

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PATIENT MEDICATION INFORMATION

APO-AMPI

Ampicillin Trihydrate, USP

Capsules

Powder for Oral Suspension

Read this carefully before you start taking APO-AMPI 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-AMPI.

What is APO-AMPI used for?

- **APO-AMPI is used to treat infections.**
- Antibacterial drugs like APO-AMPI treat only bacterial infections. They do not treat viral infections such as common cold.

How does APO-AMPI work?

APO-AMPI is an antibiotic. It stops bacteria from growing and kills them.

What are the ingredients in APO-AMPI?

Medicinal ingredient: Ampicillin Trihydrate

Non-medicinal ingredients (capsules): colloidal silicon dioxide, croscarmellose sodium, stearic acid and talc.

Non-medicinal ingredients (powder for suspension): artificial cherry flavor, FD&C Red #40, guar gum, sodium benzoate, sodium citrate and sucrose.

APO-AMPI comes in the following dosage forms:

As 250 mg and 500 mg capsules and powder for suspension 125 mg per 5mL and 250 mg per 5mL.

Do not use APO-AMPI if you:

- are allergic to penicillin.
- are allergic to a class of antibiotics called cephalosporins.

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

- allergies
- severe illness
- kidney problems
- prolonged use of antibiotics.
- are pregnant or thinking of becoming pregnant

- are breast-feeding

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

How to take APO-AMPI:

- Always take this medicine exactly as your doctor or pharmacist has told you.
- It is best to take APO-AMPI 1 hour before you eat a meal.
- Check with your doctor or pharmacist if you are not sure.
- Although you may feel better early in treatment, APO-AMPI should be used exactly as directed.
- Misuse or overuse of APO-AMPI could lead to the growth of bacteria that will not be killed by APO-AMPI (resistance). This means that APO-AMPI may not work for you in the future.
- Do not share your medicine.

Usual dose:

- Your doctor will decide how much APO-AMPI you should take and how long you should take it for.

Overdose:

If you think you have taken too much **APO-AMPI**, contact your healthcare professional, hospital emergency department or regional poison control center immediately, even if there are no symptoms.

Missed Dose:

- If you miss a dose, take it as soon as you remember. If you do not remember until it is almost time for your next dose, skip the missed dose and take the next dose at your regular time.
- Do not take two doses of APO-AMPI at the same time.
- If you are not sure what to do, call your doctor or pharmacist.

What are possible side effects from using APO-AMPI?

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

Side effects may include:

- Nausea
- Vomiting
- Diarrhea

Serious side effects and what to do about them		
Symptom / effect	Talk to your healthcare professional	
	Only if severe	In all cases
		Stop taking drug and get immediate medical help

Allergic reactions: difficulty breathing, difficulty swallowing, fever, hives, itchy skin, rash, swelling of your tongue or throat.	√		
Pseudomembranous colitis (inflammation of the intestine): abdominal cramps, pain or tenderness, dehydration, fever, nausea, watery or bloody diarrhea.			√
Glossitis (inflammation of the tongue): red, sore or swollen tongue.		√	
Black hairy tongue	√		
Stomatitis (mouth sores and swelling): burning sensation and pain in the mouth, difficulty eating, swelling or sores in the mouth.			
Skin rash or peeling skin.			
Anemia (decreased red blood cells): dizziness, feeling tired and weak, loss of energy, shortness of breath.		√	
Thrombocytopenia (decreased platelets in the blood): bleeding, bruising, fatigue, weakness. Leukopenia (decreased white blood cells): aches, feeling tired, fever, flu-like symptoms, infections.			

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:

Store at room temperature 15°C to 30°C in a tightly closed container.

The reconstituted suspension is stable for 21 days when refrigerated at 4.5°C. Do not freeze.

If you want more information about APO-AMPI:

- 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://health-products.canada.ca/dpd-bdpp/index-eng.jsp>). Find the Patient Medication Information on the manufacturer's website (<http://www.apotex.ca/products>), or by calling 1-800-667-4708.

This leaflet was prepared by Apotex Inc.

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