

**PART III: CONSUMER INFORMATION**

**PrIMURAN® Tablets and Injection  
azathioprine**

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

**ABOUT THIS MEDICATION**

**What the medication is used for:**

IMURAN®, 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:**

IMURAN® 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 IMURAN® if you:

- are allergic to azathioprine or any of the other ingredients of IMURAN®

**What the medicinal ingredient is:**

Azathioprine

**What the important non-medicinal ingredients are:**

IMURAN® 50 mg tablets contain the following non-medicinal ingredients: lactose, magnesium stearate, potato starch, povidone, and stearic acid.

IMURAN® 50 mg for injection contains the following non-medicinal ingredients: sodium hydroxide to adjust pH.

**What dosage forms it comes in:**

The IMURAN® tablet 50 mg is a yellow to off-white tablet with an overlapping circle (dumbbell) shape, imprinted

"IMURAN® 50" on one side and with converging scored lines on the other side. IMURAN® Tablets are available in bottles of 100 tablets.

IMURAN® for Injection is available as sterile lyophilized powder. Each 17 mL single dose vial contains the equivalent of 50 mg azathioprine as sodium salt.

**WARNINGS AND PRECAUTIONS**

**Serious Warnings and Precautions**

- **IMURAN® may increase your risk of developing cancer, especially skin cancer and lymphoma**
- **IMURAN® 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**
- **IMURAN® can cause harm to an unborn child when taken by a pregnant woman**
- **IMURAN® 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 IMURAN® 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 IMURAN® 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 IMURAN® have experienced gastrointestinal hypersensitivity reactions including severe nausea and vomiting.

BEFORE you use IMURAN® talk to your doctor or pharmacist if:

- you have rheumatoid arthritis and have been previously treated with alkylating agents (cyclophosphamide, chlorambucil, melphalan or others)
- 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 IMURAN<sup>®</sup> 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<sup>®</sup> (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, 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.

IMURAN<sup>®</sup> for injection should be given in the hospital through the vein (intravenous infusion).

The amount of IMURAN<sup>®</sup> 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 IMURAN<sup>®</sup>, 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 IMURAN<sup>®</sup>. 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 IMURAN<sup>®</sup> 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 accidentally take too many tablets tell your doctor or pharmacist, or contact your nearest hospital emergency department without delay.

### 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, IMURAN<sup>®</sup> can cause side effects.

Some people can be allergic to medicines. If you have any of the following symptoms soon after taking IMURAN<sup>®</sup> 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 IMURAN<sup>®</sup>:

- 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.

You may notice some hair loss while taking IMURAN<sup>®</sup>. Often hair does grow again, even if you carry on taking IMURAN<sup>®</sup>. 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	
<b>Common</b>	signs of fever or infection (in the non-transplant population infection is uncommon)		✓	
	unexpected bruising or bleeding		✓	
	nausea		✓	
<b>Uncommon</b>	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 diarrhoea 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 25°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 IMURAN<sup>®</sup> tablets out of reach of children.

**REPORTING SUSPECTED SIDE EFFECTS**

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

toll-free telephone: 866-234-2345  
 toll-free fax 866-678-6789  
 By email: [cadmp@hc-sc.gc.ca](mailto:cadmp@hc-sc.gc.ca)

By regular mail:  
 National AR Centre  
 Marketed Health Products Safety and Effectiveness  
 Information Division  
 Marketed Health Products Directorate  
 Tunney's Pasture, AL 0701C  
 Ottawa ON K1A 0K9

*NOTE: Before contacting Health Canada, you should contact your physician or pharmacist.*

**MORE INFORMATION**

This document plus the full product monograph, prepared for health professionals can be found at: [www.tritonpharma.ca](http://www.tritonpharma.ca) or by contacting the sponsor,

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