

ALPHACLAV® DUO VIATRIS 500/125 & ALPHACLAV® DUO FORTE VIATRIS 875/125

Amoxicillin & Clavulanic Acid

Consumer Medicine Information

What is in this leaflet

Please read this leaflet carefully before you take ALPHACLAV DUO VIATRIS 500/125 or ALPHACLAV DUO FORTE VIATRIS 875/125 tablets.

This leaflet answers some common questions about ALPHACLAV DUO VIATRIS 500/125 and ALPHACLAV DUO FORTE VIATRIS 875/125 tablets. It does not contain all of the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Sometimes new risks are found even when a medicine has been used for many years. Your doctor has weighed the expected benefits of you taking ALPHACLAV DUO VIATRIS 500/125 and ALPHACLAV DUO FORTE VIATRIS 875/125 tablets against the risks this medicine could have for you.

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

Keep this leaflet with the medicine.

You may need to read it again.

What are ALPHACLAV DUO VIATRIS 500/125 and ALPHACLAV DUO FORTE VIATRIS 875/125 tablets used for

ALPHACLAV DUO VIATRIS 500/125 and ALPHACLAV DUO FORTE VIATRIS 875/125 tablets contain two active ingredients. One of these is a penicillin called amoxicillin and the other is clavulanic acid.

ALPHACLAV DUO VIATRIS 500/125 and ALPHACLAV DUO FORTE VIATRIS 875/125 tablets belong to the penicillin group of antibiotics.

ALPHACLAV DUO VIATRIS 500/125 and ALPHACLAV DUO FORTE VIATRIS 875/125 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.

ALPHACLAV DUO VIATRIS 500/125 and ALPHACLAV DUO FORTE VIATRIS 875/125 tablets work by killing the bacteria that cause these infections. ALPHACLAV DUO VIATRIS 500/125 and ALPHACLAV DUO FORTE VIATRIS 875/125 tablets will not work against infections caused by viruses such as colds or the flu.

Your doctor may prescribe ALPHACLAV DUO VIATRIS 500/125 and ALPHACLAV DUO FORTE VIATRIS 875/125 tablets for another use. If you want more information, ask your doctor.

There is no evidence that ALPHACLAV DUO VIATRIS 500/125 and ALPHACLAV DUO FORTE VIATRIS 875/125 tablets are addictive.

Before you take ALPHACLAV DUO VIATRIS 500/125 or ALPHACLAV DUO FORTE VIATRIS 875/125 tablets

Do not take ALPHACLAV DUO VIATRIS 500/125 and ALPHACLAV DUO FORTE VIATRIS 875/125 tablets if:

- you have had an allergic reaction to penicillin or similar types of antibiotics (such as cephalosporins) or any of the ingredients contained in ALPHACLAV DUO VIATRIS 500/125 or ALPHACLAV DUO FORTE VIATRIS 875/125 tablets. The ingredients are 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 DUO VIATRIS 500/125 and ALPHACLAV DUO FORTE VIATRIS 875/125 tablets or any other medicines.
- The expiry date (EXP) printed on the pack has passed.
- The packaging is torn or shows signs of tampering.

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

If you are not sure whether you should start taking ALPHACLAV DUO VIATRIS 500/125 and ALPHACLAV DUO FORTE VIATRIS 875/125 tablets, talk to your doctor.

Tell your doctor if:

- you have ever had an allergic reaction (such as a rash) to antibiotics or other substances in the past.
- you are allergic to foods, dyes, preservatives or any other medicines
- you have experienced liver problems after taking ALPHACLAV DUO VIATRIS 500/125 and ALPHACLAV DUO FORTE VIATRIS 875/125 tablets or any other medicines.
- you have glandular fever (mononucleosis) or leukaemia.
- you are pregnant or think you may be pregnant or are breast-feeding. Your doctor will discuss with you the possible risks and benefits of taking ALPHACLAV DUO VIATRIS 500/125 and ALPHACLAV DUO FORTE VIATRIS 875/125 tablets during pregnancy or while you are breast-feeding. ALPHACLAV DUO VIATRIS 500/125 and ALPHACLAV DUO FORTE VIATRIS 875/125 tablets can pass to your baby from breast milk.
- you have any kidney or liver problems. The dosage of ALPHACLAV DUO VIATRIS 500/125 and ALPHACLAV DUO FORTE VIATRIS 875/125 tablets may need to be changed or you may need to be given an alternative medicine
- you have to test your urine for sugar. ALPHACLAV DUO VIATRIS 500/125 and ALPHACLAV DUO FORTE

VIATRIS 875/125 tablets may affect the results of these tests.

