CURAM® DUO & CURAM® DUO FORTE tablets

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 Duo or Curam Duo Forte?

Curam Duo or Curam Duo Forte tablets contains the active ingredients amoxicillin and potassium clavulanate. Curam Duo or Curam Duo Forte tablets are used for the short term treatment of a wide range of infections caused by bacteria. For more information, see Section 1. Why am I using Curam Duo or Curam Duo Forte? in the full CMI.

2. What should I know before I use Curam Duo or Curam Duo Forte tablets?

Do not use if you have ever had an allergic reaction to amoxicillin trihydrate, potassium clavulanate, penicillin or similar types of 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 I use Curam Duo or Curam Duo Forte tablets? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Curam Duo or Curam Duo Forte tablets 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 or Curam Duo Forte tablets?

Follow the directions given to you by your doctor or pharmacist. Their directions may differ from the information contained in this leaflet. More instructions can be found in Section 4. How do I use Curam Duo or Curam Duo Forte tablets? in the full CMI.

5. What should I know while using Curam Duo or Curam Duo Forte tablets?

| Things you should do | Take Curam Duo or Curam Duo Forte tablets as exactly as your doctor has prescribed. Tell your doctor if, for any reason, you have not taken your medicine exactly as directed. Remind any doctor, dentist or pharmacist you visit that you are using Curam Duo or Curam Duo Forte tablets. Tell your doctor if the symptoms of your infection become worse, or do not improve within a few days of starting Curam Duo or Curam Duo Forte tablets. | |
|-----------------------------|--|--|
| Things you should not do | Do not use to treat any other complaints unless your doctor says to. Do not give this medicine to anyone else, even if their symptoms seem similar to yours. | |
| Driving or using machines | Be careful before your drive or use any machines or tools until you know how Curam Duo or Curam Duo Forte tablets affects you. | |
| Drinking alcohol | Alcohol should be avoided during and for several days after treatment with Curam Duo or Curam Duo tablets. | |
| Looking after your medicine | Keep your tablets in the original pack until it is time to take them. Store it in a cool dry place below 25°C, away from moisture, heat or sunlight. | |

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

6. Are there any side effects?

The most common side effects of Curam Duo and Curam Duo Forte tablets are diarrrhoea, nausea and vomiting.

For more information, including what to do if you have any side effects, see Section <u>6. Are there any side effects?</u> in the full CMI.

CURAM DUO & CURAM DUO FORTE tablets

Active ingredient(s): amoxicillin (as trihydrate) and clavulanic acid (as potassium clavulanate)

Consumer Medicine Information (CMI)

This leaflet provides important information about using Curam Duo or Curam Duo Forte tablets. 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 or Curam Duo Forte tablets.

Where to find information in this leaflet:

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

1. Why am I using Curam Duo or Curam Duo Forte tablets?

Curam Duo or Curam Duo Forte tablets contains two active ingredients. One of these is a penicillin called amoxicillin and the other is clavulanic acid.

Curam Duo or Curam Duo Forte tablets belong to the penicillin group of antibiotics. Curam Duo or Curam Duo Forte tablets works by killing the bacteria that cause these infections. It will not work against infections caused by viruses such as colds or the flu.

Curam Duo or Curam Duo Forte tablets are used for the short term treatment of a wide range of infections in the body caused by bacteria. These infections may affect the chest (bronchitis or pneumonia), bladder (cystitis), sinuses (sinusitis), the ears (otitis media) or the skin.

Your doctor may prescribe Curam Duo or Curam Duo tablets for another use. If you want more information, ask your doctor.

There is no evidence that Curam Duo or Curam Duo Forte tablets are addictive.

2. What should I know before I use Curam Duo or Curam Duo Forte tablets?

Warnings

Do not use Curam Duo or Curam Duo Forte tablets if:

- you are allergic to amoxicillin trihydrate or potassium clavulanate, or similar types of antibiotics (e.g. penicillins (such as cephalosporins), or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
 - Some of the symptoms of an allergic reaction may include skin rash, itching, difficulty in breathing and swelling of the face or tongue.
- you have previously experienced liver problems after taking Curam Duo or Curam Duo tablets or any other medicines.
- the expiry date (EXP) printed on the pack has passed.
- the packaging is torn or show signs of tampering.

