

Azathioprine 50mg Film-coated Tablets

(Azathioprine)

PACKAGE LEAFLET: INFORMATION FOR THE USER

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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2. What you need to know before you take Azathioprine 50mg Tablets
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1. WHAT AZATHIOPRINE 50MG TABLETS ARE AND WHAT THEY ARE USED FOR

Azathioprine 50mg Tablets belong to a group of medicines called immunosuppressants. These medicines reduce the activity of your body's immune system. Azathioprine 50mg Tablets are used to:

- stop your body rejecting an organ transplant
- treat diseases where your immune system reacts against your own body (called autoimmune diseases, such as rheumatoid arthritis).

Ask your doctor, nurse or pharmacist if you would like any further explanation about these uses.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE AZATHIOPRINE 50MG TABLETS

Do not take Azathioprine if:

- You are allergic to azathioprine, mercaptopurine or any of the other ingredients of Azathioprine (listed in section 6).
- You are pregnant or likely to become pregnant (see Pregnancy, breast-feeding and fertility).

Do not take Azathioprine if any of the above apply to you. If you are not sure, talk to your doctor, nurse or pharmacist before taking Azathioprine.

Warnings and precautions

Talk to your doctor, nurse or pharmacist before taking Azathioprine if:

- you have liver or kidney disease

- you have 'Lesch-Nyhan Syndrome'. This is a rare condition that runs in families caused by a lack of something called HPRT or 'hypoxanthine- guanine- phosphoribosyltransferase'
- you have a condition where your body produces too little of something called TPMT or 'thiopurine methyltransferase'
- you have ever suffered from chickenpox or shingles.

NUDT15-gene mutation

If you have an inherited mutation in the NUDT15-gene (a gene which is involved in the break-down of Azathioprine in the body), you have a higher risk of infections and hair loss and your doctor may in this case give you a lower dose.

If you are not sure if any of the above apply to you, talk to your doctor, nurse or pharmacist before taking Azathioprine.

Talk to your doctor, pharmacist or nurse before taking Azathioprine

If you are receiving immunosuppressive therapy, taking Azathioprine could put you at greater risk of:

- tumours, including skin cancer. Therefore, when taking Azathioprine, avoid excessive exposure to sunlight, wear protective clothing and use protective sunscreen with a high protection factor.
- lymphoproliferative disorders
 1. treatment with Azathioprine increases your risk of getting a type of cancer called lymphoproliferative disorder. With treatment regimen containing multiple immunosuppressants (including thiopurines), this may lead to death.
 2. A combination of multiple immunosuppressants, given concomitantly increases the risk of disorders of the lymph system due to a viral infection (Epstein-Barr virus (EBV)-associated lymphoproliferative disorders).

Taking Azathioprine could put you at greater risk of:

- developing a serious condition called Macrophage Activation Syndrome (excessive activation of white blood cells associated with inflammation), which usually occurs in people who have certain types of arthritis.

Other medicines and Azathioprine 50mg Tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines obtained without a prescription, including herbal medicines. This is because Azathioprine can affect the way some medicines work.

Also some other medicines can affect the way Azathioprine works.

In particular, tell your doctor, nurse or pharmacist if you are taking any of the following medicines:

- Allopurinol, oxipurinol and thiopurinol - used for gout
- tubocurarine or succinylcholine – used during operations

- Warfarin - used for blood clots
- penicillamine - used for rheumatoid arthritis
- co-trimoxazole - used for infections
- Captopril - used for high blood pressure or heart problems
- Cimetidine - used for stomach ulcers and indigestion
- Indomethacin - used for pain and inflammation
- Furosemide - used for high blood pressure and heart problems
- Olsalazine or mesalazine - used for a bowel problem called ulcerative colitis
- Sulfasalazine or balsalazide - used for rheumatoid arthritis or ulcerative colitis.

If you are not sure if any of the above apply to you, talk to your doctor, nurse or pharmacist before taking Azathioprine.

Having vaccines while you are taking Azathioprine

If you are going to have a vaccination speak to your doctor or nurse before you have it. This is because vaccines may not work properly while you are taking Azathioprine.

Tests you may have while taking Azathioprine

Your doctor may ask you to have a blood test while you are taking Azathioprine. This is to check your blood cell count. Your doctor may change your dose of Azathioprine after the test.

Pregnancy, breast-feeding and fertility

- Do not take Azathioprine if you are a man trying to have a baby. This is because it may affect the baby.
- Do not take Azathioprine if you are a woman who is pregnant or think you might become pregnant. This is because it may affect the baby.
- Do not take Azathioprine if you are breast-feeding. This is because small amounts may pass into the mother's milk. Ask your doctor, midwife or pharmacist for advice before taking any medicine, if you are pregnant or breast-feeding.

Azathioprine and the sun

While taking Azathioprine you may be more likely to develop some types of cancers such as skin cancer. Some people also become sensitive to sunlight which can cause skin discolouration or a rash. Take care to avoid too much sun, cover up and use sunscreen.

