

# ALPHACLAV<sup>®</sup> DUO VIATRIS 500/125 & ALPHACLAV<sup>®</sup> DUO FORTE VIATRIS 875/125

## 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 ALPHACLAV tablets?

ALPHACLAV DUO VIATRIS or ALPHACLAV DUO FORTE VIATRIS tablets contain the active ingredients amoxicillin and clavulanic acid and are used for the short term treatment of a wide range of infections caused by bacteria. These products will be referred to as ALPHACLAV throughout.

For more information, see Section [1. Why am I using ALPHACLAV tablets?](#) in the full CMI.

### 2. What should I know before I use ALPHACLAV 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 ALPHACLAV tablets?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with ALPHACLAV DUO VIATRIS or ALPHACLAV DUO FORTE VIATRIS 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 ALPHACLAV tablets?

Follow the directions given to you by your doctor and pharmacist. Their directions may differ from the information contained in this leaflet. More instructions can be found in Section [4. How do I use ALPHACLAV tablets?](#) in the full CMI.

### 5. What should I know while using ALPHACLAV tablets?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Take ALPHACLAV tablets exactly as your doctor has prescribed.</li><li>• Tell your doctor if, for any reason, you have not taken your medicine exactly as directed.</li><li>• Remind any doctor, dentist or pharmacist you visit that you are using ALPHACLAV tablets.</li><li>• Tell your doctor if the symptoms of your infection become worse, or do not improve within a few days of starting ALPHACLAV tablets.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not give this medicine to anyone else, even if their symptoms seem similar to yours.</li><li>• Do not use to treat any other complaints unless your doctor says to</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• Be careful before you drive or use any machines or tools until you know how ALPHACLAV tablets affect you.</li></ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"><li>• Alcohol should be avoided during and for several days after treatment with ALPHACLAV tablets</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Keep your tablets in the original pack until it is time to take them.</li><li>• Store it in a cool dry place away from moisture, heat or sunlight.</li></ul>

For more information, see Section [5. What should I know while using ALPHACLAV tablets?](#) in the full CMI.

### 6. Are there any side effects?

The most common side effects of ALPHACLAV 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.

# ALPHACLAV<sup>®</sup> DUO VIATRIS 500/125 & ALPHACLAV<sup>®</sup> DUO FORTE VIATRIS 875/125 tablets

Active ingredient(s): amoxicillin trihydrate & potassium clavulanate

## Consumer Medicine Information (CMI)

This leaflet provides important information about using ALPHACLAV DUO VIATRIS or ALPHACLAV DUO FORTE VIATRIS 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 ALPHACLAV DUO VIATRIS or ALPHACLAV DUO FORTE VIATRIS tablets.**

**Where to find information in this leaflet:**

1. [Why am I using ALPHACLAV tablets?](#)
2. [What should I know before I use ALPHACLAV tablets?](#)
3. [What if I am taking other medicines?](#)
4. [How do I use ALPHACLAV tablets?](#)
5. [What should I know while using ALPHACLAV tablets?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

## 1. Why am I using ALPHACLAV tablets?

ALPHACLAV DUO VIATRIS and ALPHACLAV DUO FORTE VIATRIS tablets contain two active ingredients. One of these is a penicillin called amoxicillin and the other is clavulanic acid. ALPHACLAV tablets belong to the penicillin group of antibiotics and work by killing bacteria that cause infections. ALPHACLAV tablets will not work against infections caused by viruses such as colds or the flu.

ALPHACLAV tablets are 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.

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

There is no evidence that ALPHACLAV tablets are addictive.

## 2. What should I know before I use ALPHACLAV tablets?

### Warnings

**Do not use ALPHACLAV DUO VIATRIS or ALPHACLAV DUO FORTE VIATRIS 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 ALPHACLAV tablets or any other medicines.
- the expiry date printed on the pack has passed.
- the packaging is torn or shows signs of tampering.

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

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 experienced liver problems after taking ALPHACLAV tablets or any other medicines.
- have glandular fever (mononucleosis) or leukaemia.
- have any kidney or liver problems.

The dosage of ALPHACLAV tablets may need to be changed or you may need to be given an alternative medicine.

- have to test your urine for sugar.

ALPHACLAV 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 [6. Are there any side effects?](#)

### 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 taking ALPHACLAV tablets during pregnancy or while you are breast-feeding. The active ingredients in ALPHACLAV 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 used to treat gout (e.g. probenecid or allopurinol).
- other antibiotics. These may interfere with the actions of ALPHACLAV 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 ALPHACLAV tablets.

**Some medicines may interfere with ALPHACLAV DUO VIATRIS or ALPHACLAV DUO FORTE VIATRIS 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 ALPHACLAV DUO VIATRIS or ALPHACLAV DUO FORTE VIATRIS tablets.**

#### 4. How do I use ALPHACLAV 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 ALPHACLAV tablet with a full glass of water or other liquid.

ALPHACLAV tablets should be taken immediately before or with the first mouthful of food. ALPHACLAV tablets work best when taken this way. It may also help to prevent stomach upsets. However, ALPHACLAV tablets will still work if they are taken without food.

