

CURAM[®] DUO 400/57

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 is my child using Curam Duo 400/57?

Curam Duo 400/57 contains the active ingredients amoxicillin and clavulanic acid. Curam Duo 400/57 is used for the short term treatment of a wide range of infections caused by bacteria. These infections may affect the chest (e.g. bronchitis or pneumonia), bladder (e.g. cystitis), sinuses (e.g. sinusitis), the ears (e.g. otitis media) or the skin.

For more information, see Section [1. Why is my child using Curam Duo 400/57?](#) in the full CMI.

2. What should I know before giving my child Curam Duo 400/57?

Do not use if you have ever had an allergic reaction to amoxicillin, clavulanic acid, other penicillin based antibiotics or similar antibiotics (such as cephalosporins) 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 giving my child Curam Duo 400/57?](#) in the full CMI.

3. What if my child is taking other medicines?

Some medicines may interfere with Curam Duo 400/57 and affect how it works.

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

4. How do I give Curam Duo 400/57?

- Always use this medicine exactly as the doctor or pharmacist has told you to.
- The usual dose of this medicine is one dose taken twice a day. The dose may vary depending on your child's weight.

More instructions can be found in Section [4. How do I give Curam Duo 400/57?](#) in the full CMI.

5. What should I know while giving Curam Duo 400/57?

Things you should do	<ul style="list-style-type: none">• Tell your doctor, if, for any reason, your child has not taken this medicine exactly as directed.• Remind any doctor, dentist or pharmacist your child visits that your child is using Curam Duo 400/57.• If your child is about to be started on any new medicines, tell the doctor or pharmacist that your child is taking Curam Duo 400/57.
Things you should not do	<ul style="list-style-type: none">• Do not use this medicine to treat any other complaints unless your child's doctor says to.• Do not give this medicine to anyone else, even if their symptoms seem similar to your child's.
Driving or using machines	<ul style="list-style-type: none">• Be careful before you drive or use any machines or tools until you know how Curam Duo 400/57 affects you.
Looking after your medicine	<ul style="list-style-type: none">• Once made up, the suspension should be stored in a refrigerator (2°C to 8°C). Do not freeze.• Dispose of any unused suspension 7 days after first making up.

For more information, see Section [5. What should I know while giving Curam Duo 400/57?](#) in the full CMI.

6. Are there any side effects?

Side effects include diarrhoea, thrust, nausea, vomiting, dizziness, headache, indigestion, skin rash, and itching. Serious side effects include severe allergic reactions, skin reactions, yellowing of skin/eyes (liver problems), and severe diarrhoea.

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[®] DUO 400/57

Active ingredient(s): amoxicillin trihydrate & potassium clavulanate

Consumer Medicine Information (CMI)

This leaflet provides important information about using Curam Duo 400/57. **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 Duo 400/57.**

Where to find information in this leaflet:

- [1. Why is my child using Curam Duo 400/57?](#)
- [2. What should I know before giving my child Curam Duo 400/57?](#)
- [3. What if my child is taking other medicines?](#)
- [4. How do I give Curam Duo 400/57?](#)
- [5. What should I know while giving Curam Duo 400/57?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why is my child using Curam Duo 400/57?

Curam Duo 400/57 contains two active ingredients. One of these is a penicillin called amoxicillin and the other is clavulanic acid. Curam Duo 400/57 belongs to the penicillin group of antibiotics.

Curam Duo 400/57 is used for the short term treatment of a wide range of infections caused by bacteria. These infections may affect the chest (e.g. bronchitis or pneumonia), bladder (e.g. cystitis), sinuses (e.g. sinusitis), the ears (e.g. otitis media) or the skin.

Curam Duo 400/57 works by killing the bacteria that cause these infections.

Curam Duo 400/57 is used for the treatment of the infections listed. However, the doctor may prescribe these medicines for another use. If you want more information, ask the doctor.

There is no evidence that Curam Duo 400/57 is addictive.

