PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S4

Co-Amoxyclav ES Sandoz® 600 mg + 42,9 mg/5 mL

(Powder for oral suspension extra strength)

Amoxicillin & Clavulanic acid

Sugar free

Contains artificial sweetener (5,0 mg saccharin sodium per 5 mL)

Read all of this leaflet carefully before you start taking CO-AMOXYCLAV ES SANDOZ.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- CO-AMOXYCLAV ES 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-AMOXYCLAV ES SANDOZ is and what it is used for
2. What you need to know before you take CO-AMOXYCLAV ES SANDOZ
3. How to take CO-AMOXYCLAV ES SANDOZ
4. Possible side effects
5. How to store CO-AMOXYCLAV ES SANDOZ
6. Contents of the pack and other information

1. What CO-AMOXYCLAV ES SANDOZ is and what it is used for

CO-AMOXYCLAV ES 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, a beta-lactamase inhibitor) stops this from happening.

CO-AMOXYCLAV ES SANDOZ is used to treat:

- infections caused by organisms, sensitive for CO-AMOXYCLAV ES SANDOZ.

2. What you need to know before you take CO-AMOXYCLAV ES SANDOZ

Do not take CO-AMOXYCLAV ES SANDOZ:

- If you are hypersensitive (allergic) to amoxicillin, clavulanic acid, penicillin or any of the other ingredients of CO-AMOXYCLAV ES SANDOZ (listed in section 6).
- If you were previously treated with amoxicillin or clavulanic acid and developed jaundice (yellow skin and eyes) or liver problems as a result of the treatment.
- Safety in children under 2 months of age has not been established. There are no clinical data in children under 3 months of age.

Do not give CO-AMOXYCLAV ES SANDOZ to your child if any of the above apply to your child. If you are not sure, talk to your doctor or pharmacist before taking CO-AMOXYCLAV ES SANDOZ.

Warnings and precautions

Special care should be taken with CO-AMOXYCLAV ES SANDOZ:

- If you have ever had a severe allergic reaction to any other beta-lactam agent (e.g. a cephalosporin, carbapenem or monobactam), you may also be allergic to CO-AMOXYCLAV ES SANDOZ antibiotics. This can include a skin rash or swelling of the

face or throat.

- 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-AMOXYCLAV ES SANDOZ.
- If you have a sore throat.
- If you have existing medical problems such as severe diarrhoea or other gastrointestinal diseases, bleeding disorders, jaundice, liver or kidney problems, syphilis or lymphatic leukaemia.
- If you are taking a medicine called probenecid for gout.
- If you develop a red, spotty rash when you start taking CO-AMOXYCLAV ES SANDOZ.
- If you develop diarrhoea during or after treatment with CO-AMOXYCLAV ES SANDOZ.
- If you are going for any blood tests, you must tell your doctor that you are taking CO-AMOXYCLAV ES SANDOZ.
- If you are not passing water regularly.
- If you are breastfeeding your infant.

Other medicines and CO-AMOXYCLAV ES SANDOZ

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

Concurrent use of probenecid and CO-AMOXYCLAV ES SANDOZ may increase and prolong blood levels of amoxicillin.

CO-AMOXYCLAV ES SANDOZ may reduce the efficacy of your oral contraceptives, making it less reliable.

CO-AMOXYCLAV ES SANDOZ with food, drink and alcohol

CO-AMOXYCLAV ES SANDOZ may be taken on a full or empty stomach. If you take it at the start of a meal, it may decrease the incidence of gastrointestinal side effects such as nausea, vomiting and diarrhoea.
Ingestion of alcohol should be avoided during and for several days after treatment.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist, or other health care professional for advice before taking CO-AMOXYCLAV ES SANDOZ.
It is not yet known if CO-AMOXYCLAV ES SANDOZ is safe for pregnant women. Use should be avoided during pregnancy, unless considered essential by your doctor.

You should not breastfeed your baby if you are taking CO-AMOXYCLAV ES SANDOZ. Amoxicillin and clavulanic acid are excreted into breast milk. If you are breastfeeding your baby while taking CO-AMOXYCLAV ES SANDOZ, your baby may experience some of the side effects associated with amoxicillin, such as diarrhoea, fungal infections, or a skin rash.

CO-AMOXYCLAV ES SANDOZ may reduce the efficacy of oral contraceptives (the pill). If you are using an oral contraceptive whilst being treated with CO-AMOXYCLAV ES SANDOZ, you should use additional contraceptive methods.

Driving and using machines

CO-AMOXYCLAV ES SANDOZ can have side effects (e.g., allergic reactions, dizziness, convulsions), which may influence your ability to drive and use machines. You should refrain from driving or using machinery until you know how this medicine affects your ability to concentrate.

CO-AMOXYCLAV ES SANDOZ contains saccharin sodium

Patients with phenylketonuria (a rare inherited disorder that causes an amino acid called phenylalanine to build up in your body) should not take CO-AMOXYCLAV ES SANDOZ, as it contains the artificial sweetener, saccharin sodium.

3. How to take CO-AMOXYCLAV ES SANDOZ

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

Always take CO-AMOXYCLAV ES SANDOZ exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

Children weighing less than 40 kg

All doses are worked out depending on the body weight in kilograms.

- Your doctor will advise how much CO-AMOXYCLAV ES SANDOZ you should give to your baby or child.
- The usual dose is 90 mg/6,4 mg for each kilogram of body weight per day, given in two divided doses.

How to give CO-AMOXYCLAV ES SANDOZ

ALWAYS SHAKE CO-AMOXYCLAV ES SANDOZ BEFORE EACH DOSE.

