1.3.2.1 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

IMURAN 50 mg film-coated tablets

Azathioprine

Contains sugar: Lactose monohydrate 74 mg

Read all of this leaflet carefully before you start taking IMURAN

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- IMURAN has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet:

1. What IMURAN is and what it is used for
2. What you need to know before you take IMURAN
3. How to take IMURAN
4. Possible side effects
5. How to store IMURAN
6. Contents of the pack and other information

1. What IMURAN is and what it is used for

IMURAN contains the active substance azathioprine. It belongs to a group of medicines called immunosuppressants. These medicines reduce the activity (strength) of your body's immune system. IMURAN may be used on its own, but it is more often used in combination with other medicines.

IMURAN is used to:

- stop your body rejecting an organ after an organ transplant,
- treat inflammatory bowel disease if the first line therapy has failed for you,
- treat diseases where your immune system reacts against your own body (called autoimmune diseases, such as rheumatoid arthritis).

2. What you need to know before you take IMURAN

Do not take IMURAN:

- if you are hypersensitive (allergic) to azathioprine, 6-mercaptopurine or any of the other ingredients of IMURAN (listed in section 6).
- if you are pregnant or planning to fall pregnant in the near future.
- if you are breastfeeding your baby.
- if you suffer from rheumatoid arthritis (a chronic progressive disease causing inflammation in the joints) and you have been treated with medicines referred to as alkylating medicines (e.g. cyclophosphamide, chlorambucil, melphalan or others).
- if you have an infection.

Warnings and precautions

Take special care with IMURAN:

- if you have any kidney or liver problems.
- if you have a genetic condition called TPMT deficiency (where your body produces too little of an enzyme called ‘thiopurine methyltransferase’).
- if you have had hepatitis B (a liver disease caused by a virus).
- if you have an inherited mutation in the NUDT15-gene (a gene which is involved in the break-down of IMURAN in the body). You have a higher risk of infections and hair loss and your doctor may in this case give you a lower dose.
- if you have a genetic condition known as ‘Lesch-Nyhan Syndrome’. This is a rare condition that runs in families caused by a lack of an enzyme called HPRT or ‘hypoxanthine-guanine-phosphoribosyltransferase’.
- when using IMURAN, you are at a greater risk of developing other infections such as PML (Progressive Multifocal Leukoencephalopathy) which is an opportunistic infection. If you experience any signs of infection please contact your doctor.
- if you are taking continuous IMURAN together with corticosteroids you may have a persistent negative nitrogen balance. This means that the amount of nitrogen excreted from the body is greater than the amount of nitrogen ingested.
- if you develop unexpected bruising or bleeding.
- if you experience loss of appetite, nausea, vomiting or diarrhoea.
- when using IMURAN, you are at a greater risk of developing tumours or other types of cancers such as lymphoproliferative disorder. With a treatment regime that contains more than one medicine that suppresses your immune system, this could lead to death.

- if you are taking a combination of multiple medicines that suppresses your immune system, it may increase your risk of developing disorders of the lymph system due to a viral infection (Epstein-Barr virus (EBV)-associated lymphoproliferative disorders).
- if you are exposed to sunlight and UV light. You should limit your time in the sun, wear protective clothing and use a sunscreen with a high protection factor as you are at a greater risk of developing skin cancer and skin sensitivity reactions while using IMURAN.
- if you are planning to have a baby, IMURAN may harm the sperm, eggs and/or baby, so highly effective contraceptive precautions must be taken to avoid pregnancy whilst you or your partner are receiving IMURAN; ask your doctor for advice.
- when using IMURAN, you are at a greater risk of developing a serious condition called Macrophage Activation Syndrome (excessive activation of white blood cells associated with inflammation), which usually occurs in people who have certain types of arthritis.
- if you develop chickenpox or shingles. You should avoid contact with any person that has chickenpox or shingles.
- if you have recently received or are due to receive a vaccination (vaccine). If you take IMURAN, you should not have a live organism vaccine (for example; flu vaccine, measles vaccine, BCG vaccine, etc.) until advised it is safe to do so by your doctor. This is because some vaccines may give you an infection if you receive them while you are taking IMURAN.
- if you are going to have an operation (this is because medicines including tubocurarine, or succinylcholine used as muscle relaxants during operations may

interact with IMURAN). You should inform your anaesthesiologist of your treatment with IMURAN prior to surgery.

- tell your doctor immediately if you experience diarrhoea, 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 improve the condition.

If you are receiving immunosuppressive therapy, IMURAN could put you at greater risk of:

- Tumours, including skin cancer. Therefore, when taking IMURAN, avoid excessive exposure to sunlight, wear protective clothing and use protective sunscreen with a high protection factor.
- Lymphoproliferative disorders

  Treatment with IMURAN increases your risk of getting a type of cancer called lymphoproliferative disorder. With treatment regimen containing multiple immunosuppressants (including thiopurines), this may lead to death.

