

Azathioprine Sandoz®

azathioprine film-coated tablets

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Azathioprine Sandoz.

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 this medicine 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 Azathioprine Sandoz is used for

This medicine is used to prevent the body from rejecting transplanted organs.

Azathioprine Sandoz can also be used to treat 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.

It contains the active ingredient azathioprine.

Azathioprine belongs to a group of medicines called immunosuppressants.

It works by reducing the body's own natural immunity.

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

Your doctor may have prescribed it for another reason.

This medicine is not addictive.

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

Before you take Azathioprine Sandoz

When you must not take it

Do not take this medicine if you have an allergy to:

- azathioprine, the active ingredient, or to any of the other ingredients listed at the end of this leaflet under Product Description
- any other similar medicines such as mercaptopurine (Puri-Nethol®).

Some of the symptoms of an allergic reaction may include:

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

Do not take this medicine if you have been previously treated with alkylating agents (such as chlorambucil, melphalan or cyclophosphamide) for rheumatoid arthritis.

Do not take this medicine if you are pregnant, may be pregnant,

intend to become pregnant or to father a child.

It may cause birth defects if either the male or female is taking it at the time of conception. It may also affect your developing baby if you take it during pregnancy. You and your partner should take adequate contraceptive precautions while you are taking Azathioprine Sandoz.

Do not breastfeed if you are taking this medicine.

The active ingredient in Azathioprine Sandoz passes into breast milk and there is a possibility that your baby may be affected.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

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

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

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

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

- any other medical conditions.

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

Azathioprine Sandoz may affect the way the vaccine works or your reaction to the vaccine.

Tell your doctor if you are currently having or planning to have dental treatment.

Any dental work should be done before treatment with Azathioprine Sandoz is started or delayed until your blood cell counts are normal.

If you have not told your doctor about any of the above, tell him/her before you start taking Azathioprine Sandoz.

Taking other medicines

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

Some medicines and Azathioprine Sandoz may interfere with each other. These include:

- allopurinol, oxypurinol or thiopurinol, medicines used to treat gout
- succinylcholine or tubocurarine, medicines used to relax muscles during surgery
- other medicines used to suppress the body's immune defence system
- warfarin, a medicine used to prevent blood clots
- aminosaliculates such as sulfasalazine, mesalazine and olsalazine, medicines used to treat inflammation of the bowel
- cimetidine, a medicine used to treat heartburn or stomach ulcers
- penicillamine, a medicine used to treat rheumatoid arthritis
- co-trimoxazole and erythromycin, medicines used to treat bacterial infections
- rifampicin, a medicine used to treat tuberculosis

- ketoconazole, a medicine used to treat fungal infections
- indomethacin, a non-steroidal anti-inflammatory drug
- frusemide, a diuretic medicine
- phenytoin and phenobarbital, medicines used to treat epilepsy
- methotrexate, used in the treatment of cancer
- ribavirin, used to treat a type of respiratory infection
- captopril, a medicine used to treat high blood pressure.

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

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to take Azathioprine Sandoz

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions, ask your doctor or pharmacist for help.

How much to take

Ask your doctor or pharmacist if you are unsure of the correct dose for you.

They will tell you exactly how much to take.

Follow the instructions they give you.

If you take the wrong dose, Azathioprine Sandoz may not work as well and your problem may not improve.

Your dose will depend on your body weight and how you respond to the medicine. Your doctor will determine the right dose for you.

Your doctor may change the number of tablets you need to take, particularly at the beginning of treatment.

How to take it

Swallow the tablets whole with a full glass of water.

Do not break, chew or crush the tablets.

These tablets have a special coating to stop them dissolving until they have gone through the stomach and into the intestines, where they can start to work. If you break, chew or crush them, the coating is destroyed.

When to take Azathioprine Sandoz

Take your medicine at about the same time each day, preferably after a meal.

Taking it at the same time each day will help you remember when to take it. Take it at least one hour before or three hours after food or milk. If you take it on an empty stomach, it may increase the likelihood of vomiting, nausea (feeling sick) and stomach upsets.

How long to take Azathioprine Sandoz

Continue taking your medicine for as long as your doctor tells you.

