

AZAMUN™

Azathioprine

25 mg, 50 mg, 75 mg and 100 mg tablets

What is in this leaflet

Please read this leaflet carefully before you start taking AZAMUN.

This leaflet answers some common questions about AZAMUN. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking AZAMUN against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What AZAMUN is used for

AZAMUN belongs to a group of medicines called immunosuppressants. It works by reducing the body's own natural immunity.

AZAMUN tablets are used to:

- treat patients who have received an organ transplant to help prevent their body from rejecting the transplanted organs (e.g. heart or kidney).
- treat some diseases where your immune system is reacting against your own body (autoimmune diseases) including hepatitis (liver disease), a condition called systemic lupus erythematosus (SLE), various blood and bleeding disorders and skin disorders.
- treat severe rheumatoid arthritis.

- treat severe inflammation of the gut (Crohn's disease or ulcerative colitis).

AZAMUN is usually taken in combination with other medicines such as corticosteroids or other immunosuppressive drugs.

Your doctor may have prescribed AZAMUN for another reason.

Ask your doctor if you have any questions about why AZAMUN has been prescribed for you.

This medicine is available only with a doctor's prescription.

There is no evidence that it is addictive.

Before you take AZAMUN

When you must not take it

Do not take AZAMUN if you have an allergy to:

- any medicine containing azathioprine or a class of medicines called immunosuppressants (e.g. 6-mercaptopurine)
- any of the ingredients listed at the end of this leaflet

Some of the symptoms of an allergic reaction may include:

- difficulty in breathing or wheezing
- shortness of breath
- swelling of the face, tongue, lips, or other parts of the body
- hives on the skin, rash, or itching.

Do not take this medicine if you are pregnant, may be pregnant, plan to become pregnant or intending to father a child. This medicine may cause birth defects if either the male or female are taking it at the time of conception. Women taking AZAMUN or the

female partners of men taking Azamun must not become pregnant during treatment and for 6 months afterwards. Both men and women taking AZAMUN must use effective contraception during treatment with and for 6 months afterwards. Intrauterine devices are not suitable for contraception in women taking AZAMUN (or in women whose male partners are taking AZAMUN).

Do not breastfeed without consulting your doctor if you are taking this medicine. This is because small amounts may pass into breast milk and may cause serious side effects to your baby.

Do not take AZAMUN if you have rheumatoid arthritis that has previously been treated with some other medicines, such as chlorambucil, melphalan or cyclophosphamide.

Do not take it after the expiry date (EXP) printed on the back. If you take it after the expiry date has passed, it may not work as well.

Do not take it if the packaging is torn or shows signs of tampering.

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

Before you start to take it

Tell your doctor if:

- 1. you have:**
 - liver or kidney disease
 - chickenpox or shingles
 - hepatitis B
 - a condition where your body produces too little of a natural chemical called thiopurine methyltransferase (TPMT)
 - Lesch-Nyhan Syndrome
 - you have an enlarged spleen
- 2. you have allergies to:**
 - Any other medicines including azathioprine
 - Any other substances, such as foods, preservatives or dyes

3. you are pregnant, may be pregnant, intend to become pregnant or intending to father a child. Your doctor can discuss with you the risks and benefits involved.

4. you are breastfeeding or planning to breastfeed. Small amounts may pass into breast milk and may cause serious side effects to your baby. Your doctor can discuss with you the risks and benefits involved.

5. You have been recently vaccinated or immunised or plan to do so. AZAMUN may affect the way the vaccine works or your reaction to the vaccine.

If you have not told your doctor about any of the above, tell them before you start taking AZAMUN.

Tell your dentist that you are taking AZAMUN.

Dental work, whenever possible, should be completed before you start taking AZAMUN or delayed until your blood cell counts are normal.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop. You should also tell any health professional who is prescribing a new medication for you that you are taking AZAMUN.

Some medicines may interfere with AZAMUN. These include:

- allopurinol, oxipurinol, thiopurinol or febuxostat used mainly to treat gout
- warfarin and acenocoumarol, a medicine used to prevent blood clots
- co-trimoxazole, used to treat infections.
- cimetidine, used to treat stomach ulcers and indigestion

- indomethacin used as a painkiller and anti-inflammatory
- penicillamine, used mainly in the treatment of rheumatoid arthritis
- tubocurarine, succinylcholine, used during anaesthesia
- mesalazine, olsalazine or sulphasalazine, used mainly to treat ulcerative colitis
- methotrexate, used in the treatment of cancer
- furosemide, may be used to reduce swelling caused by excess fluid
- ribavirin, used to treat a type of respiratory infection
- captopril, used mainly to treat high blood pressure and heart failure
- phenytoin, phenobarbital, rifampicin, ketoconazole, erythromycin
- infliximab, used to treat various autoimmune diseases

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

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking AZAMUN.

How to take AZAMUN

How much to take

Take AZAMUN tablets only as directed by your doctor.

Your doctor has carefully determined your dose of AZAMUN. Your dose of AZAMUN 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.

From time to time, while you are taking

AZAMUN, 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.

AZAMUN tablets should only be taken orally.

How to take it

Swallow the tablets whole with a glass of water. Do not crush, break or chew them.

When to take it

Take AZAMUN at the same time every day. Keeping a regular time for taking AZAMUN will help remind you to take them.

Take AZAMUN tablets at least 1 hour before or 3 hours after food or milk. This will help reduce the incidence of vomiting and nausea.

How long to take 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 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 continuously to reduce the risk of the body rejecting the transplanted organ

If you forget to take 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 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.

While you are taking AZAMUN

Things you must do

Take AZAMUN exactly as prescribed by your doctor.

