

PACKAGE LEAFLET: INFORMATION FOR THE USER

Amoclav 250mg/125mg Film-coated tablets amoxicillin/clavulanic acid

Read all of this leaflet carefully before you start taking 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 you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- 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.

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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 adults and children to treat the following infections:

- sinus infections
- urinary tract infections
- skin infections
- dental infections.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE AMOCLAV

Do not take Amoclav:

- if you are allergic (hypersensitive) to amoxicillin, clavulanic acid, penicillin or any of the other ingredients of Amoclav (listed in section 6)
- if you 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 you have ever had liver problems or jaundice (yellowing of the skin) when taking an antibiotic.

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

Take special care with Amoclav

Talk to your doctor or pharmacist before taking this medicine if you:

- 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 you, talk to your doctor or pharmacist before taking Amoclav.

In some cases, your doctor may investigate the type of bacteria that is causing your infection. Depending on the results, you 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 you are 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 you are 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 you 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 you are using or have recently used any other medicines. This includes medicines that can be bought without a prescription and herbal medicines.

If you are taking allopurinol (used for gout) with Amoclav, it may be more likely that you'll have an allergic skin reaction.

If you are 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 mycophenylate mofetil (a medicine used to prevent the rejection of transplanted organs) works.

Pregnancy and breast-feeding

If you are pregnant, you think you might be pregnant or if you are breast-feeding, please tell your doctor or pharmacist.

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

Driving and using machines

Amoclav can have side effects and the symptoms may make you unfit to drive. Don't drive or operate machinery unless you are feeling well.

Important information about some of the ingredients of Amoclav

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

This medicine contains 24.5 mg potassium per tablet. To be taken into consideration by patients with reduced kidney function or patients on a controlled potassium diet.

3. HOW TO TAKE AMOCLAV

Always take 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

The usual dose is:

- 1 tablet three times a day.

Children weighing less than 40 kg

Children aged 6 years or less should preferably be treated with Amoclav oral suspension.

Amoclav 250mg/125mg Film-coated Tablets are not recommended.

Patients with kidney and liver problems

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

How to take Amoclav

- Swallow the tablets whole with a glass of water 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 take Amoclav for more than 2 weeks. If you still feel unwell you should go back to see the doctor.

If you take more Amoclav than you should

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

If you forget to take Amoclav

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

If you stop taking Amoclav

Keep taking Amoclav until the treatment is finished, even if you feel better. You need 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.

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 you get 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. It is a certain kind of allergic reaction with the leading symptom of repetitive vomiting (1-4 hours after drug administration). Further symptoms could comprise abdominal pain, lethargy, diarrhoea, and low blood pressure.

➔ **Contact your doctor as soon as possible** for advice if you get 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 before food
- 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))
- Rash with blisters arranged in a circle with central crusting or like a string of pearls (linear IgA disease)
- Inflammation of the membranes that surround the brain and spinal cord (aseptic meningitis).

➔ **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
- stained teeth (in children), usually removed by brushing.

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 renal 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 HPRA 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

Do not store above 25°C. Keep the blisters in the outer carton.

Keep out of the sight and reach of children.

Do not use Amoclav tablets after the expiry date which is stated on the carton and blister foil. The expiry date refers to the first day of that month.

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. CONTENTS OF THE PACK AND OTHER INFORMATION

What Amoclav contains

The active substances are amoxicillin and clavulanic acid. Each film-coated tablet contains amoxicillin trihydrate equivalent to 250mg of amoxicillin and potassium clavulanate equivalent to 125mg of clavulanic acid. Amoxicillin is an antibiotic and clavulanic acid is a beta-lactamase inhibitor, which is commonly combined with the penicillin group antibiotics to overcome antibiotic resistance.

The other ingredients in the tablets are –

Magnesium stearate (E572), talc, povidone, microcrystalline cellulose (E460), croscarmellose sodium, triethyl citrate, hypromellose (E464), cetyl alcohol, ethylcellulose, sodium laurilsulfate and titanium dioxide (E171).

What Amoclav looks like and contents of the pack

Amoclav 250mg/125mg Film-coated tablets are white to light-yellow, oblong, convex, film coated tablets with markings 'AXC 375' on one side and 'G G' on the other side. Both sides carry a scoreline.

Amoclav 250mg/125mg Film-coated tablets come in packs of 3, 6, 15, 16, 21, 30, 50 or 90 film-coated tablets. Hospital packs of 100 and 500 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturers

Marketing Authorisation Holder

Rowex Ltd., Bantry, Co Cork, Ireland.

Manufacturers

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

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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.