

IMURAN(R) Tablets

Azathioprine

Consumer Medicine Information

What is in this leaflet?

Please read this leaflet carefully before you start taking IMURAN.

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 this medicine is expected to 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 which belongs to a group of medicines called immunosuppressants.

IMURAN works by reducing the body's ability to make cells that are involved in the body's immune defence system. This suppression of the body's own immune defence system helps prevent the body from rejecting transplanted organs (for example, a kidney or heart).

IMURAN can also be used to control other diseases involving the body's immune defence system such as:

severe rheumatoid arthritis; systemic lupus erythematosus (SLE); chronic active hepatitis; certain skin, muscle, and blood diseases.

IMURAN is usually taken with other drugs, particularly corticosteroids (e.g. prednisolone).

Your doctor may have prescribed IMURAN for another reason.

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

IMURAN tablets are not addictive.

Before you take IMURAN

When you must not take it

- * **Do not take IMURAN if you have ever had an allergic reaction to azathioprine or mercaptopurine (Puri-Nethol), or any of the ingredients listed at the end of this leaflet.**
Symptoms of an allergic reaction may be mild or severe. They usually include some or all of the following: wheezing, swelling of the lips/mouth, difficulty in breathing, hayfever, lumpy rash ('hives') or fainting.
- * **Do not take IMURAN if you are pregnant, may be pregnant, intending to become pregnant or to father a child. IMURAN 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. IMURAN passes into breast milk and 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 (EXP.) printed on the pack.**

If you take IMURAN 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.**
If you're not sure whether you should be taking IMURAN, talk to your doctor.

Before you start to take it

You must tell your doctor if:

- * **you are allergic to foods, dyes, preservatives or any other medicines.**
- * **you are pregnant, may be pregnant, planning to become pregnant or to father a child.**
You or your partner should take adequate contraceptive precautions while you are taking IMURAN.
- * **you are breastfeeding or planning to breastfeed.**
- * **you are currently having or planning to have dental treatment.**

- * you have recently been vaccinated or immunised, or plan to do so.
- * you have liver or kidney disease.
- * if you have a condition where your body produces too little of a natural chemical called thiopurine methyltransferase (TPMT).
- * if you suffer from the condition known as Lesch-Nyhan Syndrome.
- * if you have ever suffered from chickenpox or shingles.
- * you have any other medical conditions.

Taking other medicines

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

Some medicines may affect the way others work. Your doctor or pharmacist will be able to tell you what to do when taking IMURAN tablets with other medicines.

Some of the medicines that can interact with Imuran include: allopurinol, oxipurinol, thiopurinol, tubocurarine, succinylcholine, warfarin, penicillamine, co-trimoxazole, cimetidine, indomethacin, olsalazine, mesalazine, sulphasalazine, frusemide, phenytoin, phenobarbital, rifampicin, ketoconazole, erythromycin, captopril, other immunosuppressive medicines.

Tell your doctor if you are taking any of the above medicines.

Use in children

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

How to take IMURAN

The pharmacist's label on the pack will tell you how many tablets to take and how often you should take them. If there is something you do not understand, ask your doctor or pharmacist.

How much to take

Your dose will depend on your body weight and how you respond to the medicine. Your doctor will work out the right dose of IMURAN for you and may change the number of tablets you need to take, particularly at the beginning of treatment. If there is something you do not understand, ask your doctor or pharmacist.

How to take it

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

When to take it

Take IMURAN at the same time every day, preferably after a meal.

Keeping a regular time for taking IMURAN will help to remind you to take them.

Vomiting, nausea (feeling sick) and stomach discomfort can be reduced by taking IMURAN after meals.

How long to take it

Your doctor will discuss with you how long you need to take IMURAN tablets. It could take some weeks or months for IMURAN to take full effect.

Patients with a transplant will need to take IMURAN tablets continuously to reduce the risk of rejecting a 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, 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, if you think you or anyone else may have taken too much IMURAN tablets, even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Keep telephone numbers for these places handy.

