

# CURAM<sup>®</sup> Powder for injection

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

### 1. Why am I using Curam?

Curam contains two active ingredients. One of these is a penicillin called amoxicillin and the other is clavulanic acid. Curam is used to treat a wide range of infections caused by bacteria.

For more information, see Section [1. Why am I using Curam?](#) in the full CMI.

### 2. What should I know before I use Curam?

Do not use if you have ever had an allergic reaction to penicillins and cephalosporins or clavulanic acid, or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I use Curam?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with Curam and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I use Curam?

- Curam 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.

More instructions can be found in Section [4. How do I use Curam?](#) in the full CMI.

### 5. What should I know while using Curam?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are using Curam.</li><li>• If the symptoms of your infection do not improve within a few days, or if they become worse, tell your doctor.</li><li>• 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.</li></ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"><li>• Tell your doctor if you drink alcohol.</li><li>• Avoid alcohol during and for several days after treatment.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Curam should be stored below 25°C.</li><li>• It should be used immediately after reconstitution.</li><li>• If storage is required, it may be stored at 5°C.</li><li>• 3 hours at 20-25°C: Ringers Solution, Hartmann's Solution; Ringer-Lactate Solution, Potassium Chloride and Sodium Intravenous Infusion B.P</li><li>• 4 hours at 20-25°C: Sodium Lactate Intravenous Infusion, Sodium Chloride Intravenous Infusion B.P. 0.9% (w/v), Water sterile for injection</li><li>• 8 hours at 2-8°C: Water sterile for injection, Sodium Chloride Intravenous Infusion B.P. 0.9% (w/v)</li></ul>

For more information, see Section [5. What should I know while using Curam?](#) in the full CMI.

### 6. Are there any side effects?

Side effects include headache, nausea, vomiting, diarrhoea, indigestion, dizziness, soreness of the mouth or tongue, and overgrowth of yeast infections(thrush). 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.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# CURAM<sup>®</sup> Powder for injection

Active ingredient(s): amoxicillin and clavulanic acid

## Consumer Medicine Information (CMI)

This leaflet provides important information about using Curam. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Curam.**

Where to find information in this leaflet:

- [1. Why am I using Curam?](#)
- [2. What should I know before I use Curam?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Curam?](#)
- [5. What should I know while using Curam?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I using Curam?

Curam 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.

Curam 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.**

## 2. What should I know before I use Curam?

### Warnings

Do not use Curam if:

- you are allergic to penicillins and cephalosporins or clavulanic acid.
- you have a previous history of amoxicillin/ clavulanic acid associated jaundice / hepatic dysfunction.
- 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.

- the packaging is torn or shows signs of tampering.
- 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.**

Check with your doctor if 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.
- you have any allergies to any other medicines or any other substances, such as foods, preservatives or dyes.
- you have any other medical conditions, including:
  - asthma, hayfever or hives
  - kidney problems
  - glandular fever (infectious mononucleosis)
- you have or have had any medical conditions, especially either of the following:
  - reduced kidney function
  - on controlled potassium intake

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

### Pregnancy and breastfeeding

Check with 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.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Your doctor will discuss the possible risks and benefits of taking / using Curam while breastfeeding.

## 3. What if I am taking other medicines?

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

**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
- methotrexate, a medicine used to treat cancer and severe psoriasis

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.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Curam.**

## 4. How do I use Curam?

### How Curam is given

- 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.

### When to take Curam

- Curam 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.

### If you use too much Curam

As Curam will most likely be given to you in hospital or under the supervision of your doctor, it is very unlikely that you will receive an overdose.

If you think that you have been given too much Curam, you may need urgent medical attention.

**You should immediately:**

- phone the Australian Poisons Information Centre (**by calling 13 11 26**), or the New Zealand National Poisons Information Centre (**by calling 0800 POISONS or 0800 764 766**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

## 5. What should I know while using Curam?

### Things you should do

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

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.

**Call your doctor straight away 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.
- get severe diarrhoea. Do this even if it occurs several weeks after Curam has been stopped.

Remind any doctor, dentist or pharmacist you visit that you are being treated with Curam.

### Drinking alcohol

**Tell your doctor if you drink alcohol.**

Avoid alcohol during and for several days after treatment.

### Looking after your medicine

- **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)

### Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

### Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> <li>Headache</li> <li>Nausea</li> <li>Vomiting</li> <li>Diarrhoea</li> <li>Indigestion</li> <li>Dizziness</li> <li>Soreness of the mouth or tongue</li> <li>Overgrowth of yeast infections(thrush).</li> </ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

### Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> <li>Wheezing, swelling of the lips/mouth, difficulty in breathing, hayfever, lumpy rash (hives) or fainting. These could be symptoms of an allergic reaction</li> <li>pain around the site of injection</li> <li>unusual bleeding or bruising</li> <li>yellowing of the skin or eyes</li> <li>dark urine or pale stools</li> <li>Difficulty or pain on passing urine.</li> <li>Severe diarrhoea.</li> <li>chest pain in the context of allergic reactions, which may be a symptom of allergy triggered cardiac infarction (Kounis syndrome)</li> <li>severe and on-going pain in the stomach area, which could be a sign of acute pancreatitis</li> <li>repetitive vomiting (1-4 hours after drug administration), abdominal pain, lethargy, diarrhoea and low blood pressure (drug-induced enterocolitis syndrome)</li> <li>crystals in urine leading to acute kidney injury</li> <li>rash with blisters arranged in a circle with central crusting or like a string of pearls (linear IgA disease)</li> </ul>	<p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p>

<ul style="list-style-type: none"> <li>inflammation of the membranes that surround the brain and spinal cord (aseptic meningitis)</li> </ul>	
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**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.

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

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

### Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems) or to Medsafe at [pophealth.my.site.com/carmreportnz/s/](http://pophealth.my.site.com/carmreportnz/s/). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

This medicine is only available with a doctor's prescription.

### What Curam contains

<b>Active ingredient (main ingredient)</b>	Amoxicillin sodium Potassium clavulanate
<b>Other ingredients (inactive ingredients)</b>	N/A

**Do not take this medicine if you are allergic to any of these ingredients.**

## What Curam looks like

Curam 500/100 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 (Aust R 289317).

Curam 1000/200 Powder for Injection: sterile white to offwhite powder providing amoxicillin sodium equivalent to 1000 mg amoxicillin and potassium clavulanate equivalent to 200 mg clavulanic acid (Aust R 289316).

Curam 2000/200 Powder for Injection: sterile white to offwhite powder providing amoxicillin sodium equivalent to 2000 mg amoxicillin and potassium clavulanate equivalent to 200 mg clavulanic acid (Aust R 289315).

## Who distributes Curam

### Australia

Sandoz Pty Ltd  
100 Pacific Highway  
North Sydney, NSW 2060  
Australia  
Tel 1800 726 369

### New Zealand

Sandoz New Zealand Limited  
12 Madden Street  
Auckland 1010  
New Zealand  
Tel: 0800 726 369

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