

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr **PRO-AMOXI CLAV**

Amoxicillin and Clavulanate Potassium Tablets, USP

Read this carefully before you start taking **PRO-AMOXI 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 **PRO-AMOXI 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 PRO-AMOXI CLAV's medicinal ingredients. See 'Serious side effects and what to do about them' Table.

What is PRO-AMOXI CLAV used for?

PRO-AMOXI CLAV is an antibiotic used to treat bacterial infections.

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

How does PRO-AMOXI CLAV work?

PRO-AMOXI CLAV's ingredients work in 2 ways. Amoxicillin causes bacterial death. Clavulanic acid helps amoxicillin kill bacteria.

What are the ingredients in PRO-AMOXI CLAV?

Medicinal ingredients: amoxicillin trihydrate and clavulanate potassium.

Non-medicinal ingredients:

Cellulose microcrystalline, Crospovidone, Colloidal Silicon Dioxide, Ethyl cellulose Dispersion, Hypromellose, Magnesium Stearate, Polyethylene Glycol, Sodium Starch Glycolate and Titanium Dioxide.

PRO-AMOXI CLAV comes in the following dosage forms:

PRO-AMOXI CLAV Tablets (amoxicillin / clavulanic acid): 250 mg/125 mg, 500 mg/125 mg and 875 mg/125 mg.

Do not use PRO-AMOXI CLAV if:

- You or your child are allergic to:

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

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

- Have had an allergic reaction (such as a rash) when taking an antibiotic.
- Start to have a skin rash while taking PRO-AMOXI CLAV then:
 - stop taking PRO-AMOXI CLAV.
 - tell your healthcare professional right away.
- Have mononucleosis.
- Have liver or kidney problems.
- Have phenylketonuria (PKU). This is because PRO-AMOXI CLAV has aspartame in it.
- Are pregnant or planning to become pregnant.
- Are breastfeeding or planning to breastfeed:
 - The amoxicillin in PRO-AMOXI 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 PRO-AMOXI CLAV.

Other warnings you should know about:

1. PRO-AMOXI CLAV treats only bacterial infections, not viral infections like the common cold.
2. Although you may feel better early in treatment, use PRO-AMOXI CLAV exactly as directed.
3. Using too much PRO-AMOXI CLAV or using it in the wrong way may cause:
 - more bacteria to grow
 - bacteria that will not be killed (resistance).
 - it not to work for you in the future (resistance).

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 PRO-AMOXI 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 PRO-AMOXI 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 PRO-AMOXI CLAV for 48 to 72 hours more depending on how it works for you.

It is better to take PRO-AMOXI 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 doses is 1 PRO-AMOXI CLAV 500 mg/125 mg tablet every 12 hours or 1 PRO-AMOXI CLAV 250 mg/125 mg tablet every 8 hours. For more severe infections and infections of the lower respiratory tract, your healthcare professional may prescribe 1 PRO-AMOXI CLAV 875 mg/125 mg tablet every 12 hours or 1 PRO-AMOXI CLAV 500 mg/125 mg tablet every 8 hours.

N.B. Since both the PRO-AMOXI CLAV 250 mg/125 mg and PRO-AMOXI CLAV 500 mg/125 mg tablets contain the same amount of clavulanic acid (125 mg as the potassium salt) two PRO-AMOXI CLAV 250 mg/125 mg tablets are not equivalent to one PRO-AMOXI CLAV 500 mg/125 mg tablet. Therefore, two PRO-AMOXI CLAV 250 mg/125 mg tablets should not be substituted for one PRO-AMOXI CLAV 500 mg/125 mg tablet.

Children:

The children's dosage should not exceed that recommended for adults. Children weighing more than 38 kg should be dosed according to the 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 PRO-AMOXI CLAV, contact a healthcare professional, hospital emergency department, or regional poison control centre or Health Canada's toll-free number, 1-844-764-7669 immediately, even if there are no signs or symptoms.

Missed Dose:

If you or your child miss a dose of PRO-AMOXI 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 PRO-AMOXI CLAV?

These are not all the possible side effects you may have when taking **PRO-AMOXI 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

PRO-AMOXI 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 PRO-AMOXI 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			✓

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	
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 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			✓

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	
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 PRO-AMOXI 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	✓		

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 how 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 room temperature (15°C - 25°C).
Keep out of reach and sight of children.

If you want more information about PRO-AMOXI 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>); or by contacting Pro Doc Ltée at 1-800-361-8559, www.prodoc.qc.ca or medinfo@prodoc.qc.ca.

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Last Revised: OCT 04, 2024