

THIOPRINE® 50

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using THIOPRINE 50?

THIOPRINE 50 contains the active ingredient azathioprine. THIOPRINE 50 is used to help prevent the rejection of transplanted organs, or to treat other diseases called autoimmune diseases where your immune system is reacting against your own body.

For more information, see Section [1. Why am I using THIOPRINE 50?](#) in the full CMI.

2. What should I know before I use THIOPRINE 50?

Do not use if you have ever had an allergic reaction to azathioprine, 6-mercaptopurine or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use THIOPRINE 50?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with THIOPRINE 50 and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use THIOPRINE 50?

- The dose of THIOPRINE 50 varies from patient to patient. Your doctor will tell you how much to take.
- Take THIOPRINE 50 tablets at least 1 hour before or 3 hours after food or milk.

More instructions can be found in Section [4. How do I use THIOPRINE 50?](#) in the full CMI.

5. What should I know while using THIOPRINE 50?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using THIOPRINE 50.• Visit your doctor regularly, so they can make sure that THIOPRINE 50 is working properly and to check for any unwanted side-effects.• Protect yourself from the sun while you are taking THIOPRINE 50.• Avoid contact with anyone suffering from chickenpox or shingles. Tell your doctor if you do.
Things you should not do	<ul style="list-style-type: none">• Do not stop taking Azithromycin Sandoz or change the dose without first checking with your doctor.• Do not break, chew or crush the tablets.
Driving or using machines	<ul style="list-style-type: none">• Be careful before you drive or use any machines or tools until you know how THIOPRINE 50 affects you.
Looking after your medicine	<ul style="list-style-type: none">• Keep it in a cool dry place away from moisture, heat, or light where the temperature stays below 25°C.• Keep THIOPRINE 50 tablets in the pack until it is time to take them.

For more information, see Section [5. What should I know while using THIOPRINE 50?](#) in the full CMI.

6. Are there any side effects?

Tell your doctor immediately if you experience any side effects while taking THIOPRINE 50. Side effects may include any infection or fever; unexpected bruising or bleeding, black tarry stools or blood in 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 heartbeat; sores in the mouth and on the lips; feeling of ants creeping in or under the skin; changes in sense of smell or taste; or reactivation of hepatitis B. More serious side effects of THIOPRINE 50 include an allergic-type reaction; 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; yellowing of the skin/eyes; and serious skin reactions such as blistering or peeling.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

THIOPRINE[®] 50

Active ingredient(s): *azathioprine*

Consumer Medicine Information (CMI)

This leaflet provides important information about using THIOPRINE 50. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using THIOPRINE 50.**

Where to find information in this leaflet:

- [1. Why am I using THIOPRINE 50?](#)
- [2. What should I know before I use THIOPRINE 50?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use THIOPRINE 50?](#)
- [5. What should I know while using THIOPRINE 50?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using THIOPRINE 50?

THIOPRINE 50 contains the active ingredient azathioprine. It belongs to a group of medicines called immunosuppressants.

THIOPRINE 50 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.

THIOPRINE 50 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.

THIOPRINE 50 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 THIOPRINE 50 has been prescribed for you.

Your doctor may have prescribed it for another purpose. There is no evidence that it is addictive.

2. What should I know before I use THIOPRINE 50?

Warnings

Do not use THIOPRINE 50 if:

- you are allergic to azathioprine, 6-mercaptopurine (Puri-Nethol, a medicine which is similar to THIOPRINE 50), or 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.
- you have any of the following:
 - rheumatoid arthritis that has been previously treated with some other medicines, such as chlorambucil, melphalan or cyclophosphamide.
- the expiry date printed on the pack has passed.
- the packaging is torn or shows signs of tampering.

Check with your doctor if you:

- have or have had any other medical conditions, especially the following:
 - 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.
- have recently been vaccinated or immunized or plan to do so.
 - THIOPRINE 50 may affect the way the vaccine works or your reaction to the vaccine.
- take any medicines for any other condition
- have had any allergy to any other medicines, or any other substances, such as foods, preservatives, or dyes.
- have any upcoming dental procedures.
 - Dental work, whenever possible, should be completed before you start taking THIOPRINE 50 or delayed until your blood cell counts are normal.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Do not take THIOPRINE 50 if you are pregnant, may be pregnant, plan to become pregnant or intending to father a child.

