PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

AZAMUN 50 mg (azathioprine), tablets

Read all of this leaflet carefully before you start using AZAMUN

Keep this leaflet. You may need to read it again.

If you have further questions, please ask your doctor or your pharmacist.

AZAMUN has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

1. WHAT AZAMUN CONTAINS:

Each tablet contains the active substance azathioprine.

The other inactive ingredients are: Croscarmellose sodium, maize starch, mannitol, microcrystalline cellulose (Avicel pH 101), povidone K25, purified water, sodium stearyl fumarate, and tablet coating Opadry Clear OY-7240 consisting out of hypromellose and macrogol.

2. WHAT AZAMUN IS USED FOR:

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

AZAMUN 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).

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

AZAMUN tablets are used to treat patients in whom corticosteroid therapy is required, in patients who cannot tolerate corticosteroid therapy, or patients whose disease is refractory to other standard first line therapy.

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

3. BEFORE YOU TAKE AZAMUN:

Follow your doctor's instructions carefully. They may differ from the general instructions in this leaflet.

Do not take AZAMUN:

- If you have ever had an unusual or allergic reaction to azathioprine or to another immunosuppressant medicine (e.g. 6-mercaptopurine), or to any other ingredients of AZAMUN, listed at the beginning of this leaflet.

See POSSIBLE SIDE EFFECTS below for the signs of an allergic reaction.

- 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. AZAMUN is contraindicated 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 AZAMUN. If you are using IUD contraceptives it is recommended that additional methods of contraception are employed.

- If you are breastfeeding or are planning to breastfeed.

Take special care with AZAMUN if you:

- Are allergic to foods, dyes, preservatives or any other medicines. AZAMUN can cause serious allergic reactions. If you notice any signs of an allergic reaction, contact your doctor immediately or go to the casualty department of your nearest hospital. See POSSIBLE SIDE EFFECTS below for the signs of an allergic reaction.

- Develop a fever or notice any other signs of infection, experience abnormal bleeding or bruising, feel excessively tired, weak and short of breath, contact your doctor immediately. Be especially aware of these symptoms if you are taking AZAMUN together with other medicines such as corticosteroids. AZAMUN can interfere with your body's ability to produce enough healthy blood cells (white cells, red cells and platelets). Your doctor may reduce the dose of AZAMUN or tell you to stop taking AZAMUN. Your doctor will do regular blood tests to monitor your condition.

- Have any other medical conditions.

- Have liver or kidney disease.

- Experience loss of appetite, nausea, vomiting or diarrhoea, contact your doctor immediately. The dose of AZAMUN you are taking may need to be adjusted by your doctor.

- Experience difficulty breathing, severe abdominal pain, feeling weak, loss of vision or blurred vision, hair loss, joint pain, discoloration of the urine and change in the amount of urine, pigmentation of the skin and nails, skin of the hands and feet becomes pale and feel numb.

- Finished your treatment with AZAMUN and are planning on having a baby. The ability to conceive if either you or your partner has recently stopped taking AZAMUN may be less than normal since AZAMUN have long term effects on the male and female reproductive organs. You may also be at risk of transferring chromosomal abnormalities to your unborn child. Tell your doctor before you get pregnant.

- Had an organ transplant or are taking AZAMUN for an auto-immune disease. You may be at risk of developing blood, lymph, uterine, cervical or skin cancer. Tell your doctor if you notice any changes in your body and are concerned that it could be serious.

If any of these apply to you, tell your doctor before you take AZAMUN.

Taking AZAMUN with food and drink:

AZAMUN can be taken with or without food. Do not crush or chew the tablets, it should be swallowed whole with a glass of water. AZAMUN tablets may sometimes cause mild nausea and vomiting. Take AZAMUN after food or at bedtime to minimise stomach upset.

Pregnancy and Breastfeeding:

Pregnant women should not use AZAMUN.

AZAMUN is contraindicated during pregnancy. Do not take AZAMUN 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. AZAMUN 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 AZAMUN. If you are using IUD contraceptives it is recommended that additional methods of contraception are employed. Do not take AZAMUN if you are breastfeeding your baby. AZAMUN is contraindicated during breastfeeding.

It is important to check with your doctor immediately if you think you may have become pregnant or are planning to become pregnant.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional before taking AZAMUN.

Driving and using machines:

Be careful driving or operating machinery until you know how AZAMUN affects you. AZAMUN generally does not cause any problems with your ability to drive a car or operate machinery. However, as with many other medicines, AZAMUN tablets may cause headache or dizziness in some people.

Taking AZAMUN with other medicines:

Always tell your healthcare professional if you are taking any other medicines. (This includes complementary or traditional medicines.)

AZAMUN interacts with the following medicines:

- Allopurinol, oxipurinol and thiopurinol - may reduce the removal of AZAMUN from your body.
- Corticosteroids (cortisone like medicines) these may be prescribed by your doctor to increase the effects of AZAMUN.
- Cytotoxic medicines (e.g. mercaptopurine, chlorambucil, ciclosporin, cyclophosphamide).
- Warfarin – AZAMUN inhibits the anticlotting effect of warfarin.
- Muscle relaxants (e.g. suxamethonium).
- Captopril (medicine to treat high blood pressure).
- Cimetidine (medicine to treat ulcer or heartburn).
- Furosemide (water reducing medicine).
- Sulphasalazine or mesalazine.

