

APO-AZATHIOPRINE TABLET

Azathioprine (50mg)

What is in this leaflet

1. What Apo-Azathioprine is used for
2. How Apo-Azathioprine works
3. Before you use Apo-Azathioprine
4. How to use Apo-Azathioprine
5. While you are using it
6. Side effects
7. Storage and Disposal of Apo-Azathioprine
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision

What Apo-Azathioprine is used for

Azathioprine is used to prevent your body from rejecting a transplanted organ, like kidney and liver. It is also used to treat symptoms where control of the immunity system is required.

Apo-Azathioprine is usually taken in combination with other medicines such as corticosteroids or other immunosuppressive medicines

How Apo-Azathioprine works

Apo-Azathioprine contains azathioprine, which is a type of immunosuppressant. It works by lowering your body's immune system.

The immune system helps your body fight infections; however, the immune system can also fight or "reject" a transplanted organ such as a liver or kidney. This is because the immune system treats the new organ as an invader. Azathioprine is used to prevent your body from rejecting a transplanted kidney. It also works in particular cases where the immune system requires adjustment.

Before you use Apo-Azathioprine

- When you must not use it

Do not take this medication if you are allergic to azathioprine or any other ingredients in this medication.

Pregnancy and lactation

Do not take Apo-Azathioprine if you are pregnant, trying to get pregnant or think you may be pregnant.

Do not take Apo-Azathioprine if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

- Before you start to use it

Before you start using this medication, you need to inform your doctor if:

- you are planning to undergo any form of surgery during, and after the period of taking Apo-Azathioprine.
- you have a condition where your body produces too little of a natural chemical called thiopurine methyltransferase (TPMT)
- you (regardless of gender), are planning to have a child.
- you have any other sort of medical history, or medical condition.

- Taking other medicines

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

Inform your doctor before taking Apo-Azathioprine if you are taking the below medicines:

- Olsalazine, mesalazine or sulfasalazine (inflammatory bowel disease)
- Allopurinol (reduce body uric acid)
- Warfarin
- Penicillamine

This is not a complete list of medicines that may be interact with Apo-Azathioprine if taken together. Always consult your doctor or pharmacist if you are not sure.

How to use Apo-Azathioprine

- How much to use

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet.

The dose is adjusted individually based on your therapeutic response and your body's condition. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Continue taking Apo-Azathioprine for as long as your doctor recommends.

The therapeutic effect of Azathioprine may be evident only after several weeks or months of treatment.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking Apo-Azathioprine.

Tell your doctor immediately if you become pregnant while taking this medication.

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

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give Apo-Azathioprine to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Get emergency medical help if you have any of these signs of allergic reaction: hives; difficulty breathing; swelling of your face, lips, tongue, or throat.

You would also need to avoid:

- Any “live” vaccine.
- Activities that increase your risk of bleeding injuries.
- Being near to sick or infected individuals.

Driving and using machines

This medicine may affect your ability to drive or use machines. If the tablets make you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

Side effects

Like all medicines, Apo-Azathioprine can cause side effects, although not everybody gets them.

Side effects might include:

- *Infection and infestation:* Viral, fungal and bacterial infections.
- *Neoplasms benign and malignant (including cysts and polyps):* Cancer of the lymphocytes, skin cancers, sarcomas (a malignant cancer made of fat, muscle, bone) and uterine cervical cancer
- *Blood and lymphatic system disorders:* Depression of bone marrow function or thrombocytopenia (low platelet in the blood)
- *Gastrointestinal disorder:* Pancreatitis (inflammation of the pancreas), or abnormal bowel movement, colitis.
- *Hepato-biliary disorders:* Cholestasis (decrease in bile flow)
- *Skin and subcutaneous tissue disorder:* Alopecia (hair loss)
- *Immune system disorder:* Hypersensitivity reactions

Visit your doctor or pharmacist immediately if you experience any side effects mentioned above, any other serious side effect or discomfort after taking this medicine.

You may report any side effects or adverse drug reactions directly to the National Centre for adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Apo-Azathioprine

- Storage

Keep out of the reach and sight of children.
Store below 30 °C.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

Pale yellow, peanut-shaped, flat-faced, beveled edge tablets, scored and

engraved “AZ 50” on one side and “APO” on the other side.

- Ingredients

- Active ingredient: Azathioprine
- Inactive ingredients: Lactose Monohydrate, Microcrystalline Cellulose, Corn Starch, Magnesium Stearate.

- MAL number:

MAL09011432ACRZ

Manufacturer

RPG Life Sciences Limited
Plot: 3102/A G.I.D.C Estate
Ankleshwar, Dist Bharuch,
Gujarat State
393002 Inida

Product Registration Holder

Pharmaforte(M) Sdn Bhd
2, Jalan PJU 3/49,
Sunway Damansara,
47810 Petaling Jaya,
Selangor

Date of revision

5/8/2022

Serial Number

BPFFK(R4/1)161115/00422