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## AMOXICLAV Devatis Duo 400 mg/57 mg/5 ml Powder for Oral Suspension

*Each 5 ml suspension contains potassium clavulanate/amoxicillin trihydrate equivalent to 57 mg clavulanic acid/400 mg amoxicillin.*

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### Consumer Medicine Information (CMI)

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#### What is in this leaflet

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This leaflet answers some common questions about AMOXICLAV Devatis Duo. It does not contain all the available information. It does not take the place of talking to your doctor, nurse or pharmacist.

Please read this leaflet before you start taking AMOXICLAV Devatis Duo. If you are helping someone else take AMOXICLAV Devatis Duo, please read this leaflet before you give the first dose.

All medicines have risks and benefits. Your doctor has weighed the expected benefits against possible risks of you using AMOXICLAV Devatis Duo. 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.**

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#### What AMOXICLAV Devatis Duo is used for

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

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

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

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

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#### Before you take AMOXICLAV Devatis Duo

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**Do not take AMOXICLAV Devatis Duo if:**

- you have an allergy to AMOXICLAV Devatis Duo, 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 Duo 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 Duo) before.
- the packaging is torn or shows signs of tampering, or the suspension 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 Duo, contact your doctor.

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

### ***Before you start to take AMOXICLAV Devatis Duo***

#### **Tell 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 Duo 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 pregnant or intend to become pregnant. Your doctor will discuss with you the possible risks and benefits of using AMOXICLAV Devatis Duo during pregnancy.
- you are breastfeeding or wish to breastfeed. Your doctor will discuss with you the possible risks and benefits of using AMOXICLAV Devatis Duo during breastfeeding.
- you are taking any other medicines or herbal remedies

AMOXICLAV Devatis Duo is not addictive.

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

### ***Taking other medicines with AMOXICLAV Devatis Duo***

#### **Tell your doctor if you are taking:**

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

*Some medicines may affect the way other medicines work. Your doctor or pharmacist will be able to tell you which medicines are safe to take with AMOXICLAV Devatis Duo.*

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## **How to take AMOXICLAV Devatis Duo**

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

Read the label carefully. If you have any concerns about how to take AMOXICLAV Devatis Duo, 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:** 2.5 ml of AMOXICLAV Devatis Duo 2 times daily. In severe infections this may be increased to 5 ml of AMOXICLAV Devatis Duo 2 times a day.

**Children 2-6 years:** 1.25 ml of AMOXICLAV Devatis Duo 2 times a day. In severe infections this may be increased to 2.5 ml AMOXICLAV Devatis Duo 2 times a day.

**Children 9 months - 2 years:** 0.625 ml of AMOXICLAV Devatis Duo 2 times a day.

**Children 3-9 months:** No dosage recommendations can be made for this category.

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

Preparation of AMOXICLAV Devatis Duo suspension:

1. Tap bottle until all powder flows freely.
2. Add approximately 2/3 of total water for reconstitution. Shake vigorously to wet the powder.



3. Add water up to the mark on the bottle (remaining 1/3) and shake well again.
4. The dose recommended by your doctor is given to the patient using a syringe that is supplied with the bottle.

Volume of water to be added at reconstitution (ml)	Final volume of reconstituted oral suspension (ml)
32	35
62	70
87	100
122	140

Shake the bottle well before each dose.

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 Duo

The syringe is only for use with AMOXICLAV Devatis Duo 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.

***How and when to take AMOXICLAV Devatis Duo***

Shake the suspension well before each dose, and 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 Duo at the start of a meal. This makes it less likely to cause stomach upset or discomfort.

***How long to take AMOXICLAV Devatis Duo***

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 Duo is not usually used for longer than 14 days without another check-up by the doctor.

***If you forget to take a dose of AMOXICLAV Devatis Duo***

If you forget to take a dose of AMOXICLAV Devatis Duo take it as soon as you remember. If it is nearly time for your next dose skip the dose you have missed and take the next dose as you are meant to. Do not take a double dose to make up for the dose you have missed. Try and remember to take it at the start of a meal.

If you are not sure whether to skip the dose, talk to your doctor or pharmacist.

It is important to take the suspension as prescribed so it will work properly. If you have trouble remembering to take the doses ask your pharmacist for hints.

