

PACKAGE LEAFLET: INFORMATION FOR THE USER

Amoclav 125 mg/31.25 mg per 5 ml Powder for oral suspension Amoxicillin/clavulanic acid

Read all of this leaflet carefully before you start giving your child this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist or nurse.
- This medicine has been prescribed for a baby or child only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as your child's.
- If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

In this leaflet:

1. What Amoclav is and what it is used for
2. What you need to know before you give Amoclav
3. How to give Amoclav
4. Possible side effects
5. How to store Amoclav
6. Contents of the pack and other information

1. WHAT AMOCLAV IS AND WHAT IT IS USED FOR

Amoclav is an antibiotic and works by killing bacteria that cause infections. It contains two different medicines called amoxicillin and clavulanic acid. Amoxicillin belongs to a group of medicines called "penicillins" that can sometimes be stopped from working (made inactive). The other active component (clavulanic acid) stops this from happening.

Amoclav is used in babies and children to treat the following infections:

- middle ear and sinus infections
- respiratory tract infections
- urinary tract infections
- skin and soft tissue infections including dental infections
- bone and joint infections

2. WHAT YOU NEED TO KNOW BEFORE YOU GIVE AMOCLAV

Do not give your child Amoclav:

- if they are allergic (hypersensitive) to amoxicillin, clavulanic acid, penicillin or any of the other ingredients of Amoclav (listed in section 6)
- if they have ever had a severe allergic (hypersensitive) reaction to any other antibiotic. This can include a skin rash or swelling of the face or neck
- if they have ever had liver problems or jaundice (yellowing of the skin) when taking an antibiotic.

➔ **Do not give Amoclav to your child if any of the above apply to your child.** If you are not sure, talk to their doctor or pharmacist before giving Amoclav.

Take special care with Amoclav

Talk to their doctor or pharmacist before giving your child this medicine if they:

- have glandular fever
- are being treated for liver or kidney problems
- are not passing water regularly.

If you are not sure if any of the above apply to your child, talk to their doctor or pharmacist before giving Amoclav.

In some cases, your doctor may investigate the type of bacteria that is causing your child's infection. Depending on the results, your child may be given a different strength of Amoclav or a different medicine.

Conditions you need to look out for

Amoclav can make some existing conditions worse, or cause serious side effects. These include allergic reactions, convulsions (fits) and inflammation of the large intestine. You must look out for certain symptoms while your child is taking Amoclav, to reduce the risk of any problems. See '*Conditions you need to look out for*' in **Section 4**.

Blood and urine tests

If your child is having blood tests (such as red blood cell status tests or liver function tests) or urine tests (for glucose), let the doctor or nurse know that they are taking Amoclav. This is because Amoclav can affect the results of these types of tests.

Using other medicines

Please tell your doctor or pharmacist if your child is using or have recently used any other medicines. This includes medicines that can be bought without a prescription and herbal medicines.

If your child is taking allopurinol (used for gout) with Amoclav, it may be more likely that they will have an allergic skin reaction.

If your child is taking probenecid (used for gout), your doctor may decide to adjust your dose of Amoclav.

If medicines to help stop blood clots (such as warfarin) are taken with Amoclav then extra blood tests may be needed.

Amoclav can affect how methotrexate (a medicine used to treat cancer or rheumatic diseases) works.

Amoclav may affect how mycophenolate mofetil (a medicine used to prevent the rejection of transplanted organs) works.

Pregnancy and breast-feeding

If your child who is about to take this medicine is pregnant or breast-feeding, please tell your doctor or pharmacist.

Ask your doctor or pharmacist for advice before taking any medicine.

Important information about some of the ingredients of Amoclav.

- Amoclav contains 8.5 mg aspartame (E951) in each 5 ml dose. Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly. Amoclav contains maltodextrin (glucose). If you have been told by your

doctor that you or your child has an intolerance to some sugars, contact your doctor before taking this medicinal product.

This medicine contains 0.13 mg sorbitol (E420) in each 5 ml dose.

- This medicine contains less than 1 mmol sodium (23 mg) per 5 ml suspension, that is to say essentially 'sodium-free'
- This medicine contains sulphur dioxide (E 220). May rarely cause severe hypersensitivity reactions and bronchospasm.

3. HOW TO GIVE AMOCLAV

Always give Amoclav exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Adults and children weighing 40 kg and over

- This suspension is not usually recommended for adults and children weighing 40 kg and over.
Ask your doctor or pharmacist for advice

Children weighing less than 40 kg

All doses are worked out depending on the child's bodyweight in kilograms.

