PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

CURAM 625 (film-coated tablets)

CURAM 1000 (film-coated tablets)

Read all of this leaflet carefully before you start taking CURAM 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.
- CURAM 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 CURAM CONTAINS:

The active substances are amoxicillin trihydrate and potassium clavulanate.

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

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

The other ingredients:

Curam 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.

Curam 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 CURAM IS USED FOR:

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

CURAM is used in the treatment of infections caused by sensitive organisms.

3. BEFORE YOU TAKE CURAM:

Do not take CURAM:

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

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

Taking CURAM with food or drink:

You may take CURAM 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 CURAM.

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

You should not breastfeed your baby if you are taking CURAM tablets.

Amoxicillin and clavulanic acid are excreted into breast milk. If you are breastfeeding your baby while taking CURAM, 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 this medicine affects your ability to concentrate.

Using other medicines with CURAM:

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

CURAM may reduce the efficacy of your oral contraceptives, making it less reliable.

Taking CURAM 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.

CURAM 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 CURAM; 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 CURAM.

4. HOW TO TAKE CURAM:

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

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

If your doctor prescribed CURAM 625 film-coated tablets, the usual dose is one tablet every 8 hours at the start of a meal.

If your doctor prescribed CURAM 1000 film-coated tablets, 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 CURAM 625 film-coated tablet 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 CURAM 1000 film-coated tablets.

If you take more CURAM 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 CURAM:

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:

CURAM film-coated tablets can have side effects.

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

If any of the following happens, stop taking CURAM 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 Steven-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 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-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 CURAM. 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 infection 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, 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 CURAM:

- Store at or below 25ºC. Protect from light and moisture.
- **KEEP 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 CURAM:

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

Curam 1000: 10 film-coated tablets in aluminium foil blisters.

8. IDENTIFICATION OF CURAM:

Curam 625**:** off-white, oval, biconvex, film-coated tablet, scored on both sides.

Curam 1000: white to pale yellow, oblong, film-coated tablet, scored on both sides.

9. REGISTRATION NUMBERS:

CURAM 625: 34/20.1.2/0378

CURAM 1000: 36/20.1.2/0181

10. NAME AND BUSINESS ADDRESS OF THE HOLDER OF CERTIFICATE OF REGISTRATION:

Sandoz SA (Pty) Ltd[1]

72 Steel Road

Spartan

Kempton Park

1619

South Africa

11. DATE OF PUBLICATION:

Date of registration:

Curam 625 : 09 October 2001

Curam 1000: 02 July 2004

Date of most recent approval of patient information leaflet: 22 August 2019

[1] Company Reg No 1990/001979/07