PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S4**

PROPRIETARY NAMES, STRENGTHS AND PHARMACEUTICAL FORM:

SANDOZ CO-AMOXYCLAV 625 DISP TABLET (Dispersible tablets)

SANDOZ CO-AMOXYCLAV 1000 DISP TABLET (Dispersible tablets)

Please read this leaflet carefully before taking SANDOZ CO-AMOXYCLAV 625 or 1000 DISP TABLET.

- 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 625 or 1000 DISP TABLET 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 DISP TABLET CONTAINS

Active ingredients:

Each Sandoz Co-Amoxyclav 625 Disp Tablet contains amoxicillin trihydrate equivalent to amoxicillin 500 mg and potassium clavulanate equivalent to clavulanic acid 125 mg.

Each Sandoz Co-Amoxyclav 1000 Disp Tablet contains amoxicillin trihydrate equivalent to amoxicillin 875 mg and potassium clavulanate equivalent to clavulanic acid 125 mg.

Inactive ingredients:

Crospovidone Type A, Silicon Dioxide, Iron oxide yellow (E172), Sweet orange flavour (powdered), Sucralose, Magnesium stearate, Silicified microcrystalline cellulose (Type 50) – dried.

Contains artificial sweetener (sucralose).

Each Sandoz Co-Amoxyclav 625 Disp Tablet contains sweetener (sucralose 5.500 mg per tablet).

Each Sandoz Co-Amoxyclav 1000 Disp Tablet contains sweetener (sucralose 8.208 mg per tablet).

2. WHAT SANDOZ CO-AMOXYCLAV 625 and 1000 DISP TABLETS ARE USED FOR

SANDOZ CO-AMOXYCLAV DISP TABLET is a broad spectrum antibiotic

SANDOZ CO-AMOXYCLAV DISP TABLET can be used for the treatment of:

- Upper respiratory tract infections, such as sinusitis, recurrent otitis media (middle ear infection) and tonsillitis.
- Lower respiratory tract infections, such as bronchitis and bronchopneumonia.
- Genito-urinary tract infections, such as infections of the bladder (cystitis), urethra (urethritis) and kidney (pyelonephritis).
- Skin and soft tissue infections.

3. BEFORE YOU TAKE SANDOZ CO-AMOXYCLAV DISP TABLET

Do not take SANDOZ CO-AMOXYCLAV DISP TABLET:

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

Take special care with SANDOZ CO-AMOXYCLAV DISP TABLET:

Before you take SANDOZ CO-AMOXYCLAV DISP TABLET, 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 DISP TABLETS.
- 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 breastfeeding your baby.

Taking SANDOZ CO-AMOXYCLAV DISP TABLET with food or drink:

You may take SANDOZ CO-AMOXYCLAV DISP TABLET on a full or empty stomach. If you take it with food, 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 while taking SANDOZ CO-AMOXYCLAV DISP TABLET, please consult your doctor, pharmacist or other health care professional for advice.

It is not known if SANDOZ CO-AMOXYCLAV DISP TABLET are safe for pregnant and breastfeeding women.

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

Driving and using machinery:

You should refrain from driving or using machinery until you know how SANDOZ CO-AMOXYCLAV DISP TABLET affects your ability to concentrate.

Using other medicines with SANDOZ CO-AMOXYCLAV DISP TABLET:

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of SANDOZ CO-AMOXYCLAV DISP TABLET with these medicines may cause undesirable interactions. Tell your doctor or pharmacist if you are taking any other medicines, including any you have bought at your pharmacy, supermarket or health food shop. Please consult your doctor, pharmacist or other healthcare professional for advice.

Inform your doctor if you are taking any the following medicines:

- With Probenecid (medicine used for gout) may increase and prolong blood levels of amoxicillin.
- SANDOZ CO-AMOXYCLAV DISP TABLET may reduce the efficacy of your oral contraceptives, making it less reliable.
- Allopurinol (medicine used in the treatment of gout) may increase the incidence of skin rashes.
- Tetracyclines and other bacteriostatic medicines may interfere with the bactericidal effects of amoxicillin.

