Curam® Powder for Oral Suspension

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 the active ingredient potassium clavulanate/amoxicillin trihydrate. Curam is used for the short term treatment of infections in different parts of the body 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 Curam 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?

• The usual dose may depend on the type of infection and how severe it is 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?

Things you should do	 Remind any doctor, dentist, pharmacist or nurse you visit that you are using Curam. Keep taking this medicine for the full time of treatment, even if you begin to feel better after a few days. 	
Things you should not do	 Do not stop taking Curam because you are feeling better, unless advised by your doctor. Do not give Curam to anyone else, even if they have the same condition as you. Do not use Curam to treat any other complaints unless your doctor tells you to 	
Driving or using machines	Curam does not usually affect the ability to drive or operate machinery.	
Looking after your medicine	 Keep the bottle tightly closed between doses. Curam should be used within 7 days of being made up at the pharmacy. Store in a refrigerator - the temperature should be between 2°C to 8°C. 	

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

6. Are there any side effects?

Tell your doctor if you notice any of the common side effects of oral thrush or vaginal thrush and serious side effects in particular nausea, chest pain, yellowing of skin, fever, rash or burning skin, abdominal cramps, diarrhoea etc.

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® Powder for Oral Suspension

Active ingredient(s): 125/31.25: Once reconstituted with 95 mL of water, each 5 mL contains amoxicillin trihydrate/potassium clavulanate equivalent to 125 mg amoxicillin/31.25 mg clavulanic acid

250/62.5: Once reconstituted with 90 mL of water, each 5 mL contains amoxicillin trihydrate/potassium clavulanate equivalent to 250 mg amoxicillin/62.5 mg 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 the active ingredient potassium clavulanate/amoxicillin trihydrate equivalent to 31.25 mg clavulanic acid/125 mg amoxicillin.

Potassium clavulanate/amoxicillin trihydrate equivalent to 62.5 mg clavulanic acid/250 mg amoxicillin.

Curam is an antibiotic that belongs to a group of medicines called penicillins. These antibiotics work by killing the bacteria that are causing your infection.

Curam will not work against infections caused by viruses such as colds or the flu. This medicine is available only with a doctor's prescription.

Curam is an antibiotic used for the short-term treatment of infections in different parts of the body caused by bacteria.

2. What should I know before I use Curam?

Warnings

Do not use Curam if:

- you are allergic to Curam, other penicililns or any of the ingredients listed at the end of this leaflet.
 Some of the symptoms of an allergic reaction may include skin rash, itching, or difficulty breathing.
- you have had an allergic reaction to cephalosporins (another type of antibiotic). You may have an increased chance of being allergic to Curam if you are allergic to cephalosporins.

- you have had liver disease or yellowing of the skin and/or eyes, also called jaundice when you have taken amoxicillin/clavulanic acid (or Curam) before.
- the packaging is torn or shows signs of tampering, or the product has changed colour.
- the expiry date (EXP) printed on the pack has passed.
 If you take this medicine after the expiry date has passed, it may not work.

Check with your doctor if you:

- have any allergies to any other medicines or any other substances, such as foods, preservatives or dyes
- have phenylketonuria as Curam contains aspartame
- have glandular fever. If Curam is used with glandular fever a rash may develop
- have liver disease
- your kidneys do not work as well as they should
- are taking warfarin (CoumadinTM, MarevanTM) or other medicines used to prevent blood clots
- are passing less urine
- are taking any other medicines or herbal remedies.

Curam is not addictive.

Curam does not usually affect the ability to drive or operate machinery.

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 <u>6</u>. <u>Are there any side effects?</u>

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

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

Your doctor will discuss with you the possible risks and benefits of using Curam during pregnancy.

