

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PATIENT MEDICATION INFORMATION

^{Pr}**APO-AMOXI**

amoxicillin (as amoxicillin trihydrate)

Read this carefully before you start taking **APO-AMOXI** 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 **APO-AMOXI**.

What is APO-AMOXI used for?

APO-AMOXI 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 APO-AMOXI work?

APO-AMOXI 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. APO-AMOXI **does not** kill viruses.

What are the ingredients in APO-AMOXI?

Medicinal ingredients: amoxicillin (as amoxicillin trihydrate)

Non-medicinal ingredient:

250 mg and 500 mg capsules: In addition to amoxicillin, each capsule contains the non-medicinal ingredients colloidal silicon dioxide, croscarmellose, stearic acid and talc.

125 mg / mL, 250 mg / mL suspension: the suspension contains the non-medicinal ingredients artificial strawberry flavour (125 mg/5 mL only), artificial banana flavour (250 mg/5 mL only), D&C yellow #10 (250 mg/5 mL only), guar gum, sodium benzoate, sodium citrate and sucrose. Sugar content/5 mL: 125 mg suspension 0.12 g equivalent to 0.47 cal.; 250 mg suspension 0.23 g equivalent to 0.92 cal.

125 mg / mL, 250 mg / mL Sugar Free Suspension: the sugar free suspension contains the non-medicinal ingredients artificial banana flavour (250 mg/5 mL only), artificial strawberry flavour (125 mg/5 mL only), aspartame, colloidal silicon dioxide, D&C yellow #10 (250 mg/5 mL only), FD&C red #40 (125 mg/5 mL only), sodium benzoate, sodium citrate, sorbitol, 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.

APO-AMOXI comes in the following dosage forms:

APO-AMOXI Capsules

Each red and gold APO-AMOXI capsule, imprinted 'APO 250' or 'APO 500' contains amoxicillin trihydrate equivalent to 250 or 500 mg of amoxicillin, respectively. Available in bottles of 100, 500 (500 mg only) and 1000 (250 mg only) capsules.

APO-AMOXI (Regular or Sugar Free) Suspension

After reconstitution, each ml of strawberry or banana-flavoured suspension contains amoxicillin trihydrate equivalent to 25 or 50 mg of amoxicillin, respectively. The reconstituted suspension is stable for 7 days at room temperature and 14 days if refrigerated. Available in bottles of 75, 100 and 150 ml.

Do not use APO-AMOXI if:

- You have any allergies to this drug or to its ingredients (See “What are the ingredients in APO-AMOXI?”).
- You have allergy to packaging components of this drug.
- You have allergy to penicillins, cephalosporins or similar antibiotics such as amoxicillin, ampicillin, cephalexin 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 APO-AMOXI. 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 APO-AMOXI?”.
- 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 **APO-AMOXI**.

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 APO-AMOXI:

- 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 APO-AMOXI.

How to take APO-AMOXI:

Antibacterial drugs like APO-AMOXI treat only bacterial infections. They do not treat viral infections. Although you may feel better early in the treatment, APO-AMOXI should be used exactly as directed. Misuse or overuse of APO-AMOXI could lead to the growth of bacterial that will not be killed by APO-AMOXI (resistance). This means that APO-AMOXI 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 APO-AMOXI.

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 APO-AMOXI 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.

For the oral suspension, please administer 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 APO-AMOXI between meals with a glass of water.
 Tell your doctor if your condition does not improve.

Overdose:

If you think you have taken too much APO-AMOXI, contact your 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 APO-AMOXI?

These are not all the possible side effects you may feel when taking **APO-AMOXI**. 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 headness). | | √ | |
| 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 fell asleep (insomnia). | | √ | |
| confusion or changes in behavior. | | √ | |
| Changes in blood cell count test results. | | √ | |

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.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:

For Capsules: store between 15°C and 30 °C.

Blister strips should be stored between 15 °C and 30 °C and protected from high humidity.

Powder: Store: 20°C to 25°C (Controlled Room Temperature). Protect from light and moisture. Keep bottle tightly closed.

Reconstituted Suspension: 14 days under refrigeration (2°C to 8°C) or 7 days at room temperature (20°C to 25°C). Protect from light. Keep bottle tightly closed.

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

If you want more information about amoxicillin:

- 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 (<http://hc-sc.gc.ca/index-eng.php>); the manufacturer's website <http://www.apotex.ca/products>, or by calling 1-800-667-4708.

This leaflet can also be found at: <http://www.apotex.ca/products>.

This leaflet was prepared by Apotex Inc., Toronto, Ontario, M9L 1T9.

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