

**READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE
PATIENT MEDICATION INFORMATION**

**Pr APO-ALLOPURINOL
Allopurinol Tablets USP**

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

What is APO-ALLOPURINOL used for?

APO-ALLOPURINOL is used for the:

- treatment of gout, a painful form of arthritis caused by high levels of uric acid in the blood;
- treatment of kidney problems due to high uric acid levels;
- treatment or prevention of uric acid build-up in tissues or kidneys in patients receiving certain cancer treatments (which may cause high levels of uric acid in the blood);
- prevention of kidney stones in patients with high levels of uric acid in the blood or urine.

How does APO-ALLOPURINOL work?

APO-ALLOPURINOL works by reducing the production of uric acid in the body.

What are the ingredients in APO-ALLOPURINOL?

Medicinal ingredients: allopurinol

Non-medicinal ingredients: colloidal silicon dioxide, croscarmellose sodium, magnesium stearate and Sunset Yellow Aluminium Lake 40% (dye, in 200 mg and 300 mg tablets only)

APO-ALLOPURINOL comes in the following dosage forms:

Tablets: 100 mg, 200 mg and 300 mg

Do not use APO-ALLOPURINOL if:

- you are allergic to any of the ingredients in APO-ALLOPURINOL;
- you are breastfeeding;
- you are under the age of 18 (except in children with a high level of uric acid in the blood due to cancer or Lesch-Nyhan syndrome).

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

- have kidney problems;
- have liver problems;
- have heart disease;
- are pregnant or plan to become pregnant.

Other warnings you should know about:

Serious skin and allergic reactions: Some serious skin and allergic reactions such as rash, skin reddening, pain, swelling or blistering of lips, eyes or mouth, skin peeling and flu-like symptoms have been reported in patients taking APO-ALLOPURINOL. If you experience skin reactions of any kind (e.g., skin rash), stop taking APO-ALLOPURINOL **immediately** and contact your physician. Some skin reactions could lead to life-threatening allergic reactions.

APO-ALLOPURINOL should not be started until a gout attack has completely settled down.

In new patients, APO-ALLOPURINOL may cause gout attacks at the start of treatment.

APO-ALLOPURINOL may cause drowsiness. Do not drive or use machines until you know how APO-ALLOPURINOL affects you.

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-ALLOPURINOL:

- mercaptopurine - a drug used to treat leukemia;
- azathioprine - a drug that reduces the strength of the immune system (immunosuppressant);
- uricosurics (e.g., probenecid) - drugs that help remove uric acid from the body through the urine;
- salicylates (e.g., Aspirin) - anti-inflammatory drugs;
- coumarin anticoagulants (e.g., dicumarol) - a type of blood-thinner;
- chlorpropamide - a drug used to control blood-sugar levels;
- vidarabine - an anti-viral drug;
- phenytoin - a drug used to control seizures;
- theophylline - a drug used to treat certain breathing problems;
- ampicillin/amoxicillin - types of antibiotics;
- cyclophosphamide, doxorubicin, bleomycin, procarbazine and mechloroethamine - drugs used to treat cancer; and
- cyclosporine - a drug used to treat autoimmune conditions or to prevent organ rejection after transplantation.

How to take APO-ALLOPURINOL:

Follow the directions given to you by your healthcare professional.

Take APO-ALLOPURINOL:

- by mouth;
- with food;
- with plenty of fluids during treatment.

Usual dose:

Your dose will depend on your medical condition and the recommendations of your healthcare professional. If you take 300 mg or less of APO-ALLOPURINOL each day, you may take it as a single dose, once a day. If you take more than 300 mg of APO-

ALLOPURINOL each day, it should be divided in 2 or 3 doses per day (of not more than 300 mg per dose). Your dose may be adjusted depending on how well APO-ALLOPURINOL is working.

Overdose:

If you think you have taken too much APO-ALLOPURINOL, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

If you miss a dose, take it as soon as you remember. If it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule. Do not take a double dose to make up for a missed dose.

What are possible side effects from using APO-ALLOPURINOL?

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

Side effects may include:

- diarrhea;
- abdominal pain;
- nausea;
- vomiting;
- change in normal bowel habits;
- changes in taste sensation;
- mouth ulcers;
- headache;
- dizziness;
- drowsiness;
- unsteadiness when walking.

Your doctor will perform regular kidney and liver function tests when you are taking APO-ALLOPURINOL.

APO-ALLOPURINOL may cause abnormal blood test results. Your doctor will decide when to perform blood tests and will interpret the 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	
COMMON			
Skin reactions: itchy or flaky skin, reddening of skin, raised skin rash			√
RARE			
Allergic reaction:			√

difficulty breathing, swelling of the face and throat, rash, skin reddening, pain, swelling or blistering of lips, eyes or mouth, hives, skin peeling, flu-like symptoms			
Lymphadenopathy (swollen glands): swollen glands in the neck, armpit or groin			√
VERY RARE			
Vomiting blood			√
Liver problems: yellowing of the skin and the whites of eyes, nausea and vomiting, a general sense of feeling unwell, abdominal pain and swelling, a tendency to bruise and bleed easily and mental disorientation or confusion		√	
Kidney problems: any change in the amount, frequency or colour of urine.		√	
Steatorrhea (excessive fat in stool): pale, bulky, foul-smelling stool	√		
UNKNOWN			
Depression		√	
Infertility		√	
Changes in vision		√	
Feeling of weakness, pain, numbness, prickling or tingling in hands or feet		√	
Impotence		√	
Too much sugar in the blood (diabetes)		√	
Red, swollen, painful bumps under the skin (boils)		√	

Chest pain		√	
High blood pressure		√	
Slow heart beat		√	
Buildup of fluid leading to swelling in the arms or legs		√	
Hair loss	√		
Discoloration of hair	√		
Enlarged breasts in men	√		

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). Preserve in well-closed containers

Keep out of reach and sight of children.

If you want more information about APO-ALLOPURINOL:

- 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 \(https://health-products.canada.ca/dpd-bdpp/index-eng.jsp\)](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.

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