IMPORTANT: PLEASE READ

PART III: CONSUMER INFORMATION

AZATHIOPRINE – 50
Azathioprine Tablets USP

This leaflet is part III of a three-part "Product Monograph" published when AZATHIOPRINE (Azathioprine Tablets USP) was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about AZATHIOPRINE. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

AZATHIOPRINE (Azathioprine Tablets USP), an immunosuppressant agent is used in the following conditions:

- Renal Homotransplantations: as an adjunct (with other medications) in the prevention of rejection of kidney transplants.
- Rheumatoid Arthritis in adult patients who cannot be treated with other medications and treatments.

What it does:

AZATHIOPRINE belongs to a group of medicines called immunosuppressants. This means that it reduces the strength of your immune system.

Immunosuppressant medicines are sometimes necessary to help your body accept an organ transplant, such as a new kidney or to treat rheumatoid arthritis where your immune system is reacting against your own body (autoimmune diseases).

When it should not be used:

You should NOT take AZATHIOPRINE if you:

- are allergic to azathioprine or any of the other ingredients of AZATHIOPRINE (see What the non-medicinal ingredients are).

What the medicinal ingredient is:

Azathioprine

What the important non-medicinal ingredients are:

In addition to azathioprine, each AZATHIOPRINE Tablet contains the non-medicinal ingredients lactose, magnesium stearate, microcrystalline cellulose and starch.

What dosage forms it comes in:

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

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

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

Patients taking immunosuppressive medicines may have an increased risk of developing tumours including skin cancer. Therefore while taking AZATHIOPRINE tablets you should avoid too much exposure to sunlight. You are advised to wear protective clothing and to use a sunscreen with a high protection factor.

Patients receiving AZATHIOPRINE alone or in combination with other immunosuppressants, particularly corticosteroids, have shown increased susceptibility to infections.

Infection with chickenpox or shingles can become severe in patients taking immunosuppressive medicine. Therefore you should avoid contact with anyone suffering from chickenpox or shingles.

Patients receiving AZATHIOPRINE have experienced gastrointestinal hypersensitivity reactions including severe nausea and vomiting.

BEFORE you use AZATHIOPRINE talk to your doctor or pharmacist if:

- you have rheumatoid arthritis and have been previously treated with alkylating agents (cyclophosphamide, chlorambucil, melphalan or others)
- you are under 18 years of age
- you are pregnant or breast feeding
- you are planning to have a baby - discuss this with your doctor whether you are male or female
- 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 suffered from chickenpox or shingles

INTERACTIONS WITH THIS MEDICATION

Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines, even those that you have bought yourself without a doctor's prescription.

Certain medicines can interact with AZATHIOPRINE (Azathioprine Tablets USP) such as those listed below:

- angiotensin-converting enzyme inhibitors such as captopril (used mainly to treat high blood pressure and heart failure)
- co-trimoxazole also known as SEPTRA® (used to treat infections).
- allopurinol (used mainly to treat gout)
- curare, d-tubocurarine, tubocurarine, succinylcholine (used during anaesthesia and as muscle relaxants)
- warfarin (used to prevent blood clots)
- mesalazine, olsalazine or sulphasalazine (used mainly to treat ulcerative colitis).

PROPER USE OF THIS MEDICATION

It is important to take your medicine at the right times. You must take it in the way your doctor has told you to. Swallow the tablet whole with water do not break the tablet.

It is important that you and/or your caregivers are aware of the need for safe handling of this medicine. Please consult your pharmacist or doctor for advice.

The amount of azathioprine people take can be very different. Your dose will depend on the condition your doctor is treating.

Your doctor will tell you how long your treatment will last. Do not stop treatment early.

From time to time, while you are taking AZATHIOPRINE (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 Dose for Adults for Renal Homotransplantation:
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. This is likely to be between 1 to 3 mg/kg bodyweight per day.

Usual Dose for Adults for Rheumatoid Arthritis:
If you are receiving AZATHIOPRINE 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:

In case of overdose, contact a healthcare professional, hospital emergency department or regional poison control centre, 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. Speak to your doctor as soon as you can about the doses you may have missed.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medicines, AZATHIOPRINE (Azathioprine Tablets USP) can cause side effects.

Some people can be allergic to medicines. If you have any of the following symptoms soon after taking AZATHIOPRINE STOP taking this medicine and tell your doctor immediately or go to the nearest hospital emergency department:

- you develop muscle or bone pain
- you develop kidney problems
- you start feeling faint especially on standing up
- you develop bad diarrhoea and/or abdominal pain
- you develop a serious skin reaction (e.g. blistering and/or peeling)

Tell your doctor immediately if any of the following happen to you while you are taking AZATHIOPRINE:

- you start to notice any signs of a fever or an infection
- you have any unexpected bruising or bleeding
- you develop any new marks on your skin or any change to marks that you may have had previously
- you develop a cough or difficulty breathing similar to a chest infection
- you have nausea and vomiting
- you feel tired, dizzy or generally unwell
- you come into contact with anyone who is suffering from chickenpox or shingles.

Stevens-Johnson syndrome and toxic epidermal necrolysis (skin conditions) have been reported very rarely in post-marketing surveillance.
Cases of hepatosplenic T-cell lymphoma (HSTCL) have been reported.
You may notice some hair loss while taking

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

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
		Only if severe	In all cases	
Common	signs of fever or infection (in the non-transplant population infection is uncommon)		√	
	unexpected bruising or bleeding		√	
	nausea		√	
Un-common	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			√
	serious skin reaction (e.g. blistering and/or peeling)			√

If you notice any side effects not mentioned in this leaflet, tell your doctor or pharmacist.

HOW TO STORE IT

Store between 15°C and 30°C. Protect from light.

Do not take the medicine after the expiry date shown on the tablet pack.

If your doctor tells you to stop taking the tablets, please return any which are left over to your pharmacist. Only keep them if your doctor tells you to.

As with all medicines, keep AZATHIOPRINE (Azathioprine Tablets USP) tablets out of reach of children.

REPORTING SUSPECTED SIDE EFFECTS

To monitor drug safety, Health Canada through the Canada Vigilance Program collects information on serious and unexpected side effects of drugs. If you suspect you have had a serious or unexpected reaction to this drug you may notify Canada Vigilance:

By toll-free telephone: 866-234-2345
By toll-free fax: 866-678-6789
Online: www.healthcanada.gc.ca/medeffect
By email: CanadaVigilance@hc-sc.gc.ca

By regular mail:
Canada Vigilance National Office
Marketed Health Products Safety and Effectiveness Information Bureau
Marketed Health Products Directorate
Health Products and Food Branch
Health Canada
Tunney's Pasture, AL 0701E
Ottawa ON K1A 0K9

NOTE: Should you require information related to the management of the side effects, please contact your health care provider before notifying Canada Vigilance. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found by contacting Pro Doc Ltée at 1-800-361-8559, www.prodoc.qc.ca or info@prodoc.qc.ca.

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