THIOPRINE 50 may cause birth defects if either the male or female is taking it at the time of conception. You or your THIOPRINE 50 partner should take adequate contraceptive precautions while you are taking THIOPRINE 50.

Do not take THIOPRINE 50 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.

3. What if I am taking other medicines?

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

Some medicines may interfere with THIOPRINE 50 and affect how it works. 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
- furosemide, may be used to reduce swelling caused by excess fluid
- warfarin, used to prevent blood clots
- mesalazine, olsalazine or sulfasalazine, 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 THIOPRINE 50 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.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect THIOPRINE 50.

4. How do I use THIOPRINE 50?

How much to take

Your doctor will tell you how much THIOPRINE 50 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 THIOPRINE 50, 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.

When to take THIOPRINE 50

Take THIOPRINE 50 tablets at least 1 hour before or 3 hours after food or milk.

How to take THIOPRINE 50

Swallow THIOPRINE 50 tablets whole with a glass of water.

Do not break, chew or crush the tablets.

How long to take THIOPRINE 50

Patients with a transplant will need to take THIOPRINE 50 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 use THIOPRINE 50

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 use too much THIOPRINE 50

If you think that you have used too much THIOPRINE 50, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using THIOPRINE 50?

Things you should do

- **Take THIOPRINE 50 exactly as your doctor has prescribed.**
- **Visit your doctor regularly, so they can make sure that THIOPRINE 50 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 THIOPRINE 50.
- **Tell any other doctor, dentist or pharmacist who is treating you that you are THIOPRINE 50, especially if you are about to be started on any new medicines.**
- **Tell your doctor if you have recently been vaccinated or immunized or plan to do so.**
THIOPRINE 50 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 must have an operation, tell your surgeon and anaesthetist that you are taking THIOPRINE 50.**
- **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 THIOPRINE 50, 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 THIOPRINE 50.

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 THIOPRINE 50.

Things you should not do

- **Do not stop taking THIOPRINE 50 or change the dose without first checking with your doctor.**
- **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 like yours.**

Driving or using machines

Be careful before you drive or use any machines or tools until you know how THIOPRINE 50 affects you.

Looking after your medicine

Keep THIOPRINE 50 tablets in the pack until it is time to take them.

Store it in a cool dry place, away from moisture, heat, or light where the temperature stays below 25°C.

For example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> • 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 	<p>Tell your doctor immediately if you notice any of these side effects</p>

<ul style="list-style-type: none"> • headache, stiff neck and extreme sensitivity to bright light • nausea and vomiting • tiredness, dizziness or generally unwell • irregular heartbeat • 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. 	
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Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • 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. <p>Reported particularly in organ transplant patients:</p> <ul style="list-style-type: none"> • viral, fungal and bacterial infections • hair loss (particularly following a kidney transplant) • diarrhoea, usually with blood and mucus • stomach pain with fever and vomiting. 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

THIOPRINE 50 could cause your hepatitis B to become active again.

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

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at

www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What THIOPRINE 50 contains

Active ingredient (main ingredient)	<ul style="list-style-type: none">• azathioprine 50 mg/tablet
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">• lactose monohydrate• maize starch• povidone• colloidal anhydrous silica• magnesium stearate• hypromellose• microcrystalline cellulose• PEG-8 stearate• purified talc• titanium dioxide.
Potential allergens	lactose

Do not take this medicine if you are allergic to any of these ingredients.

What THIOPRINE 50 looks like

THIOPRINE 50 50 mg - round, biconvex white to yellowish-white film-coated tablets, with one-sided breaking notch. Available in blisters of 100 tablets. (Aust R 221962)

Who distributes THIOPRINE 50

Sponsor

Sandoz Pty Ltd
100 Pacific Highway
North Sydney, NSW 2060
Australia
Tel 1800 726 369

Distributor

Alphapharm Pty Ltd trading as Viatrix
Level 1, 30 The Bond
30 – 34 Hickson Road
Millers Point NSW 2000
www.viatrix.com.au
Phone: 1800 274 276

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THIOPRINE® is a Viatrix company trade mark.