

AZAMUN TABLETS

Azathioprine (50mg)

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What AZAMUN tablets is used for
AZAMUN tablet is used to treat patients who have received an organ transplant to help prevent their body from rejecting the transplanted organs (e.g. a heart or kidney).

AZAMUN tablet is also used to suppress the body's immunity to treat "autoimmune" conditions like rheumatoid arthritis, and SLE (systemic lupus erythematosus).

AZAMUN tablets may also be used to treat other conditions as determined by your doctor.

How AZAMUN tablets works
AZAMUN tablets contain the active ingredient Azathioprine. It belongs to a group of medicines called immunosuppressants which work by reducing the body's own natural immunity.

Before you use AZAMUN tablets

- When you must not use it

Do not use **AZAMUN tablets**:

- If you are female and you are pregnant or there is a chance that you may become pregnant; Azathioprine is not recommended during pregnancy. It may cause birth defects if using it at the time of conception. Your partner should take adequate contraceptive precautions while you are taking **AZAMUN tablets**. If you are using IUD contraceptives it is recommended that additional methods of contraception are employed.
- If you are breastfeeding or are planning

to breastfeed.

- If you have ever had an allergy to **AZAMUN tablets** or any of its ingredients (listed at the end of this leaflet), or to another immunosuppressant medicine (eg. 6-mercaptopurine). Symptoms of an allergic reaction may be mild or severe. Signs if you are suffering an allergic reaction usually include some of the following: wheezing, swelling of the lips / mouth, difficulty in breathing, hayfever, lumpy rash (hives) or fainting.
- If you have rheumatoid arthritis, which has, previously been treated with an alkylating agent (eg. chlorambucil, melphalan or cyclophosphamide).
- If you have chickenpox or recently had it (including recent exposure).
- If you have herpes zoster (Shingles)
- If you take **AZAMUN tablets** after the expiry date (EXP.) printed on the pack. If you take **AZAMUN tablets** after the expiry date is passed, it may not work as well.
- Do not take **AZAMUN tablets** if the packaging is torn or the blister foil is broken or shows signs of tampering. If you're not sure whether you should be taking **AZAMUN tablets**, talk to your doctor.

Inform your doctor if you have any problem stated above, as Azamun may not suits you

- Before you start to use it

Tell your doctor if you:

- Are allergic to foods, dyes, preservatives or any other medicines.
- Have any other medical conditions.
- Have liver or kidney disease.
- Have been or are considering being vaccinated.
- Are currently having or are considering dental treatment.

- Taking other medicines

You should always tell your doctor about any other medicines that you take, even if you have bought the medicines, vitamins or herbal products without a doctor's prescription. Some medicines can affect the way **AZAMUN tablets** works.

It is especially important that you tell your doctor if you are taking any of the following:

- Allopurinol – medicine used to treat gout
- Corticosteroids (cortisone like medicines) these may be prescribed by your doctor to increase the effects of **AZAMUN**.
- Other immunosuppressants (eg. mercaptopurine, chlorambucil, cyclosporine, cyclophosphamide).
- Muscle relaxants (eg. D-tubocurarine, suxamethonium).
- Trimethoprim
- Captopril

How to use AZAMUN tablets

- How much to use

Use **AZAMUN tablets** only as directed by your doctor. Your doctor has carefully determined your dose of **AZAMUN tablets**. Your dose of **AZAMUN tablets** is determined by the condition being treated, your body weight and any other medical conditions that you may have.

Do not alter the amount you are taking or change your treatment regime unless directed to do so by your doctor.

AZAMUN tablets may be used in children. Your doctor will advise the dose to use for children.

- When to use it

AZAMUN tablets should only be taken orally.

Swallow **AZAMUN tablets** with a glass of water. Do not crush or chew the tablets.

Take **AZAMUN tablets** at the same time every day.

Keeping a regular time for taking **AZAMUN tablets** will help to remind you to take them.

AZAMUN tablets may sometimes cause mild nausea and vomiting

- How long to use it

Do not stop taking **AZAMUN tablets** without first checking with your doctor

Your doctor will discuss with you how long you need to take **AZAMUN tablets**. You could have to take **AZAMUN tablets** for some weeks or months before you will be able to receive the full effects.

Patients that are taking **AZAMUN tablets** because they have had an organ transplant will need to take **AZAMUN tablets** continuously to reduce the risk of the body rejecting the transplanted organ

- *If you forget to use it*

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to. Otherwise, take it as soon as you remember, and then go back to taking **AZAMUN tablets** as you would normally.

Never take a double dose to make up for the dose that you missed.

If you are not sure what to do, ask your doctor or pharmacist.

