AMOXICILLIN/CLAVULANIC ACID VIATRIS 500/125 & AMOXICILLIN/CLAVULANIC ACID VIATRIS 875/125 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 Amoxicillin/Clavulanic Acid Viatris 500/125 or Amoxicillin/Clavulanic Acid Viatris 875/125?

Amoxicillin/Clavulanic Acid Viatris 500/125 or Amoxicillin/Clavulanic Acid Viatris 875/125 tablets contains the active ingredients amoxicillin and clavulanic acid. Amoxicillin/Clavulanic Acid Viatris 500/125 or Amoxicillin/Clavulanic Acid Viatris 875/125 tablets are used for the short term treatment of a wide range of infections. For more information, see Section 1. Why am I using Amoxicillin/Clavulanic Acid Viatris 500/125 or Amoxicillin/Clavulanic Acid Viatris 875/125 tablets? in the full CMI.

2. What should I know before I use Amoxicillin/Clavulanic Acid Viatris 500/125 or Amoxicillin/Clavulanic Acid Viatris 875/125 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 Amoxicillin/Clavulanic Acid Viatris 500/125 or Amoxicillin/Clavulanic Acid Viatris 875/125 tablets? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Amoxicillin/Clavulanic Acid Viatris 500/125 or Amoxicillin/Clavulanic Acid Viatris 875/125 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 Amoxicillin/Clavulanic Acid Viatris 500/125 or Amoxicillin/Clavulanic Acid Viatris 875/125 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 Amoxicillin/Clavulanic Acid Viatris 500/125 or Amoxicillin/Clavulanic Acid Viatris 875/125 tablets? in the full CMI.

5. What should I know while using Amoxicillin/Clavulanic Acid Viatris 500/125 or Amoxicillin/Clavulanic Acid Viatris 875/125 tablets?

Things you should do	 Take Amoxicillin/Clavulanic Acid Viatris 500/125 or Amoxicillin/Clavulanic Acid Viatris 875/125 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 Amoxicillin/Clavulanic Acid Viatris 500/125 or Amoxicillin/Clavulanic Acid Viatris 875/125 tablets. Tell your doctor if the symptoms of your infection become worse, or do not improve within a few days of starting Amoxicillin/Clavulanic Acid Viatris 500/125 or Amoxicillin/Clavulanic Acid Viatris 875/125 tablets.
Things you should not do	 Do not give this medicine to anyone else, even if their symptoms seem similar to yours. Do not use to treat any other complaints unless your doctor says to.
Driving or using machines	Be careful before your drive or use any machines or tools until you know how Amoxicillin/Clavulanic Acid Viatris 500/125 or Amoxicillin/Clavulanic Acid Viatris 875/125 tablets affects you.
Drinking alcohol	 Alcohol should be avoided during and for several days after treatment with Amoxicillin/Clavulanic Acid Viatris 500/125 or Amoxicillin/Clavulanic Acid Viatris 875/125 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 away from moisture, heat or sunlight.

For more information, see Section <u>5. What should I know while using Amoxicillin/Clavulanic Acid Viatris 500/125 or Amoxicillin/Clavulanic Acid Viatris 875/125 tablets?</u> in the full CMI.

6. Are there any side effects?

The most common side effects of Amoxicillin/Clavulanic Acid Viatris 500/125 and Amoxicillin/Clavulanic Acid Viatris 875/125 tablets are diarrhoea, nausea and vomiting.

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.

Amoxicillin/Clavulanic Acid Viatris 500/125 & Amoxicillin/Clavulanic Acid Viatris 875/125 tablets

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

Consumer Medicine Information (CMI)

This leaflet provides important information about using Amoxicillin/Clavulanic Acid Viatris 500/125 or Amoxicillin/Clavulanic Acid Viatris 875/125 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 Amoxicillin/Clavulanic Acid Viatris 500/125 or Amoxicillin/Clavulanic Acid Viatris 875/125 tablets.