  A combination of multiple immunosuppressants, given concomitantly increases the risk of disorders of the lymph system due to a viral infection (Epstein-Barr virus (EBV)-associated lymphoproliferative disorders).
- Developing a serious condition called Macrophage Activation Syndrome (excessive activation of white blood cells associated with inflammation), which usually occurs in people who have certain types of arthritis.
- Severe chickenpox or shingles infection. Therefore, when taking IMURAN, avoid contact with people who have chickenpox or shingles.
- A previous hepatitis B infection becoming active again.

- Other infections such as PML (Progressive Multifocal Leukoencephalopathy) which is an opportunistic infection. If you experience any signs of infection, please contact your doctor.

Tests you may have while taking IMURAN

Your doctor may ask you to have blood tests while you are taking IMURAN. This is to check your blood cell count, liver and kidney function. Your doctor may change your dose of IMURAN after the test or even stop IMURAN.

Other medicines and IMURAN

Always tell your healthcare provider if you have recently taken, are taking or might take any other medicine (this includes complementary or traditional medicines). This is because IMURAN can affect the way some medicines work.

Tell your doctor if you are taking or are planning to take any of the following:

- Vaccines. If you have recently received or are due to have a vaccination. If you take IMURAN, you should not have a live organism vaccine (for example; flu vaccine, measles vaccine, BCG vaccine, etc.) until advised it is safe to do so by your doctor or pharmacist. This is because some vaccines may give you an infection if you receive them while you are taking IMURAN.
- Ribavirin: medicine used to treat viral infections such as Respiratory syncytial virus (RSV) infection and hepatitis C.
- Xanthine oxidase inhibitors (e.g. allopurinol, oxipurinol, thiopurinol, febuxostat): medicine used to treat gout.

- Neuromuscular blocking medicines (e.g. tubocurarine, curare, pancuronium, succinylcholine): medicines used during operations to relax muscles. You should inform your anaesthesiologist of your treatment with IMURAN prior to surgery.
- Cytostatic medicines: medicines used to treat various types of cancer or medicines that suppress the immune system (e.g. penicillamine: medicine used to treat rheumatoid arthritis).
- Trimethoprim/sulfamethoxazole (co-trimoxazole): medicine used to treat bacterial infections.
- ACE inhibitors (e.g. captopril): medicine used to treat high blood pressure or heart problems.
- Cimetidine: medicine used to treat stomach ulcers and indigestion.
- Indomethacin: medicine used to treat pain and inflammation.
- Furosemide: medicine used to treat high blood pressure or heart problems.
- Aminosalicylates (e.g. olsalazine, mesalazine or sulfasalazine): medicines mainly used in the treatment of ulcerative colitis and Crohn's disease.
- Methotrexate: medicine used to treat cancer and autoimmune diseases.
- Infliximab: medicine used to treat chronic inflammatory diseases (ulcerative colitis and Crohn's disease).
- Anticoagulants (e.g. warfarin, acenocoumarol): medicines used treat or prevent blood clots.

IMURAN with food and drink

IMURAN should be taken at least one hour before or three hours after food or milk.

Pregnancy, breastfeeding and fertility

You should not take IMURAN if you are pregnant or breastfeeding your baby.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking IMURAN.

Talk to your doctor immediately if you experience intense itching without a rash during your pregnancy. 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).

Do not use IMURAN if you are a man and trying to father a child. IMURAN may affect the baby.

Small amounts of IMURAN may pass into the breast milk. It is recommended that women taking IMURAN should avoid breastfeeding.

Reliable contraceptive precautions must be taken to avoid pregnancy whilst you or your partner is taking IMURAN and for at least three months for men and for at least six months for women after stopping IMURAN treatment.

The effects of IMURAN on fertility are not known.

Driving and using machines

IMURAN has a moderate influence on the ability to drive and use machines.

It is not always possible to predict to what extent IMURAN may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which IMURAN affects you (see section 4).

IMURAN contains lactose monohydrate

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking IMURAN.

3. How to take IMURAN

Do not share medicines prescribed for you with any other person.
Always take IMURAN exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

IMURAN should be taken at least one hour before or three hours after food or milk.

Recommended dose of IMURAN in adults:

Adults who have had an organ transplant:

On the first day of treatment, the usual dose is up to 5 mg per kilogram of body weight, then a usual daily dose of 1 mg to 4 mg per kilogram of body weight. During treatment your doctor will adjust the dose depending on your reaction to the medicine.

Adults with Multiple Sclerosis:

The usual dose is 2 mg to 3 mg per kilogram of body weight per day.

Adults with other conditions:

The usual starting dose is 1 mg to 3 mg per kilogram of body weight, then a usual daily dose of less than 1 mg to 3 mg per kilogram of body weight. During treatment your doctor will adjust the dose depending on your reaction to the medicine.

Elderly patients may need a reduced dose.

Patients with kidney or liver problems may need a reduced dose.

Recommended dose of IMURAN in children:

Children who have had organ transplant:

The dosing for children who have had an organ transplant is the same as adults.

Children with other conditions:

The dosing for children with other conditions is the same as adults.

The use of IMURAN is not recommended in children with multiple sclerosis.