- *If you use too much (overdose)*

Immediately contact either your doctor, or accident and emergency department at your nearest hospital if you think that you or anyone else may have taken too many **AZAMUN tablets**. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical treatment.

While you are using it AZAMUN tablets

Things you must do

Make regular visits to your doctor, so that the doctor will be able to ensure that **AZAMUN tablets** are working properly for you and that you are not suffering any unwanted side effects. Your doctor may take regular blood tests to check how you are reacting to **AZAMUN tablets**.

If you have to have or are planning to have an operation, tell your surgeon and anaesthetist that you are taking **AZAMUN tablets**.

AZAMUN tablets suppress your immune system, lowering your body's immune defence system. This increases your risk of skin cancer and other cancers while taking **AZAMUN tablets**.

Always protect yourself from the sun, wear sunscreen, a hat and protective clothing.

Tell your doctor:

- If you become pregnant or you are trying to become pregnant
- If you plan to have any vaccinations or immunisations.
- If you notice any new moles or changes in existing moles.
- If you notice any lumps on your body or if you feel unwell.

- Things you must not do

Do not:

- stop taking **AZAMUN tablets** or change the dose without first checking with your doctor.
- give this medicine to anyone else, even if their symptoms seem similar to yours.
- have any immunisations without your doctor's approval. Avoid contact with any person in your household who has had an oral polio vaccine recently. Try to avoid contact with people who have infectious diseases (such as the 'flu).
- participate in contact sports or other situations where bruising or injury may occur. Be careful to avoid cutting yourself with sharp objects (eg. razors).

- Things to be careful of

Be careful driving or operating machinery until you know how **AZAMUN tablets** affects you.

AZAMUN tablets generally does not cause any problems with your ability to drive a car or operate machinery. However, as with many other medicines, **AZAMUN tablets** may cause headache or dizziness in some people.

Side effects

Tell your doctor or pharmacist if you notice any of the following serious side effects. Allergic reactions, the signs may include:

- general tiredness, dizziness, feeling sick (nausea), being sick (vomiting), diarrhoea, fever, chills
- redness of the skin, skin nodules or a skin rash (including blisters, itching or peeling skin)
- Pain in the muscles or joints
- Drop in blood pressure
- Changes in urine volume and color (kidney problems)
- Yellowing of the skin or the whites of the eyes (jaundice)

Check with your doctor if you experience any problems while taking **AZAMUN tablets**, even if you do not think that the problems you are having have anything to do with you taking **AZAMUN tablets**.

Your doctor will have assessed the risk of possible side effects against the importance of you taking this medication. Some side effects may have signs or symptoms that you can see or feel. Your doctor will watch for other side effects by performing certain tests. Ensure that you have regular check-ups with your doctor.

Tell the doctor immediately if you notice any of the following:

- any infection, unexpected bruising or bleeding, black tarry stools or blood in the urine or stools
- coughing, difficulty in breathing and wheezing
- yellow discolouration of the skin and eyes
- fever
- nausea, vomiting

IMMEDIATELY CONTACT YOUR DOCTOR or go to the accident and emergency department at your nearest hospital if you observe any of the following symptoms as you may be having an allergic reaction to **AZAMUN tablets**:

- Wheezing
- Swelling of the lips / mouth
- Difficulty in breathing
- Hay fever
- Lumpy rash
- Fainting

This is not a complete list of possible side effects. You may react in a different way.

Contact your Doctor or Pharmacist if you notice anything else that is making you feel unwell, even if it is not on this list.

You may report any side effects or adverse drug reactions directly to The National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of AZAMUN Tablet

- Storage

Medicines should not be kept indefinitely.

Keep your tablets in the blister strip until it is time to take them. If you take the tablets out of the blister strip, they may not keep as well.

Keep **AZAMUN tablets** in a cool dry place where the temperature stays below 30°C.

Do not leave or store **AZAMUN tablets** in the bathroom, near a sink or stove, on a windowsill or in a car.

Heat and dampness can destroy some medicines.

Keep **AZAMUN tablets** where children cannot reach them.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

- Disposal

Tell your doctor if you stop taking the tablets or the tablets have passed their expiry date. Ask your pharmacist what to do with any tablets, which are left over.

Product Description

- What it looks like

AZAMUN 50 mg - A light yellow, circular, biconvex tablet, engraved with 'AZA' and '50' separated by a line on one side and plain on the other side.

- Ingredients

Active ingredient azathioprine.

- Inactive ingredient

Mannitol, maize starch, croscarmellose sodium, sodium stearyl fumarate, purified water, Avicel PH 101, PVP K25 in the tablet core. The tablet coating contains Opadry clear OY- 7240

- MAL number:

MAL20021382AZ

Manufacturer

Douglas Manufacturing Ltd
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Product Registration Holder

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