- Your doctor will advise you on how much Amoclav you should give to your baby or child.
- You may be provided with a plastic measuring spoon or measuring cup. You should use this to give the correct dose to your baby or child.
- Usual dose -20 mg/5 mg to 60 mg/15 mg for each kilogram of body weight a day, given in three divided doses.

Patients with kidney and liver problems

- If your child has kidney problems the dose might be lowered. A different strength or a different medicine may be chosen by your doctor.
- If your child has liver problems they may have more frequent blood tests to check how your liver is working.

How to give Amoclav

- Always shake the bottle well before each dose
- Give at the start of a meal or slightly before
- Space the doses evenly during the day, at least 4 hours apart. Do not take 2 doses in 1 hour.
- Do not give your child Amoclav for more than 2 weeks. If your child still feels unwell they should go back to see the doctor.

If you give more Amoclav than you should

If you give your child too much Amoclav, signs might include an upset stomach (feeling sick, being sick or diarrhoea) or convulsions. Talk to their doctor as soon as possible. Take the medicine bottle to show the doctor.

If you forget to give Amoclav

If you forget to give your child a dose, give it as soon as you remember. You should not give your child the next dose too soon, but wait about 4 hours before giving the next dose.

If your child stops taking Amoclav

Keep giving your child Amoclav until the treatment is finished, even if they feel better. Your child needs every dose to help fight the infection. If some bacteria survive they can cause the infection to come back.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Amoclav can cause side effects, although not everybody gets them. The side effects below may happen with this medicine

Conditions you need to look out for

Allergic reactions:

- skin 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 (angioedema), causing difficulty in breathing
- collapse
- chest pain in the context of allergic reactions, which may be a symptom of allergy triggered cardiac infarction (Kounis syndrome)

➔ **Contact a doctor immediately** if your child gets any of these symptoms. **Stop taking Amoclav.**

Inflammation of large intestine

Inflammation of the large intestine, causing watery diarrhoea usually with blood and mucus, stomach pain and/or fever.

Acute inflammation of the pancreas (acute pancreatitis)

If you have severe and on-going pain in the stomach area this could be a sign of acute pancreatitis.

Drug-induced enterocolitis syndrome (DIES):

DIES has been reported mainly in children receiving amoxicillin/clavulanate. It is a certain kind of allergic reaction with the leading symptom of repetitive vomiting (1-4 hours after drug intake). Further symptoms could comprise abdominal pain, lethargy, diarrhoea and low blood pressure.

➔ **Contact your doctor as soon as possible** for advice if your child gets these symptoms.

Very common side effects

These may affect more than 1 in 10 people

- diarrhoea (in adults).

Common side effects

These may affect up to 1 in 10 people

- thrush (*candida* - a yeast infection of the vagina, mouth or skin folds)
- feeling sick (nausea), especially when taking high doses
- ➔ if affected take Amoclav with a meal
- vomiting
- diarrhoea (in children).

Uncommon side effects

These may affect up to 1 in 100 people

- skin rash, itching
- raised itchy rash (hives)
- indigestion
- dizziness
- headache.

Uncommon side effects that may show up in your blood tests:

- increase in some substances (enzymes) produced by the liver.

Rare side effects

These may affect up to 1 in 1000 people

- 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*)
- if you notice any of these symptoms contact a doctor urgently.

Rare side effects that may show up in your blood tests:

- low number of cells involved in blood clotting
- low number of white blood cells.

Other side effects

Other side effects have occurred in a very small number of people but their exact frequency is unknown.

- Allergic reactions (see above)
- Inflammation of the large intestine (see above)
- Serious skin reactions:
 - a widespread rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals (*Stevens-Johnson syndrome*), and a more severe form, causing extensive peeling of the skin (more than 30% of the body surface – *toxic epidermal necrolysis*)
 - widespread red skin rash with small pus-containing blisters (*bullous exfoliative dermatitis*)
 - a red, scaly rash with bumps under the skin and blisters (*exanthemous pustulosis*).
 - 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))
 - a red rash commonly seen on both sides of buttocks, upper inner thighs, armpits, neck (Symmetrical Drug-Related Intertriginous and Flexural Exanthema (SDRIFE)).
- Inflammation of the protective membranes surrounding the brain and spinal cord (*aseptic meningitis*)
- Rash with blisters arranged in a circle with central crusting or like a string of pearls (linear IgA disease)

