PATIENT INFORMATION LEAFLET FOR
SANDOZ CO-AMOXYCLAV BD SUSPENSION

SCHEDULING STATUS: S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

SANDOZ CO-AMOXYCLAV BD SUSPENSION (powder for suspension)

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or your pharmacist.
- SANDOZ CO-AMOXYCLAV BD SUSPENSION 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.

1. WHAT SANDOZ CO-AMOXYCLAV BD SUSPENSION CONTAINS:

- Each 5 mℓ of reconstituted suspension contains: amoxycillin trihydrate equivalent to 400 mg amoxycillin and potassium clavulanate equivalent to 57 mg clavulanic acid.
- Each 2,5 mℓ of reconstituted suspension contains: amoxycillin trihydrate equivalent to 200 mg amoxycillin and potassium clavulanate equivalent to 28,5 mg clavulanic acid.
- Each 1 mℓ of reconstituted suspension contains: amoxycillin trihydrate equivalent to 80 mg amoxycillin and potassium clavulanate equivalent to 11,4 mg clavulanic acid.

The active substances are amoxycillin trihydrate and potassium clavulanate.

The other ingredients: aspartame, citric acid anhydrous, guar, lemon flavouring powdered, orange flavouring powdered, peach apricot flavouring powdered, silicon dioxide, talc, trisodium citrate anhydrous.

Contains sugar (guar, 25,0 mg per 5 mℓ).

Contains artificial sweetener (8,5 mg aspartame per 5 mℓ).

2. WHAT SANDOZ CO-AMOXYCLAV BD SUSPENSION IS USED FOR:

SANDOZ CO-AMOXYCLAV BD SUSPENSION is a broad spectrum antibiotic consisting of penicillin (amoxycillin) and a beta-lactamase inhibitor (clavulanic acid).

SANDOZ CO-AMOXYCLAV BD SUSPENSION is used in the treatment of infections caused by sensitive organisms.

3. BEFORE YOU TAKE SANDOZ CO-AMOXYCLAV BD SUSPENSION:

Do not take SANDOZ CO-AMOXYCLAV BD SUSPENSION:

- If you are hypersensitive (allergic) to penicillins or to cephalosporins or any of the other ingredients of SANDOZ CO-AMOXYCLAV BD SUSPENSION. If you are allergic to cephalosporin antibiotic, such as cephalexin and cefuroxime, you may also be allergic to SANDOZ CO-AMOXYCLAV BD SUSPENSION antibiotics.
- If you were previously treated with amoxycillin or clavulanic acid and developed jaundice (yellow skin and eyes) or liver problems as a result of the treatment.

Take special care with SANDOZ CO-AMOXYCLAV BD SUSPENSION:

Before taking SANDOZ CO-AMOXYCLAV BD SUSPENSION, tell your doctor:

- If you are allergic to anything or if you have a history of penicillin or cephalosporin hypersensitivity. You may experience severe allergic reactions with SANDOZ CO-AMOXYCLAV BD SUSPENSION.
- If you have a sore throat with sores in your 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 allopurinol for gout.

- If you develop a red, spotty rash when you start taking SANDOZ CO-AMOXYCLAV BD SUSPENSION.
- If you develop diarrhoea during or after treatment with SANDOZ CO-AMOXYCLAV BD SUSPENSION.
- If you are going for any blood tests, you must tell your doctor that you are taking SANDOZ CO-AMOXYCLAV BD SUSPENSION.
- If you are breastfeeding your infant.

Taking SANDOZ CO-AMOXYCLAV BD SUSPENSION with food or drink:

SANDOZ CO-AMOXYCLAV BD SUSPENSION 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.

Pregnancy and breastfeeding:

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other health care professional for advice before taking SANDOZ CO-AMOXYCLAV BD SUSPENSION.

It is not yet known if this medicine is safe for pregnant women.

Amoxycillin and clavulanic acid are excreted into breast milk. If you are breastfeeding your baby while taking SANDOZ CO-AMOXYCLAV BD SUSPENSION, your baby may experience some of the side effects associated with amoxicillin, such as diarrhoea, fungal infections or a skin rash.

You should not breastfeed your baby if you are taking SANDOZ CO-AMOXYCLAV BD SUSPENSION.

Driving and using machinery:

You should refrain from driving or using machinery until you know how this medicine affects your ability to concentrate.

Important information about some of the ingredients of SANDOZ CO-AMOXYCLAV BD SUSPENSION:

Patients with the rare hereditary condition of galactose intolerance e.g. galactosaemia or glucose-galactose malabsorption should not take SANDOZ CO-AMOXYCLAV BD SUSPENSION.

SANDOZ CO-AMOXYCLAV BD SUSPENSION may have an effect on the control of your blood sugar if you have diabetes mellitus.

Patients with phenylketonuria (a rare inherited disorder that causes an amino acid called phenylalanine to build up in your body) should not take SANDOZ CO-AMOXYCLAV BD SUSPENSION.

Using other medicines with SANDOZ CO-AMOXYCLAV BD SUSPENSION:

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

Concurrent use of probenecid and SANDOZ CO-AMOXYCLAV BD SUSPENSION may increase and prolong blood levels of amoxycillin.

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

Taking SANDOZ CO-AMOXYCLAV BD SUSPENSION together with allopurinol (medicine used in the treatment of gout) may increase the incidence of skin rashes.