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

While you are taking IMURAN

Things you must do

Tell your doctor or pharmacist that you are taking IMURAN tablets if you are about to be started on any new medicines, or if any of your regular medicines are stopped.

Visit your doctor regularly, so he/she can make sure that IMURAN is working properly, and to check for any unwanted side-effects. Your doctor may order regular blood tests for you while you are taking IMURAN, to check how this medicine affects you.

Tell your doctor if you plan to have any immunisations or vaccinations.

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 tablets.

Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed.

Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.

Because immunosuppressant drugs, like IMURAN tablets, lower the body's immune defence system, there may be an increased risk of skin and other cancers whilst taking these drugs.

Protect yourself from the sun while you are taking IMURAN.

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

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

Things you must not do

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

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

Do not use IMURAN to treat any other complaints unless your doctor says to.

Things to be careful of

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

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

Side-Effects

Check with your doctor as soon as possible if you have any problems while taking IMURAN, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

Like other medicines, IMURAN can cause some side-effects. Some may be minor and temporary. However, some may be serious and need medical attention.

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

Tell your doctor or pharmacist 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
- * coughing, difficulty in breathing, and wheezing
- * headache, stiff neck and extreme sensitivity to bright light
- * nausea, vomiting, diarrhoea
- * muscle pain or stiffness
- * severe joint pain
- * yellow discoloration of the skin/eyes
- * irregular heart beat
- * dizziness or feeling faint
- * muscle weakness, with or without a skin rash
- * severe abdominal pain
- * you come into contact with anyone who is suffering from chickenpox or shingles

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

Other side-effects reported include:

- * sores in the mouth and on the lips

- * feeling of ants creeping in or under the skin
- * change in sense of smell or taste
- * skin rash
- * tiredness and generally feeling unwell
- * low blood cell count
- * increased likelihood of viral, fungal and bacterial infections

If you think you are having an allergic reaction to IMURAN, TELL YOUR DOCTOR IMMEDIATELY or go to the casualty department at your nearest hospital. Symptoms usually include some or all of the following:

- * wheezing
- * swelling of the lips/mouth
- * difficulty in breathing
- * hay fever
- * lumpy rash ('hives')
- * fainting

This is not a complete list of all possible side-effects. Others may occur in some people and there may be some side-effects not yet known.

Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on this list.

Ask your doctor or pharmacist if you don't understand anything in this list.

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

After taking IMURAN

Storage

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 your IMURAN tablets in a cool, dry place, protected from light where it stays below 30 degrees C.

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

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

Heat and dampness can destroy some medicines.

Keep your 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 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 IMURAN looks like.

IMURAN tablets come in two strengths:

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

IMURAN 50 mg tablets 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.

Tablets are blister packed in cartons containing 100 tablets.

Ingredients

IMURAN 25 mg tablets contain 25 mg of the active ingredient azathioprine.

IMURAN 25 mg tablets also contain lactose, maize starch, starch pregelatinised maize, stearic acid, magnesium stearate, hypromellose, macrogol 400, titanium dioxide, iron oxide yellow CI77492 and iron oxide red CI77491.

IMURAN 50 mg tablets contain 50 mg of the active ingredient azathioprine.

IMURAN 50 mg tablets also contain lactose, maize starch, starch pregelatinised maize, stearic acid, magnesium stearate, hypromellose and macrogol 400.

IMURAN tablets do not contain gluten.

Supplier

IMURAN is supplied by:

GlaxoSmithKline Australia Pty Ltd
1061 Mountain Highway
Boronia Victoria 3155
Australia.

Further Information

Pharmaceutical companies are not in a position to give people an individual diagnosis or medical advice. Your doctor or pharmacist is the best person to give you advice on the treatment of your condition. You may also be able to find general information about your disease and its treatment from books, for example in public libraries.

Do not throw this leaflet away.

You may need to read it again.

This leaflet was prepared on 5 February 2004.

The information provided applies only to: IMURAN(R) tablets.

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IMURAN 25 mg tablets: AUST R 31393

IMURAN 50 mg tablets: AUST R 31398

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