Consumer Medicine Information (CMI) summary

The <u>full CMI</u> 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 Duo 500/125?

Curam Duo 500/125 contains the active ingredient potassium clavulanate/amoxicillin trihydrate. Curam Duo 500/125 is used for the short-term treatment of infections in different parts of the body caused by bacteria.

For more information, see Section <u>1. Why am I using Curam Duo 500/125?</u> in the full CMI.

2. What should I know before I use Curam Duo 500/125?

Do not use if you have ever had an allergic reaction to Curam Duo 500/125 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 Duo 500/125? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Curam Duo 500/125 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 Duo 500/125?

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

More instructions can be found in Section <u>4. How do I use Curam Duo 500/125?</u> in the full CMI.

5. What should I know while using Curam Duo 500/125?

Things you should do	 Remind any doctor, dentist, pharmacist or nurse you visit that you are using Curam Duo 500/125. 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 Duo 500/125 because you are feeling better, unless advised by your doctor. Do not give Curam Duo 500/125 to anyone else, even if they have the same condition as you. Do not use Curam Duo 500/125 to treat any other complaints unless your doctor tells you to. 	
Driving or using machines		
Looking after your medicine		

For more information, see Section 5. What should I know while using Curam Duo 500/125? 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 Duo 500/125 tablets

Active ingredient(s): Potassium clavulanate/amoxicillin trihydrate equivalent to 125 mg clavulanic acid/500 mg amoxicillin

Consumer Medicine Information (CMI)

This leaflet provides important information about using Curam Duo 500/125. 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 500/125.

Where to find information in this leaflet:

- 1. Why am I using Curam Duo 500/125?
- 2. What should I know before I use Curam Duo 500/125?
- 3. What if I am taking other medicines?
- 4. How do I use Curam Duo 500/125?
- 5. What should I know while using Curam Duo 500/125?
- 6. Are there any side effects?
- 7. Product details

1. Why am I using Curam Duo 500/125?

Curam Duo 500/125 contains the active ingredient potassium clavulanate/amoxicillin trihydrate equivalent to 125 mg clavulanic acid/500 mg amoxicillin.

Curam Duo 500/125 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 Duo 500/125 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 Duo 500/125 is an antibiotic used for the shortterm treatment of infections in different parts of the body caused by bacteria.

2. What should I know before I use Curam Duo 500/125?

Warnings

Do not use Curam Duo 500/125 if:

 you have an allergy to Curam Duo 500/125, other penicillins 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 Duo 500/125 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 Duo 500/125) 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.

If you are not sure whether you should start taking Curam Duo 500/125, contact your doctor.

Do not give this medicine to anyone else. Your doctor has prescribed it specifically for you and your condition.

Check with your doctor if:

- you have any allergies to any other medicines or any other substances, such as foods, preservatives or dyes
- you have glandular fever.
 If Curam Duo 500/125 is used with glandular fever a rash may develop
- you have liver disease
- your kidneys do not work as well as they should
- you are taking warfarin (Coumadin[™], Marevan[™]) or other medicines used to prevent blood clots
- you are passing less urine
- you are taking any other medicines or herbal remedies.

Curam Duo 500/125 is not addictive.

Curam Duo 500/125 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. 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 Duo 500/125 during pregnancy.

Your doctor will discuss with you the possible risks and benefits of using Curam Duo 500/125 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 may interfere with Curam Duo 500/125 and affect how it works. These include:

- Probenecid, Allopurinol (usually used to treat gout).
- Birth control pills ("the pill", oral contraceptives).
 Birth control pills may not work as well in preventing pregnancy when Curam Duo 500/125 is used. Talk to your doctor about the need for an additional method of contraception while taking Curam Duo 500/125.
- Warfarin (Coumadin[™], Marevan[™]) 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)

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 Duo 500/125.

4. How do I use Curam Duo 500/125?

How much to take

The usual dose for adults and children 40 kg and over is one tablet twice a day or one or two tablets three times a day, depending on the type of infection and how severe it is.