Tetracyclines and other antibiotics may interfere with the bactericidal effects of amoxycillin.

SANDOZ CO-AMOXYCLAV BD SUSPENSION may cause toxicity if taken with methotrexate.

If you are taking warfarin your doctor may want to monitor your bleeding time while you are also taking SANDOZ CO-AMOXYCLAV BD SUSPENSION or your dose of warfarin may be adjusted.

If you are taking mycophenolate mofetil, your doctor may want to closely monitor you during and after your treatment with SANDOZ CO-AMOXYCLAV BD SUSPENSION.

4. HOW TO USE SANDOZ CO-AMOXYCLAV BD SUSPENSION:

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

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

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

SHAKE SANDOZ CO-AMOXYCLAV BD SUSPENSION BEFORE EACH DOSE.

The usual dose is 0,3 mℓ to 10 mℓ twice per day depending on the age of the patient.

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

If you take more SANDOZ CO-AMOXYCLAV BD SUSPENSION than you should:

You may experience nausea, vomiting and diarrhoea.

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 SANDOZ CO-AMOXYCLAV BD SUSPENSION:

Take the missed dose as soon as possible. However, if it is almost time for your next dose, continue

to take the next tablet 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.

5. POSSIBLE SIDE EFFECTS:

SANDOZ CO-AMOXYCLAV BD SUSPENSION can have side effects.

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

If any of the following happens, stop taking SANDOZ CO-AMOXYCLAV BD SUSPENSION and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Sudden life-threatening allergic reaction sudden signs of allergy such as rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing.
- Liver disease with nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and eyes, and dark coloured urine.
- Serious rare skin condition with severe blisters and bleeding in the lips, eyes, mouth, nose and genitals are signs of Stevens-Johnson syndrome.
- Severe skin reaction which starts with painful red areas, then large blisters and ends with peeling of layers of skin. This is accompanied by fever and chills, aching muscles and generally feeling unwell are signs of toxic epidermal necrolysis.
- Severe condition of the skin that may affect the mouth and other parts of the body with 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. The spots may blister or may progress to form raised, red, pale-cantered

marks. Those affected may have fever, sore throat, headache and/or diarrhoea, which are signs of erythema multiforme.

- Infection around the brain or spinal cord with fever, nausea, vomiting, headache, stiff neck and extreme sensitivity to bright light are signs of meningitis.
- Fits or convulsions.

These are all very serious side effects. If you have them, you may have had a serious reaction to SANDOZ CO-AMOXYCLAV BD SUSPENSION. 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:

- Illness resulting from the destruction of red blood cells, tiredness, headaches, being short of breath when exercising, dizziness, looking pale and yellowing of the skin and/or eyes signs of haemolytic anaemia.
- *Candida* infections symptoms include white or yellow streaks on the nails, thrush, sore, creamy-yellow, raised patches in the mouth, vaginal itching or thick-white discharge.
- *Clostridium difficile* (also called *C. difficile*) are bacteria that can cause swelling and irritation of the large intestine, or colon.
- Kidney problems causing pain or discomfort when urinating, crystals in the urine or inflammation of the kidneys.

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

Tell your doctor if you notice any of the following:

- Irregular liver blood test results.
- Irregular cells in the blood causing fever, severe chills, sore throat or mouth ulcers, bleeding or bruising more easily than normal.
- Skin rash, white spots accompanied by blistering, hives, or itching.

- Protein in urine.
- Redness on skin.
- Hyperactivity, headache, dizziness.
- Colitis (diarrhoea, usually with blood and mucus, stomach pain and fever).
- Nausea, vomiting, diarrhoea, indigestion, burning of tongue.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

6. STORING AND DISPOSING OF SANDOZ CO-AMOXYCLAV BD SUSPENSION:

- The suspension must be stored in a refrigerator (2 to 8 °C). The medicine will not remain effective if you leave it outside the refrigerator.
- You must use the suspension within 7 days.
- Discard any unused portion after 7 days.
- Your pharmacist will mix the SANDOZ CO-AMOXYCLAV BD SUSPENSION dry powder with sterile water before giving it to you. However, should you be requested to store the dry powder, it must be stored below 25 ºC. Protect the powder from light and moisture. Keep in the original container. Keep the container tightly closed.
- The dry powder should not be mixed and should not be used after the expiry date printed on the bottle.
- **STORE ALL MEDICINES OUT OF REACH OF CHILDREN.**
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

7. PRESENTATIONS OF SANDOZ CO-AMOXYCLAV BD SUSPENSION:

60 mℓ or 120 mℓ amber glass bottles containing powder for reconstitution to suspension.

8. IDENTIFICATION OF SANDOZ CO-AMOXYCLAV BD SUSPENSION:

SANDOZ CO-AMOXYCLAV BD SUSPENSION is a white to off-white powder, and white to off white

ready-for-use suspension (reconstituted suspension) with a fruity odour, characteristic of the active ingredient.

9. REGISTRATION NUMBER:

A 39/20.1.2/0071

10. NAME AND ADDRESS OF REGISTRATION HOLDER:

Sandoz SA (Pty) Ltd[1]

72 Steel Road, Spartan

Kempton Park 1619

South Africa

11. DATE OF PUBLICATION:

Date of registration: 23 September 2005

Date of most recent approval of professional information: 23 November 2017

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