Your doctor will discuss with you the possible risks and benefits of using Curam during 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 and Curam may interfere with each other. These include:

- Probenecid, Allopurinol (used to treat gout).
- Birth control pills ("the pill", oral contraceptives). Birth control pills may not work as well in preventing pregnancy when Curam is used. Talk to your doctor about the need for an additional method of contraception while taking Curam.
- Warfarin (CoumadinTM, MarevanTM) or other medicines used to prevent blood clots
- Mycophenolate mofetil, (used to suppress your immune system).
- Methotrexate (used to treat conditions such as cancer and severe psoriasis)

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

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 much to take / use

- Take Curam as directed by your doctor or pharmacist.
- The usual dose of Curam is one dose given three times a day. If the dose is for a child, it may vary depending on your child's weight.
- Ask your doctor or pharmacist if you are unsure of the correct dose for your child. They will tell you exactly how much to give. Follow the instructions they give you.
- If you give the wrong dose, Curam may not work as well and your condition may not improve.

When to take / use Curam

- Space the doses as evenly as possible throughout the day. If you are taking Curam three times a day, give a dose about every eight hours.
- Curam should be given immediately before or with the first mouthful of food. Curam works best when given this way. It may also help to prevent stomach upsets. However, this medicine will still work if given without food.

How to take / use Curam

- Shake the bottle well and accurately measure the dose with a medicine measure.
- Shaking the bottle and using a medicine measure will make sure that you get the correct dose. A medicine measure is included with the product. Make sure the whole dose is swallowed each time.

How to long to take / use Curam

- Continue giving this medicine until the course is finished or for as long as your doctor advises. Do not stop giving this medicine just because you feel better as the infection can return.
- Do not stop giving Curam, or change the dose without first checking with your doctor.

If you forget to take / use Curam

Curam should be used regularly at the same time each day.

Give the missed dose as soon as you remember, and continue to give it as you would normally.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not give two doses within four hours of each other.

Do not take a double dose to make up for the dose you missed.

- If you are not sure whether to skip the dose, talk to your doctor or pharmacist.
- It is important to take Curam as prescribed so it will work properly. If you have trouble remembering to take the doses, ask your pharmacists for hints.

If you use too much Curam

If you think that you have used too much Curam, you may get diarrhoea and nausea and need urgent medical attention.

You should immediately:

- phone 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

- Tell your doctor if the symptoms of your infection do not improve within a few days, or if they become
- If you are about to start taking any new medicine, tell your doctor and pharmacist that you are taking Curam.
- If you have to have any blood tests tell your doctor you are taking Curam. Curam may affect the results of some blood tests.
- Drink plenty of water, juice or other fluids (e.g. 6-8 glasses per day).
- Tell any doctor, dentist and pharmacist treating you that you are taking Curam.

Call your doctor straight away if you:

- develop itching with swelling or skin rash or difficulty breathing while you are taking Curam. Do not take any more and contact your doctor immediately.
- get severe diarrhoea or stomach cramps tell your doctor, pharmacist or nurse immediately. Do this even if it occurs several weeks after Curam has been stopped. Diarrhoea or stomach cramps may mean that you have a serious condition affecting your bowel. You may need urgent medical care. Do not take any diarrhoea medicine without first checking with your doctor.

- get a sore white mouth or tongue while taking or soon after stopping Curam, tell your doctor. Also tell your doctor if you get vaginal itching or discharge. This may mean you have a fungal infection called thrush.
- become pregnant while you are taking Curam.

Remind any doctor, dentist, pharmacist or nurse you visit that you are using Curam.

Things you should not do

- Do not stop taking Curam because you are feeling better, unless advised by your doctor.
- If you do not complete the full course prescribed by your doctor, all the bacteria causing your infection may not be killed. These bacteria may continue to grow and multiply so that your infection may not clear completely, or it may return.
- Do not give Curam to anyone else, even if they have the same condition as you.
- Do not use Curam to treat any other complaints unless your doctor tells you to.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Curam affects you.

Curam does not usually affect the ability to drive or operate machinery.

