

CURAM®

amoxicillin and clavulanic acid Powder for injection

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about Curam injection.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. In deciding to give you Curam, your doctor has weighed the risks of you taking Curam against the benefits it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with this medicine.

You may need to read it again.

WHAT CURAM IS USED FOR

This product contains two active ingredients. One of these is a penicillin called amoxicillin and the other is clavulanic acid.

Curam injection belongs to the penicillin group of antibiotics.

This product is used to treat a wide range of infections caused by bacteria. These infections may affect the respiratory tract (bronchitis, pneumonia, tonsillitis, sinusitis), genito-urinary tract (cystitis, urethritis, pyelonephritis, gonorrhoea), gastrointestinal tract (peritonitis, intra-abdominal sepsis) the ears (otitis media) and the skin. This product can also be used to prevent infections in major surgical procedures.

Amoxicillin/ clavulanic acid injection works by killing the bacteria that cause these infections.

This medicine will not work against infections caused by viruses such as colds or the flu.

Your doctor may have prescribed this medicine for another reason.

Ask your doctor or pharmacist if you have any questions about why this medicine has been prescribed for you.

BEFORE YOU TAKE IT

When you must not use Curam

1. **Do not use Curam if you are allergic to penicillins and cephalosporins or clavulanic acid.**
2. **Do not use Curam if you have a previous history of amoxicillin/ clavulanic acid associated jaundice / hepatic dysfunction.**
3. **You have had an allergic reaction to cephalosporin antibiotics. You may have an increased chance of being allergic to Curam if you are allergic to cephalosporins.**
4. **The packaging is torn or shows signs of tampering.**
5. **The expiry date (EXP) printed on the pack has passed. If you use this medicine after the expiry date has passed, it may not work as well.**

Talk to your doctor if you are unsure whether you have any of the conditions listed above.

Do not use Curam if the packaging is torn or shows signs of tampering.

Do not use it to treat any other complaint unless your doctor says it is safe. Do not give this medicine to anyone else.

Before you are given Curam

You must tell your doctor if:

1. **You have any type of allergic reaction to penicillin, amoxicillin or cephalosporin antibiotics. You may have an increased chance of being allergic to Curam if you are allergic to cephalosporins.**
2. **You have any allergies to any other medicines or any other substances, such as foods, preservatives or dyes.**
3. **You have any other medical conditions, including:**
 - asthma, hayfever or hives
 - kidney problems
 - glandular fever (infectious mononucleosis)
4. **Tell your doctor if you are pregnant or intend to become pregnant. Your doctor will discuss the possible risks and benefits of using Curam during pregnancy.**
5. **You are breast-feeding or plan to breast-feed. Your doctor will discuss the possible risks and benefits of taking / using Curam while breast-feeding.**

Tell your doctor if you have or have had any medical conditions, especially either of the following:

- Reduced kidney function
- On controlled potassium intake

If you have not told your doctor about any of the above, tell them before you use this medicine.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food store.

Some medicines may interfere with Curam. These include:

- allopurinol and probenecid, drugs used to treat high levels of uric acid in the blood such as gout and stone formations
- The contraceptive pill. As with other antibiotics, you may need to use extra birth control methods eg. condoms.
- Other antibiotics such as tetracyclines, erythromycin, chloramphenicol and gentamicin.
- Anticoagulants (used to prevent blood clots) such as warfarin.
- Due to risk of disulfiram (Antabuse) like reaction in some patients treated with beta-lactam antibiotics, the ingestion of alcohol should be avoided during and for several days after treatment with Curam.

These medicines may be affected by Curam, or they may affect how well it works. You may need different medicines.

Your doctor will advise you.

Your doctor may have more information on medicines to be careful with or to avoid while taking Curam.

You need to tell your doctor if you are using any other medicines.

If you are unsure whether you are taking one of the drugs that may interact with Curam, ask your doctor or pharmacist.

Your doctor or pharmacist can tell you what to do if you are taking any of such medicines.

If you have not told your doctor about any of these things, tell them before you take Curam.

HOW CURAM IS GIVEN

How Curam is given

It must only be given by a doctor or nurse. Your doctor will decide what dose and how long you will receive it. This depends on your infection and other factors, such as your weight.

Amoxicillin/ clavulanic acid may be administered either by slow intravenous injection over a period of 3 to 4 min directly into a vein or via a drip tube or by infusion over 30 to 40 min. This medicine is not suitable for intramuscular administration.

Children aged less than 3 months should be administered amoxicillin/ clavulanic acid by infusion only.