Where to find information in this leaflet:

- 1. Why am I using Amoxicillin/Clavulanic Acid Viatris 500/125 or Amoxicillin/Clavulanic Acid Viatris 875/125 tablets?
- 2. What should I know before I use
 Amoxicillin/Clavulanic Acid Viatris 500/125 or
 Amoxicillin/Clavulanic Acid Viatris 875/125 tablets?
- 3. What if I am taking other medicines?
- <u>4. How do I use Amoxicillin/Clavulanic Acid Viatris</u> 500/125 or Amoxicillin/Clavulanic Acid Viatris 875/125 tablets?
- <u>What should I know while using</u>
 <u>Amoxicillin/Clavulanic Acid Viatris 500/125 or</u>
 <u>Amoxicillin/Clavulanic Acid Viatris 875/125 tablets?</u>
- <u>6.</u> <u>Are there any side effects?</u>
- 7. Product details
- Why am I using Amoxicillin/Clavulanic Acid Viatris 500/125 or Amoxicillin/Clavulanic Acid Viatris 875/125 tablets?

Amoxicillin/Clavulanic Acid Viatris 500/125 or Amoxicillin/Clavulanic Acid Viatris 875/125 tablets contains two active ingredients. One of these is a penicillin called amoxicillin and the other is clavulanic acid. Amoxicillin/Clavulanic Acid Viatris 500/125 or Amoxicillin/Clavulanic Acid Viatris 875/125 tablets belong to the penicillin group of antibiotics. Amoxicillin/Clavulanic Acid Viatris 500/125 or Amoxicillin/Clavulanic Acid Viatris 875/125 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.

Amoxicillin/Clavulanic Acid Viatris 500/125 or Amoxicillin/Clavulanic Acid Viatris 875/125 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 Amoxicillin/Clavulanic Acid Viatris 500/125 or Amoxicillin/Clavulanic Acid Viatris

875/125 tablets for another use. If you want more information, ask your doctor.

There is no evidence that Amoxicillin/Clavulanic Acid Viatris 500/125 or Amoxicillin/Clavulanic Acid Viatris 875/125 tablets are addictive.

2. What should I know before I use Amoxicillin/Clavulanic Acid Viatris 500/125 or Amoxicillin/Clavulanic Acid Viatris 875/125 tablets?

Warnings

Do not use Amoxicillin/Clavulanic Acid Viatris 500/125 or Amoxicillin/Clavulanic Acid Viatris 875/125 tablets if:

- you are allergic to amoxicillin trihydrate, potassium clavulanate, penicillin or similar types of antibiotics (such as cephalosporins), 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, difficulty in breathing and swelling of the face or tongue.
- you have previously experienced liver problems after taking Amoxicillin/Clavulanic Acid Viatris 500/125 or Amoxicillin/Clavulanic Acid Viatris 875/125 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.
- are allergic to foods, dyes, preservatives or any other medicines.
- have glandular fever (mononucleosis) or leukaemia.
- have any kidney or liver problems.
- The dosage of Amoxicillin/Clavulanic Acid Viatris 500/125 or Amoxicillin/Clavulanic Acid Viatris 875/125 tablets may need to be changed or you may need to be given an alternative medicine.
- have to test your urine for sugar.
- Amoxicillin/Clavulanic Acid Viatris 500/125 or Amoxicillin/Clavulanic Acid Viatris 875/125 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 Amoxicillin/Clavulanic Acid Viatris 500/125 or Amoxicillin/Clavulanic Acid Viatris 875/125 tablets during pregnancy or while you are breastfeeding. Amoxicillin/Clavulanic Acid Viatris 500/125 or Amoxicillin/Clavulanic Acid Viatris 875/125 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
- mycophenolate
- medicines to treat gout (e.g. probenecid or allopurinol)
- other antibiotics. These may interfere with the actions of Amoxicillin/Clavulanic Acid Viatris 500/125 or Amoxicillin/Clavulanic Acid Viatris 875/125 tablets.
- methotrexate (a medicine used to treat cancer or rheumatic diseases.
- contraceptive pill. As with other antibiotics, you may need to use extra birth control methods (e.g. condoms) while taking Amoxicillin/Clavulanic Acid Viatris 500/125 or Amoxicillin/Clavulanic Acid Viatris 875/125 tablets.

