

## Consumer Medicine Information

### What is in this leaflet

This leaflet answers some of the common questions about AZAPIN. 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 AZAPIN 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 AZAPIN is used for

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

AZAPIN tablets are 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).

This medicine is also used to suppress the body's immunity to treat "autoimmune" conditions like rheumatoid arthritis, and SLE (systemic lupus erythematosus).

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

AZAPIN 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.**

### Before you take it

#### *When you must not take it*

**Do not take AZAPIN if you have ever had an allergic reaction to:**

- azathioprine
- 6-mercaptopurine (Puri-Nethol), a medicine which is similar to AZAPIN
- 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.

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

This medicine may cause birth defects if either the male or female is taking it at the time of conception.

**Do not take AZAPIN 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.

**Do not take AZAPIN if you have rheumatoid arthritis that has previously been treated with some other medicines, such as chlorambucil, melphalan or cyclophosphamide.**

**Do not take AZAPIN after the expiry date printed on the pack.**

If you take this medicine after the expiry date has passed, it may not work as well

**Do not take AZAPIN 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.**

**Do not give this medicine to anyone else, even if their symptoms seem similar to yours.**

*Before you start to take it*

**Tell your doctor if you:**

**Are allergic to foods, dyes, and preservatives.**

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

- 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

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

AZAPIN 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 AZAPIN.

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

AZAPIN is not recommended for use while breastfeeding as it may cause serious side effects to your baby.

**Tell your dentist that you are taking AZAPIN.**

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

#### *Taking other medicines*

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

Some medicines may interfere with AZAPIN. 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
- 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 AZAPIN 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.

Your doctor or pharmacist has a more complete list of medicines to avoid while taking AZAPIN

### How to take it

#### *How much to take*

**Use AZAPIN tablets only as directed by your doctor.**

Your dose 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*

AZAPIN tablets should only be taken orally.

**Swallow your tablets whole with a glass of water. Do not crush or chew the tablets**

#### *When to take it*

AZAPIN tablets may sometimes cause mild nausea and vomiting. Take your medicine after food or at bedtime to minimise stomach upset.

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

**Do not stop taking AZAPIN tablets without first checking with your doctor.**

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

Patients that are taking AZAPIN because they have had an organ transplant will need to take it 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 AZAPIN 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 AZAPIN tablets if the blister foil is broken or show 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 AZAPIN 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 using it

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##### *Things you must do*

**Take AZAPIN exactly as your doctor has prescribed.**

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 AZAPIN.

**Tell any other doctor, dentist or pharmacist who is treating you that you are taking AZAPIN, 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.** AZAPIN 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 have to have an operation, tell your surgeon and anaesthetist that you are taking AZAPIN.**

**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 AZAPIN, 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 AZAPIN.**

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 AZAPIN

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

**Do not:**

- **Stop taking AZAPIN 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 doctors approval. Avoid contact with any person in your household who has an oral polio vaccine recently. Try to avoid contact with people who have infectious diseases (such as the 'flu).**
- **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 AZAPIN affects you.**

This medicine generally does not cause any problems with your ability to drive a car or operate machinery. However, as with many

other medicines, AZAPIN tablets may cause headache or dizziness in some people.

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#### Side Effects

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**Tell your doctor as soon as possible if you do not feel well while you are taking AZAPIN.**

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

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

**Tell your 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
- nausea and vomiting
- tiredness, dizziness or generally unwell
- irregular heart beat
- 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.

AZAPIN could cause your hepatitis B to become active again.

**Tell your doctor immediately, or go to Accident and Emergency at your nearest hospital if you notice any of the following symptoms:**

- 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.

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.

**Tell your doctor 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 referred to in this leaflet.**

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

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

You may not experience any of them.

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#### After using it

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

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

Heat and dampness can destroy some medicines.

**Keep AZAPIN 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 AZAPIN tablets look like*

**AZAPIN 50 mg** – yellow film coated tablet, embossed AZA, break line 50 on one face, the other face plain.

##### *Ingredients*

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

Azathioprine.

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

Cellulose microcrystalline, mannitol, povidone, maize starch, croscarmellose sodium, sodium stearyl fumarate and Opadry clear OY-7240 (macrogol 400 and hypromellose).

AZAPIN tablets do not contain sucrose or gluten.

##### **SPONSOR**

Arrotex Pharmaceuticals Pty Ltd  
15 – 17 Chapel street  
Cremorne VIC 3121

**AZAPIN 50 mg tablets AUST R 92801**

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