- Tell your doctor or pharmacist if you are taking any other medicines, including medicines 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 (eg. probenecid or allopurinol).
 - other antibiotics. These may interfere with the actions of ALPHACLAV DUO VIATRIS 500/125 and ALPHACLAV DUO FORTE VIATRIS 875/125 tablets.
 - the contraceptive pill. As with other antibiotics, you may need to use extra birth control methods (e.g. condoms) while taking ALPHACLAV DUO VIATRIS 500/125 and ALPHACLAV DUO FORTE VIATRIS 875/125 tablets.
- Some medicines may affect the way other medicines work. Your doctor or pharmacist will be able to tell you what to do when taking ALPHACLAV DUO VIATRIS 500/125 and ALPHACLAV DUO FORTE VIATRIS 875/125 tablets with other medicines.

How to take ALPHACLAV DUO VIATRIS 500/125 and ALPHACLAV DUO FORTE 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

Take as directed by your doctor or pharmacist.

The usual dose of ALPHACLAV DUO VIATRIS 500/125 and ALPHACLAV DUO FORTE VIATRIS 875/125 is one tablet twice a day.

How to take it

Swallow the ALPHACLAV DUO VIATRIS 500/125 and ALPHACLAV DUO FORTE VIATRIS 875/125 tablet with a full glass of water or other liquid.

ALPHACLAV DUO VIATRIS 500/125 and ALPHACLAV DUO FORTE VIATRIS 875/125 tablets should be taken immediately before or with the first mouthful of food. ALPHACLAV DUO VIATRIS 500/125 and ALPHACLAV DUO FORTE VIATRIS 875/125 tablets work best when taken this way. It may also help to prevent stomach upsets. However, ALPHACLAV DUO VIATRIS 500/125 and ALPHACLAV DUO FORTE 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 ALPHACLAV DUO VIATRIS 500/125 and ALPHACLAV DUO FORTE VIATRIS

875/125 tablets twice a day, take a dose about every twelve hours

How long to take it

Keep taking ALPHACLAV DUO VIATRIS 500/125 and ALPHACLAV DUO FORTE VIATRIS 875/125 tablets until the course is finished or for as long as your doctor tells you.

Do not stop taking ALPHACLAV DUO VIATRIS 500/125 and ALPHACLAV DUO FORTE VIATRIS 875/125 tablets just because you feel better as the infection can return.

Do not stop taking ALPHACLAV DUO VIATRIS 500/125 and ALPHACLAV DUO FORTE VIATRIS 875/125 tablets, or change the dose, without first checking with your doctor.

If you forget to take it

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 that you have missed.

Taking more than the prescribed dose can increase the chance of unwanted side-effects.

If you take too much? (Overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 131126) for advice if you think you or anyone else may have taken too much, even if there are no signs of discomfort or poisoning.

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

If you are not sure what to do, contact your doctor, pharmacist or nearest hospital. Be sure to show the doctor the ALPHACLAV DUO VIATRIS 500/125 or ALPHACLAV DUO FORTE VIATRIS 875/125 pack.

While you are taking ALPHACLAV DUO VIATRIS 500/125 and ALPHACLAV DUO FORTE VIATRIS 875/125 tablets

Things you must do

Take ALPHACLAV DUO VIATRIS 500/125 and ALPHACLAV DUO FORTE 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, dentist or pharmacist you are taking ALPHACLAV DUO VIATRIS 500/125 and ALPHACLAV DUO FORTE VIATRIS 875/125 tablets before starting any other medicines. Some medicines may affect the way other medicines work.

Tell your doctor if the symptoms of your infection become worse, or do not improve within a few days of starting ALPHACLAV DUO VIATRIS 500/125 and ALPHACLAV DUO FORTE VIATRIS 875/125 tablets.

Things you must 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

Alcohol should be avoided during and for several days after treatment with ALPHACLAV DUO VIATRIS 500/125 and ALPHACLAV DUO FORTE VIATRIS 875/125 tablets. Some people who drink alcohol while taking antibiotics similar to ALPHACLAV DUO VIATRIS 500/125 and ALPHACLAV DUO FORTE VIATRIS 875/125 tablets have experienced adverse effects.

Be careful driving or operating machinery until you know how ALPHACLAV DUO VIATRIS 500/125 and ALPHACLAV DUO FORTE VIATRIS 875/125 tablets affect 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 DUO VIATRIS 500/125 and ALPHACLAV DUO FORTE VIATRIS 875/125 tablets may cause dizziness or tiredness in some people.

If you develop severe diarrhoea either when taking ALPHACLAV DUO VIATRIS 500/125 and ALPHACLAV DUO FORTE 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®).

What are the side-effects?

Check with your doctor as soon as possible if you think you are experiencing any side-effects or allergic reactions due to taking ALPHACLAV DUO VIATRIS 500/125 and ALPHACLAV DUO FORTE VIATRIS 875/125 tablets, even if the problem is not listed below.

