

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr **MAR-ALLOPURINOL**

Allopurinol Tablets, USP

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

Serious Warnings and Precautions

Serious skin and allergic reactions: **MAR-ALLOPURINOL** might cause serious **skin and allergic reactions, including:**

1. **Drug reaction with eosinophilia and systemic symptoms (DRESS)** (serious skin reaction that may affect more than one or more organs),
2. **Stevens-Johnson syndrome (SJS)** (severe skin rash), and
3. **Toxic Epidermal Necrolysis (TEN)** (severe skin reaction)

If you have skin reactions of any kind (e.g., skin rash), stop taking **MAR-ALLOPURINOL** **right away** and contact your healthcare professional. Some skin reactions could lead to deadly allergic reactions. These reactions are more common in people of Han Chinese, Thai or Korean descent. Your healthcare professional may perform a test before you start treatment. This test will reveal if you are at increased risk of developing such a reaction. See the Serious side effects and what to do about them table, below, for more information on these and other serious side effects.

What is **MAR-ALLOPURINOL** used for?

MAR-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 **MAR-ALLOPURINOL** work?

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

What are the ingredients in **MAR-ALLOPURINOL**?

Medicinal ingredients: allopurinol

Non-medicinal ingredients: lactose monohydrate, corn starch, sodium starch glycolate, povidone, stearic acid and Sunset Yellow Aluminium Lake (dye, in 200 mg and 300 mg tablets only)

MAR-ALLOPURINOL comes in the following dosage forms:

Tablets: 100 mg, 200 mg and 300 mg

Do not use MAR-ALLOPURINOL if:

- you are allergic to allopurinol or any other ingredients in MAR-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 MAR-ALLOPURINOL. Talk about any health conditions or problems you may have, including if you:

- have thyroid problems.
- have kidney problems.
- have liver problems.
- have heart disease.
- have diabetes.
- have high blood pressure (hypertension).
- are pregnant or plan to become pregnant.

Other warnings you should know about:

- MAR-ALLOPURINOL should not be started until a gout attack has completely settled down.
- In new patients, MAR-ALLOPURINOL may cause gout attacks at the start of treatment.

Driving and using machines

- MAR-ALLOPURINOL may cause drowsiness. Do NOT drive or use machines until you know how MAR-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 MAR-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 used to treat fever, pain and swelling.
- 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 used to treat bacterial infections.
- cyclophosphamide, doxorubicin, bleomycin, procarbazine and mechloroethamine - drugs used to treat cancer.
- cyclosporine - a drug used to treat autoimmune conditions or to prevent organ rejection after transplantation.
- didanosine - a drug used to treat HIV infection.
- Angiotensin-Converting Enzyme (ACE) inhibitors - drugs used to treat heart problems or high blood pressure.
- diuretics (water tablets) - drugs used to treat high blood pressure.

Aluminum hydroxide (a type of antacid) may reduce the effectiveness of MAR-ALLOPURINOL. If you need to use aluminum hydroxide, take it 3 hours before or 3 hours after taking MAR-ALLOPURINOL.

How to take MAR-ALLOPURINOL:

- Follow the directions given to you by your healthcare professional.
- Take MAR-ALLOPURINOL by mouth.
- Take after a meal.
- Drink plenty of fluids to stay hydrated during treatment with MAR-ALLOPURINOL.

Usual dose:

Your dose will depend on your medical condition and the recommendations of your healthcare professional. Your healthcare professional may change or stop your dose depending on how well MAR-ALLOPURINOL is working for you. Continue taking MAR-ALLOPURINOL for as long as your healthcare professional tells you to.

If you take **300 mg or less** of MAR-ALLOPURINOL each day, you may take it as a single dose, once a day.

If you take **more than 300 mg** of MAR-ALLOPURINOL each day, it should be divided in 2 or 3 doses per day (of not more than 300 mg per dose).

Overdose:

If you think you, or a person you are caring for, have taken too much MAR-ALLOPURINOL, contact a 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 MAR-ALLOPURINOL?

These are not all the possible side effects you may have when taking MAR-ALLOPURINOL. If you experience any side effects not listed here, tell 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
- feeling of weakness, pain, numbness, prickling or tingling in hands or feet
- boils (red, swollen, painful bumps under the skin)
- hair loss
- discoloration of hair
- impotence (not able to have an erection)
- infertility in men
- enlarged breasts in men

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

MAR-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 seek immediate medical help
	Only if severe	In all cases	
COMMON			
Skin reactions: itchy or flaky skin, reddening of skin, raised skin rash			√
RARE			
Allergic reactions (including Angioedema): sudden difficulty in breathing or swallowing, swelling of face, eyes, lips, tongue and/or throat, hands or feet, rash, skin reddening, pain, hives, skin peeling, flu-like symptoms			√
Lymphadenopathy (swollen glands): swollen glands in the neck, armpit or groin			√
Drug reaction with eosinophilia and systemic symptoms (DRESS)			√

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and seek immediate medical help
	Only if severe	In all cases	
(serious skin reaction that may affect more than one or more organs): fever, severe rash, swollen lymph glands, flu-like feeling, yellow skin or eyes, shortness of breath, dry cough, chest pain or discomfort, feel thirsty, urinate less often, less urine			
Stevens-Johnson syndrome (SJS) (severe skin rash): redness, blistering and/or peeling of the skin and/or inside of the lips, eyes, mouth, nasal passages or genitals, accompanied by fever, chills, headache, cough, body aches or swollen glands			√
Toxic Epidermal Necrolysis (TEN) (severe skin reaction): redness, blistering and/or peeling of large areas of the skin			√
VERY RARE			
Hematemesis (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: sad mood, lack of interest in usual activities, change in sleep and appetite		√	
Changes in vision: sudden blurry vision		√	
Diabetes (too much sugar in the blood): increased thirst, frequent		√	

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and seek immediate medical help
	Only if severe	In all cases	
urination, extreme fatigue or lack of energy, dry skin, headache, blurred vision, tingling or numbness in the hands or feet			
Angina (chest pain)		√	
Hypertension (high blood pressure): shortness of breath, fatigue, severe headache, dizziness or fainting, lightheaded, chest pain or pressure, swelling in your ankles and legs, bluish colour to your lips and skin, racing pulse or palpitations		√	
Bradycardia (slow heart beat): dizziness, light-headedness, or fainting		√	

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 to 30°C).

Keep out of reach and sight of children.

If you want more information about MAR-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://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>). Find the Product Monograph on the manufacturer's website
(www.marcapharma.com), or by calling 1-855-627-2261.

This leaflet was prepared by Marcan Pharmaceuticals Inc.

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