***If you take too much (Overdose)***

**If you take too much AMOXICLAV Devatis Duo you may get diarrhoea and nausea. If too much suspension has been taken immediately telephone your doctor or the National Poisons Information Centre (telephone 0800 POISON or 0800 764 766) for advice. Do this even if there are no signs of discomfort or poisoning. Keep telephone numbers of these places handy.**

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**While you are taking AMOXICLAV Devatis Duo**

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***Things you must do***

- If the symptoms of your infection do not improve within a few days, or if they become worse, tell your doctor.
- If you develop itching with swelling or skin rash or difficulty breathing while you are taking AMOXICLAV Devatis Duo do not take any more and contact your doctor immediately.
- If you get severe diarrhoea or stomach cramps tell your doctor, pharmacist or nurse immediately. Do this even if it occurs several weeks after AMOXICLAV Devatis Duo 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.
- If you get a sore white mouth or tongue while taking or soon after stopping AMOXICLAV Devatis Duo, tell your doctor. Also tell your doctor if you get vaginal itching or discharge. This may mean you have a fungal infection called thrush.
- If you become pregnant while you are taking AMOXICLAV Devatis Duo, tell your doctor.
- If you are about to start taking any new medicine, tell your doctor and pharmacist that you are taking AMOXICLAV Devatis Duo.
- If you have to have any blood tests tell your doctor you are taking AMOXICLAV Devatis Duo. AMOXICLAV Devatis Duo 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 Duo.

***Things to be careful of***

- Do not stop taking your suspension 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 Duo to anyone else, even if they have the same condition as you.
- Do not use AMOXICLAV Devatis Duo to treat any other complaints unless your doctor tells you to.

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**Side effects**

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**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking AMOXICLAV Devatis Duo.**

Like other medicines, AMOXICLAV Devatis Duo can cause some side effects. If they occur, they are most likely to be minor and temporary. However, rarely some may be serious and need medical attention.

**Ask your doctor or pharmacist to answer any questions you may have.**

### *Mild Effects*

**Tell your doctor if you notice any of the following that are troublesome or ongoing:**

- oral thrush - white, furry, sore tongue and mouth
- vaginal thrush - sore and itchy vagina and/or discharge
- diarrhoea, nausea, vomiting or indigestion.

### *More Serious Effects*

**Tell your doctor immediately if you notice any of the following:**

- nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and eyes (jaundice), and dark coloured urine. This may be a sign of liver disease. It may occur while taking AMOXICLAV Devatis Duo or even a few weeks after stopping AMOXICLAV Devatis Duo.
- symptoms such as fever, severe chills, sore throat or mouth ulcers which can be a sign of lack of white blood cells
- rash – even if it starts a few days or more after starting AMOXICLAV Devatis Duo
- itchy or burning skin – even if it starts a few days or more after starting AMOXICLAV Devatis Duo

You may need urgent medical attention. Serious side effects are rare.

**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 Duo:**

- severe abdominal cramps or stomach cramps
- watery and severe diarrhoea, which may also be bloody
- fever, in combination with 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.

**If any of the following happen, stop taking AMOXICLAV Devatis Duo and tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital:**

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

These are very serious side effects. You may need urgent medical attention or hospitalization. These side effects are rare.

**Other side effects reported with AMOXICLAV Devatis Duo include:**

- Seizures (very rare), dizziness, headache.
- 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)
- flu like symptoms with a rash, fever, swollen glands, and abnormal blood test results (including increased white blood cells (eosinophilia) and liver enzymes) (Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS)).

Some people may get other side effects while taking AMOXICLAV Devatis Duo.

Ask your doctor or pharmacist if you don't understand anything in this list.  
Do not be alarmed by this list of possible side effects. You may not experience any of them.

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## After taking AMOXICLAV Devatis Duo

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### **Storage**

Keep AMOXICLAV Devatis Duo 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 Duo 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.

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## Product description

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### **What it looks like**

AMOXICLAV Devatis Duo is a white to creamy white coloured powder supplied in an amber coloured glass bottle of 100 ml, 125 ml or 200 ml.

Once made up, the bottle contains 35 ml or 70 ml (100 ml bottle), 100 ml (125 ml bottle) or 140 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 80 mg amoxicillin and potassium clavulanate equivalent to 11.4 mg of clavulanic acid. 5 ml of suspension contain amoxicillin trihydrate equivalent to 400 mg amoxicillin and potassium clavulanate equivalent to 57 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.

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## Sponsor

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