Your doctor will discuss with you for how long you need to take your medicine. It could take some weeks or months for Azathioprine Sandoz to take full effect.

Transplant patients will need to take Azathioprine Sandoz continuously to reduce the risk of organ rejection.

If you forget to take it

Take your dose as soon as you remember, and continue to take it as you would normally.

If it is almost time for your next dose, skip the dose you missed and

take your next dose when you are meant to.

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

This may increase the chance of you getting an unwanted side effect.

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

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone Australia 13 11 26 or New Zealand 0800 POISON or 0800 764766) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Azathioprine Sandoz. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are taking Azathioprine Sandoz

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Azathioprine Sandoz.

Tell any other doctors, dentists and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, including any dental work, tell the surgeon, anaesthetist or dentist that you are taking this medicine.

It may affect other medicines used during surgery.

If you become pregnant while taking this medicine, are trying to become pregnant or planning to father a child, tell your doctor immediately.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor may order regular blood tests to make sure the medicine is working and to prevent unwanted side effects.

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

If you come into contact with anyone who is suffering from chickenpox or shingles, tell your doctor immediately.

Always protect yourself from the sun while you are taking Azathioprine Sandoz.

Wear sunscreen, a hat and protective clothing.

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

Azathioprine Sandoz lowers your body's immune system and may increase your risk of skin and other cancers while you are taking this medicine.

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.

Things you must not do

Do not take Azathioprine Sandoz to treat any other complaints unless your doctor tells you to.

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

Do not stop taking your medicine or change the dosage without checking with your doctor.

Your doctor may want you to gradually reduce the amount you are taking before stopping completely.

Do not break, chew or crush the tablets.

Things to be careful of

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

This medicine may cause dizziness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Be careful when drinking alcohol while you are taking this medicine.

If you drink alcohol, dizziness may be worse.

Side effects

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

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

Do not be alarmed by the following lists of side effects. You may not experience any of them.

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

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- sores in the mouth and on the lips
- feeling of pins and needles
- changes in smell or taste
- dizziness or feeling faint
- tiredness and generally feeling unwell.

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
- nausea, vomiting or diarrhoea
- stomach discomfort or severe abdominal pain

- muscle weakness, tenderness, pain or stiffness
- severe joint pain
- yellowing of the skin and/or eyes (jaundice)
- irregular heart beat
- coughing, difficulty breathing and wheezing
- new marks on skin or any change to marks that may have been there previously
- feeling of ants creeping in or under the skin
- headache, stiff neck and extreme sensitivity to bright light. Azathioprine could cause your hepatitis B to become active again.

Side effects reported particularly in organ transplant patients are:

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

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

- swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing
- rash, itching or hives on the skin
- shortness of breath or wheezing
- fainting.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.

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

Some side effects, such as low blood cell count, can only be found when your doctor does tests from time to time to check your progress.

After taking Azathioprine Sandoz

Storage

Keep your medicine in the original container.

If you take it out of its original container it may not keep well.

Keep your medicine in a cool dry place where the temperature stays below 25°C.

Do not store Azathioprine Sandoz or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

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 the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

Azathioprine Sandoz comes in two types of tablets:

Azathioprine Sandoz 50mg - white to yellowish white, round, biconvex, film-coated tablets with a one-sided score notch.

Available in blisters of 100 tablets.

Azathioprine Sandoz 25mg - white to yellowish white, round, biconvex, film-coated tablets.

Available in blisters of 100 tablets

Ingredients

Active ingredients:

- Azathioprine Sandoz 50mg - 50mg azathioprine.
- Azathioprine Sandoz 25mg - 25mg azathioprine

Inactive ingredients:

- lactose monohydrate
- starch - maize
- povidone
- silica - colloidal anhydrous
- magnesium stearate
- hypromellose
- cellulose - microcrystalline
- PEG-8 stearate
- talc - purified
- titanium dioxide.

This medicine does not contain sucrose, gluten, tartrazine or any other azo dyes.

Supplier

Sandoz Pty Ltd
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50mg film-coated tablets: AUST R 74407

25mg film-coated tablets: AUST R 74404