

IMAZAN™

Azathioprine 25 mg and 50 mg tablets

Consumer Medicine Information

What is in this leaflet

This leaflet answers some of the common questions about IMAZAN.

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 IMAZAN against the benefits the 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 IMAZAN is used for

IMAZAN contains azathioprine. This belongs to a group of medicines called immune suppressants which work by reducing the body's own natural immunity.

IMAZAN 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).

IMAZAN is also used to suppress the body's immunity to treat "autoimmune" conditions like rheumatoid arthritis, systemic lupus erythematosus or chronic active hepatitis.

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

IMAZAN is a very powerful medicine. Never let anyone else take your medicine even if his or her condition seems similar to yours.

Have regular check ups with your doctor.

IMAZAN tablets are not addictive.

Before you take IMAZAN

When you must not take it:

- **If you are female and you are pregnant or there is a chance that you may become pregnant; or if you are male and there is a chance that you may father a child.** IMAZAN is not recommended during pregnancy. **It may cause birth defects if either the male or female are using it at the time of conception.** Your partner should take adequate contraceptive precautions while you are taking IMAZAN.
- **If you are breastfeeding or are planning to breastfeed.** IMAZAN passes into breast milk and may cause serious side effects to your baby.
- **If you are taking any other medicines or drugs.**
- **If you have ever had an allergy to azathioprine, the active in IMAZAN, any of its ingredients (listed at the end of this leaflet), or to another immune suppressant medicine (e.g. 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 (e.g. chlorambucil, melphalan or cyclophosphamide).**
- **If you take IMAZAN after the expiry date (EXP.) printed on the pack. If you take IMAZAN after the expiry date has passed, it may not work as well.**
- **Do not take IMAZAN if the packaging is torn or shows signs of tampering.**

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

All of these factors need to be taken into consideration by your doctor when he/she considers the most appropriate dose for you.

Before you start to take 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;**
- **Have been exposed to chickenpox or herpes zoster or have never had chickenpox or herpes zoster; and**
- **Are currently having or are considering dental treatment.**

Taking other medicines:

If you are taking other medicines you must tell your doctor.

This includes medicines that you can buy without a prescription from a pharmacy, supermarket or a health food shop.

Some medicines are affected by others. Your doctor or pharmacist will be able to tell you what you should do when you have to take other medicines while you are on IMAZAN.

Use in children:

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

How to take IMAZAN

How much to take:

Use IMAZAN only as directed by your doctor. Your doctor has carefully determined your dose of IMAZAN. Your dose of IMAZAN 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.

How to take it:

IMAZAN should only be taken orally.

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

When to take it:

Take IMAZAN at the same time every day.

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

IMAZAN may sometimes cause mild nausea and vomiting.

Take your medicine after food or at bedtime to minimise stomach upset.

How long to take it:

Do not stop taking IMAZAN without first checking with your doctor.

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

Patients that are taking IMAZAN because they have had an organ transplant will need to take IMAZAN 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 IMAZAN 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.

Do not use IMAZAN if the blister foil is broken or shows signs of tampering.

If you take too much (overdose):

Immediately telephone your doctor or Poisons Information Centre (Australia: 13 11 26) if you think that you or anyone else may have taken too many IMAZAN. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical treatment.

While you are using IMAZAN

Things you must do:

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 IMAZAN works.

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

- Allopurinol - may reduce the removal of IMAZAN from your body;
- Corticosteroids (cortisone like medicines) these may be prescribed by your doctor to increase the effects of IMAZAN;
- Cytotoxic medicines (e.g. mercaptopurine, chlorambucil, cyclosporin, cyclophosphamide); and
- Warfarin - IMAZAN inhibits the anticoagulant effect of warfarin.

Make regular visits to your doctor to ensure that IMAZAN is 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 IMAZAN.

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

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

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 or you are planning to father a child;
- If you plan to have any vaccinations or immunisations;
- If you have come into contact with an infected person with chickenpox or herpes zoster;
- If you notice any new moles or changes in existing moles; and
- If you notice any lumps on your body or if you feel unwell.

Things you must not do:

Do not:

- **Stop taking IMAZAN 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, chickenpox or herpes zoster).
- **Participate in contact sports or other situations where bruising or injury may occur. Be careful to avoid cutting yourself with sharp objects (e.g. razors).**

Things to be careful of:

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

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

Side effects

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

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.

Side effects commonly found 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;
- sores in the mouth and on the lips;
- feeling of pins and needles;
- change in sense of smell or taste;
- skin rash, skin peeling and sores on the mucous membranes; and
- tiredness and generally feeling unwell.

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;

- headache, stiff neck and extreme sensitivity to bright light;
- muscle pain or stiffness;
- severe joint pain;
- coughing, difficulty in breathing and wheezing;
- muscle weakness, with or without skin rash;
- irregular heart beat;
- yellow discolouration of the skin and eyes;
- fever;
- severe abdominal pain;
- nausea, vomiting, diarrhoea; and
- dizziness or feeling faint.

Immediately contact your doctor or go to the casualty department at your nearest hospital if you observe any of the following symptoms as you may be having an allergic reaction to IMAZAN:

- wheezing;
- swelling of the lips / mouth;
- difficulty in breathing;
- hay fever;
- lumpy rash; and
- 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.

After using IMAZAN

Storage:

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 IMAZAN in a cool dry place where the temperature stays below 30°C. Be sure to protect IMAZAN from light and moisture.

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

Heat and dampness can destroy some medicines.

Keep IMAZAN 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.

Safe handling of IMAZAN:

Azathioprine tablets should not be divided, crushed or broken. Provided that the film coating is intact, there is no risk in handling film-coated tablets.

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 IMAZAN looks like:

- **IMAZAN 25 mg***
- Peach coloured, film-coated, circular, biconvex tablet, engraved "AZA 25" on one face, the other face is plain. They are available in blister packs of 100 tablets.

- **IMAZAN 50 mg***
- Yellow film-coated tablet, embossed AZA, break line 50 on one face, the other face plain. They are available in blister packs of 100 tablets.

*Some pack sizes and strengths may not be marketed.

Ingredients:

Active ingredient:

Azathioprine

Other ingredients (excipients):

- Microcrystalline cellulose,
- croscarmellose sodium mannitol,
- povidone,
- sodium stearyl fumarate
- and maize starch.

25 mg only: Opadry Buff OY-3682, Opadry Buff OY-3690 and Opadry OY-1315G.

50 mg only: Opadry clear OY-7240.

Distributor

ERIS Pharmaceuticals (Australia) Pty Ltd
6 Eastern Road,
South Melbourne VIC 3205
www.eris-pharma.com.au



This leaflet was prepared in February 2014.

25 mg: AUST R 184923

50 mg: AUST R 184924