

CURAM[®] POWDER FOR ORAL SUSPENSION

Consumer Medication Information Leaflet (RiMUP)

(Amoxicillin & Clavulanic Acid 125/31.25 mg/5 ml and Amoxicillin & Clavulanic Acid 250/62.5 mg/ 5ml)

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What CURAM is used for

CURAM is used to treat infections such as middle ear and sinus infections, respiratory tract infections, urinary tract infections, skin and soft tissue infections including dental infections, bone and joint infections.

How CURAM works

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 by bacteria). The other active component (clavulanic acid) stops this from happening.

Before you use CURAM

- When you must not use it
- If you are allergic (hypersensitive) to amoxicillin, clavulanic acid, penicillin or any of the other ingredients of Curam
- If you have ever had a severe allergic (hypersensitive) reaction to any other antibiotic. This can include a skin rash or swelling of the face or neck
- If you have ever had liver problems or jaundice (yellowing of the skin) when taking an antibiotic

Pregnancy and breast-feeding

Curam should not be used while breastfeeding.

If you are pregnant, or you think you might be pregnant, ask your doctor for advice before taking any medicine. Use should be avoided during pregnancy unless the benefit outweighs the risk.

If you are not sure, talk to your doctor or pharmacist before taking Curam.

- Before you start use it

Check with your doctor or pharmacist before taking this medicine if you:

- any allergic conditions
- fits/ convulsions
- severe and persistent diarrhea
- are being treated for liver or kidney problems
- liver problems

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.

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.

- Taking other medicines

Please tell your doctor or pharmacist if you are taking, or have recently taken, any other medicine. This includes medicines that can be bought without a prescription.

Inform your doctor if you are taking:

- oral anticoagulants (medicines to help stop blood clots such as warfarin)
- methotrexate (a medicine used to treat cancer or rheumatic diseases)
- probenecid (used for gout)
- allopurinol (used for gout) with Curam, it may be more likely that they will have an allergic skin reaction
- mycophenolate

How to use CURAM

- How much to use

Always take Curam exactly as your doctor has told you. You should check with your doctor or pharmacist, if you are not sure.

Children 7 to 12 years: 10 ml Curam 156.25 mg/5 ml suspension three times a day or 5 ml Curam 312.5 mg/5 ml suspension three times a day.

Children 2 to 7 years: 5 ml Curam 156.25 mg/5 ml suspension three times a day

Children 9 months to 2 years: 2.5 ml Curam 156.25 mg/5 ml suspension three times a day

Patients with kidney and liver problems

If you have kidney problems the dose might be reduced depending on the severity of your kidney problem.

If you have liver problems, you may have more frequent blood tests to check how your liver is working.

- How to take Curam

Curam is for oral use.

Administer with a meal to minimise potential gastrointestinal intolerance.

- **After opening of the screw cap, ensure that the bottom cap seal is tightly attached to the bottle rim. Do not use if not intact.**
- **In case of any signs of leakage (e.g. powder outside the bottle), do not use this bottle.**
- **Do not use this medicine if lumps of powder are visible in the bottle before reconstitution.**
- **Do not use the reconstituted suspension if the colour is not off-white.**
- Fill the bottle with drinking water to just below the ring-mark and shake well at once. Then add water exactly to the ring-mark and shake vigorously again.
- Shake the bottle well before every withdrawal.
- Give it with meal.

- When to use it

Always take this medicine exactly as your doctor told you. Please ask your doctor or pharmacist if you are not sure.

- How long to use it

Keep taking Curam until the

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treatment is finished, even if you feel better. You need every dose to help fight the infection. If some bacteria survive they can cause the infection to come back.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

Do not take Curam for more than 2 weeks. If you still feel unwell you should go back to see the doctor.

- If you forget to use it

It is important to use your medicine every day. However, if you forget to use one or more doses, take it as soon as you remember and then go on as prescribed. Do not take double dose.

- If you use too much (overdose)

If you take too much Curam, signs might include an upset stomach (feeling sick, being sick or diarrhea) or convulsions. Talk to your doctor as soon as possible.

Take the medicine to show the doctor.

While you are using CURAM

- Things you must do

- Take your medicine exactly as your doctor has told you.
- Tell all the doctors, dentists and pharmacists treating you that you are taking Curam.
- Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

- Do not stop taking the medicine unless advised by your doctor.
- Do not take any new medicines without consulting your doctor.
- Do not give Curam to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Driving and using machines

Effects on ability to drive or operate machinery are not known. However, undesirable effects may occur (e.g. allergic reactions, dizziness, convulsions), which may influence the ability to drive and use machines.

Side effects

Like all medicines, Curam can cause side effects, although not everybody gets them.

Curam may cause severe allergy and serious skin reactions.

Stop using Curam and seek medical assistance immediately if you experience any of the following symptoms:

- skin reddening, blisters, rash, fever, sore throat or eye irritation

Stop taking Curam and contact your doctor immediately if you experience any of the following:

- Serious allergic reactions such as Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS). DRESS appears initially as flu-like symptoms with a rash on the face and then with an extended rash, high temperature and enlarged lymph nodes.

Common side effects

- Thrush (*candida* - a yeast infection of the vagina, mouth or skin folds)
- Diarrhoea, feeling sick (nausea) and vomiting

Uncommon side effects

- Dizziness, headache
- Indigestion
- Increase in some substances (*enzymes*) produced by the liver
- Skin rash, itching
- Raised itchy rash (*hives*)

Rare side effects

- Low number of cells involved in blood clotting
- Low number of white blood cells
- Skin rash, which may blister

Other side effects

Other side effects have occurred in a very small number of people but their exact frequency is unknown.

- Allergic reactions (see above)
- Inflammation of the large intestine
- Serious skin reactions: a widespread rash with blisters and peeling skin

- Inflammation of tubes in the kidney
- Crystals in urine

If you get side effects, tell your doctor or pharmacist if any of the side effects become severe or troublesome, or if you notice any side effects not listed in this leaflet.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my (Consumers → Reporting → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)).

Storage and disposal of CURAM

- Storage

Keep out of the reach and sight of children.

Do not use this medicine after the expiry date which is stated on the carton.

Powder for oral suspension: Store below 30°C, protect from light and moisture.

Reconstituted suspension should be stored in a refrigerator (2-8°C) and used within 7 days.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product description

- What it looks like

Off-white powder.

After reconstitution, the ready-for-use suspension is off-white suspension.

- Ingredients

Active ingredients

Curam Powder for Oral Suspension 125/31.25 mg/5 ml

Each 5 ml reconstituted suspension contain 125 mg amoxicillin and 31.25 mg clavulanic acid.

Curam Powder for Oral Suspension 250/62.5 mg/5 ml

Each 5 ml reconstituted suspension

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contain 250 mg amoxicillin and
62.5 mg clavulanic acid.

Inactive ingredients

Citric acid, trisodium citrate,
aspartame, talc, guar, silicon dioxide,
lemon flavouring, peach-apricot
flavouring, orange flavouring.

MAL number

**Curam 125/31.25 mg/5 ml powder
for oral suspension:**

MAL05072020ASZ

**Curam 250/62.5 mg/5 ml powder
for oral suspension:**

MAL05072028ASZ

Manufacturer and product registration holder

Manufacturer

Sandoz GmbH
Biochemiestr. 10
A-6250 Kundl, Austria

Product Registration Holder

Sandoz Products Malaysia Sdn. Bhd.
3A-2 & 3A-3, Level 3A, Menara
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