

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr **PRO-AMOX-125**

Pr **PRO-AMOX-250**

Amoxicillin for Oral Suspension

Read this carefully before you start taking **PRO-AMOX** 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-AMOX**.

What is PRO-AMOX used for?

PRO-AMOX is used to treat certain bacterial infections. It may also be used to prevent infections in:

- Mouth, nose, tonsils and throat.
- Heart.
- Emergency situation.

How does PRO-AMOX work?

PRO-AMOX interferes with bacterial cell wall. This helps to:

- Stop growth of bacteria.
- Kill the bacteria.
- Reduce the infection.

Some infections are caused by viruses, such as the common cold. **PRO-AMOX does not** kill viruses.

What are the ingredients in PRO-AMOX?

Medicinal ingredients: amoxicillin (as amoxicillin trihydrate)

Non-medicinal ingredients:

Bubble gum flavour, colloidal silicon dioxide, edetate disodium, FD&C Red No.3, silicon dioxide, sodium benzoate, sodium citrate, sucrose and xanthan gum.

If you are on a special diet, or if you are allergic to any substance, ask your doctor or pharmacist whether any of these ingredients may cause a problem.

PRO-AMOX comes in the following dosage forms:

PRO-AMOX (Regular) Suspension

- PRO-AMOX Powder for Suspension: 125 mg/5 mL and 250 mg/5 mL
- After reconstitution, each ml of bubble gum flavored Pink suspension contains amoxicillin trihydrate equivalent to 25 or 50 mg of amoxicillin, respectively. The reconstituted suspension is stable for 7 days at room temperature (15°C to 30°C) and 14 days if refrigerated (2°C to 8°C). Discard unused suspension after 7/14 days. Available in bottles of 100 mL and 150 mL.

Do not use PRO-AMOX if:

- You have any allergies to this drug or to its ingredients (See “What are the ingredients in PRO-AMOX?”).
- You have allergy to packaging components of this drug.
- You have allergy to penicillins, cephalosporins or similar antibiotics such as amoxicillin, ampicillin, cephalixin and others.
- You have a mononucleosis (either suspected or confirmed).

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

- have a history of hypersensitivity reactions to beta-lactams (ampicillin, piperacillin, etc). See “What are the possible side effects from using PRO-AMOX?”.
- have been taken blood thinners (such as warfarin, etc.).
- have a history of mild diarrhea or colitis influenced by the use of antibiotics.
- have kidney problems.
- are pregnant or plan to become pregnant.
- are breastfeeding or plan to breastfeed. Talk to your doctor about how to feed your baby while you are taking **PRO-AMOX**.

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-AMOX:

- anti-cancer drug (such as Methotrexate).
- medicines used for heartburn or gout (such as probenecid, cimetidine, etc.).
- blood thinner medications (such as warfarin, etc.) that used to thin the blood and prevent clots – may predispose you to the development of bleeding problems.
- birth control pills (it may reduce effect of contraceptives).
- antibacterial medicines (such as tetracyclines) may lower effectiveness of PRO-AMOX.

How to take PRO-AMOX:

Antibacterial drugs like PRO-AMOX treat only bacterial infections. They do not treat viral

infections. Although you may feel better early in the treatment, PRO-AMOX should be used exactly as directed. Misuse or overuse of PRO-AMOX could lead to the growth of bacterial that will not be killed by PRO-AMOX (resistance). This means that PRO-AMOX may not work in the future.

Do not share your medicine.

Ask your pharmacist about the other products you take. Some medicines will affect the way that your body absorbs PRO-AMOX.

Usual adult dose:

For infections: 250 mg – 500 mg every 8 hours or a single dose of 3 g.

For prevention: 3 g once before procedure, then 1.5 g every 6 hours.

Usual children's dose:

Your doctor will tell you how much PRO-AMOX to give your child based on their weight and the severity of their infection. The children's dose should not exceed the adult dose. For children over 20 kg, the adult dose should be used.

Administer oral solution using the syringe provided by your pharmacist to ensure the correct dose is given.

Take this medication by mouth as directed by your doctor.

Take PRO-AMOX between meals.

Tell your doctor if your condition does not improve.

Overdose:

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

Symptoms of overdose may include: severe dizziness.

Missed Dose:

If you miss a dose, take it as soon as you remember. If it is near the time of the next dose, skip the missed dose and resume your usual dosing schedule. Do not double the dose to catch up.

What are possible side effects from using PRO-AMOX?

These are not all the possible side effects you may feel when taking **PRO-AMOX**. If you experience any side effects not listed here, contact your healthcare professional.

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	
COMMON			
Skin rash.			√
Skin eruption or other effect on skin or eyes.			√
Nausea.			√
Vomiting.			√
Diarrhea.			√
Bloody stool.			√
Black “hairy” tongue (glossitis).		√	
Change of tooth color in children (brown, yellow or gray staining).		√	
Dizziness (light headedness).		√	
Anxiety.		√	
UNCOMMON			
Hives, itch.		√	
Red rash on the face.		√	
Swelling		√	
Anaphylaxis (severe allergic reactions such as swollen nose, eyes, throat, difficulty breathing, skin blistering, rash, peeling).			√
Signs of kidney problems (such as cloudy urine).			√
Signs of liver problems (such as persistent nausea/vomiting, stomach/abdominal pain, unusual tiredness, yellowing eyes/skin, dark urine).			√
RARE			
Severe skin reaction (flu-like symptoms, blistering and peeling skin).			√
Difficulty to fall asleep (insomnia).		√	
Confusion or changes in behavior.		√	
Changes in blood cell count test results.		√	

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	
Severe Cutaneous Adverse Reactions (SCAR) (severe skin reactions that may also affect other organs): <ul style="list-style-type: none"> • Skin peeling, scaling, or blistering (with or without pus) which may also affect your eyes, mouth, nose or genitals, itching, severe rash, bumps under the skin, skin pain, skin color changes (redness, yellowing, purplish) • Swelling and redness of eyes or face • Flu-like feeling, fever, chills, body aches, swollen glands, cough • Shortness of breath, chest pain or discomfort 			√
NOT KNOWN			
Aseptic meningitis (inflammation of the protective lining of the brain that is not caused by bacteria): confusion, fever, nausea, fatigue, sudden headache, or stiffness of your neck, sensitivity to light, vomiting			√

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

Dry Powder: Store at room temperature (15°C to 30°C). Protect from light and moisture. Keep bottle tightly closed.

Reconstituted Suspension: The reconstituted suspension is stable for 7 days at room temperature (15°C to 30°C) and 14 days if refrigerated (2°C to 8°C). Discard unused suspension after 7/14 days. Protect from light. Keep bottle tightly closed.

Do not use after the expiry date. Generally, all expired medications should be returned to your pharmacist.

Keep out of reach and sight of children.

If you want more information about PRO-AMOX:

- 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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