

#### amoxicillin/clavulanic acid

#### Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist. - This medicine has been prescribed for you only. Do not pass it on
- to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

#### What is in this leaflet

- 1. What Curam is and what it is used for
- 2. What you need to know before you take Curam
- 3. How to take Curam
- 4. Possible side effects
- 5. How to store Curam
- 6. Contents of the pack and other information

### 1. What Curam® is and what it is used for

Curam is an 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) stops this from happening.

Curam is used in adults and children to treat the following infections: Middle ear and sinus infections.

- Respiratory tract infections.
- · Urinary tract infections.
- Skin and soft tissue infections including dental infections.
- Bone and joint infections.

### What you need to know before you take Curam® Do not take Curam:

- If you are allergic to amoxicillin, clavulanic acid, penicillin or any of the other ingredients of this medicine (listed in section 6). If you have ever had a severe allergic reaction to any other antibiotic.
- This can include a skin rash or swelling of the face or throat. • If you have ever had liver problems or jaundice (yellowing of the
- skin) when taking an antibiotic.

Do not take Curam if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Curam.

### Warnings and precautions

Talk to your doctor or pharmacist before taking this medicine if you: · Have glandular fever.

- · Are being treated for liver or kidney problems.
- Are not passing water regularly.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Curam. In some cases, your doctor may investigate the type of bacteria that is

causing your infection. Depending on the results, you may be given a different strength of Curam or a different medicine. Conditions you need to look out for

### Curam can make some existing conditions worse, or cause serious

side effects. These include allergic reactions, convulsions (fits) and inflammation of the large intestine. You must look out for certain symptoms while you are taking Curam, to reduce the risk of any problems. See 'Conditions you need to look out for' in Section 4.

## Blood and urine tests

If you are having blood tests (such as red blood cell status tests or liver function tests) or urine tests (for glucose), let the doctor or nurse know that you are taking Curam. This is because Curam can affect the results of these types of tests.

#### Other medicines and Curam Tell your doctor or pharmacist if you are taking, have recently taken

or might take any other medicines. If you are taking allopurinol (used for gout) with Curam, it may be

more likely that you'll have an allergic skin reaction.

If you are taking probenecid (used for gout), concomitant use of probenecid may reduce the excretion of amoxicillin and is not recommended.

If medicines to help stop blood clots (such as warfarin) are taken with Curam then extra blood tests may be needed. Methotrexate (used to treat cancer and severe psoriasis), penicillins

xcretion of methotrexate causing a potential increase in side effects. Curam may affect how mycophenolate mofetil (a medicine used to

prevent the rejection of transplanted organs) works. Pregnancy, breast-feeding and fertility: If you are pregnant or breast-feeding, think you may be pregnant or

#### are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines: Curam can have side effects and the symptoms may make you unfit to

# Don't drive or operate machinery unless you are feeling well.

Curam contains sodium

This medicine contains less than 1 mmol (23 mg) sodium per film-coated tablet, that is to say essentially sodium-free.

# 3. How to take Curam®

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist, if you are not sure.

#### Adults and children weighing 40 kg and over Usual dose – 1 tablet two times a day • Higher dose - 1 tablet three times a day

- Children weighing less than 40 kg
- Children aged 6 years or less should preferably be treated with Curam oral suspension or sachets. Ask your doctor or pharmacist for advice when giving Curam tablets

to children weighing less than 40 kg. The tablets are not suitable for children weighing less than 25 kg.

Patients with kidney and liver problems • If you have kidney problems the dose might be changed. A different strength or a different medicine may be chosen by your doctor. If you have liver problems you may have more frequent blood tests

# to check how your liver is working.

- How to take Curam Swallow the tablets whole with a glass of water with a meal
- Tablets can be broken along the score line to make them easier to swallow. You must take both pieces of the tablets at the same time. • Space the doses evenly during the day, at least 4 hours apart. Do
- not take 2 doses in 1 hour. • Do not take Curam for more than 2 weeks. If you still feel unwell you should go back to see the doctor.

