

IMURAN® tablets

azathioprine

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about IMURAN. It does not contain all of 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 IMURAN 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 IMURAN is used for

IMURAN contains azathioprine as the active ingredient. Azathioprine belongs to a group of medicines called immunosuppressants.

IMURAN is used to help prevent the rejection of a transplanted organ such as a kidney, liver or heart. It works by suppressing the body's immune defence system.

IMURAN 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
- chronic active hepatitis
- certain skin, muscle, and blood diseases.

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

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

Your doctor may have prescribed it for another purpose.

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

There is no evidence that it is addictive.

Before you take it

When you must not take it

Do not take IMURAN if you have ever had an allergic reaction to:

- azathioprine
- 6-mercaptopurine (Puri-Nethol), a medicine which is similar to IMURAN
- any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty in breathing; swelling of the face, lips, tongue or any other parts of the body; rash, itching or hives on the skin.

Do not take IMURAN 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 is taking it at the time of conception.

Do not take IMURAN if you are breastfeeding unless you and your

doctor have discussed the risks and benefits involved.

It is not recommended for use while breastfeeding as it may cause serious side effects to your baby.

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

Do not take IMURAN after the expiry date printed on the pack.

If you take this medicine after the expiry date has passed, it may not work as well.

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

Do not take this medicine to treat any other complaints unless your doctor has instructed you to do so.

Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

Before you start to take it

Tell your doctor if you are allergic to any other medicines or any foods, dyes or preservative.

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

- liver or kidney disease
- a condition where your body produces too little of a natural chemical called thiopurine methyltransferase (TPMT)
- Lesch-Nyhan Syndrome
- chickenpox or shingles
- hepatitis B.

Tell your doctor if you have recently been vaccinated or immunised or plan to do so.

IMURAN may affect the way the vaccine works or your reaction to the vaccine.

Tell your doctor if you are pregnant, may be pregnant, plan to become pregnant or intending to father a child.

You or your partner should take adequate contraceptive precautions while you are taking IMURAN.

Tell your doctor if you are breastfeeding or planning to breastfeed.

IMURAN is not recommended for use while breastfeeding as it may cause serious side effects to your baby.

Tell your dentist that you are taking IMURAN.

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

Taking other medicines

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

Some medicines may interfere with IMURAN. These include:

- penicillamine, used mainly in the treatment of rheumatoid arthritis
- captopril, used mainly to treat high blood pressure and heart failure
- cimetidine, used to treat stomach ulcers and indigestion
- indomethacin, used as a painkiller and anti-inflammatory
- co-trimoxazole, used to treat infections
- allopurinol, oxipurinol or thiopurinol, used mainly to treat gout
- tubocurarine, succinylcholine, used during anaesthesia

- frusemide, may be used to reduce swelling caused by excess fluid
- warfarin, used to prevent blood clots
- mesalazine, olsalazine or sulphasalazine, used mainly to treat ulcerative colitis
- phenytoin, phenobarbital, rifampicin, ketoconazole, erythromycin
- methotrexate, used in the treatment of cancer
- ribavirin, used to treat a type of respiratory infection.

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

Your doctor or pharmacist has a more complete list of medicines to avoid while taking IMURAN.

How to take it

How much to take

Your doctor will tell you how much IMURAN to take.

The dose will depend on the condition being treated, your bodyweight and how you respond to the medicine. Your initial dose will be maintained or adjusted until a satisfactory response is noted.

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.

How to take it

Swallow IMURAN tablets whole with a glass of water.

Do not break, chew or crush the tablets.

When to take it

Take IMURAN tablets at least 1 hour before or 3 hours after food or milk.

How long to take it

Patients with a transplant will need to take IMURAN tablets continuously to reduce the risk of organ rejection.

For other conditions, your doctor will discuss with you how long you need to take this medicine. It could take some weeks or months for it to take full effect.

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, then go back to taking it as you would normally.

Do not take a double dose to make up for the dose that you missed.

If you take too much (overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 131126) for advice, or go to Accident and Emergency at your nearest hospital if you think that you or anyone else may have taken too much IMURAN. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are taking it

Things you must do

Take IMURAN exactly as your doctor has prescribed.

Visit your doctor regularly, so they can make sure that IMURAN is working properly and to check for any unwanted side-effects.