Chickenpox /Shingles infection

Infection with chickenpox or shingles can become severe in patients taking immunosuppressive medicine. Therefore you should avoid contact with anyone suffering from chickenpox or shingles.

3. HOW TO TAKE AZATHIOPRINE 50MG TABLETS

Always take Azathioprine exactly as your doctor has told you. You should check with your doctor, nurse or pharmacist if you are not sure. The dose of Azathioprine you take depends on your illness and how bad it is.

The dose also depends on your age, your weight and how well your liver and kidneys are working. Your doctor will explain this to you.

To stop your body rejecting an organ transplant

On the first day

- The usual dose is up to 5 mg per kg of body weight.

For the rest of your treatment

- You will take between 1 and 4 mg per kg of body weight each day.

For other conditions

At the start of your treatment

- You will take 1 to 3 mg per kg of body weight each day
- Your doctor may reduce your dose later.

If you take more Azathioprine than you should

If you take more Azathioprine than you should, talk to your doctor or go to a hospital straight away. Take the medicine pack with you.

If you forget to take Azathioprine

- If you forget to take Azathioprine, tell your doctor.
- Do not take a double dose to make up for a forgotten dose.

If you have any further questions about Azathioprine and how to take it, ask your doctor, nurse or pharmacist."

4. POSSIBLE SIDE EFFECTS

Like all medicines, Azathioprine can cause side effects, although not everybody gets them. The following side effects may happen with this medicine:

Stop taking Azathioprine and see a doctor straight away, if you notice any of the following serious side effects, you may need urgent medical treatment:

- allergic reaction, the signs may include:
 - general tiredness, dizziness, feeling sick (nausea), being sick (vomiting) or diarrhoea
 - high temperature (fever), shivering or chills
 - redness of the skin or a skin rash
 - pain in the muscles or joints
 - changes in the amount and colour of the urine (kidney problems)
 - dizziness, confusion, feeling light headed or weak, caused by low blood pressure
- You bruise more easily or notice any unusual bleeding

- you have a high temperature (fever) or other signs of an infection
- you feel extremely tired
- you notice lumps anywhere on your body
- you notice any changes to your skin, for example blisters or peeling
- your health suddenly gets worse
- you come into contact with anyone who is suffering from chickenpox or shingles. If you notice any of the above, stop taking Azathioprine and see a doctor straight away.
- liver problems, which may cause pale stools, dark urine, itchiness and yellowing of your skin and eyes.

Other side effects include:

Very common (affects more than 1 in 10 people)

- infections caused by a virus, fungus or bacteria
- reduction in your bone marrow function, which may make you feel unwell or show up in your blood tests
- low white blood cell level in your blood tests, which may cause an infection.

Common (affects less than 1 in 10 people)

- low blood platelet level, which may cause you to bruise or bleed easily.

Uncommon (affects less than 1 in 100 people)

- low red blood cell level, which may cause you to be tired, get headaches, be short of breath when exercising, feel dizzy and look pale
- inflammation of the pancreas, which may cause you severe upper stomach pain, with feeling sick (nausea) and being sick (vomiting)

Rare (affects less than 1 in 1,000 people)

- problems with your blood and bone marrow which may cause weakness, tiredness, paleness, headaches, sore tongue, breathlessness, bruising or infections
- problems with your bowel leading to diarrhoea, abdominal pain, constipation, feeling sick (nausea) and being sick (vomiting)
- hair loss which may get better even though you continue to take Azathioprine
- severe liver damage which can be life threatening
- various types of cancers including blood, lymph and skin cancers
- sensitivity to sunlight which can cause skin discolouration or a rash.

Very rare (affects less than 1 in 10,000 people)

- inflammation of your lungs causing breathlessness, cough and a fever.

If any of the side effects gets serious, or if you notice any other side effects not listed in this leaflet, please tell your doctor, nurse or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE AZATHIOPRINE 50MG TABLETS

Store in the outer carton in order to protect from light.

Keep out of the sight and reach of children.

Do not use Azathioprine 50mg Tablets after the expiry date which is stated on the carton and blister foil.

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.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Azathioprine 50mg Tablets contain

The active substance is Azathioprine.

Each tablet contains 50mg of azathioprine.

The other ingredients are Microcrystalline cellulose, Mannitol, Maize starch, Povidone K25, Croscarmellose sodium, Sodium stearyl fumarate, Hypromellose and Macrogol.

What Azathioprine 50mg Tablets look like and contents of the pack.

Azathioprine 50mg Tablets are pale yellow, circular coated tablets. On one side of each tablet are the letters 'AZA', then a score line and the number "50".

Your Azathioprine 50mg Tablets come in blister packs of 56 and 100 tablets.

Marketing Authorisation Holder and Manufacturer

The Marketing Authorisation Holder is:-

Relonchem Limited, Cheshire House, Gorse Lane, Widnes WA8 0RP, United Kingdom.

This leaflet was last approved in March 2019.

Product license number: PA1128/001/001.