Curam injection should be reconstituted with water for injection before use.

Treatment with amoxicillin/ clavulanic acid may be initiated by the use of an intravenous preparation and completed with an appropriate oral presentation as will be considered appropriate for you.

WHILE YOU ARE TAKING CURAM

Things you must do

If the symptoms of your infection do not improve within a few days, or if they become worse, tell your doctor.

If you develop itching with swelling or skin rash or difficulty breathing while you are receiving Curam, do not have any more and tell your doctor immediately.

If you get severe diarrhoea, tell your doctor, pharmacist or nurse immediately. Do this even if it occurs several weeks after Curam has been stopped.

If you become pregnant while you are receiving Curam, tell your doctor.

If you are about to start taking any new medicine, tell your doctor and pharmacist that you are receiving Curam.

If you have to have any blood or urine tests, tell your doctor you are being given Curam. It may affect the results of some blood and urine tests.

Tell all the doctors, dentists and pharmacists who are treating you that you are being treated with Curam.

Avoid alcohol during and for several days after treatment.

SIDE EFFECTS

Tell your doctor or pharmacist as soon as possible if you do not feel well while using Curam.

All medicines can have side effects.

Check with your doctor as soon as possible if you have any problems while being treated with Curam, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

Like other medicines, Curam can cause some side effects. If they occur, most are likely to be minor and temporary. However, some may be serious and need medical attention.

Tell your doctor if you notice any of the following and they worry you:

- Headache
- Nausea
- Vomiting
- Diarrhoea
- Indigestion

- Dizziness
- Soreness of the mouth or tongue
- Overgrowth of yeast infections (thrush).

Tell your doctor immediately if you notice any of the following:

- Wheezing, swelling of the lips/mouth, difficulty in breathing, hayfever, lumpy rash (hives) or fainting. These could be symptoms of an allergic reaction.
- pain around the site of injection
- unusual bleeding or bruising
- yellowing of the skin or eyes
- dark urine or pale stools
- Difficulty or pain on passing urine.
- Severe diarrhoea.

Some people may get other side effects while being treated with Curam.

Ask your doctor or pharmacist if you don't understand anything in this list.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

Do not take any diarrhoea medicine without first checking with your doctor.

HOW IS CURAM STORED

Curam should be stored below 25°C.

It should be used immediately after reconstitution.

If storage is required, it may be stored at 5°C.

- 3 hours at 20-25°C: Ringers Solution, Hartmann's Solution; Ringer-Lactate Solution, Potassium Chloride and Sodium Intravenous Infusion B.P
- 4 hours at 20-25°C: Sodium Lactate Intravenous Infusion, Sodium Chloride Intravenous Infusion B.P. 0.9% (w/v), Water sterile for injection
- 8 hours at 2-8°C: Water sterile for injection, Sodium Chloride Intravenous Infusion B.P. 0.9% (w/v)

amoxicillin and potassium clavulanate equivalent to 200 mg clavulanic acid.

Ingredients

Active Ingredient:

Amoxicillin sodium
Potassium clavulanate

Supplier

Sandoz Pty Ltd
54 Waterloo Road
Macquarie Park, NSW 2113
Australia
Tel: 1800 726 369

This leaflet was prepared in August 2018

Australian Register Numbers:

500 mg/1000 mg powder for injection vial: AUST R 289317

1000 mg/200 mg powder for injection vial: AUST R 289316

2000 mg/200 mg powder for injection vial: AUST R 289315

AFTER TAKING CURAM

Tell your doctor immediately if you notice any of the following side effects, particularly if they occur several weeks after stopping treatment with Curam:

- severe stomach cramps or abdominal cramps
- watery and severe diarrhoea, which may also be bloody
- fever, in combination with one or both of the above.

These are rare but serious side effects. You may have a rare but serious condition affecting your bowel which may need urgent medical attention.

PRODUCT DESCRIPTION

What it looks like

Curam 500 mg/100 mg Powder for Injection: sterile white to off-white powder providing amoxicillin sodium equivalent to 500 mg amoxicillin and potassium clavulanate equivalent to 100 mg clavulanic acid.

Curam 1000 mg/200 mg Powder for Injection: sterile white to off-white powder providing amoxicillin sodium equivalent to 1000 mg amoxicillin and potassium clavulanate equivalent to 200 mg clavulanic acid.

Curam 2000 mg/200 mg Powder for Injection: sterile white to off-white powder providing amoxicillin sodium equivalent to 2000 mg