

## APO-Azathioprine

Contains the active ingredient azathioprine

### Consumer Medicine Information

For a copy of a large print leaflet, Ph:  
1800 195 055

#### What is in this leaflet

Read this leaflet carefully before taking your medicine.

This leaflet answers some common questions about azathioprine. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the last page. More recent information on this medicine may be available.

#### Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

You can also download the most up-to-date leaflet from [www.apotex.com.au](http://www.apotex.com.au).

All medicines have risks and benefits. Your doctor has weighed the risks of you using this medicine against the benefits they expect it will have for you.

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

Keep this leaflet with your medicine. You may want to read it again.

#### What this medicine is used for

The name of your medicine is APO-Azathioprine tablets. It contains the active ingredient azathioprine.

It is used to:

- help prevent the body from rejecting transplanted organs (e.g. a heart or kidney)
- treat other diseases called autoimmune diseases where your immune system is reacting against your own body. These include:
  - severe rheumatoid arthritis
  - systemic lupus erythematosus
  - chronic active hepatitis
  - certain skin, muscle, and blood diseases.

Azathioprine is usually taken in combination with other medicines such as corticosteroids or other immunosuppressant's.

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

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

#### How it works

Azathioprine belongs to a group of medicines called immunosuppressant's. It works by suppressing the body's immune defence system.

Azathioprine helps prevent the rejection of a transplanted organ such as a kidney, liver or heart.

There is no evidence that this medicine is addictive.

#### Before you take this medicine

##### When you must not take it

Do not take this medicine if:

- **You have or have had any of the following:**
  - rheumatoid arthritis previously treated with alkylating agents (medicines such as chlorambucil, melphalan or cyclophosphamide).
- **You are pregnant, you may be pregnant or you are likely to become pregnant in the near future.**  
Azathioprine may affect your developing baby if you take it during pregnancy.
- **You are hypersensitive to, or have had an allergic reaction to, azathioprine, 6-mercaptopurine (Puri-Nethol) or any of the ingredients listed at the end of this leaflet.**

Symptoms of an allergic reaction may include: cough, shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin; fainting; or hay fever-like symptoms.

**If you think you are having an allergic reaction, do not take any more of the medicine and contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.**

- **The expiry date (EXP) printed on the pack has passed.**
- **The packaging is torn, shows signs of tampering or it does not look quite right.**

##### Before you start to take it

Before you start taking this medicine, tell your doctor if:

1. You have allergies to:
  - any other medicines
  - any other substances, such as foods, preservatives or dyes.
2. You have or have had any 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
  - irritable bowel disease
  - and a history of cytomegalovirus disease.
3. You are pregnant, you may be pregnant, you are likely to become pregnant in the near future or you are intending to father a child. Both you and your partner should take adequate contraceptive precautions while taking azathioprine.
4. You are currently breastfeeding or you plan to breastfeed. Use of this medicine during breastfeeding is not recommended.
5. You have recently been vaccinated or immunised or plan to get a vaccination or immunisation.
7. You are planning to have surgery or an anaesthetic.

8. You are currently receiving or are planning to receive dental treatment. Tell your dentist that you are taking azathioprine. Dental work, whenever possible, should be completed before you start taking azathioprine or delayed until your blood cell counts are normal.
9. You are taking or are planning to take any other medicines. This includes vitamins and supplements that are available from your pharmacy, supermarket or health food shop.

Some medicines may interact with azathioprine. These include:

- penicillamine, used in the treatment of rheumatoid arthritis
- captopril, used in the treatment of 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 in the treatment of 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 in the treatment of ulcerative colitis
- phenytoin, phenobarbital, rifampicin, ketoconazole, erythromycin
- methotrexate, used in the treatment of cancer
- ribavirin, used to treat a type of respiratory infection.

If you are taking any of these you may need a different dose or you may need to take different medicines.

Other medicines not listed above may also interact with azathioprine.

#### How to take this medicine

Follow carefully all directions given to you by your doctor. Their instructions may be different to the information in this leaflet.

##### How much to take

Your doctor will tell you how much of this medicine you should take. This will depend on your condition and whether you are taking any other medicines.

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

##### How to take it

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

##### When to take it

Take this medicine at least one hour before or three hours after food or milk.

Take this medicine at the same time each day. Taking it at the same time each day will have the best effect and will also help you remember when to take it.

##### How long to take it for

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

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

Make sure you have enough to last over weekends and holidays.

### *If you forget to take it*

If it is almost time to take your next dose, skip the missed dose and take your next dose at the usual time. Otherwise, take it as soon as you remember and then go back to taking your medicine as you would normally.

### **Do not take a double dose to make up for missed doses.**

This may increase the chance of you experiencing side effects.

