

AMOXICLAV Devatis Forte 250 mg/62.5 mg/5 ml Powder for Oral Suspension

Potassium clavulanate/amoxicillin trihydrate equivalent to 62.5 mg clavulanic acid/250 mg amoxicillin

Consumer Medicine Information (CMI)

This leaflet provides important information about using AMOXICLAV Devatis Forte. **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 AMOXICLAV Devatis Forte.**

Where to find information in this leaflet:

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

1. Why am I using AMOXICLAV Devatis Forte?

AMOXICLAV Devatis Forte contains the active ingredient potassium clavulanate/amoxicillin trihydrate equivalent to 62.5 mg clavulanic acid/250 mg amoxicillin.

AMOXICLAV Devatis Forte is an antibiotic that belongs to a group of medicines called penicillins. These antibiotics work by killing the bacteria that are causing your infection.

AMOXICLAV Devatis Forte will not work against infections caused by viruses such as colds or the flu.

This medicine is available only with a doctor's prescription.

AMOXICLAV Devatis Forte is an antibiotic used for the short term treatment of infections in different parts of the body caused by bacteria.

2. What should I know before I use AMOXICLAV Devatis Forte?

Warnings

Do not take AMOXICLAV Devatis Forte if:

- You have an allergy to AMOXICLAV Devatis Forte, other penicillins 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 breathing.
- You have had an allergic reaction to cephalosporins (another type of antibiotic). You may have an increased chance of being allergic to AMOXICLAV Devatis Forte if you are allergic to cephalosporins.
- You have had liver disease or yellowing of the skin and/or eyes, also called jaundice when you have taken amoxicillin/clavulanic acid (or AMOXICLAV Devatis Forte) before.
- The packaging is torn or shows signs of tampering, or the solution has changed colour.
- The expiry date (EXP) printed on the pack has passed. If you take this medicine after the expiry date has passed, it may not work.

If you are not sure whether you should start taking AMOXICLAV Devatis Forte, contact your doctor.

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 any allergies to any other medicines or any other substances, such as foods, preservatives or dyes
- you have glandular fever. If AMOXICLAV Devatis Forte is used with glandular fever a rash may develop.
- you have liver disease
- your kidneys do not work as well as they should
- you are taking warfarin or other medicines used to prevent blood clots
- you are passing less urine
- you are taking any other medicines or herbal remedies

AMOXICLAV Devatis Forte is not addictive.

AMOXICLAV Devatis Forte does not usually affect the ability to drive or operate machinery.

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 using AMOXICLAV Devatis Forte during pregnancy.

Your doctor will discuss with you the possible risks and benefits of using AMOXICLAV Devatis Forte during breastfeeding.

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.

- Probenecid, Allopurinol (used to treat gout)
- Birth control pills (“the pill”, oral contraceptives) Birth control pills may not work as well in preventing pregnancy when AMOXICLAV Devatis Forte is used. Talk to your doctor about the need for an additional method of contraception while taking AMOXICLAV Devatis Forte.
- Warfarin or other medicines used to prevent blood clots
- Mycophenolate mofetil (used to suppress your immune system).
- Methotrexate (used to treat conditions such as cancer and severe psoriasis)

Some medicines may interfere with AMOXICLAV Devatis Forte 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 AMOXICLAV Devatis Forte.

4. How do I use AMOXICLAV Devatis Forte?

Follow your doctor’s instructions about how and when to take AMOXICLAV Devatis Forte.

Read the label carefully. If you have any concerns about how to take AMOXICLAV Devatis Forte, talk to your

doctor or pharmacist.

How much to take

The usual doses are below. These may depend on the type of infection and how severe it is.

Children 7-12 years: 5 ml of AMOXICLAV Devatis Forte three times a day. In severe infections this may be increased to 10 ml AMOXICLAV Devatis Forte suspension 3 times a day.

Children 2-6 years: 2.5 ml of AMOXICLAV Devatis Forte three times daily. In severe infections this may be increased to 5 ml of AMOXICLAV Devatis Forte suspension three times a day.

Children 9 months - 2 years: 1.25 ml of AMOXICLAV Devatis Forte three times a day.

Children 3-9 months: 0.625 ml of AMOXICLAV Devatis Forte three times a day.

Premature: No dosage recommendations can be made for this category.

AMOXICLAV Devatis Forte powder for oral suspension

To make up 100 ml, first shake bottle to loosen powder. Then add 85 ml water and shake well.

To make up 150 ml, first shake bottle to loosen powder. Then add 130 ml water and shake well.

When reconstituted, each 5 ml contains amoxicillin trihydrate equivalent to 250 mg amoxicillin and potassium clavulanate equivalent to 62.5 mg clavulanic acid. Shake the bottle before each use.

Volume of water to be added at reconstitution (ml)	Final volume of reconstituted oral suspension (ml)
85	100
130	150

After reconstitution of the powder the medicinal product is a white to creamy white suspension.

Instructions for using the syringe

A syringe is supplied to administer AMOXICLAV Devatis Forte

The syringe is only for use with AMOXICLAV Devatis Forte and must not be used to administer any other medicines, because the markings are specific to this product. The syringe is supplied with an adaptor which allows it to attach to the bottle.