Visit your doctor regularly, so they 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 are about to be started on any new medicine, tell your doctor, dentist and pharmacist that you are taking AZAMUN.

Protect your skin when you are in the sun. If you are outdoors, wear a hat, protective clothing and use sunscreen.

Tell your doctor immediately if you notice new moles, changes in existing moles, any lumps on your body or you feel unwell. 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.

Tell your doctor that you are taking corticosteroids (cortisone like medicines) these medicines may be prescribed by your doctor to increase the effects of AZAMUN.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine. It may affect other medicines used during surgery.

Tell your doctor if you become pregnant while taking this medicine or are trying to become pregnant or to father a child.

Avoid contact with anyone suffering from chickenpox or shingles.

Tell your doctor if you experience symptoms of liver damage while taking AZAMUN (see Side effects)

Treatment with AZAMUN may affect the liver and your doctor will monitor your liver function regularly.

Things you must not do

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

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

Do not have any immunisations without your doctor's approval. Vaccination with live vaccines is not advised.

Try to avoid contact with people who have infectious diseases (such as the 'flu' or anyone suffering from chickenpox or shingles).

Do not participate in contact sports or other situations where bruising or injury may occur. Be careful to avoid cutting yourself with sharp object (e.g. razors).

Things to be careful of

Be careful driving or operating machinery until you know how AZAMUN affects you. Studies on the effects of AZAMUN on the ability to drive and use machines have not been performed. This product may cause dizziness, which could affect your ability to drive or operate machinery.

In case of overdose

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766) or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much AZAMUN.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking AZAMUN.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the adverse effects.

Do not be alarmed by this list of possible adverse effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

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

- any infection or fever
- unexpected bruising or bleeding, black tarry stools or blood in the stools or urine
- headache, stiff neck and extreme sensitivity to bright light
- irregular heartbeat
- new marks on skin or any change to marks that may have been there previously
- skin rash or redness that gets worse in the sun
- diarrhoea or an upset stomach
- feeling confused, forgetful or moody
- dizziness, tiredness and generally unwell
- sores on the lips and in the mouth
- change in the sense of smell and taste
- feeling of ants in or under the skin
- change in the sense of taste and smell
- itching, possibly accompanied by nausea, loss of appetite, oily foul-smelling stool and yellowing of the skin and whites of the eyes while pregnant. These could be symptoms of cholestasis.

Azamun could cause your hepatitis B to become active again.

If any of the following happen, stop taking AZAMUN and tell your doctor immediately, or go to Accident and Emergency at your nearest hospital:

- allergic reaction, the signs may include sudden wheeziness, difficulty in breathing, swelling of the eyelids, face or lips, throat, rash or itching.
- serious skin reactions such as blistering or peeling
- red, painful nodules on the shins and/or lower legs
- muscle weakness, with or without a skin rash
- muscle stiffness or pain
- severe joint pain
- kidney problems
- feeling faint especially when standing up
- severe abdominal pain
- diarrhoea

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

Side effects commonly reported in patients who have received an organ transplant are:

- viral, fungal and bacterial infections that include the skin
- hair loss (common in kidney transplant patients)
- stomach pain with vomiting and fever
- diarrhoea, usually with blood and mucus

Azamun can cause severe liver damage which can be life threatening, especially in patients who receive long-term treatment (like liver injury, non-cirrhotic portal hypertension, portosinusoidal vascular disease).

Tell your doctor immediately if you experience any of the following symptoms:

- yellowing of the skin and the whites of the eyes (jaundice)

- bruising easily
- abdominal discomfort
- loss of appetite
- fatigue
- nausea, or vomiting.

Tell your doctor if you notice any other effects.

Other adverse effects not listed above may also occur in some patients.

After taking AZAMUN

Storage

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.

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

Keep your AZAMUN 25 mg and 50 mg tablets in a cool dry place where the temperature stays at or below 30°C. **Keep your AZAMUN 75 mg and 100 mg tablets in a cool dry place** where the temperature stays at or below 25°C.

Do not store AZAMUN in the bathroom or near a sink. Do not leave it in the car or on a windowsill. Heat and dampness can destroy some medicines.

Keep it where children cannot reach it. A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or they have passed their expiry date, ask your pharmacist what to do with any unused medicine. **Return any unused medicine to your pharmacist.**

Product description

What it looks like

AZAMUN 25 mg Tablets: light yellow, circular, biconvex tablet engraved “AZA” and “25” on one side and plain on the other side.

AZAMUN 50 mg Tablets: light yellow, circular, biconvex tablet, engraved “AZA” and “50” separated by a line on one side and plain on the other side.

AZAMUN 75 mg Tablets: light yellow, circular, biconvex tablet engraved “AZA” and “75” on one side and plain on the other side.

AZAMUN 100 mg Tablets: light yellow, circular, biconvex tablet engraved “AZA” and “100” on one side and plain on the other side.

The line on one side of the Azamun 50 mg tablet is not intended for breaking the tablet.

Ingredients

Active ingredient:

- each tablet contains either 25 mg, 50 mg, 75 mg or 100 mg of azathioprine.

Inactive ingredients:

- cellulose microcrystalline, mannitol, povidone, maize starch, croscarmellose sodium, sodium stearyl fumarate in the tablet core. The tablet coating contains Opadry clear OY-7240 (macrogol 400 and hypromellose)

AZAMUN does not contain sucrose or gluten.

Sponsor details

AZAMUN is supplied in New Zealand by:

Douglas Pharmaceuticals Ltd

P O Box 45 027

Auckland 0651

New Zealand

Phone: (09) 835 0660

Date of preparation

27 May 2025

(based on data sheet dated 01 May 2025)