When to take Curam Duo 500/125

- Curam Duo tablets should be taken immediately before or with the first mouthful of food.
- If you take it on an empty stomach, it may cause stomach upset.

How long to take Curam Duo 500/125

- Keep taking this medicine for the full time of treatment, even if you begin to feel better after a few days.
- If you do not complete the full course prescribed by your doctor, the infection may not clear completely, or your symptoms may return.
- Curam Duo 500/125 is not usually used for longer than 14 days without another check-up by the doctor.

If you forget to use Curam Duo 500/125

Curam Duo 500/125 should be taken regularly at the same time each day.

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 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 Duo 500/125 tablets 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 Duo 500/125

If you think that you have used too much Curam Duo 500/125, you may get diarrhoea and nausea and need urgent medical attention.

You should immediately:

- phone the 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 Duo 500/125?

Things you should do

- Tell your doctor if the symptoms of your infection do not improve within a few days, or if they become worse.
- If you are about to start taking any new medicine, tell your doctor and pharmacist that you are taking Curam Duo 500/125.
- If you have to have any blood tests tell your doctor you are taking Curam Duo 500/125. Curam Duo 500/125 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 Duo 500/125.

Call your doctor straight away if you:

- Develop itching with swelling or skin rash or difficulty breathing while you are taking Curam Duo 500/125 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 Duo 500/125 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 Duo 500/125, 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 Duo 500/125

Remind any doctor, dentist, pharmacist or nurse you visit that you are using Curam Duo 500/125.

Things you should not do

 Do not stop taking Curam Duo 500/125 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 Duo 500/125 to anyone else, even if they have the same condition as you.
- Do not use Curam Duo 500/125 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 Duo 500/125 affects you.

Curam Duo 500/125 does not usually affect the ability to drive or operate machinery.

Looking after your medicine

- Keep this medicine in the original container.
 If you take the tablets out of its original container it may not keep well.
- Store in a cool dry place where the temperature stays below 25°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 Duo 500/125 or the medicine has passed its expiry date, ask your pharmacist what to do with any tablets that are 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. 	Speak to your doctor if you have any of these less serious side

•	change in colour of teeth (rare)	effects and
	 this usually just brushes off 	they worry you.
	using a toothbrush.	
•	change in colour of the tongue	
	with a furry appearance (very	
	rare).	
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
	ergic reaction 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	What to do 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.
•	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.	
•	er 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 Duo 500/125 or even a few weeks after stopping Curam Duo 500/125.	
 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, abnormal blood test results (including increased white blood cells (eosinophilia) and liver enzymes) (Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS))
- Symmetrical drug related intertriginous and flexural exanthema (SDRIFE) (baboon syndrome).
- 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 Duo 500/125.
- Itchy or burning skin even if it starts a few days or more after starting Curam Duo 500/125.

Nervous system disorders

• Seizures (very rare), dizziness, headache.

Other side effects reported with Curam Duo 500/125 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 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.

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.

immediately if you notice any of the following side effects, particularly if they occur several weeks after stopping treatment with Curam Duo 500/125.

Tell your doctor

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects via <u>https://pophealth.my.site.com/carmreportnz/s/</u>. 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 Duo 500/125 contains

Active ingredient (main ingredient)	Amoxicillin trihydrate Potassium clavulanate
Other ingredients (inactive ingredients)	Magnesium stearate, purified talc, povidone, croscarmellose sodium, microcrystalline cellulose, triethyl citrate, ethylcellulose, sodium lauryl sulfate, cetyl alcohol, Hypromellose, titanium dioxide.
Potential allergens	Curam Duo 500/125 tablets do 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 500/125 looks like

Curam Duo 500/125 - Off-white, oval, biconvex, filmcoated tablet, scored on both sides.

Available in strip packs or blister packs of 10 tablets.

Who distributes Curam Duo 500/125

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

This leaflet was prepared in March 2024.

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