Like other medicines, ALPHACLAV DUO VIATRIS 500/125 and ALPHACLAV DUO FORTE VIATRIS 875/125 tablets can cause some side-effects. If they occur, they are most likely to be minor and temporary. However, some may be serious and need medical attention. Tell your doctor about any effect which is troublesome or ongoing.

MILD EFFECTS

- **Tell your doctor if you notice any of the following that are troublesome or ongoing:**
 - diarrhoea (several loose bowel movements per day), indigestion, pain in the stomach, feeling sick or being sick
 - white, furry, sore tongue and mouth (oral thrush), abnormal taste
 - soreness or itching of the vagina or vaginal discharge (vaginal thrush)
 - aseptic meningitis, headache, dizziness, tiredness, hot flushes
 - tooth discolouration
 - unusually active (hyperactivity)

MORE SERIOUS EFFECTS

- **Tell your doctor immediately if you notice any of the following during or after taking ALPHACLAV DUO VIATRIS 500/125 and ALPHACLAV DUO FORTE VIATRIS 875/125 tablets:**
 - itching, rash
 - dark urine or pale stools
 - yellowing of the skin or eyes (jaundice)

- severe stomach cramps
 - severe watery or bloody diarrhoea
 - unusual bleeding or bruising
- These may be symptoms of rare but serious side-effects and require urgent medical attention.

- **Stop taking ALPHACLAV DUO VIATRIS 500/125 and ALPHACLAV DUO FORTE VIATRIS 875/125 tablets and immediately contact your doctor or go to the emergency department of your nearest hospital if any of the following happens:**

- 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.

These may be signs of an allergic reaction or other reaction to ALPHACLAV DUO VIATRIS 500/125 and ALPHACLAV DUO FORTE VIATRIS 875/125 tablets.

Allergy to these antibiotics is rare.

- Fits/seizures.

- **Rare events that have been reported with ALPHACLAV DUO VIATRIS 500/125 and ALPHACLAV DUO FORTE VIATRIS 875/125 tablets include:**

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

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 ALPHACLAV DUO VIATRIS 500/125 and ALPHACLAV DUO FORTE 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 any side-effects from your medicine which are not mentioned here.

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

After using ALPHACLAV DUO VIATRIS 500/125 and ALPHACLAV DUO FORTE VIATRIS 875/125 tablets?

Storage

Keep your tablets in the original pack until it is time to take them. If you take the tablets out of the pack, they may not keep well.

Keep the pack in a cool dry place. Do not leave it in the car on a hot day. Do not store medicine in the bathroom or near a sink. Heat and dampness can destroy ALPHACLAV DUO VIATRIS 500/125 and ALPHACLAV DUO FORTE VIATRIS 875/125 tablets.

Store all medicines out of the reach of children, such as in a locked cupboard.

If your doctor tells you to stop taking ALPHACLAV DUO VIATRIS 500/125 and ALPHACLAV DUO FORTE VIATRIS 875/125 tablets or if the expiry date has

passed, ask your pharmacist what to do with any tablets that are left over.

Product description

What they look like

ALPHACLAV DUO VIATRIS 500/125 tablets come as white, oval shaped, film coated tablet with marking “CA625” on one side.

ALPHACLAV DUO FORTE VIATRIS 875/125 tablets come as white elongated capsule shaped film coated tablet.

Other ingredients

ALPHACLAV DUO VIATRIS 500/125 tablets contain the following inactive ingredients: magnesium stearate, croscarmellose sodium, purified talc and microcrystalline cellulose. The coating on the tablets contains the colouring agent titanium dioxide, hypromellose, ethyl cellulose, hypromellose and propylene glycol.

ALPHACLAV DUO FORTE VIATRIS 875/125 tablets contain the following inactive ingredients: magnesium stearate, croscarmellose sodium, purified talc and microcrystalline cellulose. The coating on the tablets contains the colouring agent titanium dioxide, hypromellose, ethyl cellulose, hypromellose and propylene glycol.

ALPHACLAV DUO VIATRIS 500/125 and ALPHACLAV DUO FORTE VIATRIS 875/125 tablets contain 25 mg of elemental potassium per tablet.

ALPHACLAV DUO VIATRIS 500/125 and ALPHACLAV DUO FORTE VIATRIS 875/125 tablets are available only with a doctor's prescription.

ALPHACLAV DUO VIATRIS 500/125 tablets come in blister packs of ten tablets. (AUST R 255078).

ALPHACLAV DUO FORTE VIATRIS 875/125 tablets come in blister packs of ten tablets. (AUST R 255073).

Sponsor

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AUSTRALIA

Distributor

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500/125, ALPHACLAV DUO FORTE
VIATRIS 875/125 _cml\May23/00**