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 ever had an allergic reaction (such as a rash) to antibiotics or other substances in the past.
- have allergies to any other medicines, foods, preservatives or dyes.
- have experienced liver problems after taking Curam Duo or Curam Duo tablets or any other medicines
- have any other medical conditions
 - kidney disease
 - o liver disease
 - glandular fever (mononucleosis), leukaemia or blood disorder.

The dosage of Curam Duo or Curam Duo tablets may need to be changed or you may need to be given alternative medicine.

have to test your urine for sugar.

Curam Duo or Curam Duo tablets may affect the results of these tests.

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 the risks and benefits of taking Curam Duo or Curam Duo Forte tablets during pregnancy or while you are breastfeeding. Curam Duo or Curam Duo Forte tablets can pass to your baby from breast milk.

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.

In particular, tell your doctor or pharmacist if you are taking any of the following:

- warfarin or other medicines used to prevent blood clots
- medicines to treat gout (e.g. probenecid or allopurinol)
- contraceptive pill. As with other antibiotics, you may need to use extra birth control methods (e.g. condoms) while taking Curam Duo or Curam Duo Forte tablets
- · other antibiotics
- mycophenolate

Some medicines may interfere with Curam Duo and Curam Duo Forte tablets 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 Duo or Curam Duo Forte tablets.

4. How do I use Curam Duo or Curam Duo Forte tablets?

Follow the directions given to you by your doctor and 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 take this medicine, talk to your doctor or pharmacist.

How much to take

- Swallow the Curam Duo or Curam Duo Forte tablets with a full glass of water or other liquid. Curam Duo Forte tablets tablets can be broken in half, but should not be chewed.
- Curam Duo or Curam Duo Forte tablets should be taken immediately before or with the first mouthful of food. Curam Duo or Curam Duo Forte tablets work best when taken this way. It may also help to prevent stomach upsets. However, Curam Duo or Curam Duo Forte tablets will still work if they are taken without food.
- Space the doses as evenly as possible throughout the day. If you are taking Curam Duo or Curam Duo Forte tablets twice a day, take a dose about every twelve hours.

How long to take it for

- Keep taking Curam Duo or Curam Duo Forte tablets until the course is finished or for as long as your doctor tells you.
- Do not stop taking Curam Duo or Curam Duo Forte tablets just because you feel better as the infection can return.
- Do not stop taking Curam Duo or Curam Duo Forte tablets, or change the dose, without first checking with your doctor.

If you forget to take Curam Duo or Curam Duo Forte tablets

If your next dose is due within six hours, skip the dose you missed and take your next dose at the normal time. Otherwise, take the missed dose as soon as you remember and then go back to taking your tablets as directed by your doctor.

Do not take a double dose to make up for the dose you missed. Taking more than the prescribed dose can increase the chance of unwanted side-effects.

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

If you use too much Curam Duo or Curam Duo Forte tablets

If you think that you have used too much Curam Duo or Curam Duo Forte, you may need urgent medical attention.

Symptoms of overdose include mild to severe nausea, vomiting, cramps and diarrhoea.

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 using Curam Duo or Curam Duo Forte?

Things you should do

- Take Curam Duo or Curam Duo Forte tablets exactly as your doctor has prescribed.
- Tell your doctor if, for any reason, you have not taken your medicine exactly as directed. Otherwise your doctor may think that it was not working as it should and change your treatment unnecessarily.
- Tell your doctor if the symptoms of your infection become worse, or do not improve within a few days of starting Curam Duo or Curam Duo Forte tablets.
- Remind any doctor, dentist or pharmacist you visit that you are using Curam Duo or Curam Duo Forte tablets before starting any other medicines. Some medicines may affect the way other medicines work.

Things you should not do

- Do not take this medicine to treat any other complaint unless your doctor says so.
- Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

Things to be careful of

If you develop severe diarrhoea either when taking Curam Duo or Curam Duo Forte tablets or within several weeks after treatment, tell your doctor as soon as possible. Do not take any medication to stop the diarrhoea (eg. Lomotil® or Imodium®).

Driving or using machines

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

Generally, these tablets do not cause any problems with your ability to drive a car or operate machinery. However, as with many other medicines, it may cause dizziness or tiredness in some people.

