Patient Medication Information

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

[Pr]IMURAN®

Azathioprine Tablets
Azathioprine Sodium for Injection

This Patient Medication Information is written for the person who will be taking **IMURAN**. This may be you or a person you are caring for. Read this information carefully. Keep it as you may need to read it again.

This Patient Medication Information is a summary. It will not tell you everything about this medication. If you have more questions about this medication or want more information about **IMURAN**, talk to a healthcare professional.

Serious warnings and precautions box

- 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 IMURAN is used for:
IMURAN, 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 IMURAN work:
IMURAN 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).

The ingredients in IMURAN are:
IMURAN tablets
Medicinal Ingredients: Azathioprine
Non-medicinal Ingredients: Lactose, magnesium stearate, microcrystalline cellulose and starch

IMURAN for injection
Medicinal Ingredients: Azathioprine (as azathioprine sodium)
Non-medicinal Ingredients: Sodium hydroxide (to adjust pH)

IMURAN comes in the following dosage forms:
Tablets: 50 mg
Powder for Solution: 50mg per vial

Do not use IMURAN if:

- You are allergic to azathioprine or to any of the other ingredients in IMURAN (see **"What are the ingredients in IMURAN"** above)

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take IMURAN. 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 been told you have an inherited mutation in the NUDT15 gene
- you have never had chickenpox or shingles
- you have had chickenpox or hepatitis B (a liver disease caused by a virus) in the past
- you are going to have an operation. Medicines including tubocurarine, or succinylcholine that are used as muscle relaxants during surgery may interact with IMURAN). You should tell your doctor you are taking IMURAN before your surgery.
- you are pregnant. You should not take IMURAN 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 IMURAN can be transferred through your breast milk.
- you are planning to get a vaccine. You should not receive live vaccines while taking IMURAN.
- you have had an allergic reaction to a medicine used to treat certain cancers called mercaptopurine.

Other warnings you should know about:

General: If you are receiving immunosuppressive therapy, taking IMURAN 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 IMURAN, you should avoid too much exposure to sunlight. You should wear sunscreen with a high protections factor and wear protective clothing.

Use with other immunosuppressant, particularly corticosteroids: Patients taking IMURAN 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 IMURAN.

Infections
You are more likely to get a viral, fungal, or bacterial infection while you are taking IMURAN. If you do get an infection, it may become more severe. Talk to your doctor if you have questions about infections while taking or receiving IMURAN.

NUDT15 gene mutation
Tell your doctor before you start taking IMURAN if you have an inherited mutation in the NUDT15 gene. The NUDT15 gene is involved in the break-down of azathioprine in the body, you have a higher risk of getting infections and hair loss if you have this mutation. Your doctor may need to give you a lower dose of IMURAN.

Fertility: It is not known if IMURAN affects fertility in humans. When tested in animals, IMURAN decreased fertility in animals that mated. It also decreased sperm viability and count in male animals. Talk to your doctor if you have questions about your fertility while taking or receiving IMURAN. If you are planning on having a child, it is recommended that you consult on sperm cryopreservation or genetic counselling (for male or female patients) before you start taking IMURAN.

Contraception: Both males and females taking IMURAN should use reliable and effective birth control to avoid pregnancy. It is recommended that males continue to use birth control for 3 months after treatment and females use birth control for 6 months after treatment.

Pregnancy: You should not take IMURAN 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

Itching during pregnancy: You need to inform your doctor immediately if you experience intense, excessive itching, but without a rash during your pregnancy, especially in the second trimester. You may also experience nausea, and loss of appetite together with itching, which indicates that you have a condition called cholestasis of pregnancy (condition affecting the liver during pregnancy). Your doctor may order blood tests, while you are taking azathioprine and based on the results of this tests, your doctor may change your dose of azathioprine or stop it completely.

Breastfeeding: IMURAN is not recommended if you are breastfeeding. The ingredient in IMURAN can be transferred through your breast milk.

