PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S4

Co-Amoxiclav 1 000 SR Sandoz® (prolonged-release tablets)

Amoxicillin 1 000 mg / Clavulanic acid 62,5 mg

Sugar-Free

Read all of this leaflet carefully before you start taking CO-AMOXICLAV 1 000 SR SANDOZ

- 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 1 000 SR SANDOZ 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 1 000 SR SANDOZ is and what it is used for
2. What you need to know before you take CO-AMOXICLAV 1 000 SR SANDOZ
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1. What CO-AMOXICLAV 1 000 SR SANDOZ is and what it is used for

CO-AMOXICLAV 1 000 SR SANDOZ is a broad-spectrum 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 1 000 SR SANDOZ is used in adults and children over 16 years to treat respiratory tract (airway) infections such as pneumonia, bronchitis and sinusitis.

2. What you need to know before you take CO-AMOXICLAV 1 000 SR SANDOZ

Do not take CO-AMOXICLAV 1 000 SR SANDOZ:

- if you are hypersensitive (allergic) to amoxicillin, clavulanic acid, penicillins or any of the other ingredients of this medicine (listed in section 6).
- if you have ever had a severe allergic reaction to any other antibiotic.
- if you have ever had liver problems or jaundice (yellowing of the skin and eyes) when previously treated with amoxicillin and clavulanic acid.

Warnings and precautions:

Special care should be taken with CO-AMOXICLAV 1 000 SR SANDOZ:

Talk to your doctor, pharmacist or nurse before taking this medicine if you:

- are allergic to anything, or if you have a history of penicillin or cephalosporin hypersensitivity. You may experience severe allergic reactions with CO-AMOXICLAV 1 000 SR SANDOZ.
- have glandular fever, or a sore throat, which may be glandular fever.
- have existing medical conditions such liver or kidney problems, severe diarrhoea, bleeding disorders, syphilis (a sexually transmitted disease) or lymphatic leukaemia (cancer of the blood and bone marrow).
- are on a controlled sodium and/or potassium diet.

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 strength of CO-AMOXICLAV 1 000 SR SANDOZ or a different medicine.

Conditions you need to look out for:

CO-AMOXICLAV 1 000 SR SANDOZ can make some existing conditions worse, or cause serious side effects. These include allergic reactions, serious skin reactions and inflammation of the large intestine (presenting as stomach cramps, bloody stools, fever, watery diarrhoea). You must look out for certain symptoms while you are taking CO-AMOXICLAV 1 000 SR SANDOZ, to reduce the risk of any problems (See Section 4 – Possible side effects).

Blood and urine tests:

If you are having blood tests (such as red or white blood cell status tests, determination of blood clotting time, liver function tests, estrogen levels in pregnancy) or urine tests (for glucose), let the doctor or nurse know that you are taking CO-AMOXICLAV 1 000 SR SANDOZ as this medicine can affect the results of these types of tests.

Maintenance of Adequate Fluid Intake:

Whilst taking CO-AMOXICLAV 1 000 SR SANDOZ, ensure you drink plenty of fluids to reduce the possibility of crystals forming in the urine.

Children and adolescents:

CO-AMOXICLAV 1 000 SR SANDOZ is not to be taken by children and adolescents below 16 years of age.

Other medicines and CO-AMOXICLAV 1 000 SR SANDOZ:

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

You should specifically tell them if you take any of the following medicines:

- Probenecid (used for gout); your doctor may decide to prescribe a different medicine.

- Allopurinol (used for gout), as it may be more likely that you'll have an allergic skin reaction.
- Medicine to help stop blood clots (such as warfarin), as extra blood tests may be needed or the dose of the medicine adjusted.
- Oral contraceptives, as they may become less effective.
- Tetracyclines or other antibiotics; as they may interfere with the efficacy of CO-AMOXICLAV 1 000 SR SANDOZ.

CO-AMOXICLAV 1 000 SR SANDOZ with food and drink:

CO-AMOXICLAV 1 000 SR SANDOZ should be taken at the start of a meal, as this may decrease the incidence of gastrointestinal side effects such as nausea, vomiting and diarrhoea. CO-AMOXICLAV 1 000 SR SANDOZ should not be taken with a high fat meal, because clavulanate absorption is decreased.