The dose is indicated on the oral dosing syringe in millilitres (ml). You should give your child the dose recommended by their doctor.

Check cleanliness of syringe before use, rinse with clean water if required.

1. Shake the bottle suspension well before each dose.
2. Remove adaptor from syringe. Hold the bottle firmly and insert the adaptor into the neck of the bottle (the adaptor should remain in place).
3. Insert the syringe into the adaptor ensuring it is secure.
4. Invert bottle holding the syringe in place and withdraw the required dose as indicated by your doctor.
5. Place bottle upright and remove syringe.
6. To give the dose, carefully put the tip of the syringe into the mouth and slowly push down on the plunger of the syringe (repeat steps 3, 4, 5 and 6 if more than one syringe is needed to deliver the dose).
7. Rinse syringe thoroughly in clean water. Allow the syringe to dry completely before next use.
8. Replace the bottle cap.
9. Store in a refrigerator and always shake before use. Once made up, the suspension should be used within 7 days.

When to take AMOXICLAV Devatis Forte

- Shake the suspension well before each dose, then make sure you measure the dose accurately. Your pharmacist will be able to recommend a good measure to use. Screw the lid back onto the bottle tightly after measuring the dose. Take AMOXICLAV Devatis Forte at the start of a meal. This makes it less likely to cause stomach upset or discomfort.

How long to use AMOXICLAV Devatis Forte

- Keep taking this medicine for the full time of treatment, even if you begin to feel better after a few days.
- If you do not complete the full course prescribed by your doctor, the infection may not clear completely or your symptoms may return.
- AMOXICLAV Devatis Forte is not usually used for longer than 14 days without another check-up by the doctor.

If you forget to use AMOXICLAV Devatis Forte

AMOXICLAV Devatis Forte should be taken regularly at the same time each day..

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you have missed.

- If you are not sure whether to skip the dose, talk to your doctor or pharmacist.
- It is important to take the syrup as prescribed so it will work properly. If you have trouble remembering to take the doses ask your pharmacist for hints.

If you use too much (Overdose)

If you think that you have taken too much AMOXICLAV Devatis Forte you may get diarrhoea and nausea and need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 0800 POISON or 0800 764 766**), 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 AMOXICLAV Devatis Forte?

Things you should do

- Tell your doctor if the symptoms of your infection do not improve within a few days, or if they become worse
- If you are about to start taking any new medicine, tell your doctor and pharmacist that you are taking AMOXICLAV Devatis Forte.
- If you have to have any blood tests tell your doctor you are taking AMOXICLAV Devatis Forte. AMOXICLAV Devatis Forte may affect the results of some blood tests.
- Drink plenty of water, juice or other fluids (e.g. 6-8 glasses per day).
- Tell any doctor, dentist and pharmacist treating you that you are taking AMOXICLAV Devatis Forte.

Call your doctor straight away if you:

- Develop itching with swelling or skin rash or difficulty breathing while you are taking AMOXICLAV Devatis Forte do not take any more and contact your doctor immediately.
- Get severe diarrhoea or stomach cramps tell your doctor, pharmacist or nurse immediately. Do this even if it occurs several weeks after AMOXICLAV Devatis Forte has been stopped. Diarrhoea or stomach cramps may

mean that you have a serious condition affecting your bowel. You may need urgent medical care. Do not take any diarrhoea medicine without first checking with your doctor.

- Get a sore white mouth or tongue while taking or soon after stopping AMOXICLAV Devatis Forte, tell your doctor. Also tell your doctor if you get vaginal itching or discharge. This may mean you have a fungal infection called thrush.
- Become pregnant while you are taking AMOXICLAV Devatis Forte.

Remind any doctor, dentist, pharmacist or nurse you visit that you are using AMOXICLAV Devatis Forte.

Things you should not do

- Stop taking AMOXICLAV Devatis Forte because you are feeling better, unless advised by your doctor.
- If you do not complete the full course prescribed by your doctor, all of the bacteria causing your infection may not be killed. These bacteria may continue to grow and multiply so that your infection may not clear completely or it may return.
- Do not give AMOXICLAV Devatis Forte to anyone else, even if they have the same condition as you.
- Do not use AMOXICLAV Devatis Forte to treat any other complaints unless your doctor tells you to.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how AMOXICLAV Devatis Forte affects you.

AMOXICLAV Devatis Forte does not usually affect the ability to drive or operate machinery.

Storage

Keep AMOXICLAV Devatis Forte out of the reach and sight of children and in its original container.

Dry powder: Store below 25°C in the original package in order to protect from light and moisture.

Liquid suspension: Reconstituted suspension should be stored at 2°C–8°C (Refrigerate, do not freeze).

Heat and dampness can destroy some medicines. Do not keep medicines in the bathroom or near a sink. Do not leave it in the car or on window sills.

Keep the bottle tightly closed between doses. The suspension should be used within 7 days of being made up.

Disposal

Do not use this medicine after the expiry date which is stated on the carton after “EXP”. The expiry date refers to the last day of that month.

