

AMCLAVOX DUO 500/125 & AMCLAVOX DUO FORTE 875/125 TABLETS

Amoxicillin and clavulanic acid

CONSUMER MEDICINE INFORMATION

What is in this leaflet?

Please read this leaflet carefully before you take AMCLAVOX DUO & AMCLAVOX DUO FORTE tablets.

This leaflet answers some common questions about AMCLAVOX DUO & AMCLAVOX DUO FORTE 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 AMCLAVOX DUO & AMCLAVOX DUO FORTE 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 AMCLAVOX DUO & AMCLAVOX DUO FORTE tablets used for?

AMCLAVOX DUO & AMCLAVOX DUO FORTE tablets contain two active ingredients. One of these is a penicillin called amoxicillin and the other is clavulanic acid.

AMCLAVOX DUO & AMCLAVOX DUO FORTE tablets belong to the penicillin group of antibiotics. AMCLAVOX DUO & AMCLAVOX DUO FORTE 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.

AMCLAVOX DUO & AMCLAVOX DUO FORTE tablets work by killing the bacteria that

cause these infections. AMCLAVOX DUO & AMCLAVOX DUO FORTE tablets will not work against infections caused by viruses such as colds or the flu.

Your doctor may prescribe AMCLAVOX DUO & AMCLAVOX DUO FORTE tablets for another use. If you want more information, ask your doctor.

There is no evidence that AMCLAVOX DUO & AMCLAVOX DUO FORTE tablets are addictive.

Before you take AMCLAVOX DUO & AMCLAVOX DUO FORTE tablets

Do not take AMCLAVOX DUO & AMCLAVOX DUO FORTE 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

AMCLAVOX DUO &
AMCLAVOX DUO
FORTE 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 AMCLAVOX DUO & AMCLAVOX DUO FORTE tablets or any other medicines.
- The expiry date (EXPIRY) 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 AMCLAVOX DUO & AMCLAVOX DUO FORTE 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 AMCLAVOX DUO & AMCLAVOX DUO FORTE tablets or any other medicines.
- You have glandular fever (mononucleosis) or leukaemia.
- You are pregnant or think you may be pregnant or are breastfeeding. *Your doctor will discuss with you the possible risks and benefits of taking AMCLAVOX DUO & AMCLAVOX DUO FORTE tablets during pregnancy or while you are breastfeeding. AMCLAVOX DUO & AMCLAVOX DUO FORTE tablets can pass to your baby from breast milk.*
- You have any kidney or liver problems. *The dosage of AMCLAVOX DUO & AMCLAVOX DUO FORTE tablets may need to be changed or you may need to be*

given an alternative medicine.

- You have to test your urine for sugar. *AMCLAVOX DUO & AMCLAVOX DUO FORTE 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 (e.g. probenecid or allopurinol).
 - Other antibiotics. *These may interfere with the actions of AMCLAVOX DUO & AMCLAVOX DUO FORTE tablets.*
 - The contraceptive pill. As with other antibiotics, you may need to use extra birth control methods (e.g. condoms) while taking AMCLAVOX DUO & AMCLAVOX DUO FORTE 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 AMCLAVOX DUO & AMCLAVOX DUO FORTE tablets with other medicines.

**How to take
AMCLAVOX DUO &
AMCLAVOX 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 directions 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 AMCLAVOX DUO & AMCLAVOX DUO FORTE tablets is one tablet twice a day.

How to take it:

Swallow the AMCLAVOX DUO & AMCLAVOX DUO FORTE tablets with

a full glass of water or other liquid.

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

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

How long to take it:

Keep taking AMCLAVOX DUO & AMCLAVOX DUO FORTE tablets until the course is finished or for as long as your doctor tells you.

Do not stop taking AMCLAVOX DUO & AMCLAVOX DUO FORTE tablets just because you feel better as the infection can return.

Do not stop taking AMCLAVOX DUO & AMCLAVOX DUO FORTE 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 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.

What do I do if I take too much? (Overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 131126) for advice if you think you or anyone else has 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 AMCLAVOX DUO & AMCLAVOX DUO FORTE pack.

