PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

PROPRIETARY NAMES, STRENGTH AND PHARMACEUTICAL FORM:

SANDOZ CO-AMOXYCLAV 375 (film-coated tablets)

SANDOZ CO-AMOXYCLAV 625 (film-coated tablets)

SANDOZ CO-AMOXYCLAV 1000 (film-coated tablets)

Read all of this leaflet carefully before you start taking SANDOZ CO-AMOXYCLAV 375, 625 or 1000 film-coated tablets.

- 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 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 CONTAINS:

The active substances are amoxicillin trihydrate and potassium clavulanate.

Each Sandoz Co-Amoxyclav 375 film-coated tablet contains amoxicillin trihydrate equivalent to amoxicillin 250 mg and potassium clavulanate equivalent to clavulanic acid 125 mg.

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

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

The other ingredients:

Sandoz Co-Amoxyclav 375 and 625 film-coated tablets: Croscarmellose sodium, ethylcellulose aqueous dispersion (ethyl cellulose, sodium lauryl sulphate, cetyl alcohol), hypromellose, magnesium stearate, microcrystalline cellulose, povidone (K 25), talc, titanium dioxide and triethyl citrate.

***Sandoz Co-Amoxyclav 1000 film-coated tablets*:** Colloidal silicone dioxide, croscarmellose sodium, ethylcellulose aqueous dispersion, hypromellose, magnesium stearate, microcrystalline cellulose, povidone (K 25), talc, titanium dioxide and triethyl citrate.

Sugar free.

2. WHAT SANDOZ CO-AMOXYCLAV IS USED FOR:

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

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

3. BEFORE YOU TAKE SANDOZ CO-AMOXYCLAV:

Do not take SANDOZ CO-AMOXYCLAV:

- If you are hypersensitive (allergic) to penicillins or to cephalosporins or any of the other ingredients of SANDOZ CO-AMOXYCLAV. If you are allergic to cephalosporin antibiotic, such as cephalexin and cefuroxime, you may also be allergic to SANDOZ CO-AMOXYCLAV antibiotics.
- 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.

Take special care with SANDOZ CO-AMOXYCLAV:

Before taking SANDOZ CO-AMOXYCLAV, 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.

- 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.
- If you develop diarrhoea during or after treatment with SANDOZ CO-AMOXYCLAV.
- If you are going for any blood tests, you must tell your doctor that you are taking SANDOZ CO-AMOXYCLAV.
- If you are breastfeeding your infant.

Taking SANDOZ CO-AMOXYCLAV with food or drink:

You may take SANDOZ CO-AMOXYCLAV 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, please consult your doctor, pharmacist or other health care professional for advice before taking SANDOZ CO-AMOXYCLAV.

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

Amoxicillin and clavulanic acid are excreted into breast milk. If you are breastfeeding your baby while taking SANDOZ CO-AMOXYCLAV, 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.

Driving and using machinery:

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

Using other medicines with SANDOZ CO-AMOXYCLAV:

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

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

Taking SANDOZ CO-AMOXYCLAV 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 amoxicillin.

Probenecid (a medicine used to treat gout) may increase the amount of the active substance, amoxicillin.

SANDOZ CO-AMOXYCLAV 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; 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.

4. HOW TO USE SANDOZ CO-AMOXYCLAV:

Do not share medicines prescribed for you with any other person.
Always take SANDOZ CO-AMOXYCLAV 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 will last. Do not stop

treatment early because the infection might come back and it will be even more difficult to treat.
If you have the impression that the effect of SANDOZ CO-AMOXYCLAV is too strong or too weak, talk to your doctor or pharmacist.

Swallow the tablets whole with a glass of water at the start of a meal or slightly before.

The usual adult dose is one SANDOZ CO-AMOXYCLAV 375 film-coated tablet every 8 hours at the start of a meal.

SANDOZ CO-AMOXYCLAV 625 and 1000 film-coated tablets are reserved for more severe infections and infections of the respiratory tract.

If your doctor prescribed SANDOZ CO-AMOXYCLAV 625, the usual dose is one tablet every 8 hours at the start of a meal.

If your doctor prescribed SANDOZ CO-AMOXYCLAV 1000, the usual dose is one tablet every 12 hours at the start of a meal.

If you have mild impairment of your kidney function, your doctor does not need to reduce the dosage. However, if you have moderate or severe kidney impairment, your doctor should reduce the SANDOZ CO-AMOXYCLAV 375 and 625 dosages to one tablet every 12 hours (moderate impairment) or half a tablet every 12 hours (severe impairment).

If you have moderate or severe kidney impairment, you should not use SANDOZ CO-AMOXYCLAV 1000.

If you take more SANDOZ CO-AMOXYCLAV 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:

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

If any of the following happens, stop taking SANDOZ CO-AMOXYCLAV 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 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 signs of toxic epidermal necrolysis.
- Severe condition of the skin that may affect the mouth and other parts of the body 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-centred marks. Those affected may have fever, sore throat, headache and/or diarrhoea signs of erythema multiforme.

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

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to SANDOZ CO-AMOXYCLAV. 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 includes 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, 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 FILM-COATED TABLETS:

- Store at or below 25 ºC. Protect from light and moisture.
- **STORE ALL MEDICINES OUT OF REACH OF CHILDREN.**
- Do not use the tablets after the expiry date printed on the carton and blister.
- 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:

Sandoz Co-Amoxyclav 375: 15, 100, 300 and 500 film-coated tablets in aluminium foil blisters.

Sandoz Co-Amoxyclav 625: 15, 100, 300 or 500 film-coated tablets in aluminium foil blisters.

Sandoz Co-Amoxyclav 1000: 10 film-coated tablets in aluminium foil blisters.

8. IDENTIFICATION OF SANDOZ CO-AMOXYCLAV :

Sandoz Co-Amoxyclav 375: Off-white, oblong, biconvex, film-coated tablet, scored on both sides.

Sandoz Co-Amoxyclav 625: Off-white, oval, biconvex, film-coated tablet, scored on both sides.

Sandoz Co-Amoxyclav 1000: White to light yellow, oblong, biconvex, film-coated tablet, scored on both sides.

9. REGISTRATION NUMBERS:

SANDOZ CO-AMOXYCLAV 375: 35/20.1.2/0318

SANDOZ CO-AMOXYCLAV 625: 34/20.1.2/0275

SANDOZ CO-AMOXYCLAV 1000: 36/20.1.2/0180

10. NAME AND ADDRESS OF REGISTRATION HOLDER:

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11. DATE OF PUBLICATION:

Dates of registration:

SANDOZ CO-AMOXYCLAV 375: 22 May 2002

SANDOZ CO-AMOXYCLAV 625: 20 May 2002

SANDOZ CO-AMOXYCLAV 1000: 28 May 2004

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