

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr **AMOXICILLIN/CLAV**

Amoxicillin and Clavulanate Potassium Tablets

Read this carefully before you start taking **AMOXICILLIN/CLAV** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **AMOXICILLIN/CLAV**.

Serious Warnings and Precautions

Hypersensitivity: Serious allergic reactions including death and severe skin adverse reactions have been reported in patients taking antibiotics, including amoxicillin, one of AMOXICILLIN/CLAV's medicinal ingredients. See 'Serious side effects and what to do about them' Table.

What is AMOXICILLIN/CLAV used for?

AMOXICILLIN/CLAV is an antibiotic used to treat bacterial infections.

Antibacterial drugs like AMOXICILLIN/CLAV treat only bacterial infections. They do not treat viral infections such as the common cold. Although you may feel better early in treatment, AMOXICILLIN/CLAV should be taken exactly as directed. Misuse or overuse of AMOXICILLIN/CLAV could lead to the growth of bacteria that will not be killed by AMOXICILLIN/CLAV (resistance). This means that AMOXICILLIN/CLAV may not work for you in the future. Do not share your medicine.

How does AMOXICILLIN/CLAV work?

AMOXICILLIN/CLAV's ingredients work in 2 ways. Amoxicillin causes bacterial death. Clavulanic acid helps amoxicillin kill bacteria.

What are the ingredients in AMOXICILLIN/CLAV?

Medicinal ingredients: amoxicillin (as trihydrate) and clavulanic acid (as clavulanate potassium).

Non-medicinal ingredients: crospovidone (875 mg / 125 mg only), ethylcellulose, hydroxypropyl methylcellulose, magnesium stearate, microcrystalline cellulose, silicon dioxide, sodium starch glycolate, talc, titanium dioxide and triethyl citrate.

AMOXICILLIN/CLAV comes in the following dosage forms:

AMOXICILLIN/CLAVs: 500 mg / 125 mg and 875 mg / 125 mg of amoxicillin / clavulanic acid.

Do not use AMOXICILLIN/CLAV if:

- You or your child are allergic to:
 - Amoxicillin
 - Beta-lactam antibiotics (such as penicillins and cephalosporins)
 - Any of the other ingredients of AMOXICILLIN/CLAV (see **What are the ingredients in AMOXICILLIN/CLAV**)
- You or your child have had a history of:
 - Jaundice (yellowing of the skin and/or eyes) or liver disease, after taking AMOXICILLIN/CLAV
- You have mononucleosis

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take AMOXICILLIN/CLAV. Talk about any health conditions or problems you may have, including if you:

- Have had an allergic reaction (such as a rash) when taking an antibiotic.
- Start to have a skin rash while taking AMOXICILLIN/CLAV then:
 - stop taking AMOXICILLIN/CLAV.
 - tell your healthcare professional right away
- Have mononucleosis.
- Have liver or kidney problems.
- Are pregnant or planning to become pregnant.
- Are breastfeeding or planning to breastfeed:
 - The amoxicillin in AMOXICILLIN/CLAV is passed into human breast milk. Talk about this with your healthcare professional.
- Are taking a birth control pill. Birth control pills may not work as well if you take AMOXICILLIN/CLAV.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with AMOXICILLIN/CLAV:

- Allopurinol or probenecid (for treatment of gout).
- Anticoagulants (used to prevent blood clots) such as warfarin.
- Mycophenolate mofetil (suppressed the immune system).
- Methotrexate (used to treat conditions such as cancer and severe psoriasis).

How to take AMOXICILLIN/CLAV:

You must use the medicine as instructed by your healthcare professional. Your healthcare professional will decide how much medicine you or your child need each day, and how many days you should take it for.

Treatment normally lasts 7 to 10 days. Your healthcare professional may ask you to take

AMOXICILLIN/CLAV for 48 to 72 hours more depending on how it works for you.

It is better to take AMOXICILLIN/CLAV at the same time as a meal, but it still works without food. If there is anything you do not understand please ask your healthcare professional.

Usual dose:

Adults:

The usual adult dose is one AMOXICILLIN/CLAV (500 mg / 125 mg) every 12 hours. For more severe infections and infections of the lower respiratory tract, your healthcare professional may prescribe one AMOXICILLIN/CLAV (875 mg / 125 mg) every 12 hours or one AMOXICILLIN/CLAV (500 mg / 125 mg) every 8 hours.

