

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

**PrAZATHIOPRINE-50
Azathioprine Tablets USP**

Read this carefully before you start taking AZATHIOPRINE-50 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 AZATHIOPRINE-50.

Serious Warnings and Precautions

AZATHIOPRINE-50:

- **may increase your risk of developing cancer, especially skin cancer and lymphoma**
- **can cause a severe decrease in the number of white blood cells and platelets thereby increasing your risk of having infection and unusual bleeding or bruising**
- **can cause harm to an unborn child when taken by a pregnant woman**
- **should be prescribed by doctors who are experienced in immunosuppressive therapy and management of organ transplant**

What is AZATHIOPRINE-50 used for?

AZATHIOPRINE-50 (Azathioprine Tablets USP), is used in adults:

- along with other medications to prevent kidney rejection after a transplant.
- with Rheumatoid Arthritis who cannot be treated with other medications and treatments.

How does AZATHIOPRINE-50 work?

AZATHIOPRINE-50 belongs to a group of medicines called immunosuppressants. It reduces the strength of your immune system. This helps your body accept an organ after a transplant. It also helps to treat rheumatoid arthritis a condition where your immune system is reacting against your own body (autoimmune diseases).

What are the *ingredients* in AZATHIOPRINE-50?

AZATHIOPRINE-50 tablets

Medicinal Ingredients: Azathioprine

Non-medicinal Ingredients: lactose, magnesium stearate, microcrystalline cellulose and starch

AZATHIOPRINE-50 comes in the following dosage forms:

The AZATHIOPRINE-50 50 mg tablet is a pale yellow, peanut-shaped tablet, scored and engraved "AZ 50" on one side and plain on the other.

Do not use AZATHIOPRINE-50 if:

- You are allergic to azathioprine or to any of the other ingredients in AZATHIOPRINE-50 (see “**What are the ingredients AZATHIOPRINE-50** above)

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take AZATHIOPRINE-50. Talk about any health conditions or problems you may have, including if:

- you have rheumatoid arthritis and have been previously treated with alkylating agents (such as cyclophosphamide, chlorambucil, melphalan or others)
- you suffer from liver or kidney disease
- you have been told you have any type of cancer
- you have a condition where your body produces too little of a natural chemical called thiopurine methyltransferase (TPMT)

- you have never had chickenpox or shingles
- you are going to have an operation. Medicines including tubocurarine, or succinylcholine that are used as muscle relaxants during surgery may interact with AZATHIOPRINE-50. You should tell your doctor you are taking AZATHIOPRINE-50 before your surgery.
- you are pregnant. You should not take AZATHIOPRINE-50 while pregnant. It can cause harm to your unborn baby.
- you are planning to have a baby - discuss this with your doctor whether you are male or female
- you are breast feeding. The ingredient in AZATHIOPRINE-50 can be transferred through your breast milk.
- you are under 18 years of age

Other warning you should know about:

General: If you are receiving immunosuppressive therapy, taking AZATHIOPRINE-50 could put you at a greater risk of developing certain types of cancers called lymphoproliferative disorders. These are cancers that affect the blood and immune system.

Exposure to Sunlight: Patients taking immunosuppressive medicines may have an increased risk for developing tumours, including skin cancer. While you are taking AZATHIOPRINE-50, you should avoid too much exposure to sunlight. You should wear sunscreen with a high protection factor and wear protective clothing.

Use with other immunosuppressant, particularly corticosteroids: Patients taking AZATHIOPRINE-50 alone or in combination with other immunosuppressants, particularly corticosteroids are at a greater risk for infections.

Chickenpox or shingles: Infection with chickenpox or shingles can become severe in patients taking immunosuppressive medicines. You should therefore avoid contact with anyone who has chickenpox or shingles. Tell your doctor right away if you do come into contact with someone with chickenpox or shingles.

Gastrointestinal hypersensitivity: Severe nausea and vomiting have been reported in patients taking AZATHIOPRINE-50.

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 AZATHIOPRINE-50:

- angiotensin-converting enzyme inhibitors such as captopril (used to treat high blood pressure and heart failure)
- trimethoprim and sulfamethoxazole (used to treat bacterial infections). It is also known as SEPTRA[®]
- allopurinol, oxipurinol, thiopurinol (used to treat gout)
- curare, d-tubocurarine, tubocurarine, pancuronium and succinylcholine (used as a muscle relaxant during surgery)
- warfarin (used to prevent blood clots)
- mesalazine, olsalazine or sulphasalazine (used to treat ulcerative colitis)

How to take AZATHIOPRINE-50:

AZATHIOPRINE-50 tablets:

Important Information: The tablets require safe handling. Consult your doctor or pharmacist for instructions on how to safely handle this product.

- It is important you take the tablets at right times
- You must take it exactly the way your doctor has told you to
- Swallow the tablet **whole** with water. **Do NOT** break the tablet

Laboratory Tests: From time to time, while you are taking AZATHIOPRINE-50 (Azathioprine Tablets USP), your doctor will want you to have a blood test. This is to check your blood cell count and to change your dose if necessary.

Usual Adult dose:

Kidney Transplant: A starting dose of up to 5 mg/kg of your bodyweight is usually given on the first day of therapy. You will then be given a maintenance dose of AZATHIOPRINE-50. This is likely to be between 1 to 3 mg/kg bodyweight per day.

Rheumatoid Arthritis: If you are receiving AZATHIOPRINE-50 for rheumatoid arthritis the dose given is likely to start at approximately 1 mg/kg of your bodyweight. Depending on how your treatment is working, your dose may be adjusted, until an optimal maintenance dose is determined.

Overdose:

If you think you have taken too much AZATHIOPRINE-50, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

If you forget to take a dose, do not take extra tablets to make up for the dose or doses you have missed. When you remember, take your next dose at the usual time and continue as before. Talk to your doctor as soon as you can about the doses you may have missed.

What are possible side effects from using AZATHIOPRINE-50:

These are not all the possible side effects you may feel when taking AZATHIOPRINE-50. If you experience any side effects not listed here, contact your healthcare professional.

Side effects include:

- Hair loss. Often hair does grow again, even if you carry on taking AZATHIOPRINE-50. If you are worried ask your doctor.

SERIOUS SIDE EFFECTS AND WHAT TO DO ABOUT THEM			
Symptom / effect	Talk with your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Common fever or infection after transplant		✓	
unexpected bruising or bleeding		✓	
nausea		✓	
Rare new marks on skin or a change to marks		✓	
cough or difficulty breathing similar to a chest infection		✓	
tired, dizzy or generally unwell		✓	
muscle or bone pain			✓
kidney problems			✓
feeling faint especially on standing up			✓
bad diarrhea and/or abdominal pain			✓

fever and infection		✓	
Serious Skin Reaction Serious Skin Reaction: Steven Johnson Syndrome (SJS): flu-like symptoms, skin rash often with blisters or lesions and shedding of the skin within days of the formation of the blisters Toxic Epidermal Necrolysis (TEN): flu-like symptoms, redness of the skin, and the detachment of the skin (epidermal layer)			✓
Hepatosplenic T-cell lymphoma (enlargement of the liver)			✓

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 between 15°C and 30°C. Protect from light.
- Do not take the medicine after the expiry date shown on the package.
- If your doctor tells you to stop taking the tablets, return any left-overs to your pharmacy for proper disposal. Only keep them if your doctor tells you to.

Keep AZATHIOPRINE-50 out of reach and sight of children.

If you want more information about **AZATHIOPRINE-50**:

- 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 (<http://www.prodqc.ca>) or by contacting Pro Doc Ltée at 1-800-361-8559 or info@prodqc.ca.

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