If your doctor advises you to stop taking AMOXICLAV Devatis Forte or the medicine has passed its expiry date, ask your pharmacist how to throw away medicines you no longer use. Do not throw away any medicines via wastewater. These measures will help protect the environment.

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
<p>Infections and infestations:</p> <ul style="list-style-type: none"> • oral thrush - white, furry, sore tongue and mouth. • change in colour of teeth (rare) – this usually just brushes off using a toothbrush. • change in colour of the tongue with a furry appearance (very rare). <p>Gastrointestinal disorders:</p> <ul style="list-style-type: none"> • diarrhoea, nausea, vomiting or indigestion. <p>Renal and urinary disorders:</p> <ul style="list-style-type: none"> • vaginal thrush - sore and itchy vagina and/or discharge. 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<p>Allergic reaction</p> <ul style="list-style-type: none"> • Signs of a serious allergic reaction called drug-induced enterocolitis syndrome; symptoms start with repetitive vomiting (1 to 4 hours after administration), and further symptoms can include stomach pain, abnormal drowsiness, diarrhoea, low blood pressure and can progress to shock. • Raised itchy rash • Inflammation of blood vessels (vasculitis) which may be visible as red or purple raised spots on the skin, but can affect other parts of the body • Fever, joint pain, swollen glands in the neck, armpit or groin • Swelling, sometimes of the face or mouth (angiodema), which may cause difficulty in swallowing or breathing • Collapse • Chest pain which can be a sign of a potentially serious allergic reaction called Kounis syndrome. <p>Liver problems</p> <ul style="list-style-type: none"> • itching, yellowing of the skin and eyes (jaundice), chest pain, and dark coloured urine. This may be a sign of liver disease. It may occur while taking AMOXICLAV Devatis Forte or even a few weeks after stopping AMOXICLAV Devatis Forte. 	<p>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.</p>

<p>Immune system disorders</p> <ul style="list-style-type: none"> • symptoms such as fever, severe chills, sore throat or mouth ulcers which can be a sign of lack of white blood cells. 	
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Serious side effects	What to do
<p>Skin and subcutaneous disorders flu like symptoms with a rash, fever, swollen glands, abnormal blood test results (including increased white blood cells (eosinophilia) and liver enzymes) (Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS)) and symmetrical drug related intertriginous and flexural exanthema (SDRIFE) (baboon syndrome).</p> <ul style="list-style-type: none"> • Skin rash, which may blister and looks like small targets (central dark spots surrounded by a paler area, with a dark ring around the edge-erythema multiforme) string of pearls (linear IgA disease)– even if it starts a few days or more after starting AMOXICLAV Devatis Forte. • itchy or burning skin – even if it starts a few days or more after starting AMOXICLAV Devatis Forte. <p>Nervous system disorders</p> <ul style="list-style-type: none"> • seizures (very rare), dizziness, headache. <p>Other side effects reported with AMOXICLAV Devatis Forte include:</p> <ul style="list-style-type: none"> • sudden signs of allergy such as rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing. 	<p>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.</p> <p>If any of the following happen, stop taking AMOXICLAV Devatis Forte and tell your doctor immediately or go to the accident and Emergency department at your nearest hospital:</p> <p>Tell your doctor immediately if you notice any of the following side effects, particularly if they occur several weeks after stopping treatment with AMOXICLAV Devatis Forte:</p>

- swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing
- chest pain.

Gastrointestinal disorders

severe abdominal cramps or stomach cramps, water diarrhoea which may also be bloody, fever in combination of one or both of the above. These are rare but serious side effects. You may have a serious condition affecting your bowel. Therefore, you may need urgent medical attention. Do not take any diarrhoea medicine without first checking with your doctor.

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 via <https://pophealth.my.site.com/carmreportnz/s/>.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

Product description

What it looks like

AMOXICLAV Devatis Forte is a white to creamy white coloured powder supplied in an amber coloured glass bottle of 125 ml or 200 ml.

Once made up, the bottle contains 100 ml (125 ml bottle) or 150 ml (200 ml bottle) of a white to creamy white liquid mixture called a suspension.

Each pack contains a 5 ml dosing syringe (polypropylene/polyethylene) with 0.5 mL graduation marks and an adaptor for the syringe (polyethylene).

Ingredients**Active ingredient**

The active substances are amoxicillin and clavulanic acid. Each ml of suspension contains amoxicillin trihydrate equivalent to 50 mg amoxicillin and potassium clavulanate equivalent to 12.5 mg of clavulanic acid. 5 ml of suspension contain amoxicillin trihydrate equivalent to 250 mg amoxicillin and potassium clavulanate equivalent to 62.5 mg of clavulanic acid.

Other ingredients

The other ingredients are silicon dioxide, microcrystalline cellulose, carmellose sodium, sucralose, tri-sodium citrate anhydrous, citric acid anhydrous, silica colloidal anhydrous, mannitol, xanthan gum, vanilla flavour, tutti-frutti flavour.

Contains 9 mg of sucralose and 2388.12 mg of mannitol per recommended maximum daily dose. Products



containing mannitol may have a laxative effect or cause diarrhoea.

Sponsor

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