

# Azathioprine AN Tablets

Azathioprine

## Consumer Medicine Information

### What is in this leaflet

This leaflet answers some of the common questions about Azathioprine AN.

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 Azathioprine AN 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 Azathioprine AN is used for

Azathioprine AN tablets contain azathioprine. This belongs to a group of medicines called immunosuppressants which work by reducing the body's own natural immunity.

Azathioprine AN tablets are used to treat patients who have received an organ transplant to help prevent their body from rejecting the transplanted organs (eg. a heart or kidney). It works by suppressing the body's immune defence system.

Azathioprine AN tablets are also used to suppress the body's immunity to treat "autoimmune" conditions where your immune system is acting against your body. These may include:

- severe rheumatoid arthritis systemic lupus erythematosus chronic active hepatitis
- certain skin, muscle and blood diseases.

Azathioprine AN is usually taken in combination with other immunosuppressive drugs.

Azathioprine AN tablets may also be used to treat other conditions as determined by your doctor.

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

Your doctor may have prescribed it for another purpose.

Azathioprine AN 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.

Azathioprine AN tablets are not addictive.

### Before you take Azathioprine AN

#### 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.

Azathioprine 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 Azathioprine AN.

- If you are breastfeeding or are planning to breastfeed.

Azathioprine 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 AN or any of its ingredients (listed at the end of this leaflet), or to another immunosuppressant medicine (eg. 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 face, lips / mouth and other parts of the body, difficulty in breathing, hayfever, lumpy rash (hives) itching or fainting.

- If you have rheumatoid arthritis which has previously been treated with an alkylating agent (eg. chlorambucil, melphalan or cyclophosphamide).
- If you take Azathioprine AN after the expiry date (EXP.) printed on the pack. If you take Azathioprine AN after the expiry date has passed, it may not work as well.
- Do not take Azathioprine AN if the packaging is torn or shows signs of tampering.

#### Do not take this medicine to treat any other complaints unless your doctor has instructed you to do so.

If you're not sure whether you should be taking Azathioprine AN, 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.
- A condition where your body produces too little of a natural chemical called thiopurine methyltransferase (TPMT).
- Lesh-Nyhan Syndrome
- Have been or are considering being vaccinated.
- Have been exposed to chickenpox or herpes zoster or have never had chickenpox or herpes zoster.
- Hepatitis-B
- Are currently having or are considering dental treatment.

Tell your doctor if you have recently been vaccinated or immunised or plan to do so. Azathioprine may affect the way the vaccine works or your reaction to the vaccine.

Tell your doctor if you are pregnant, may be pregnant, plan to become pregnant or intending to father a child.

You or your partner should take adequate contraceptive precautions while you are taking Azathioprine AN.

Tell your doctor if you are breastfeeding or planning to breastfeed.

Azathioprine is not recommended while breast feeding as it may cause serious side effects to your baby.

Tell your dentist that you are taking Azathioprine AN.

Dental work, whenever possible, should be completed before you start taking Azathioprine or delayed until your blood cell counts are normal.

#### 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 may interfere with Azathioprine. 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
- indometacin, 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
- frusemide, may be used to reduce swelling caused by excess fluid
- warfarin, used to prevent blood clots
- mesalazine, olsalazine or sulphasalazine, 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 Azathioprine 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.

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 Azathioprine AN.

#### Use in children

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

### How to take Azathioprine AN

#### How much to take

Use Azathioprine AN tablets only as directed by your doctor.

Your doctor has carefully determined your dose of Azathioprine AN. Your dose of Azathioprine AN 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.

From time to time, while you are taking Azathioprine, 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.

#### How to take it

Azathioprine AN tablets should only be taken orally.

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

#### When to take it

Take Azathioprine AN tablets at least 1 hour before or 3 hours after food or milk.

## **Take Azathioprine AN at the same time every day.**

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

Azathioprine AN tablets may sometimes cause mild nausea and vomiting.

