

IMURAN 50MG TABLET

Azathioprine (50mg)

What is in this leaflet?

1. What Imuran Tablet is used for
2. How Imuran Tablet works
3. Before you use Imuran Tablet
4. How to use Imuran Tablet
5. While you are using it
6. Side effects
7. Storage and Disposal of Imuran Tablet
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of Revision

What Imuran Tablet is used for

Imuran Tablet is used to help prevent the rejection of a transplanted organ such as a kidney, liver or heart.

Imuran Tablet can also be used to treat other diseases called autoimmune diseases where your immune system is reacting against your own body. These may include:

- severe rheumatoid arthritis
- systemic lupus erythematosus
- auto-immune chronic active hepatitis
- certain auto-immune skin, muscle, and blood diseases.

Imuran Tablet is usually taken in combination with other medicines such as corticosteroids or other immunosuppressive agents.

How Imuran Tablet works

Imuran Tablet contains azathioprine as the active ingredient. Azathioprine belongs to a group of

medicines called immunosuppressant. It works by suppressing the body's immune defence system.

Ask your doctor if you have any questions about why this medicine has been prescribed for you. Your doctor may have prescribed it for another reason.

Before you use Imuran Tablet

- When you must not use it

Do not take this medicine if you have an allergy to:

- azathioprine
- 6-mercaptopurine
- any of the other ingredients listed at the end of this leaflet

Do not take Imuran Tablet if you are pregnant, breastfeeding, planning to become pregnant or father a child unless you and your doctor have discussed the risks and benefits involved.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering. If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

- Before you start to use it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following conditions:

- liver or kidney disease
- you have recently been vaccinated or are planning to be vaccinated
- a condition where your body produces too little of a natural chemical called thiopurine methyltransferase (TPMT)
- Lesch-Nyhan Syndrome
- chickenpox or shingles
- hepatitis B

If you have not told your doctor any of the above, talk to he/she before taking Imuran Tablet.

- Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and Imuran Tablet may interfere with each other. These include:

- vaccinations with 'live' organism vaccines.
- Ribavirin (use to treat hepatitis C together with another medication)
- Allopurinol, oxipurinol or thiopurinol (use mainly to treat gout)
- Aminosalicylate e.g. mesalazine, olsalazine or sulphasalazine (use mainly to treat ulcerative colitis)
- Methotrexate (use for treatment of cancer)
- Warfarin (use for blood thinning)

These medicines may be affected by Imuran Tablet or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to use Imuran Tablet

Follow all directions given to you by your doctor and pharmacist carefully.

These directions may differ from the information contained in this leaflet.

If you do not understand the instructions on the pack, ask your doctor or pharmacist for help.

- How much to use

Always take Imuran Tablet exactly as your doctor has told you.

Your doctor will decide what dose and for how long you will be taking Imuran Tablet. This depends on factors such as your weight and your response to the treatment. Your doctor may change the dose and frequency of your medicine as your condition changes.

Your doctor may order regular blood tests while you are taking Imuran in order to monitor your blood cell count and to change your dose if necessary.

- When to use it

Take Imuran Tablet at least 1 hour before or 3 hours after food or milk.

- How long to use it

Continue taking Imuran Tablet for as long as your doctor recommends.

- If you forget to use it

Take your dose as soon as you remember, and continue to take it as you would normally.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose that you missed. This may increase the chance of you getting an unwanted side effect.

- If you use too much (overdose)

Immediately telephone your doctor for advice or go to Accident and Emergency (Casualty) at your nearest hospital if you think that you or anyone else may have taken too much Imuran Tablet.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are using it

- Things you must do

Tell all the doctors, dentists and pharmacists who are treating you that you are taking Imuran Tablet.

Tell your doctor if you are pregnant, plan to become

pregnant, breast-feeding or trying to farther a child.

Tell your doctor immediately if you notice new moles, changes in existing moles, any lumps on your body or you feel unwell. There may be an increased risk of developing infections or tumours, including skin cancer, whilst taking this medicine.

Protect yourself from the sun while you are taking Imuran Tablet.

If you are about to start taking any new medicine tell your doctor and pharmacist that you are taking Imuran Tablet.

- Things you must not do

Do not stop taking your medicine or lower the dosage without checking with your doctor.

Do not take Imuran Tablet to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

- Things to be careful of

Do not drive or operate machinery until you know how Imuran Tablet affects you.

Side effects

All medicines can have side effects. Sometimes they are serious, most of the time they are not.

Ask for the advice of your doctor or pharmacist if you have any concerns about the effects of taking this medicine.

Do not be alarmed by the following lists of side effects.

You may not experience any of them.

The following side effects have been reported with Imuran Tablet:

- Abnormal tissue growth, including cysts and polyps, may it be benign (non-cancerous) or malignant (cancerous) like skin cancers and leukaemia
- Decreased number of blood cells due to bone marrow suppression
- Hypersensitivity reactions like skin rash, itching, breathing difficulty, wheezing or coughing, skin reaction like inflammation, peeling of skin in Steven Johnson Syndrome and Toxic Epidermal Necrolysis
- Cholestasis (flow of bile from liver stops or slows) and worsening of liver function test
- Viral, fungal and bacterial infections
- Hair loss
- Nausea
- Diarrhea
- Stomach pain with fever and vomiting

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell. Other side effects not listed above may also occur in some people.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers → Reporting).

Storage and Disposal of Imuran Tablet

- Storage

Keep your medicine in its original packaging until it is time to take them.

If you take the tablets out of the pack, they may not keep well.

Keep your medicine in a place where the temperature will stay below 25°C. Protect from light.

Do not store your medicine, or any other medicine, in the bathroom or near a sink.

Keep it where children cannot reach it.

- Disposal

If your doctor or pharmacist tells you to stop taking this medicine or it has passed its expiry date, ask your pharmacist what to do with any medicine that is left over.

Product Description

- What it looks like

Yellow, round, biconvex, film-coated tablets, scored, branded GX CH1.

- Ingredients

Active ingredient:

- Azathioprine

Inactive ingredients:

- PEG 400
- Starch
- Magnesium stearate
- Maize starch
- Lactose monohydrate
- Stearic acid
- Hypromellose
- Water

- MAL number

MAL04103439ACZ

Manufacturer

Excella GmbH, Nurnberger Strasse 12, D- 90537 Feucht, Germany.

Product Registration Holder

Aspen Medical Products Malaysia Sdn Bhd (1004761-W)
Unit 1302A, Level 13A, Uptown 1, 1 Jalan SS21/58, Damansara Uptown, 47400 Petaling Jaya, Selangor, Malaysia.

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