

Curam® Duo 400/57

amoxicillin (as trihydrate) and clavulanic acid (as potassium clavulanate) 400 mg+57 mg/5 mL powder for oral suspension

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Curam Duo 400/57.

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. Your doctor has weighed the risks of your child taking this medicine against the benefits they expect it will have.

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

Keep this leaflet with the medicine.

You may need to read it again.

What Curam Duo 400/57 is used for

This medicine is used to treat a wide range of infections caused by bacteria. These infections may affect:

- the chest (bronchitis or pneumonia)
- the bladder (cystitis)
- the sinuses (sinusitis)
- the ears (otitis media)
- or the skin.

It works by killing the bacteria that cause these infections.

This medicine contains the active ingredients amoxicillin (as trihydrate) and clavulanic acid (as potassium clavulanate). Amoxicillin belongs to the penicillin group of antibiotics. Clavulanic acid is used

to increase the effectiveness of amoxicillin against certain types of bacteria.

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

Your doctor may have prescribed it for another reason.

There is no evidence that this medicine is addictive.

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

Before you give Curam Duo 400/57

When you must not give it

Do not give this medicine if your child has an allergy to:

- amoxicillin trihydrate or potassium clavulanate, the active ingredients, or to any of the other ingredients listed at the end of this leaflet under Product description
- any other similar medicines (such as penicillins, cephalosporins, carbapenems, monobactams or any other types of antibiotics).

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

If your child has ever had an allergic reaction when taking an

antibiotic, you should tell the doctor before this medicine is given.

Do not give this medicine if your child has previously experienced liver problems after taking Curam 400/57 or any other medicines.

Do not give this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether your child should be given this medicine, talk to your doctor.

Before your child starts taking it

Tell your doctor if your child has allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if your child has or has had any of the following medical conditions:

- an allergic reaction (such as a rash) to any antibiotics in the past
- glandular fever (mononucleosis) or a blood disorder
- 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.
- phenylketonuria.

Curam Duo 400/57 contains aspartame.

Tell your doctor if your child's urine has to be tested for sugar. Curam Duo 400/57 may affect the results of these tests.

If you have not told your doctor about any of the above, tell him/her before you give Curam Duo 400/57 to your child.

Taking other medicines

Tell your doctor or pharmacist if your child is taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and Curam Duo 400/57 may interfere with each other. These include:

- probenecid
- allopurinol
- warfarin or other medicines used to prevent blood clots
- mycophenolate
- methotrexate, a medicine used to treat arthritis and some types of cancer
- other antibiotics. These may interfere with the actions of Curam Duo 400/57.

These medicines may be affected by Curam Duo 400/57 or may affect how well it works. Your child may need different amounts of their medicines, or they may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to give Curam Duo 400/57 to your child

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions, ask your doctor or pharmacist for help.

How much to give

Give Curam Duo 400/57 as directed by your doctor or pharmacist.

The usual dose of Curam Duo 400/57 is one dose given twice daily. 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 it

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 it

Give the missed dose as soon as you remember, and continue to give it as you would normally. If it is almost time for the next dose, skip the dose you missed and give the next dose when you are meant to.

Do not give a double dose to make up for the dose that 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 you give too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think that your child or anyone else may have taken too much Curam Duo 400/57. Do this even if there are no signs of discomfort or poisoning.

Your child may need urgent medical attention.

There are unlikely to be any serious problems following an overdose of Curam Duo 400/57.

While you are giving Curam Duo 400/57

Things you must do

If your child is about to be started on any new medicine, remind your doctor and pharmacist that your child is taking Curam Duo 400/57.

Tell any other doctors, dentists, and pharmacists who are treating your child that he/she is taking this medicine.

If your child is about to have any blood tests, tell your doctor that, your child is taking this medicine.

It may interfere with the results of some tests.

Keep all of your doctor's appointments so that your child's progress can be checked.

Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

Tell your doctor if, for any reason, you have not given the medicine exactly as directed.

Otherwise, your doctor may think that it was not working as it should and change your child's treatment unnecessarily.

If your child develops itching, swelling or a skin rash while taking Curam Duo 400/57, do not give any more and tell the doctor immediately.

If your child develops severe diarrhoea either while taking Curam Duo 400/57 or within several weeks after treatment, tell the doctor as soon as possible. Do not give any medication to stop the diarrhoea (e.g. Lomotil® or Imodium®).

Things you must not do

Do not give Curam Duo 400/57 to treat any other complaints unless your doctor tells you to.

Do not give this medicine to anyone else, even if they have the same condition as your child.

Do not stop giving Curam Duo 400/57 or lower the dosage

without checking with your doctor.

Side effects

Tell your doctor or pharmacist as soon as possible if your child does not feel well while taking Curam Duo 400/57.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. Your child may need medical attention if he/she gets some of the side effects.

Do not be alarmed by the following lists of side effects. Your child may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you or your child notices any of the following and they worry you:

- diarrhoea (several loose bowel movements per day), indigestion, pain in the stomach, feeling sick or being sick
- soreness of the mouth or tongue, abnormal taste, hairy tongue
- aseptic meningitis, headache, dizziness, tiredness, hot flushes
- oral thrush (white, furry sore tongue and mouth)
- vaginal thrush (sore and itchy vagina, vaginal discharge)
- unusually active (hyperactive).

The above list includes the more common side effects of your medicine.

Tell your doctor as soon as possible if you or your child notices any of the following:

- itching
- rash
- yellowing of the skin or eyes
- dark urine or pale stools
- severe diarrhoea
- unusual bleeding or bruising.

The above list includes serious side effects that may require medical

attention. Serious side effects are rare.

Stop giving Curam Duo 400/57 if any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- wheezing, swelling of the lips/mouth, difficulty in breathing or swallowing, hayfever, lumpy rash (hives) or fainting joint discomfort or swelling, swollen lymph glands, nausea and vomiting. These could be symptoms of an allergic reaction.

The above list includes very serious side effects. Your child may need urgent medical attention or hospitalisation. These side effects are rare.

Rare events that have been reported with Curam Duo 400/57 include:

- inflammation of the bowel (colitis)
- inflammation of the liver or kidney
- blood disorders
- crystals in the urine (crystalluria).

Tell your doctor or pharmacist if you notice anything else that is making your child feel unwell.

Other side effects not listed above may also occur in some people.

After giving Curam Duo 400/57

Storage

Keep this medicine in the original container.

If you take it out of its original container it may not keep well.

Do not store Curam Duo 400/57 or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Keep it where children cannot reach it.

Keep the bottle in the refrigerator where the temperature stays between 2 and 8°C. Heat can destroy Curam Duo 400/57.

Do not use any suspension left in the bottle 7 days after collecting from the pharmacy or if the expiry has passed.

Disposal

If your doctor tells you to stop giving this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Supplier

Sandoz Pty Ltd
ABN 60 075 449 553
54 Waterloo Road
Macquarie Park, NSW 2113
Australia
Tel: 1800 726 369

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Australian Register Number(s)

400/57 powder for suspension:
AUST R 147109 (bottles).

Product description

What it looks like

Curam Duo 400/57 powder for suspension is 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.

Ingredients

Active ingredients:

Each 5 mL of Curam Duo 400/57 suspension contains 400 mg of amoxicillin (as trihydrate) and 57 mg of clavulanic acid (as potassium clavulanate).

Inactive ingredients:

- lemon flavouring 15.02.0598
- orange flavouring 55301 AP0551
- peach apricot flavouring 26F22
- citric acid
- sodium citrate
- aspartame
- purified talc
- guar gum
- silicon dioxide.

This medicine does not contain sucrose, gluten, tartrazine or any other azo dyes.