If you take more Curam than you should If you take too much Curam, signs might include an upset stomach (feeling sick, being sick or diarrhoea) or convulsions. Talk to your doctor as soon as possible. Take the medicine carton or bottle to

#### If you forget to take Curam If you forget to take a dose, take it as soon as you remember. You should

not take the next dose too soon, but wait about 4 hours before taking the next dose. Do not take a double dose to make up for a forgotten dose. If you stop taking Curam Keep taking Curam until the treatment is finished, even if you feel

bacteria survive they can cause the infection to come back If you have any further questions on the use of this medicine, ask your

better. You need every dose to help fight the infection. If some

# doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not

### everybody gets them. Conditions you need to look out for

# Allergic reactions:

- Inflammation of blood vessels (vasculitis) which may be visible as red or purple raised spots on the skin, but can affect other parts of Fever, joint pain, swollen glands in the neck, armpit or groin
- Swelling, sometimes of the face or throat (angioedema), causing difficulty in breathing
- taking Curam.

• Chest pain in the context of allergic reactions, which may be a symptom of allergy triggered cardiac infarction (Kounis syndrome) Contact a doctor immediately if you get any of these symptoms. Stop

Inflammation of large intestine Inflammation of the large intestine, causing watery diarrhoea usually

with blood and mucus, stomach pain and/or fever. Acute inflammation of the pancreas (acute pancreatitis) If you have severe and on-going pain in the stomach area this could be a sign of acute pancreatitis.

#### Drug-induced enterocolitis syndrome (DIES):

DIES has been reported mainly in children receiving amoxicillin/clavulanate. It is a certain kind of allergic reaction with the leading symptom of repetitive vomiting (1-4 hours after drug administration). Further symptoms could comprise abdominal pain, lethargy, diarrhoea and low blood pressure.

Contact your doctor as soon as possible for advice if you get these symptoms.

Very common side effects (may affect more than 1 in 10 people) • Diarrhoea (in adults).

Common side effects (may affect up to 1 in 10 people)

- Thrush (candida a yeast infection of the vagina, mouth or skin folds) Feeling sick (nausea), especially when taking high doses. If affected take Curam with a meal
- Vomitina
- Diarrhoea (in children).

### Uncommon side effects (may affect up to 1 in 100 people)

- Skin rash, itching
- Raised itchy rash (hives)
- Indigestion
- Dizziness Headache.
- Uncommon side effects that may show up in your blood tests:

edge - erythema multiforme)

their exact frequency is unknown.

Rare side effects (may affect up to 1 in 1000 people) Skin rash, which may blister, and looks like small targets (central

If you notice any of these symptoms contact a doctor urgently.

Increase in some substances (enzymes) produced by the liver

dark spots surrounded by a paler area, with a dark ring around the

Rare side effects that may show up in your blood tests: Low number of cells involved in blood clotting · Low number of white blood cells

Frequency not known (frequency cannot be estimated from the

- available data) Other side effects have occurred in a very small number of people but
- Allergic reactions (see above) Inflammation of the large intestine (see above)
- spinal cord (aseptic meningitis) Serious skin reactions: A widespread rash with blisters and peeling skin, particularly around

· Inflammation of the protective membranes surround the brain and

- the mouth, nose eyes and genitals (Stevens-Johnson syndrome), and a more severe form, causing extensive peeling of the skin (more than 30% of the body surface - toxic epidermal necrolysis)
- Widespread red skin rash with small pus-containing blisters (bullous exfoliative dermatitis) A red, scaly rash with bumps under the skin and blisters (exanthe-
- mous pustulosis) Flu-like symptoms with a rash, fever, swollen glands, and abnormal blood test results (including increased white blood cells (eosino-philia) and liver enzymes) (Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS))
  - Rash with blisters arranged in a circle with central crusting or like a string of pearls (linear IgA disease)
- Crystals in urine leading to acute kidney injury