Space the doses as evenly as possible throughout the day. If you are taking ALPHACLAV tablets twice a day, take a dose about every twelve hours.

##### How long to take it for

Keep taking ALPHACLAV tablets until the course is finished or for as long as your doctor tells you.

Do not stop taking ALPHACLAV tablets just because you feel better as the infection can return.

Do not stop taking ALPHACLAV tablets, or change the dose, without first checking with your doctor.

##### If you forget to use ALPHACLAV DUO VIATRIS or ALPHACLAV DUO FORTE VIATRIS 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 use too much ALPHACLAV DUO VIATRIS or ALPHACLAV DUO FORTE VIATRIS tablets

If you think that you have used too much ALPHACLAV DUO VIATRIS or ALPHACLAV DUO FORTE VIATRIS tablets, you 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.

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

**You should do this even if there are no signs of discomfort or poisoning.**

#### 5. What should I know while using ALPHACLAV tablets?

##### Things you should do

Take ALPHACLAV 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 ALPHACLAV tablets.

Remind any doctor, dentist or pharmacist you visit that you are using ALPHACLAV 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 use to treat any other complaints unless your doctor says to.

##### Things to be careful of

If you develop severe diarrhoea either when taking ALPHACLAV 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 ALPHACLAV DUO VIATRIS or ALPHACLAV DUO FORTE VIATRIS 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, ALPHACLAV tablets may cause dizziness or tiredness in some people.

## Drinking alcohol

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

## Looking after your medicine

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

Store your medicine in a cool, dry place where the temperature stays below 25°C, away from moisture, heat or sunlight. 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
<ul style="list-style-type: none"><li>• diarrhoea (several loose bowel movements per day), indigestion, pain in the stomach, feeling sick or being sick</li><li>• nausea, vomiting</li><li>• white, furry, sore tongue and mouth (oral thrush), abnormal taste</li><li>• soreness or itching of the vagina or vaginal discharge (vaginal thrush)</li><li>• headache, dizziness, tiredness, hot flushes</li><li>• tooth discolouration</li><li>• unusually active (hyperactivity)</li></ul>	<b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b>

### Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"><li>• itching, rash</li><li>• dark urine or pale stools</li><li>• yellowing of the skin or eyes (jaundice)</li><li>• severe stomach cramps</li></ul>	<b>Tell your doctor immediately if you notice any of these symptoms</b>

Serious side effects	What to do
<ul style="list-style-type: none"><li>• severe watery or bloody diarrhoea</li><li>• unusual bleeding or bruising</li></ul> <p><u>Rare events:</u></p> <ul style="list-style-type: none"><li>• inflammation of the bowel (colitis)</li><li>• inflammation of the liver (hepatitis)</li><li>• inflammation of the kidney (nephritis)</li><li>• blood disorders</li><li>• crystals in the urine (crystalluria).</li></ul>	<b>during or after taking ALPHACLAV tablets.</b>
<ul style="list-style-type: none"><li>• Fits/seizures</li><li>• aseptic meningitis</li><li>• a red rash commonly seen on both sides of buttocks, upper inner thighs, armpits, neck</li></ul> <p><u>Allergic reactions:</u></p> <ul style="list-style-type: none"><li>• 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.</li></ul>	<b>Stop taking ALPHACLAV 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.</b>

**Tell your doctor or pharmacist as soon as possible 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 you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://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 ALPHACLAV DUO VIATRIS or ALPHACLAV DUO FORTE VIATRIS tablets contains**

Active ingredient (main ingredient)	ALPHACLAV DUO VIATRIS tablets:
	<ul style="list-style-type: none"><li>• amoxicillin 500 mg</li><li>• clavulanic acid 125 mg</li></ul>

	<b>ALPHACLAV DUO FORTE VIATRIS tablets:</b> <ul style="list-style-type: none"> <li>• amoxicillin 875 mg</li> <li>• clavulanic acid 125 mg</li> </ul>
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"> <li>• magnesium stearate</li> <li>• croscarmellose sodium</li> <li>• purified talc</li> <li>• microcrystalline cellulose.</li> </ul> <p>The coating on the tablets contains the colouring agent titanium dioxide, hypromellose, ethyl cellulose, hypromellose and propylene glycol.</p>
<b>Potential allergens</b>	Each tablet contains 25 mg of elemental potassium

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

### **What ALPHACLAV DUO VIATRIS or ALPHACLAV DUO FORTE VIATRIS tablets looks like**

ALPHACLAV DUO VIATRIS 500/125 tablets come as white, oval shaped, film coated tablet with marking “CA625” on one side and come in blister packs of ten tablets. (AUST R 255078).

ALPHACLAV DUO FORTE VIATRIS 875/125 tablets come as white elongated capsule shaped film coated tablet and come in blister packs of ten tablets. (AUST R 255073).

Some strengths, pack sizes and/or pack types may not be marketed.

### **Who distributes ALPHACLAV DUO VIATRIS or ALPHACLAV DUO FORTE VIATRIS tablets**

Alphapharm Pty Ltd trading as Viatrís Pty Ltd

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

[www.viatris.com.au](http://www.viatris.com.au)

Phone: 1800 274 276

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ALPHACLAV® is a Viatrís company trade mark

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