While you are taking AMCLAVOX DUO & AMCLAVOX DUO FORTE tablets

Things you must do:

Take AMCLAVOX DUO & AMCLAVOX 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, dentist or pharmacist you are taking AMCLAVOX DUO & AMCLAVOX DUO FORTE 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 AMCLAVOX DUO & AMCLAVOX DUO FORTE 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 this medicine to treat any other complaint unless your doctor says to.

Things to be careful of:

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

Be careful driving or operating machinery until you know how AMCLAVOX DUO & AMCLAVOX DUO FORTE tablets affect you. Generally, these tablets do not cause any problems with your ability to drive a car or operate machinery. However, as with other medicines, AMCLAVOX DUO & AMCLAVOX

DUO FORTE tablets may cause dizziness or tiredness in some people.

If you develop severe diarrhoea either when taking AMCLAVOX DUO & AMCLAVOX DUO FORTE tablets or within several weeks after treatment, tells your doctor as soon as possible. Do not take any medication to stop the diarrhoea (e.g. 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 AMCLAVOX DUO & AMCLAVOX DUO FORTE tablets, even if the problem is not listed below.

Like other medicines, AMCLAVOX DUO & AMCLAVOX DUO FORTE 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)
- headache, dizziness, tiredness, hot flushes
- tooth discolouration
- unusually active (hyperactive)

MORE SERIOUS EFFECTS

Tell your doctor immediately if you notice any of the following during or after taking AMCLAVOX DUO & AMCLAVOX DUO FORTE tablets:

- rash, itching
- 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 AMCLAVOX DUO & AMCLAVOX DUO FORTE 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, difficult 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 AMCLAVOX DUO & AMCLAVOX DUO FORTE tablets. Allergy to these antibiotics is rare.

- Fits/seizures.

Rare events that have been reported with AMCLAVOX DUO & AMCLAVOX DUO FORTE tablets include:

- inflammation of the bowel (colitis)
- inflammation of the liver (hepatitis)
- inflammation of the kidney (nephritis)
- blood disorders
- crystal 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 AMCLAVOX DUO & AMCLAVOX DUO FORTE tablets.

This is not a complete list of all possible side effects. Other 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.

How do I store AMCLAVOX DUO & AMCLAVOX DUO FORTE tablets?

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 AMCLAVOX DUO & AMCLAVOX DUO FORTE tablets.

Store all medicines out of the reach of children, such as in a locked cupboard. If your doctor tells you to stop taking AMCLAVOX DUO & AMCLAVOX DUO FORTE tablets, or if the expiry date has passed, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

- AMCLAVOX DUO 500/125 - White colored capsule shaped film coated tablet debossed with '1 06' on one side and plain on other side
- AMCLAVOX DUO FORTE 875/125 - White colored capsule shaped film coated tablet debossed with '1 07' on one side and plain on other side

Ingredients

Active Ingredients:

- AMCLAVOX DUO 500/125 – 500 mg amoxicillin (as trihydrate) and 125 mg clavulanic acid (as potassium clavulanate).
- AMCLAVOX DUO FORTE 875/125 – 875 mg amoxicillin (as trihydrate) and 125 mg clavulanic acid (as potassium clavulanate).

Inactive Ingredients:

- microcrystalline cellulose
- magnesium stearate
- sodium starch glycollate Type A
- colloidal anhydrous silica
- hypromellose
- titanium dioxide
- propylene glycol
- purified talc
- ethylcellulose

This medicine does not contain lactose, gluten, sucrose, tartrazine or any other azo dyes.

AMCLAVOX DUO & AMCLAVOX DUO FORTE Available in strip or blister packs of 10 tablets.

Supplier

Micro Labs Pty Ltd
15 Melliadora Crescent,

Greensborough, VIC-3088
Australia

This leaflet was revised in MM/YYYY.

Australian Register Number(s)

AMCLAVOX DUO 500/125
Strip pack:
AUST R 289507
Blister pack:
AUST R 288118

AMCLAVOX DUO FORTE 875/125
Strip pack:
AUST R 289508
Blister pack:
AUST R 288119