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

### *If you take too much (overdose)*

**If you think that you or anyone else may have taken too much of this medicine, immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 in Australia) for advice. Alternatively, go to the Accident and Emergency department at your nearest hospital.**

**Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.**

If you take too much azathioprine, you may get an unexpected infection, ulcers in the throat, and bruising and bleeding.

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## While you are taking this medicine

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### *Things you must do*

Tell your doctor that you are taking this medicine if:

- you are about to be started on any new medicine
- you plan to have any vaccinations or immunisations
- you are pregnant, planning to become pregnant or father a child
- you are breastfeeding or are planning to breastfeed
- you are about to have any blood tests
- you are going to have surgery or an anaesthetic or are going into hospital.

Your doctor will perform blood tests every week for the first eight weeks, then at least once a month after that, while you are taking azathioprine.

Tell any other doctors, dentists and pharmacists who are treating you that you take this medicine.

**Try to avoid contact with people who have infectious diseases (such as the flu).**

**Avoid contact with anyone suffering from chickenpox or shingles.**

**Tell your doctor immediately if you do come into contact with someone who has chickenpox or shingles.**

**Avoid contact sports or other situations where bruising or injury may occur. Be careful to avoid cutting yourself with sharp objects (e.g. razors).**

**Protect yourself from the sun while you are taking azathioprine.**

Azathioprine suppresses your immune system. Lowering your body's immune defence system increases your risk of skin cancer, cervical cancer, lymphoma and other cancers.

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

**If you are female, tell your doctor if you notice unusual vaginal discharge or bleeding, and make sure to have regular Pap smears.**

### *Things you must not do*

**Do not:**

- Give this medicine to anyone else, even if their symptoms seem similar to yours.
- Take your medicine to treat any other condition unless your doctor tells you to.
- Stop taking your medicine, or change the dosage, without first checking with your doctor.

### *Things to be careful of*

Be careful when driving or operating machinery until you know how this medicine affects you. It may cause dizziness and tiredness in some people. If you have any of these symptoms, do not drive, or operate machinery or do anything else that is dangerous.

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## Possible side effects

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Tell your doctor as soon as possible if you do not feel well while you are taking azathioprine or if you have any questions or concerns.

Do not be alarmed by the following lists of side effects. You may not experience any of them. All medicines can have side effects. Sometimes they are serious but most of the time they are not.

**Tell your doctor as soon as possible 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
- you come into contact with anyone who is suffering from chickenpox or shingles
- 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
- sores in the mouth and on the lips
- feeling of ants creeping in or under the skin
- change in sense of smell or taste.

**If you experience any of the following, stop taking your medicine and contact your doctor immediately or go to the Accident and Emergency department at your nearest hospital.**

These are very serious side effects and you may need urgent medical attention or hospitalisation:

- muscle weakness, 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.

Other side effects not listed above may occur in some patients.

Some of these side effects can only be found when your doctor does tests from time to time to check your progress (e.g. low blood cell count).

### *Allergic reactions*

**If you think you are having an allergic reaction to azathioprine, do not take any more of this medicine and tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital.**

Symptoms of an allergic reaction may include some or all of the following:

- muscle weakness, with or without a skin rash
- cough, shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue, throat or other parts of the body
- rash, itching or hives on the skin
- fainting
- hay fever-like symptoms.

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## Storage and disposal

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### *Storage*

**Keep your medicine in its original packaging until it is time to take it.**

If you take your medicine out of its original packaging it may not keep well.

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

**Do not store your medicine, 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 this medicine 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 it has passed its expiry date, your pharmacist can dispose of the remaining medicine safely.

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## Product description

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### *What APO-Azathioprine tablets looks like*

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

- **25 mg tablets**  
Orange coloured, round, biconvex film coated tablet with "AZA 25" embossed on one side and break line on other side. Available in packs of 100 tablets.
- **50 mg tablets**  
Pale yellow coloured, round, biconvex film coated tablet with "AZA 50" embossed on one side and break line on other side. Available in packs of 100 tablets.

\* Not all strengths, pack types and/or pack sizes may be available.

### *Ingredients*

Each tablet contains 25 or 50 mg of azathioprine as the active ingredient.

It also contains the following inactive ingredients:

- lactose
- microcrystalline cellulose
- maize starch
- magnesium stearate
- purified water
- opadry complete film coating system 03b52231 yellow (25 mg tablet only)
- opadry clear YS-1R-7006 (50 mg tablet only).

This medicine is gluten-free, sucrose-free, tartrazine-free and free of other azo dyes.

### *Australian Registration Numbers*

- APO-Azathioprine 25 mg tablets (blister packs of 100's):  
AUST R 205759.
- APO-Azathioprine 50 mg tablets (blister packs of 100's):  
AUST R 205762.

### *Sponsor*

#### **Apotex Pty Ltd**

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This leaflet was last updated in April 2015.