Your doctor or pharmacist will tell you how long your treatment with CO-AMOXYCLAV ES SANDOZ will last. Do not stop treatment early because the infection might come back, and it will be even more difficult to treat.

Administer with a meal to minimise potential gastrointestinal (stomach) intolerance.

If your child still feels unwell after completion of the course, they should go back to see the doctor.

If you have the impression that the effect of CO-AMOXYCLAV ES SANDOZ is too strong or too weak, talk to your doctor or pharmacist.

If you take more CO-AMOXYCLAV ES SANDOZ than you should

You may experience gastrointestinal symptoms (such as nausea, vomiting and diarrhoea), disturbances of the fluid and electrolyte balances.

Crystallization of urine (crystalluria) has been reported.

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 CO-AMOXYCLAV ES SANDOZ

Take the missed dose as soon as possible. However, if it is almost time for your next dose, continue to take the next dose at the usual time. Do not take a double dose to make up for forgotten individual doses.

If you have trouble remembering when to use your medicine, ask your pharmacist for some hints.

If you stop taking CO-AMOXYCLAV ES SANDOZ

Please refer to section 3 of this patient information leaflet for information.

4. Possible side effects

CO-AMOXYCLAV ES SANDOZ can have side effects.

Not all side effects reported for CO-AMOXYCLAV ES SANDOZ are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking CO-AMOXYCLAV ES SANDOZ, please consult your doctor, pharmacist or other health care professional for advice.

If any of the following happens, stop taking CO-AMOXYCLAV ES SANDOZ 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
- Yellowing of the skin and eyes, also called jaundice

Tell your doctor if you notice any of the following side effects that have been reported frequently:

- Sore, creamy-yellow, raised patches in the mouth or itching, burning and thick, 'cottage cheese' discharge
- Diarrhoea, nausea, vomiting

Tell your doctor if you notice any of the following side effects that have been reported less frequently:

- Fever, chills, sore throat or mouth ulcers
- Bleeding or bruising more easily than normal
- Tiredness, headaches, being short of breath when exercising, dizziness, looking pale and yellowing of skin and/or eyes
- Prolongation of bleeding time
- Serious allergic reaction which causes swelling of the face or throat
- Narrowing or blockage of blood vessels
- Reversible increased activity, fits
- Indigestion, inflammation which causes abdominal pain and diarrhoea
- Tooth discoloration which can usually be removed by brushing
- Black "hairy" tongue
- Skin rash, itching, red often itchy spots similar to the rash of measles, which starts on the

limbs and sometimes on the face and the rest of the body

- Rare skin condition with severe blisters and bleeding in the lips, eyes, mouth, nose and genitals
- Inflammation of the kidney which can cause swollen ankles or high blood pressure.

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 "**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-AMOXYCLAV ES SANDOZ.

Suspected side effects can also be reported directly to the HCR via Patientsafety.sacg@novartis.com.

5. How to store CO-AMOXYCLAV ES SANDOZ

- Dry Powder: Store below 25 °C in the original package to protect from moisture.
- Reconstituted suspension: Store in a refrigerator (2 to 8°C) and use within 10 days.
- Discard any unused portion after 10 days.
- The product will only retain its stability if stored in the refrigerator.
- **STORE ALL MEDICINES OUT OF REACH OF CHILDREN.**
- Do not use after the expiry date printed on the label or carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g., toilets).

6. Contents of the pack and other information

What CO-AMOXYCLAV ES SANDOZ contains

The active substances are amoxicillin trihydrate and potassium clavulanate.

- Each 5 mL of reconstituted oral suspension contains: amoxicillin trihydrate equivalent to 600 mg amoxicillin and potassium clavulanate equivalent to 42,9 mg clavulanic acid.

Inactive ingredients in the suspension are:

Citric acid, anhydrous (E330), caramel flavour [flavouring components (≈4,4 %), maize maltodextrin (≈80,0 %), triethyl citrate E 1505 (≈10,6 %), residual moisture (≈5,0 %)], microcrystalline cellulose and carmellose sodium, microcrystalline cellulose (E460), orange flavour [flavouring preparations, natural flavouring substances, maize maltodextrin (60 %), modified maize starch E1450 (16 %), buthylated hydroxyanisole (BHA) E320 (<0,1 %)], raspberry flavour [flavouring components (≈3,2 %), maize maltodextrin (≈80,0 %), propylene glycol E120 (≈6,0 %), glyceryl triacetate E1518 (≈5,7 %), triethyl citrate E1505 (≈0,1 %), residual moisture (≈5,0 %)], saccharin sodium (E954), colloidal anhydrous silica (E551), silicon dioxide (E551), sodium citrate (E331) and xanthan gum (E415).

What CO-AMOXYCLAV ES SANDOZ looks like and contents of the pack

CO-AMOXYCLAV ES SANDOZ is a white to light-yellow powder. After reconstitution the suspension is a white to light-yellow, homogeneous suspension.

CO-AMOXYCLAV ES SANDOZ 50 mL: 100 mL amber glass bottle with white plastic screw cap with a sealing cone and a tamper evident ring, containing powder for reconstitution to 50 mL packed with a 5 mL plastic dosing pipette.

CO-AMOXYCLAV ES SANDOZ 100 mL: 180 mL amber glass bottle with white plastic screw cap with a sealing cone and a tamper evident ring, containing powder for reconstitution to 100 mL packed with a 5 mL plastic dosing pipette.

Holder of Certificate of Registration

Sandoz SA (Pty) Ltd[1]

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2090

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TBC

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