2. What should I know before giving my child Curam Duo 400/57?

Warnings

Do not give Curam Duo 400/57 if:

- your child is allergic to amoxicillin, clavulanic acid, other penicillin based antibiotics or similar antibiotics (such as cephalosporins) or any of the ingredients listed at the end of this leaflet. If your child has ever had an allergic reaction (such as a rash) when taking an antibiotic you should tell the doctor before any Curam Duo 400/57 is given.

Always check the ingredients to make sure you can use this medicine.

- your child has previously experienced liver problems or jaundice when taking an antibiotic or any other medicines.
- the expiry date (EXP) printed on the pack has passed.
- the packaging is torn or shows signs of tampering.

This medicine is for the person named by the doctor. Do not give this medicine to anyone else.

Check with your doctor if your child:

- has ever had an allergic reaction (such as a rash) to any antibiotics or medicines in the past
- is allergic to foods, dyes, preservatives or any other medicines.
- has glandular fever (mononucleosis) or a blood disorder.
- has liver or kidney problems. *The dosage of Curam Duo 400/57 may need to be changed or your child may need to be given an alternative medicine.*
- Is not urinating regularly or not able to drink very much.
- has phenylketonuria. **Curam Duo 400/57 contains aspartame.**
- is required to have urine glucose (sugar) test. This medicine may affect the results of these tests.

Curam Duo 400/57 can make some existing conditions worse, or cause serious side effects, such as severe allergic reactions, serious skin reactions, chest pain, repetitive vomiting within 1 to 4 hours of Curam Duo 400/57 administration, serious liver problems or severe diarrhoea or inflammation of the large intestines (pseudomembranous colitis). You must look out for certain symptoms while giving this medicine to your child to help reduce the risk of any problems.

During treatment, your child 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

If your child is pregnant or intend to become pregnant, do not take this medicine without checking with your doctor.

Before taking this medicine, talk to your doctor if your child is breastfeeding or intend to breastfeed.

Your doctor will consider the risks and benefits of this treatment.

3. What if my child is taking other medicines?

Tell your doctor or pharmacist if you are giving your child any other medicines, including any medicines, vitamins or

supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

In particular, tell the doctor if your child is taking any of the following:

- warfarin or other anticoagulants used to prevent blood clots
- mycophenolate
- medicines used to treat gout (e.g. probenecid or allopurinol)
- other antibiotics
- methotrexate (a medicine used to treat cancer or rheumatic diseases)
- contraceptive pill. As with other antibiotics, your child may need to use extra birth control methods (e.g. condoms) while taking Curam Duo 400/57.

These may affect how Curam Duo 400/57 works or make it more likely that your child will have side effects.

Some medicines may interfere with Curam Duo 400/57 and affect how it works.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements your child is taking and if these affect Curam Duo 400/57.

4. How do I give Curam Duo 400/57?

Always follow the directions given to you by the doctor or pharmacist. Their directions may differ from the information contained in this leaflet.

Please read the direction label carefully. If you have any concerns about how to give this medicine, talk to the doctor or pharmacist.

How much to give

- Give this medicine as directed by the doctor or pharmacist
- The usual dose of this medicine is one dose taken twice a day. The dose 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 Duo 400/57 may not work as well and your child's problem may not improve.

How to give Curam Duo 400/57

- **The suspension will be prepared by your pharmacist who checks the seal prior to reconstitution. Shake the bottle well and accurately measure the dose with a measuring spoon. Your pharmacist will explain how many millilitres of suspension will be needed to receive the correct dose.**
- **Do not use the reconstituted suspension if the colour is not off-white.**
- Shaking the bottle and using a measuring spoon will make sure that you get the correct dose. A measuring spoon is included with the product. Make sure the whole dose is swallowed each time.

When to give Curam Duo 400/57

- **Give this medicine at about the same time each day.**
- Giving this medicine at about the same time each day will have the best effect. It will also help you remember when to give it.
- Curam Duo 400/57 should be given immediately before or with the first mouthful of food. Curam Duo 400/57 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 long to give Curam Duo 400/57

- 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 your child feels better as the infection can return.
- **Do not stop giving Curam Duo 400/57, or change the dose without first checking with your doctor.**

If you forget to give Curam Duo 400/57

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 give that next dose when you are meant to.