If you have to test for the presence of glucose in your urine, you may get false positive readings during SANDOZ CO-AMOXYCLAV DISP TABLET treatment.

4. HOW TO TAKE SANDOZ CO-AMOXYCLAV DISP TABLET

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

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

You should take the tablets immediately before a meal in order to decrease the incidence of gastrointestinal side effects such as nausea, vomiting and diarrhoea.

If your doctor prescribed SANDOZ CO-AMOXYCLAV 625 DISP TABLET, the usual dose is one tablet every 8 hours at the start of a meal dissolved in half a glass of water or in the mouth before swallowing.

If your doctor prescribed SANDOZ CO-AMOXYCLAV 1000 DISP TABLET the usual dose is one tablet every 12 hours at the start of a meal dissolved in half a glass of water or in the mouth before swallowing.

If you have kidney problems, your doctor may adjust or reduce the dosage.

If you take more SANDOZ CO-AMOXYCLAV DISP TABLET than you should:

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

If you forget to take SANDOZ CO-AMOXYCLAV DISP TABLET:

Take the missed dose as soon as you remember. However, if it is almost time for your next dose, continue to take the next dose at the usual time. Do not take two doses together.

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

5. POSSIBLE SIDE EFFECTS

SANDOZ CO-AMOXYCLAV DISP TABLET can cause side effects.

Contact your doctor immediately if you experience any of the following side effects:

These side-effects have been reported frequently:

- Skin rash; hives or itching skin
- Severe stomach pain or cramps; watery and severe diarrhoea.
- Vaginal itching and discharge.

These side-effects have been reported less frequently:

- Allergic reactions, including fast or irregular breathing, swelling of the face, sudden decrease in blood pressure.
- Sore mouth with white patches on your tongue and/or mouth.
- Fever; joint pain; blistering or peeling skin.
- Yellow eyes or skin.
- Convulsions.

Other side-effects may occur that usually do not need medical attention. These side-effects may go way during treatment as your body adjust to the medicine.

These side-effects have been reported frequently:

- Headache
- Dizziness
- Tiredness
- Nausea and vomiting
- Hot flushes

These side-effects have been reported less frequently:

- Black ‘hairy’ tongue
- Tooth discolouration (which can be removed by brushing the teeth)

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

6. STORING AND DISPOSING OF SANDOZ CO-AMOXYCLAV DISP TABLET

- Do not store above 25°C.
- Store in the original package in order to protect from moisture.
- Store in the original package in order to protect from light.
- KEEP ALL MEDICINES OUT OF REACH OF CHILDREN
- Do not use the tablets after the expiry date that is printed on the carton and the blister pack.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

7. PRESENTATION OF SANDOZ CO-AMOXYCLAV DISP TABLET

Sandoz Co-Amoxyclav 625 Disp Tablet**:** 10, 14 or 16 tablets in aluminium foil blisters.

Sandoz Co-Amoxyclav 1000 Disp Tablet**:** 10, 14 or 16 tablets in aluminium foil blisters.

8. IDENTIFICATION OF SANDOZ CO-AMOXYCLAV DISP TABLET

Sandoz Co-Amoxyclav 625 Disp Tablet: Yellow brown mottled octagonal tablet, with aromatic odour.

Sandoz Co-Amoxyclav 1000 Disp Tablet: Yellow brown mottled octagonal tablet, with aromatic odour.

9. REGISTRATION NUMBERS

Sandoz Co-Amoxyclav 625 Disp Tablet: 41/20.1.2/0102

Sandoz Co-Amoxyclav 1000 Disp Tablet: 41/20.1.2/0103

10.NAME AND ADDRESS OF REGISTRATION HOLDER

Sandoz SA (Pty) Ltd1

Magwa Crescent West

Waterfall City

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2090

11.DATE OF PUBLICATION

Date of registration: 20 June 2013

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