Vaccines: You should not receive live vaccines while taking or receiving IMURAN. They can cause you get an infection. You should wait at least 3 months after you stop taking IMURAN before getting a live vaccine. Talk to your doctor if you have questions about receiving vaccines while taking IMURAN.

Vitamin B3 Deficiency: Tell your doctor immediately if you experience diarrhea, localized pigmented rash (dermatitis), and decline in your memory, reasoning or other thinking skills (dementia) as these symptoms may suggest vitamin B3 deficiency (nicotinic acid deficiency/pellagra). Your doctor will likely prescribe vitamin supplements (niacin/nicotinamide) to help you improving the condition.

Liver damage: Treatment with Imuran may affect the liver and your doctor will monitor your liver function regularly. Tell your doctor if you experience symptoms of liver damage.

Laboratory Tests: From time to time, while you are taking IMURAN, 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.

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 IMURAN:

- 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)
- live vaccines
- infliximab (used to treat autoimmune disease)

How to take IMURAN:
IMURAN 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
- You may feel sick (have nausea) when you first start taking IMURAN. If this happens, your doctor may tell you to take the tablets after meals to relieve this.
- Do not eat or drink milk or dairy products with IMURAN tablets

IMURAN for injection:

- The injection should be given to you in the hospital by your doctor
- It will be given thorough your vein as an infusion (intravenous infusion)
- The amount you will be given will depend on the condition the doctor is treating
- Your doctor will tell you how long your treatment will last

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 IMURAN. This is likely to be between 1 to 3 mg/kg bodyweight per day.

Rheumatoid Arthritis: If you are receiving IMURAN 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, or a person you are caring for, have taken too much IMURAN, contact a healthcare professional, hospital emergency department, regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs or 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.

Possible side effects from using IMURAN:
These are not all the possible side effects you may feel when taking IMURAN. If you experience any side effects not listed here, contact your healthcare professional.

Side effects include:
- Tender red bumps on your shins
- hair loss. Often hair does grow again, even if you carry on taking IMURAN. If you are worried ask your doctor.
- Inflammation of a salivary gland known as Sialoadenitis
- Tremors (involuntary trembling or shaking of muscles)

Serious side effects and what to do about them

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Stop taking this 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			✓

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
kidney problems			✓
feeling faint especially on standing up			✓
bad diarrhoea and/or abdominal pain			✓
any signs of fever and infection (sore throat and sore mouth) **Urinary tract infection** (infection in urinary system including kidneys, ureters, bladder, and urethra): Pain or burning sensation while urinating, frequent urination, blood in urine, pain in the pelvis, strong smelling urine, cloudy urine.			✓
Serious Skin Reaction: Stevens-Johnson syndrome (SJS): flu-like symptoms, skin rash often with blister 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, detachment of the skin (epidermal layer) Acute febrile neutrophilic dermatosis also known as Sweet's Syndrome (a serious inflammatory skin condition): fever, painful dark red bumps or small blisters on the face, neck, arms, legs or hands, skin and mouth lesions, skin discoloration, skin swelling, muscle or joint pain, fatigue.			✓
Hepatosplenic T-cell lymphoma (enlargement of the liver)			✓
Unknown			

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
Liver injury, Noncirrhotic portal hypertension & Portosinusoidal vascular disease (severe liver damage conditions which can be life threatening, especially in patients who receive long-term treatment): yellowing of the skin and the whites of the eyes (jaundice), bruising easily, abdominal discomfort, loss of appetite, fatigue, nausea, or vomiting.			✓

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 SUSPECTED 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 (canada.ca/drug-device-reporting) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your healthcare professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

IMURAN Tablets:

- 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-over tablets to your pharmacy for proper disposal. Only keep them if your doctor tells you to.

IMURAN for Injection:

- Store between 15°C and 25°C. Protect from light.

Keep out of reach and sight of children.

If you want more information about IMURAN:

- 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 (Drug Product Database:

Access the database); the manufacturer's website www.aspenpharma.ca, or by calling 1-844-330-1213.

This leaflet was prepared by
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