Pregnancy and breastfeeding:

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.

The safety of CO-AMOXICLAV 1 000 SR SANDOZ in pregnancy has not been established and use should be avoided during pregnancy.

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

There is no data on fertility with CO-AMOXICLAV 1 000 SR SANDOZ.

Driving and using machines:

CO-AMOXICLAV 1 000 SR SANDOZ can have side effects that may interfere with your daily activities (e.g. allergic reactions, dizziness, convulsions). Don't drive or operate machinery unless you are feeling well and are safely able to do so.

3. How to use CO-AMOXICLAV 1 000 SR SANDOZ

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

Always use CO-AMOXICLAV 1 000 SR SANDOZ exactly as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

Adults and children over 16 years:

The usual dose of CO-AMOXICLAV 1 000 SR SANDOZ is 2 tablets every 12 hours, for 7 to 10 days.

Patients with kidney and liver problems:

- If you have kidney problems the dose or time between doses might be changed.
- If you have liver problems, you may have more frequent blood tests to check how your liver is working.

Your doctor or pharmacist will tell you how long your treatment with CO-AMOXICLAV 1 000 SR SANDOZ will last. Do not stop treatment early, because your infection may not be completely cured. You should complete your course of treatment. If you have the impression that the effect of CO-AMOXICLAV 1 000 SR SANDOZ is too strong or too weak, tell your doctor or pharmacist.

How to take CO-AMOXICLAV 1 000 SR SANDOZ:

- CO-AMOXICLAV 1 000 SR SANDOZ tablets should be swallowed with a glass of water at the start of a meal.
- CO-AMOXICLAV 1 000 SR SANDOZ has a score line to aid breaking the tablets into two

halves. This is so they can be swallowed more easily. Both halves of each tablet must be taken whole at the same time.

- Do not crush or chew tablets.

If you take more CO-AMOXICLAV 1 000 SR SANDOZ than you should:

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

If you take too much CO-AMOXICLAV 1 000 SR SANDOZ, signs may include an upset stomach (feeling sick, being sick or diarrhoea), a skin rash, feeling hyperactive or feeling sleepy. In a small number of patients, kidney failure has been reported, following an overdose. You should ensure that you drink sufficient fluids to reduce the likelihood of developing kidney failure.

If you forget to take CO-AMOXICLAV 1 000 SR SANDOZ:

If you forget to take a dose, take it as soon as you remember. Do not take a double or larger dose to make up for the forgotten individual doses. Continue to take the next tablet at the usual time.

If you stop taking CO-AMOXICLAV 1 000 SR SANDOZ:

Do not stop taking CO-AMOXICLAV 1 000 SR SANDOZ before you have consulted with your doctor. Keep taking it until the treatment is finished, even if you feel better. You need to take every dose to help fight the infection. If some bacteria survive, they can cause the infection to come back.

4. Possible side effects

CO-AMOXICLAV 1 000 SR SANDOZ can have side effects.

Not all side effects reported for CO-AMOXICLAV 1 000 SR SANDOZ are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking CO-AMOXICLAV 1 000 SR SANDOZ, please consult your health care provider for advice.

If any of the following happens, stop taking CO-AMOXICLAV 1 000 SR SANDOZ and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Allergic reactions, including fast or irregular breathing, swelling of the face, sudden decrease in blood pressure.
- Inflammation of blood vessels (hypersensitivity vasculitis) which may be visible as red or purple raised spots on the skin, but can affect other parts of the body.
- White, non-itchy, swollen patches on your skin, tongue and/or mouth (angioneurotic oedema).
- Skin rash; hives or itching skin; fever; joint and muscle pain (serum sickness-like syndrome).
- Severe stomach pain or cramps; watery and severe diarrhoea.
- Yellow eyes or skin (jaundice).
- A widespread rash with blistering or 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 (acute generalised exanthemous pustulosis).
- Fits (convulsions).