### **How long to take it**

#### **Do not stop taking Azathioprine AN tablets without first checking with your doctor.**

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

Patients that are taking Azathioprine AN tablets because they have had an organ transplant will need to take Azathioprine AN 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 Azathioprine AN 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 Azathioprine AN tablets 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 (13 11 26) if you think that you or anyone else may have taken too many Azathioprine AN tablets. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical treatment.**

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## **While you are taking Azathioprine AN**

### **Things you must do**

**Take Azathioprine AN exactly as your doctor has prescribed.**

**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 Azathioprine AN works.

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

- Allopurinol (eg. ZYLOPRIM™) - may reduce the removal of azathioprine from your body
- Corticosteroids (cortisone like medicines) these may be prescribed by your doctor to increase the effects of Azathioprine AN
- Cytotoxic medicines (eg. mercaptopurine, chlorambucil, cyclosporin, cyclophosphamide)
- Warfarin (eg. Coumadin and Marevan). Azathioprine inhibits the anticoagulant effect of warfarin.

Make regular visits to your doctor to ensure that Azathioprine AN tablets are 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 Azathioprine AN tablets.

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

### **Tell any other doctor, dentist or pharmacist who is treating you that you are taking Azathioprine especially if you are about to be started on any new medicines.**

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

Azathioprine AN may affect the way some vaccines work or your reaction to the vaccine.

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

#### **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.**
- **If you notice any lumps on your body or if you feel unwell.**

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

Infection with chickenpox or shingles can become severe in patients taking drugs such as azathioprine.

#### **Things you must not do**

##### **Do not:**

- **Stop taking Azathioprine AN tablets 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 (eg. razors).**

#### **Things to be careful of**

#### **Be careful driving or operating machinery until you know how Azathioprine AN affects you.**

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

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## **Side Effects**

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

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
- tiredness and generally feeling unwell.

### **Tell the doctor 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
- new marks on skin or any change to marks that may have been there previously
- 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
- severe abdominal pain
- nausea, vomiting, diarrhoea
- dizziness or feeling faint
- sores in the mouth and on the lips
- feeling of pins and needles
- change in sense of smell or taste
- you come into contact with anyone who is suffering from chickenpox or shingles.

Azathioprine AN could cause your hepatitis B to become active again.

### **Immediately contact your doctor or go to the casualty department at your nearest hospital if you observe any of the following symptoms:**

- allergic type reactions eg. 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 discolouration of the skin / eyes
- serious skin reactions such as blistering or peeling

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 you think the problems are not connected with this medicine and are not on this list.

**Do not be alarmed by this list of possible side effects.**

You may not experience any of them.

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#### After taking Azathioprine AN

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##### **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 Azathioprine AN tablets in a cool dry place where the temperature stays below 30°C.**

**Do not leave or store Azathioprine AN tablets in the bathroom, near a sink or stove, on a windowsill or in a car.**

Heat and dampness can destroy some medicines.

**Keep Azathioprine AN tablets 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 azathioprine tablets.**

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.**

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#### Product description

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##### **What Azathioprine AN looks like**

Azathioprine AN 25 mg - peach coloured film coated tablet, embossed AZA, break line 25 on one face, the other face plain (AUST R 184935).  
Azathioprine AN 50 mg - yellow film coated tablet, embossed AZA, break line 50 on one face, the other face plain (AUST R 184936).

##### **Ingredients**

###### **Active ingredient:**

Azathioprine

###### **Other ingredients (excipients):**

- Cellulose microcrystalline,
- mannitol,
- povidone,
- maize starch,
- croscarmellose sodium,
- sodium stearylfumarate in the tablet core.

The 50 mg tablet coating contains Opadry clear OY- 7240 (macrogol 400 and hypromellose).

Azathioprine AN tablets do not contain sucrose or gluten.

##### **Name and Address of the Sponsor**

###### **Scentia Pharmaceuticals Pty Ltd**

8 - 12 Ordish Road,  
Dandenong South,  
VIC - 3175, Australia

##### **Date of Preparation**

29 November 2013

Doc ID: 41.AN.M.1.0