→ **Contact a doctor immediately if you get any of these symptoms.**

- inflammation of the liver (hepatitis)
- jaundice, caused by increases in the blood of bilirubin (a substance produced in the liver) which may make your skin and whites of the eyes appear yellow
- inflammation of tubes in the kidney
- blood takes longer to clot
- hyperactivity
- convulsions (in people taking high doses of Amoclav or who have kidney problems)

- black tongue which looks hairy

Side effects that may show up in your blood or urine tests:

- severe reduction in the number of white blood cells
- low number of red blood cells (haemolytic anaemia)
- crystals in urine leading to acute kidney injury.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRÁ Pharmacovigilance, Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE AMOCLAV

To the pharmacist: Do not store above 25°C.

Store in the original package in order to protect from light and moisture.

After opening of the screw cap, ensure that the bottle cap seal is intact and tightly attached to the bottle rim. Do not use if not intact.

To the patient/parent: Shake well before use
Reconstituted suspension

Store in a refrigerator (2-8°C) and use within 7 days.

Keep out of the sight and reach of children.

Do not use Amoclav after the expiry date which is stated on the carton. The expiry date refers to the first day of that month. Do not use this medicine if lumps of powder are visible in the bottle before reconstitution. Do not use the reconstituted suspension if the colour is not off-white.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Amoclav contains

The active substances are amoxicillin and clavulanic acid. Each 5 ml reconstituted suspension contains amoxicillin trihydrate equivalent to 125 mg amoxicillin and potassium clavulanate equivalent to 31.25 mg clavulanic acid.

This combination of antibiotics is also known as co-amoxiclav.

The other ingredients are:

Citric acid anhydrous, trisodium citrate anhydrous, aspartame (E951), talc, guar, silicon dioxide precipitated, flavouring agents: lemon; containing sorbitol (E420) and glucose, peach-apricot; containing sorbitol (E420) and orange; containing essence of bergamot. Please refer to Section 2 “ Important information about some of the ingredients of Amoclav”

What Amoclav looks like and contents of the pack

Amoclav Powder for oral suspension is off-white in colour with a fruity flavour. Amoclav 125 mg/31.25 mg/5 ml Powder for oral suspension comes in a bottle in which powder has been mixed with water by your pharmacist to make a suspension. The bottle contains 60 ml or 100 ml.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer**Product Authorisation Holder:**

Rowex Ltd., Bantry, Co Cork, Ireland

Manufacturer:

Sandoz GmbH, Biochemiestrasse 10, A-6250 Kundl, Tirol, Austria
Rowa Pharmaceuticals Ltd, Bantry, Co Cork, Ireland

This leaflet was last revised in MM/YYYY.

Advice/medical education

Antibiotics are used to treat infections caused by bacteria. They have no effect against infections caused by viruses.

Sometimes an infection caused by bacteria does not respond to a course of an antibiotic. One of the commonest reasons for this to occur is because the bacteria causing the infection are resistant to the antibiotic that is being taken. This means that they can survive and even multiply despite the antibiotic.

Bacteria can become resistant to antibiotics for many reasons. Using antibiotics carefully can help to reduce the chance of bacteria becoming resistant to them.

When your doctor prescribes a course of an antibiotic it is intended to treat only your current illness. Paying attention to the following advice will help prevent the emergence of resistant bacteria that could stop the antibiotic working.

1. It is very important that you take the antibiotic at the right dose, at the right times and for the right number of days. Read the instructions on the label and if you do not understand anything ask your doctor or pharmacist to explain.
2. You should not take an antibiotic unless it has been prescribed specifically for you and you should use it only to treat the infection for which it was prescribed.
3. You should not take antibiotics that have been prescribed for other people even if they had an infection that was similar to yours.
4. You should not give antibiotics that were prescribed for you to other people.
5. If you have any antibiotic left over when you have taken the course as directed by your doctor you should take the remainder to a pharmacy for appropriate disposal.

Instructions for reconstitution:

Check cap seal is intact before using.

Shake bottle to loosen powder. Add volume of water (as indicated below) and shake well.

<u>Strength</u>	<u>Volume of water to be added at reconstitution (ml)</u>	<u>Final volume of reconstituted oral suspension (ml)</u>
125 mg/31.25 mg/5 ml	Add 57ml	60
	Add 95ml	100

The suspension may be diluted with an equal quantity of water to provide a half strength suspension