Your doctor may order regular blood tests while you are taking this medicine to check how it affects you. The frequency of your blood tests will usually decrease the longer you continue to take IMURAN.

Tell any other doctor, dentist or pharmacist who is treating you that you are taking IMURAN, especially if you are about to be started on any new medicines.

Tell your doctor if you have recently been vaccinated or immunised or plan to do so. IMURAN may affect the way some vaccines work or your reaction to the vaccine.

Tell your doctor if you become pregnant, are trying to become pregnant or planning to father a child.

If you have to have an operation, tell your surgeon and anaesthetist that you are taking IMURAN.

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

Immunosuppressant drugs, like IMURAN, lower the body's immune defence system. 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.

If you go out in the sun, wear a hat, protective clothing and use sunscreen.

Avoid contact with anyone suffering from chickenpox or shingles.

Infection with chickenpox or shingles can become severe in patients taking drugs such as IMURAN.

Things you must not do

Do not stop taking IMURAN or change the dose without first checking with your doctor.

Do not break, chew or crush the tablets.

Things to be careful of

Be careful driving or operating machinery until you know how IMURAN affects you.

Side effects

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

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 side effects.

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

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

- any infection or fever
- unexpected bruising or bleeding, black tarry stools or blood in the urine or stools
- new marks on skin or any change to marks that may have been there previously
- headache, stiff neck and extreme sensitivity to bright light
- nausea and vomiting
- tiredness, dizziness or generally unwell
- irregular heart beat
- you come into contact with anyone who is suffering from chickenpox or shingles
- sores in the mouth and on the lips
- feeling of ants creeping in or under the skin
- change in sense of smell or taste.

IMURAN could cause your hepatitis B to become active again.

Tell your doctor immediately, or go to Accident and Emergency at your nearest hospital if you notice any of the following symptoms:

- allergic type reactions e.g. skin rash, itching and difficulty breathing, wheezing or coughing

- muscle weakness, with or without a skin rash
- muscle pain or stiffness
- severe joint pain
- kidney problems
- feeling faint especially when standing up
- severe abdominal pain
- diarrhoea
- jaundice, a yellow discoloration of the skin / eyes
- serious skin reactions such as blistering or peeling.

Side-effects reported particularly in organ transplant patients are:

- viral, fungal and bacterial infections
- hair loss (particularly following a kidney transplant)
- diarrhoea, usually with blood and mucus
- stomach pain with fever and vomiting.

Tell your doctor if you notice anything else that is making you feel unwell, even if you think the problems are not connected with this medicine and are not referred to in this leaflet.

Other side effects not listed above may also occur in some people.

Do not be alarmed by this list of possible side-effects.

You may not experience any of them.

After taking it

Storage

Keep IMURAN in a cool dry place, protected from light where it stays below 30°C.

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

Do not leave it in the car or on a window sill.

Heat and dampness can destroy some medicines.

Keep this medicine where young children cannot reach it.

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

Keep IMURAN tablets in the pack until it is time to take them.

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

Disposal

If your doctor tells you to stop taking IMURAN or the tablets have passed the expiry date, ask your pharmacist what to do with any tablets left over.

Product description

What it looks like

IMURAN tablets come in two strengths; 25 mg and 50 mg.

IMURAN 25 mg are orange film-coated tablets, round, biconvex, unscored, debossed GX EL5 on one face and plain on the other.

Available in blister packs of 100 tablets.

IMURAN 50 mg are yellow film-coated tablets, round, biconvex, scored, debossed GX above the score and CH1 below the score on one face and plain on the other.

Available in blister packs of 100 tablets.

Ingredients

Active ingredient:

Each tablet contains either 25 mg or 50 mg of azathioprine.

Inactive ingredients:

- hypromellose
- lactose
- macrogol 400
- magnesium stearate
- maize starch
- pregelatinised maize starch
- stearic acid
- iron oxide red (25 mg only)
- iron oxide yellow (25 mg only)

- titanium dioxide (25 mg only).

IMURAN tablets do not contain gluten, sucrose, tartrazine or any other azo dyes.

Sponsor

Aspen Pharmacare Australia Pty Ltd
34-36 Chandos St
St Leonards NSW 2065
Australia

Australian Registration Numbers:
25 mg tablets: AUST R 31393
50 mg tablets: AUST R 31398

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