Children weighing more than 38 kg should be dosed according to adult recommendations.

Patients with kidney problems:

If you have kidney problems, your doctor may adjust your dose.

Overdose:

If you think you, or a person you are caring for, have taken too much AMOXICILLIN/CLAV, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If you or your child miss a dose of AMOXICILLIN/CLAV, take it as soon as you remember. However, if it is almost time for the next dose, do not take the missed dose. Instead, continue with your next scheduled dose. Do not try to make up for the missed dose by taking double the dose next time.

What are possible side effects from using AMOXICILLIN/CLAV?

These are not all the possible side effects you may have when taking AMOXICILLIN/CLAV. If you experience any side effects not listed here, tell your healthcare professional.

- very common side effect in adults can be diarrhea (loose, or watery bowel movements).
- common side effects can be:
 - A yeast infection of the nails, skin, mouth, vagina, stomach or urinary tract
 - Nausea (feeling sick) or vomiting
 - Diarrhea (loose, or watery bowel movements) in children
- uncommon side effects can be:
 - Indigestion and headache
 - Mild skin rash or itching
- very rare side effects can be:
 - Your tongue may change colour to yellow, brown or black or look “hairy”

- Your teeth may discolour
 - To reduce or prevent discolouring, brush your teeth thoroughly
 - Talk to your dentist or doctor if this does not go away

AMOXICILLIN/CLAV can cause abnormal urine tests (for glucose) results or blood test (for pregnancy) results. If you are getting blood or urine tests done, let the healthcare professional know that you are taking AMOXICILLIN/CLAV.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
RARE			
Blood problems , with symptoms such as bleeding, or bruising, more easily than usual			✓
Erythema multiforme (allergic skin reaction): skin reaction which results in itchy reddish purple patches especially on the palms of the hands or soles of the feet			✓
VERY RARE			
Allergic reactions: difficulty breathing, fever, hives (itchy and red bumps on skin), itching, rash, swelling of your tongue or throat			✓
Central Nervous System (fits or seizures) problems such as convulsions (aseptic meningitis) inflammation of the protective membrane surrounding the brain			✓
<i>Clostridium difficile</i> colitis (bowel inflammation): with symptoms such as severe diarrhea (bloody or watery) with or without fever, abdominal pain, or tenderness			✓
Drug reaction with eosinophilia and systemic symptoms (DRESS) (severe life-threatening reaction): flu-like symptoms with fever, rash, swelling of the face or glands			✓
Kidney problems with symptoms such as blood in the urine which may be associated with a rash, fever, joint pain, or a reduction in			✓

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
passing water (urination)			
Liver problems with symptoms such as yellowing of the skin and/or eyes, or dark coloured urine, nausea, vomiting, abdominal pain, fever or unusual tiredness			✓
Severe skin reactions: (Steven-Johnson syndrome and toxic epidermal necrolysis) blisters and peeling skin, particularly around the mouth, nose, eyes, and genitals; or more severely, blisters and peeling skin on a lot of the body; body aches or fever (bullous exfoliative dermatitis) red itchy scaly rash with blisters and bumps under the skin (exanthemous pustulosis) widespread red skin rash with small blisters containing pus			✓
Vasculitis (blood vessel inflammation): red or purple raised spots on the skin, fatigue, fever, numbness or weakness			✓
UNKNOWN FREQUENCY			
Cardiovascular Kounis syndrome: chest pain which can be a sign of a potentially serious allergic reaction			✓
Drug-induced enterocolitis syndrome: repetitive vomiting (1 to 4 hours after taking AMOXICILLIN/CLAV), stomach pain, abnormal drowsiness, diarrhea and low blood pressure. These can be a sign of a serious allergic reaction			✓
Linear IgA disease: rash with blisters arranged in a circle with central crusting or like a string of pearls	✓		
Symmetrical drug-related intertriginous and flexural exanthema (SDRIFE): a red rash			✓

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
commonly seen on both sides of buttocks, upper inner thighs, armpits, and neck			

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Store at 15° - 25°C, protected from moisture and protected from light.

Keep out of reach and sight of children.

If you want more information about AMOXICILLIN/CLAV:

- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website <https://www.sanis.com/products/>, or by calling 1-866-236-4076.

This leaflet was prepared by Sanis Health Inc.

Last Revised: JUN 10, 2025