Drinking alcohol

Alcohol should be avoided during and for several days after treatment with Curam Duo or Curam Duo Forte tablets. Some people who drink alcohol while taking antibiotics similar to Curam Duo or Curam Duo Forte tablets have experienced adverse effects.

Looking after your medicine

Keep your tablets in the original pack until it is time to take them.

Store it in a cool dry place below 25°C 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.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

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

| Les | s serious side effects | What to do | |
|---------------------------|--|--|--|
| Fungal Infection related: | | Speak to your | |
| • | white, furry, sore tongue and mouth (oral thrush), abnormal taste soreness or itching of the vagina or vaginal discharge (vaginal thrush) | doctor if you have any of these less serious side effects and they worry you. | |
| Gut | Gut or Gastrointestinal related: | | |
| • | diarrhoea (several loose bowel movements per day), indigestion, pain in the stomach, feeling sick or being sick nausea, vomiting | | |
| General disorders: | | | |
| • | dizziness | | |
| • | headache | | |
| • | tiredness | | |
| Oth • • | ners: tooth discolouration hot flushes unusually active (hyperactive). | | |

Serious side effects

| Serious side effects | What to do | | |
|--|------------------------------|--|--|
| Bowel related: | Tell your doctor | | |
| severe stomach cramps | immediately if | | |
| Allergy related: | you notice any of these | | |
| • itching, rash | symptoms | | |
| • Liver related: | during or after | | |
| • yellowing of your skin or eyes | taking Curam Duo or Curam | | |
| (jaundice) | Duo Forte | | |
| dark urine or pale stools | tablets. | | |
| Others: | | | |
| unusual bleeding or bruising | | | |
| Rare events: | | | |
| inflammation of the bowel | | | |
| (colitis) | | | |
| inflammation of the liver (honatitic) | | | |
| (hepatitis)inflammation of the kidney | | | |
| (nephritis) | | | |
| blood disorders | | | |
| crystals in the urine | | | |
| (crystalluria). | | | |
| Brain or head related: | Stop taking | | |
| • fits or seizures | Curam Duo or | | |
| | Curam Duo | | |

Allergic reaction related:

 Wheezing, hives, severe skin reaction, fainting, swelling of limbs, face, lips, mouth or throat, difficulty swallowing or breathing, joint discomfort or swelling, swollen lymph glands, nausea and vomiting or fever. Forte tablets and 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.

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

Remember, you should tell your doctor or pharmacist as soon as possible if any of these, or any other unusual events or problems, occur during or after treatment with Curam Duo or Curam Duo Forte tablets.

This is not a complete list of all possible side-effects. Others may occur in some people and there may be some side-effects not yet known.

Do not be alarmed by this list of possible side-effects. You may not experience any of them.

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. 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 or Curam Duo Forte tablets contains

| Active ingredient (main ingredient) | Curam Duo tablets: amoxicillin 500 mg clavulanic acid 125 mg | |
|-------------------------------------|--|--|
| | Curam Duo Forte tablets: | |
| | amoxicillin 875 mg clavulanic acid125 mg | |
| | S | |
| Other ingredients | magnesium stearate | |
| (inactive ingredients) | purified talc | |
| (, | • povidone | |
| | croscarmellose sodium | |
| | microcrystalline cellulose | |
| | triethyl citrate | |
| | ethylcellulose | |
| | sodium lauryl sulfate | |
| | cetyl alcohol | |

- hypromellose
- titanium dioxide

Curam Duo Forte tablets:

silicon dioxide.

Curam Duo or Curam Duo Forte tablets do not contain sucrose, lactose, gluten, tartrazine or any other azo dyes.

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

What Curam Duo or Curam Duo Forte tablets looks like

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

Strip packs (Aust R 82830).

Blister packs of 10 tablets (AUST R 198108).

Curam Duo Forte 875/125 - White to pale yellow, oblong, biconvex, film-coated tablet, scored on both sides.

Strip packs (Aust R 82829).

Blister packs of 10 tablets (AUST R 198109).

Who distributes Curam Duo or Curam Duo Forte tablets

Sandoz Pty Ltd ABN 60 075 449 553

54 Waterloo Road

Macquarie Park, NSW 2113

Tel: 1800 726 369

This leaflet was revised in June 2023.