Looking after your medicine

- Keep the bottle tightly closed between doses.
- Curam should be used within 7 days of being made up at the pharmacy.
- Store in a refrigerator the temperature should be between 2°C to 8°C.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

When to discard your medicine

If your doctor advises you to stop taking Curam or the medicine has passed its expiry date, ask your pharmacist what to do with any that is left over.

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
 Infections and infestations: oral thrush - white, furry, sore tongue and mouth. change in colour of teeth (rare) this usually just brushes off using a toothbrush. change in colour of the tongue with a furry appearance (very rare) 	Speak to your doctor if you have any of these less serious side effects and they worry you.
Gastrointestinal disorders: diarrhoea, nausea, vomiting or indigestion.	
Renal and urinary disorders: • vaginal thrush - sore and itchy vagina and/or discharge.	

Serious side effects

Serious side effects	What to do
 Signs of a serious allergic reaction called drug-induced enterocolitis syndrome; symptoms start with repetitive vomiting (1 to 4 hours after administration), and further symptoms can include stomach pain, abnormal drowsiness, diarrhoea, low blood pressure and can progress to shock. Raised itchy rash Inflammation of blood vessels (vasculitis) which may be visible as red or purple raised spots on the skin, but can affect other parts of the body Fever, joint pain, swollen glands in the neck, armpit or groin Swelling, sometimes of the face or mouth (angiodema), which may cause difficulty in swallowing or breathing Collapse Chest pain which can be a sign of a potentially serious allergic reaction called Kounis syndrome. 	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.

Liver problems

 itching, yellowing of the skin and eyes (jaundice), chest pain, and dark coloured urine. This may be a sign of liver disease. It may occur while taking Curam or even a few weeks after stopping Curam.

Immune system disorders

 symptoms such as fever, severe chills, sore throat or mouth ulcers which can be a sign of lack of white blood cells.

Skin and subcutaneous disorders

- flu like symptoms with a rash, fever, swollen glands, and abnormal blood test results (including increased white blood cells (eosinophilia) and liver enzymes) (Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS)).
- Skin rash, which may blister and looks like small targets (central dark spots surrounded by a paler area, with a dark ring around the edge-erythema multiforme) string of pearls (linear IgA disease)— even if it starts a few days or more after starting Curam.
- itchy or burning skin even if it starts a few days or more after starting Curam.

Nervous system disorders

 seizures (very rare), dizziness, headache.

Other side effects reported with Curam include:

- 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.
- swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing
- chest pain.

Gastrointestinal disorders

 severe abdominal cramps or stomach cramps, water diarrhoea which may also be bloody, fever in combination of 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.

If any of the following happen, stop taking Curam and tell your doctor immediately or go to the accident and Emergency department at your nearest hospital.

If any of the following happen, stop taking Curam and tell your doctor immediately or go to the accident and Emergency department at your nearest hospital.

one or both of the above. These are rare but serious side effects. You may have a serious condition affecting your bowel. Therefore, you 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 Medsafe at www.medsafe.govt.nz/safety/report-a-problem.asp. 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

Active ingredient (main ingredient)	Amoxicillin trihydrate Potassium clavulanate
Other ingredients (inactive ingredients)	lemon flavouring orange flavouring peach apricot flavouring citric acid anhydrous sodium citrate anhydrous aspartame talc-purified guar gum silicon dioxide
Potential allergens	This medicine does not contain sucrose, gluten, tartrazine or any other azo dyes

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

What Curam looks like

Curam powder for suspension is available as an off-white powder, and when reconstituted with water it becomes an off-white suspension.

Available in 100 mL bottles with a measuring syringe included.

Curam, Powder for oral suspension, 125mg,31.25mg/5mL: (TT50-6268/1)

Curam, Powder for oral suspension, 250mg, 62.5mg/5mL: (TT50-6268/1a)

Who distributes Curam

Sandoz New Zealand Limited 12 Madden Street Auckland 1010 New Zealand

Tel: 0800 726 369

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