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

This may increase the chance of your child getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to give the medicine, ask your pharmacist for some hints.

If your child takes too much Curam Duo 400/57

If you think that your child has used too much Curam Duo 400/57, your child may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), 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 giving Curam Duo 400/57?

Things you should do

Tell your doctor if, for any reason, your child has not taken this medicine exactly as directed. Otherwise, your doctor may think that it was not effective and change your child's treatment unnecessarily.

If your child is about to be started on any new medicines, tell the doctor or pharmacist that your child is taking Curam Duo 400/57.

Call your doctor straight away if your child:

- develops itching, swelling or a skin rash while taking Curam Duo 400/57, do not give any more this medicine.
- develops severe diarrhoea either while taking this medicine or within several weeks after treatment. Do not give any medication to stop the diarrhoea (e.g. Lomotil® or Imodium®).

Remind any doctor, dentist or pharmacist your child visits that your child is using Curam Duo 400/57.

Things you should not do

- Do not give this medicine to anyone else, even if their symptoms seem similar to your child's.
- Do not use this medicine to treat any other complaints unless your child's doctor says to.

Driving or using machines

Be careful before your child drives or uses any machines or tools until you know how Curam Duo 400/57 affects your child.

Looking after your medicine

- Do not keep the bottle of Curam Duo 400/57 longer than 7 days after it has been made up and store in the fridge between 2°C and 8°C. Do not freeze.

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 out of the sight and reach of children.

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
Fungal Infection related: <ul style="list-style-type: none"> • soreness of the mouth or tongue, abnormal taste, white or furry tongue (oral thrush) or 	Speak to your doctor if your child has any of these less serious side

itching of the vagina and/or discharge (vaginal thrush)	effects and they worry you.
Gut or Gastrointestinal related: <ul style="list-style-type: none"> • diarrhoea (several loose bowel movements per day), indigestion, pain in the stomach, feeling sick or being sick • nausea, vomiting 	
General disorders: <ul style="list-style-type: none"> • dizziness • headache • tiredness 	
Others: <ul style="list-style-type: none"> • hot flushes • unusually active (hyperactive). 	

Serious side effects

Serious side effects	What to do
Gut or Gastrointestinal related: <ul style="list-style-type: none"> • severe diarrhoea 	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.
Allergy related: <ul style="list-style-type: none"> • itching, rash • signs of allergic reaction including wheezing, fainting, swelling of the lips/mouth, difficulty in breathing or swallowing, hayfever, lumpy rash (hives), joint discomfort or swelling, swollen lymph glands, nausea, chest pain, stomach pain, abnormal drowsiness, low blood pressure, repetitive vomiting or fever. 	
Liver related: <ul style="list-style-type: none"> • yellowing of the skin or eyes • dark urine or pale stools 	
Others: <ul style="list-style-type: none"> • unusual bleeding or bruising • collapse • aseptic meningitis • a red rash commonly seen on both sides of buttocks, upper inner thighs, armpits, neck 	

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 your child experiences, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. 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 giving any of your child's medicines.

7. Product details

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

What Curam Duo 400/57 contains

Active ingredient (main ingredient)	<ul style="list-style-type: none">• amoxicillin trihydrate• potassium clavulanate
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">• lemon flavouring 15.02.0598• orange flavouring 55301 AP0551• peach apricot flavouring 26F22• citric acid• sodium citrate• aspartame• purified talc• guar gum• silicon dioxide.

Curam Duo 400/57 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 Duo 400/57 looks like

Curam Duo 400/57 powder for suspension – available as an off-white powder, and when reconstituted with water it becomes an off-white suspension.

Available in 120 mL bottles containing 60 mL suspension, with a measuring spoon included. (Aust R 147109).

Who distributes Curam Duo 400/57

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

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