Some medicines may interfere with Amoxicillin/Clavulanic Acid Viatris 500/125 and Amoxicillin/Clavulanic Acid Viatris 875/125 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 Amoxicillin/Clavulanic Acid Viatris 500/125 or Amoxicillin/Clavulanic Acid Viatris 875/125 tablets.

4. How do I use Amoxicillin/Clavulanic Acid Viatris 500/125 or Amoxicillin/Clavulanic Acid Viatris 875/125 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 Amoxicillin/Clavulanic Acid Viatris 500/125 or Amoxicillin/Clavulanic Acid Viatris 875/125 tablets with a full glass of water or other liquid. Amoxicillin/Clavulanic Acid Viatris 875/125 tablets can be broken in half, but should not be chewed.
- Amoxicillin/Clavulanic Acid Viatris 500/125 or Amoxicillin/Clavulanic Acid Viatris 875/125 tablets should be taken immediately before or with the first mouthful of food. Amoxicillin/Clavulanic Acid Viatris 500/125 or Amoxicillin/Clavulanic Acid Viatris 875/125 tablets work best when taken this way. It may also help to prevent stomach upsets. However, Amoxicillin/Clavulanic Acid Viatris 500/125 or Amoxicillin/Clavulanic Acid Viatris 875/125 tablets will still work if they are taken without food.
- Space the doses as evenly as possible throughout the day. If you are taking Amoxicillin/Clavulanic Acid Viatris 500/125 or Amoxicillin/Clavulanic Acid Viatris 875/125 tablets twice a day, take a dose about every twelve hours.

How long to take it for

- Keep taking Amoxicillin/Clavulanic Acid Viatris 500/125 or Amoxicillin/Clavulanic Acid Viatris 875/125 tablets until the course is finished or for as long as your doctor tells you.
- Do not stop taking Amoxicillin/Clavulanic Acid Viatris 500/125 or Amoxicillin/Clavulanic Acid Viatris 875/125 tablets just because you feel better as the infection can return.
- Do not stop taking Amoxicillin/Clavulanic Acid Viatris 500/125 or Amoxicillin/Clavulanic Acid Viatris 875/125 tablets, or change the dose, without first checking with your doctor.

If you forget to take Amoxicillin/Clavulanic Acid Viatris 500/125 or Amoxicillin/Clavulanic Acid Viatris 875/125 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 Amoxicillin/Clavulanic Acid Viatris 500/125 or Amoxicillin/Clavulanic Acid Viatris 875/125 tablets

If you think that you have used too much Amoxicillin/Clavulanic Acid Viatris 500/125 or Amoxicillin/Clavulanic Acid Viatris 875/125, 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.

 What should I know while using Amoxicillin/Clavulanic Acid Viatris 500/125 or Amoxicillin/Clavulanic Acid Viatris 875/125?

Things you should do

- Take Amoxicillin/Clavulanic Acid Viatris 500/125 or Amoxicillin/Clavulanic Acid Viatris 875/125 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 Amoxicillin/Clavulanic Acid Viatris 500/125 or Amoxicillin/Clavulanic Acid Viatris 875/125 tablets.
- Remind any doctor, dentist or pharmacist you visit that you are using Amoxicillin/Clavulanic Acid Viatris 500/125 or Amoxicillin/Clavulanic Acid Viatris 875/125 tablets before starting any other medicines. Some medicines may affect the way other medicines work.

Things you should not do

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

Things to be careful of

If you develop severe diarrhoea either when taking Amoxicillin/Clavulanic Acid Viatris 500/125 or Amoxicillin/Clavulanic Acid Viatris 875/125 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 Amoxicillin/Clavulanic Acid Viatris 500/125 or Amoxicillin/Clavulanic Acid Viatris 875/125 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 Amoxicillin/Clavulanic Acid Viatris 500/125 or Amoxicillin/Clavulanic Acid Viatris 875/125 tablets. Some people who drink alcohol while taking antibiotics similar to Amoxicillin/Clavulanic Acid Viatris 500/125 or Amoxicillin/Clavulanic Acid Viatris 875/125 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.