These are all very serious side effects. If you have them, you may have had a serious reaction to CO-AMOXICLAV 1 000 SR SANDOZ. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Vaginal thrush (a yeast infection).
- Diarrhoea.
- Nausea.

- Vomiting.
- Indigestion.

Less frequent side effects:

- Abnormal increase in the number of blood platelets (thrombocytosis), as seen in a blood test.
- Blood takes longer to clot when you are bleeding.
- Feeling agitated.
- Feeling anxious.
- Changes in your mood and how you feel.
- Feeling confused.
- Being unable to sleep (insomnia).
- Feeling hyperactive.
- Dizziness.
- Headache.
- Inflammation of the tubes in the kidney.

Side effects for which the frequency is not known:

- Low number of red blood cells (haemolytic anaemia), as seen in a blood test.
- Decrease in the number of blood platelets (thrombocytopenia), as seen in a blood test.
- Low levels of the blood cells that prevent bleeding and cause bruising (thrombocytopenic purpura), as seen in a blood test.
- Abnormal increase in the number of eosinophils – a type of white blood cell (eosinophilia), as seen in a blood test.
- Decrease in the number of white blood cells (leukopenia, neutropenia), as seen in a blood test.
- Decrease in the number of blood cells which may cause bruising or bleeding or weaken the immune system (agranulocytosis), as seen in a blood test.
- Inflammation of the stomach lining.
- Inflammation inside of the mouth.

- Inflammation of the tongue.
- Black tongue which looks hairy.
- Thrush (a yeast infection).
- Staining of the teeth (brow, yellow or grey), which is usually removed by brushing or dental cleaning.
- Increase in some substances (enzymes) produced by the liver, as seen in blood tests.
- Inflammation of the liver (hepatitis).
- Skin rash.
- Skin rash of round, red, itchy welts (urticaria).
- Severe itchy skin (pruritus).
- 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).
- Crystals in the urine.
- Blood in the urine.

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. 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 1 000 SR SANDOZ.

Suspected side effects can also be reported directly to the Holder of the Certificate of Registration (HCR) via the link: https://pvi1j.solutions.iqvia.com or the e-mail address, adverse.event.sac@sandoz.com.

5. How to store CO-AMOXICLAV 1 000 SR SANDOZ

- **KEEP ALL MEDICINES OUT OF REACH OF CHILDREN.**
- Store at or below 25 °C.

- Store in the original packaging.
- Keep the tablets in the strips in the carton until required for use.
- Do not use after the expiry date stated on the strip / carton.
- Do not dispose of unused medicine in drains or sewerage systems e.g. toilets).
- Return all unused medicine to your pharmacist.

6. Contents of the pack and other information

What CO-AMOXICLAV 1 000 SR SANDOZ contains:

The active substances are amoxicillin and clavulanic acid. Each tablet contains amoxicillin trihydrate and sodium amoxicillin equivalent to 1 000 mg amoxicillin and potassium clavulanate equivalent to 62,5 mg of clavulanic acid.

The other ingredients are:

- Tablet core – Anhydrous citric acid, colloidal silicone dioxide, magnesium stearate, microcrystalline cellulose, sodium starch glycolate and xanthan gum.
- Film-coat – Hydroxypropyl methylcellulose, macrogol 3350, macrogol 8000 and titanium dioxide (E171).

What CO-AMOXICLAV 1 000 SR SANDOZ looks like and contents of the pack:

CO-AMOXICLAV 1 000 SR SANDOZ are white to cream-tinged, oval film-coated tablets, scored on one side and with the embossment “SZ 137” on the other side.

CO-AMOXICLAV 1 000 SR SANDOZ is packed in HDPE bottles with a child resistant closure. A 2 g desiccant bag is included in the bottle and a professional information leaflet attached to the outside of the bottle.

Pack sizes:

28 or 40 tablets per bottle.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

Sandoz SA (Pty) Ltd[1]

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Waterfall City

Jukskei View

Midrand

2090

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Access to the corresponding Professional Information

Not applicable

[1]Company Reg. No.: 1990/001979/07