#### Contact a doctor immediately if you get any of these symptoms. Inflammation of the liver (hepatitis)

- Jaundice, caused by increases in the blood of bilirubin (a
- substance produced in the liver) which may make your skin and whites of the eyes appear yellow Inflammation of tubes in the kidney Blood takes longer to clot

Convulsions (in people taking high doses of Curam or who have

kidney problems) · Black tongue which looks hairy

Hyperactivity

Side effects that may show up in your blood or urine tests: Severe reduction in the number of white blood cells

- Low number of red blood cells (haemolytic anaemia)
- Reporting of side effects

# If you get any side effects, talk to your doctor of pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

By reporting side effects you can help provide more information on the safety of this medicine. How to store Curam®

### Keep this medicine out of the sight and reach of children. Do not use this medicine after the expiry date which is stated on the label

and carton after EXP. The expiry date refers to the last day of that month. Do not store above 25°C. Store in the original package.

waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

Do not throw away any medicines via wastewater or household

### 6. Contents of the pack and other information What Curam contains

The active substances are amoxicillin and clavulanic acid. Each

- film-coated tablet contains 875 mg amoxicillin and 125 mg The other ingredients are: Tablet core: Colloidal anhydrous silica, magnesium stearate (E572),
- talc, povidone, croscarmellose sodium, cellulose microcrystalline. Tablet coat: Triethyl citrate, ethylcellulose, sodium lauryl sulfate, cethyl

alcohol, hypromellose, talc, titanium dioxide (E171). What Curam looks like and contents of the pack The film-coated tablets are oblong, white to pale yellow, scored on

### The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

Content of the pack: Aluminum blisters (Alu/Alu blisters) consisting of an aluminum foil with PVC coating.

#### Pack sizes: Single packs of 6, 8, 10, 12, 14, 15, 16, 20 and 100 film-coated tablets Hospital packs of 40, 50, 100 and 500 film-coated tablets.

both sides.

Not all pack sizes may be marketed. Marketing Authorisation Holder and Manufacturer

This leaflet was last revised in April 2023 Advice/medical education

Sandoz GmbH, Kundl, Austria

#### Sometimes an infection caused by bacteria does not respond to a course of an antibiotic. One of the commonest reasons for this to

could stop the antibiotic working.

occur is because the bacteria causing the infection are resistant to the antibiotic that is being taken. This means that they can survive and even multiply despite the antibiotic.

Antibiotics are used to treat infections caused by bacteria. They

have no effect against infections caused by viruses.

Using antibiotics carefully can help to reduce the chance of bacteria becoming resistant to them. When your doctor prescribes a course of an antibiotic it is intended to treat only your current illness. Paying attention to the following advice will help prevent the emergence of resistant bacteria that

at the right times and for the right number of days. Read the instructions on the label and if you do not understand anything ask your doctor or pharmacist to explain. 2. You should not take an antibiotic unless it has been prescribed specifically for you and you should use it only to treat the

1. It is very important that you take the antibiotic at the right dose,

yours. 4. You should not give antibiotics that were prescribed for you to other people. 5. If you have any antibiotic left over when you have taken the

This is a medicament • A medicament is a product which affects your health, and its

# consumption contrary to instructions is dangerous for you.

- Follow strictly the doctor's prescription, the method of use and the instruction of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risk& • Do not by yourself interrupt the period of treatment prescribed.

Union of Arab Pharmacists

Keep this medicine out of the reach of children. Council of Arab Health Ministers

Bacteria can become resistant to antibiotics for many reasons.

course as directed by your doctor you should take the remainder to a pharmacy for appropriate disposal. Curam® and SANDOZ ANDOZ ANDOZ are registered trademarks of Novartis.

• Do not repeat the same prescription without consulting your