Children who are considered to be overweight may require a higher dose.

Your doctor will tell you how long your treatment with IMURAN will last. Do not stop treatment early because IMURAN may take a long time before improvement is noticed. If you have the impression that the effect of IMURAN is too strong or too weak, tell your doctor or pharmacist.

If you take more IMURAN than you should

In the event of over dosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre. Signs and symptoms of overdosage with IMURAN can be nausea (feeling sick), vomiting and diarrhoea, lack of white blood cells which may cause frequent infections such as fever, severe chills, sore throat or mouth ulcers, disturbances of your liver function, bruising and bleeding.

If you forget to take IMURAN

Do not take a double dose to make up for forgotten individual doses.

If you stop taking IMURAN

Before you stop taking IMURAN, consult with your doctor or pharmacist. Do not stop taking IMURAN until your doctor tells you it is safe to do so.

4. Possible side effects

IMURAN can have side effects.

Not all side effects reported for IMURAN are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking IMURAN, please consult your healthcare provider for advice.

If any of the following happens, stop taking IMURAN and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting,
- blistering of the skin, mouth, eyes and genitals as these may be due to a serious allergic reaction known as Stevens-Johnson Syndrome (SJS) and detachment of the skin known as Toxic epidermal necrolysis (TEN),
- headache, nausea, vomiting, diarrhoea, tiredness, rash, fever, joint pain and liver inflammation,
- less common side effects include inflammation of the pancreas (pancreatitis), infections, lymphoma (cancer of the lymph nodes) and skin cancer.

These are all very serious side effects. If you have them, you may have had a serious reaction to IMURAN. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- inflammation of the pancreas, which may cause you severe upper stomach pain, with nausea and vomiting,
- severe liver damage or failure which can be life threatening, which may cause pale stools, dark urine, itchiness and yellowing of your skin and eyes (jaundice),
- inflammation of your lungs causing breathlessness, cough and a fever,
- various types of tumours and cancers,
- problems with your blood and bone marrow which may cause weakness, tiredness, paleness, breathlessness, dizziness, bruising, bleeding or infections,
- blood in stools or vomiting blood due to perforation or bleeding of the bowel (this can be due to internal bleeding),
- changes in the way your heart beats, for example, if you notice it beating faster,
- kidney failure with symptoms such as swelling of your ankles, painful urination, producing less urine than what is normal for you and blood in your urine.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- infections caused by a virus, fungus or bacteria. Signs of infection such a sore throat, fever or cough,
- nausea.

Less frequent side effects:

- abnormal blood tests showing how your liver and blood works,
- problems with your bowel leading to severe diarrhoea, stomach pain, constipation, nausea and vomiting,
- hair loss.

Side effects with an unknown frequency:

- abnormal levels of phosphate, nitrogen or uric acid in the blood, loss of appetite,
- headache, dizziness,
- damage to the retina of the eyes which may cause vision impairment,
- low blood pressure,
- discolouration of the fingers and/or toes after exposure to changes in temperature (hot/cold) (Raynaud's phenomenon),
- vomiting, inflammation of the stomach or the tube running from the throat to the stomach (oesophagus), mouth sores, stomach pain,
- pigmentation of the skin and nails, sensitivity to light or sunlight (photosensitivity),
- muscle pains, joint pains,
- suppression of normal function of the ovaries and testicles causing the absence of periods and the inhibition of formation of sperm,
- abnormalities in chromosomes (e.g. Down syndrome),
- tiredness, fever, shivers, weakness.

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

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to **SAHPRA** via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088/+ 27 11 239 6200

By reporting side effects, you can help provide more information on the safety of IMURAN.

5. How to store IMURAN

Store all medicines out of reach and sight of children.

Store at or below 25 °C.

Keep dry and protect from light.

Keep in the original packaging until required for use.

Do not store in a bathroom.

Do not use after the expiry date stated on the label. The expiry date refers to the last day of that month.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What IMURAN contains

The active substance is 50 mg of azathioprine.

The other ingredients are lactose monohydrate, magnesium stearate, maize starch, pregelatinised starch, stearic acid.

Film-coating: Methylhydroxypropylcellulose (hypromellose), polyethylene glycol 400 (macrogol).

What IMURAN looks like and contents of the pack

IMURAN is a yellow tablet; film-coated, round, biconvex, scored and branded 'IM 5'.

White opaque polyvinyl chloride and aluminium blisters of 100 film-coated tablets are packed into preprinted cartons together with a leaflet.

Holder of Certificate of Registration

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

Hotline: 0800 122 912/+27 11 239 6200

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Access to the corresponding Professional Information

SAHPRA Repository of Professional Information and Patient Information Leaflets:

https://www.sahpra.org.za/pi-pil-repository/

Aspen Pharmacare:

E-mail: Medinfo@aspenpharma.com

Tel: 0800 118 088/+27 11 239 6200

Botswana: IMURAN TABLETS 50 mg: BOT1703039 S2

Namibia: IMURAN TABLETS 50 mg: NS2 90/26/00580