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: white, furry, sore tongue and mouth (oral thrush), abnormal taste soreness or itching of the vagina or vaginal discharge (vaginal thrush) 	Speak to your doctor if you have any of these less serious side effects and they worry you.
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:	
dizzinessheadachetiredness	

Less serious side effects	What to do
Others:	
tooth discolourationhot flushesunusually active (hyperactive).	

What to do

Serious side effects

Serious side effects

001104001400	
Gut or Gastrointestinal related:	Tell your doctor immediately if you
severe stomach crampssevere watery or bloody diarrhoea	notice any of these symptoms during or after taking Amoxicillin/Clavulanic Acid Viatris 500/125
Allergy related:	or
• itching, rash	Amoxicillin/Clavulanic Acid Viatris 875/125 tablets.
Liver related:	
yellowing of your skin or eyes (jaundice)dark urine or pale stools	
Others:	
 unusual bleeding or bruising 	
Rare events:	
• inflammation of the	
bowel (colitis)inflammation of the liver	
(hepatitis)	
 inflammation of the kidney (nephritis) 	
blood disorders	
 crystals in the urine (crystalluria) 	
Brain or head related:	Stop taking
• fits or seizures	Amoxicillin/Clavulanic
	Acid Viatris 500/125 or
Others:	Amoxicillin/Clavulanic
aseptic meningitis	Acid Viatris 875/125 tablets and call your
 a red rash commonly seen on both sides of buttocks, 	doctor straight away,
upper inner thighs,	or go straight to the Emergency
armpits, neck	Department at your
	nearest hospital if you notice any of
Allergic reaction related:	these serious side
Wheezing, hives, severe skin reaction, fainting,	effects.

Serious side effects	What to do
swelling of limbs, face, lips, mouth or throat, difficulty swallowing or breathing, joint discomfort or swelling, swollen lymph glands, nausea and vomiting or fever.	

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 Amoxicillin/Clavulanic Acid Viatris 500/125 or Amoxicillin/Clavulanic Acid Viatris 875/125 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.

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

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 Amoxicillin/Clavulanic Acid Viatris 500/125 or Amoxicillin/Clavulanic Acid Viatris 875/125 tablets contains

Active ingredient (main ingredient)	Amoxicillin/Clavulanic Acid Viatris 500/125 tablets: amoxicillin 500 mg clavulanic acid 125 mg	
	Amoxicillin/Clavulanic Acid Viatris 875/125 tablets: amoxicillin 875 mg clavulanic acid 125 mg	
Other ingredients (inactive ingredients)	 magnesium stearate purified talc povidone croscarmellose sodium microcrystalline cellulose triethyl citrate 	

- ethylcellulose
- sodium lauryl sulfate
- cetyl alcohol
- hypromellose
- titanium dioxide

Amoxicillin/Clavulanic Acid Viatris 875/125 tablets:

silicon dioxide.

Amoxicillin/Clavulanic Acid Viatris 500/125 or Amoxicillin/Clavulanic Acid Viatris 875/125 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 Amoxicillin/Clavulanic Acid Viatris 500/125 or Amoxicillin/Clavulanic Acid Viatris 875/125 tablets looks like

Amoxicillin/Clavulanic Acid Viatris 500/125 - Off-white, oval, biconvex, film-coated tablet, scored on both sides. Blister packs of 10 tablets (AUST R 230395).

Amoxicillin/Clavulanic Acid Viatris 875/125 - White to pale yellow, oblong, biconvex, film-coated tablet, scored on both sides.

Blister packs of 10 tablets (AUST R 230396).

Who distributes Amoxicillin/Clavulanic Acid Viatris 500/125 or Amoxicillin/Clavulanic Acid Viatris 875/125 tablets

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

This leaflet was revised in June 2024.

^{*} Registered Trade Mark. The trade marks mentioned in this material are the property of their respective owners.