,5 mg, powder for suspension)

Amoxicillin, clavulanic acid

Contains sweetener: Aspartame 2,5 ml per 1 ml suspension

Read all of this leaflet carefully before you start taking CLAMENTIN

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 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 is and what it is used for.

2. What you need to know before you take CLAMENTIN**.**

3. How to give CLAMENTIN**.**

4. Possible side effects.

5. How to store CLAMENTIN**.**

6. Contents of the pack and other information.

1.3.2 Patient Information Leaflet

1. What CLAMENTIN is and what it is used for

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

CLAMENTIN is used in children to treat the following infections:

- tonsillitis (inflammation of the tonsils), middle ear and sinus infections;
- respiratory tract infections (infections of parts of the body involved in breathing, such as the throat, airways or lungs);
- urinary tract infections (infections in any part of the urinary system, the kidneys, bladder or urethra);
- skin and soft tissue infections including dental infections.

2. What you need to know before you take CLAMENTIN

Do not take CLAMENTIN:

- if you are hypersensitive (allergic) to amoxicillin, clavulanic acid, penicillin or any of the other ingredients of CLAMENTIN (*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;
- if you have ever had liver problems or jaundice (yellowing of the skin) when taking an antibiotic.
- if you are pregnant;
- if your child is under 6 months of age.

Warnings and precautions

Take special care with CLAMENTIN:

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.

- if you have glandular fever (mononucleosis);
- if you are being treated for liver or kidney problems;
- if you are not passing water regularly;
- if you develop severe diarrhoea either while taking CLAMENTIN or within several weeks after treatment, tell your doctor as soon as possible.

Conditions you need to look out for:

- CLAMENTIN can make some existing conditions worse or cause serious side effects. These include allergic reactions, convulsions (fits) and inflammation of the large intestine (large bowel, where food waste is formed). If you develop severe diarrhoea either while taking CLAMENTIN or within several weeks after treatment, tell your doctor as soon as possible.

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

Children/ and adolescents

- Safety in children under 6 months of age has not been established (*see 'Do not take CLAMENTIN'*).

Other medicines and CLAMENTIN

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:

- Allopurinol (used for gout) with CLAMENTIN may have an allergic skin reaction.
- Probenecid (used for gout). Your doctor may decide to adjust the dose of CLAMENTIN.
- Medicines to help stop blood clots (such as coumarin). When taken with CLAMENTIN extra blood tests may be needed.
- Methotrexate (a medicine used to treat cancer or rheumatic diseases). CLAMENTIN may reduce the excretion of methotrexate causing a potential increase in toxicity.
- Mycophenolate mofetil (a medicine used to prevent the rejection of transplanted organs).
- Medicine to help alcoholism (e.g. disulfiram).
- Oral contraceptives, as CLAMENTIN, may reduce the efficacy of oral contraceptives. You are advised to take supplementary non-hormonal contraceptive measures e.g. condoms.

CLAMENTIN with food and drink and alcohol

Suspensions should be taken immediately before a meal.

Pregnancy and breastfeeding and fertility

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

If you are pregnant or breastfeeding your baby, 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 CLAMENTIN.

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

Driving and using machinery

It is not always possible to predict to what extent CLAMENTIN 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 affects them (*see section 4 'Possible side effects'*).

CLAMENTIN contains aspartame

CLAMENTIN contains 2,5 mg aspartame in each ml (12.5 mg in each 5 ml) of suspension. Aspartame is a source of phenylalanine. It may be harmful for children born with phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

CLAMENTIN is sugar free.

3. How to give CLAMENTIN

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

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

The usual dose is:

- CLAMENTIN suspension should be taken immediately before a meal.
- CLAMENTIN is taken in divided doses every eight hours.
- Your doctor will tell you how long your treatment with CLAMENTIN will last.
- If you have the impression that the effect of CLAMENTIN is too strong or too weak, tell your doctor or pharmacist.

If you take more CLAMENTIN than you should

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

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

If you forget to take a dose of CLAMENTIN

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

If you stop taking CLAMENTIN

- Do not stop treatment early because the infection can come back. Take CLAMENTIN until the treatment is finished, even if you feel better.

4. Possible side effects

CLAMENTIN can have side effects.

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

If any of the following happens, stop taking CLAMENTIN 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 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*);
- 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. 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;
- 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 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;
- dizziness;
- 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 a burning sensation, bloating or gassiness, nausea or feeling full too quickly after starting to eat;
- 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;
- severe reduction in the number of white blood cells;
- low number of red blood cells (haemolytic anaemia);

- crystals in urine leading to acute kidney injury;
- a state of excessive restlessness;
- 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.

You can also report side effects to SAHPRA on the SAHPRA website at: https://medsafety.sahpra.org.za/#download, via email at: adr@sahpra.org.za or via telephone at: 0125010311

By reporting side effects, you can help provide more information on the safety of CLAMENTIN.

5. How to store CLAMENTIN

- Store all medicines out of reach of children.
- Store in a refrigerator between 2 °C – 8 °C.
- The suspension should be used within 7 days.
- Do not freeze.
- Store in the original container.
- Keep the container tightly closed.
- 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 contains:

The active substances are amoxicillin and clavulanic acid.

The other ingredients are:

Aspartame, Hydroxypropyl methylcellulose, dried (Hypromellose), Silicon Dioxide (anhydrous), Silica Colloidal Anhydrous, Xanthan Gum, Succinic Acid, Golden Syrup Dry Flavour, Raspberry Dry Flavour, Orange Dry Flavour 1, Orange Dry Flavour 2

What CLAMENTIN looks like and contents of the pack:

What CLAMENTIN looks like:

CLAMENTIN S

White powder for reconstitution to an off-white suspension.

CLAMENTIN SF

White powder for reconstitution to an off-white suspension.

Contents of the pack:

CLAMENTIN S:

Amber or clear bottles containing white powder for reconstitution to CLAMENTIN suspension.

CLAMENTIN SF:

Amber or clear bottles containing white powder for reconstitution to CLAMENTIN suspension forte.

Holder of Certificate of Registration and Manufacturer

Viatris South Africa (Pty) Ltd

4 Brewery Street

Isando, 1609

Gauteng

Republic of South Africa

This leaflet was last revised in

Date of publication: 23 October 2023

Date of revision of text: 19 February 2024

Registration number

CLAMENTIN S (suspension):

29/20.1.2/0540

CLAMENTIN SF (suspension forte):

29/20.1.2/0541

Access to the corresponding Professional Information

Can be obtained on the SAHPRA website.