- Co-trimoxazole.
- Any vaccines.
- Intra Uterine Device (IUD for contraception).

Note that not all the medicines that would interact with AZAMUN have been enclosed in this patient information leaflet. Should you be taking any other medication please consult your healthcare professional for advice.

4. HOW TO USE AZAMUN:

Do not share medicines prescribed for you with any other person.

Always take AZAMUN exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. If you have the impression that the effect of AZAMUN is too strong or too weak, talk to your doctor or pharmacist.

AZAMUN tablets should only be taken orally. Your doctor will decide your dosage depending on your condition and body weight.

When to take AZAMUN

Take AZAMUN at the same time every day. Keeping a regular time for taking AZAMUN will help to remind you to take them.

How long to take AZAMUN:

Do not stop taking AZAMUN tablets without first checking with your doctor. Your doctor will discuss with you how long you need to take AZAMUN tablets. You could have to take AZAMUN for some weeks or months before you will be able to receive the full effects.

Patients that are taking AZAMUN tablets because they have had an organ transplant will need to take AZAMUN continuously to reduce the risk of the body rejecting the transplanted organ.

If you take more AZAMUN than you should:

In the event of overdosage, consult your doctor or pharmacist immediately. If neither is available contact the nearest hospital or poison control centre. Take the remaining tablets with you so that the doctor will know what the patient has taken. There is no specific antidote for AZAMUN.

Unexplained infection, ulceration of the throat, bruising and bleeding are the main signs of overdose with AZAMUN which may be experienced after 9 – 14 days. These signs are more likely to be manifest following chronic overdosage, rather than after a single acute overdose.

If you forget to take AZAMUN:

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 AZAMUN as you would normally. Do not take a double dose to make up for the forgotten tablet.

5. POSSIBLE SIDE EFFECTS:

AZAMUN may cause unwanted reactions (side effects).

Not all side effects reported for AZAMUN are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking AZAMUN, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking AZAMUN and tell your doctor immediately or go to the casualty department at your nearest hospital:

- wheezing
- swelling of the lips / mouth
- difficulty in breathing
- hay fever
- lumpy rash
- fainting

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to AZAMUN, You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

The following side effects have been experienced frequently:

- fever or other signs of an infection if you had an organ transplant and are taking AZAMUN together with other medicines called immunospressants (e.g. corticosteroids)
- nausea, vomiting, diarrhoea, loss of appetite
- abnormal bruising or bleeding

The following side effects have been experienced less frequently:

- other signs of allergic (hypersensitivity) reactions which may include:

- hair loss (alopecia)
- muscle and joint pains
- fever, shaking or shivering
- coughing, difficulty in breathing and wheezing
- problems with your pancreas which may include severe abdominal pain, nausea and vomiting

- inflammation of the membranes surrounding the brain (meningitis) which may present as general feeling of being unwell, headache, stiffness of the neck, sensitivity to bright light, nausea, vomiting, diarrhoea
- irregular heartbeat
- problems with your kidneys which may include changes in the amount and colour of your urine
- dizziness or feeling faint, or confusion caused by low blood pressure
- red and/or itchy skin
- a general feeling of discomfort, weakness or being unwell
- problems with your liver which can be life-threatening may present as yellow discolouration of the skin and eyes, itchiness, pale stools, dark urine, feeling weak and tired, weight loss or weight gain, nausea and vomiting

• skin rash, blistering and/or peeling of the skin and mucous membranes (e.g. mouth, throat, eyes, anus and genital areas)

• feeling excessively tired, weak and short of breath

• fever or other signs of an infection if you are taking AZAMUN alone

• different cancers including blood, lymph, uterine, cervical and skin cancers

• problems with your colon which may present as abdominal pain, loss of appetite, feeling tired, bloody diarrhoea or constipation, slimy stools, stomach cramps, bloatedness, nausea and vomiting

• severe diarrhoea especially if you suffer from inflammatory bowel disease

• sores in the mouth and on the lips.

The following side effects have been experienced but the frequency is unknown:

- muscle weakness, with or without skin rash

These are all serious side effects. You may need urgent medical attention.

This is not a complete list of possible side effects. You may react in a different way.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

6. STORING AND DISPOSING OF AZAMUN:

Store at or below ~~30~~ °C.

Store your tablets in the original package.

Do not take AZAMUN after the expiry date shown on the pack.

Do not use any AZAMUN pack that is damaged or shows signs of tampering.

Store all medicines out of reach of children.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets)

7. PRESENTATION OF AZAMUN:

AZAMUN 50 mg tablets are provided in clear transparent PVC/PVDC /Aluminium blister packs containing 100 tablets.

8. IDENTIFICATION OF AZAMUN:

A light yellow, film-coated, circular, biconvex tablet. Engraved “AZA” breakline “50” on one side and plain on the other side.

9. REGISTRATION NUMBER:

36/26/0006

10. NAME AND ADDRESS OF THE REGISTRATION HOLDER:

Acino Pharma (Pty) Ltd.

106 16th Road

Midrand

1685

11. DATE OF PUBLICATION:

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