



PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

AZATHIOPRINE TABLETS USP
25 MG / 50MG
TAJ PHARMA

(AZATHIOPRINE)

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.
- 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. This includes any possible side effects not listed in this leaflet (see section 4)
- The full name of the product is Azathioprine 25 mg, 50mg Film-coated Tablets but within the leaflet it will be referred to as Azathioprine tablets.

WHAT IS IN THIS LEAFLET

1. What Azathioprine tablets are and what they are used for
2. What you need to know before you take Azathioprine tablets
3. How to take Azathioprine tablets
4. Possible side effects

5. How to store Azathioprine tablets
6. Contents of the pack and other information

1. WHAT AZATHIOPRINE TABLETS ARE AND WHAT THEY ARE USED FOR

Azathioprine belongs to a group of medicines called immunosuppressants. Azathioprine helps to reduce or suppress your body's own immune system. Your immune system helps to protect you against infections. However, sometimes it can produce illness and unwanted effects. For example, if you have just had an organ transplant, your immune system will try to reject the new organ. Azathioprine helps to prevent this immune response, and so allows the organ to carry on working. It is therefore used together with other medicines such as corticosteroids to:

- improve the survival of organ transplants

Azathioprine is also used to treat conditions caused by your immune system over reacting or reacting abnormally. For example:

- Rheumatoid arthritis (inflammation and pain in your joints)
- Hepatitis (inflamed liver)
- Systemic lupus erythematosus (a disease which affects your skin and major organs)
- blood disorders such as thrombocytopenia

(reduced numbers of blood cells called platelets). This can affect blood clotting and increase the risk of bleeding or bruising.

- haemolytic anaemia (when you do not have enough red blood cells)
- Pemphigus blisters and sores on your skin
- dermatomyositis (inflammation of your muscles and skin)
- polyarteritis nodosa (inflammation of your blood vessels)

For these conditions, Azathioprine may be used alone, or in combination with other medicines.

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

Do not take Azathioprine if you

- are allergic to azathioprine, to mercaptopurine (a medicine used to treat leukaemia, a cancer of the white blood cells) or any of the other ingredients of this medicine (listed in section 6).
- Are pregnant or intend to become pregnant
- Are breast-feeding.

Warnings and precautions
Talk to your doctor or pharmacist before taking this medicine if you:

- know you have a metabolic abnormality called Lesch-Nyhan syndrome. Azathioprine is not recommended if you have this condition.
- know you have a shortage of a liver enzyme called thiopurine methyltransferase (TPMT). TPMT breaks down azathioprine and other medicines.
- have liver or kidney disease. You may have to take a lower dose and your doctor will closely monitor you.
- have ever suffered from chickenpox or shingles.

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

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.

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.

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.

Your doctor will need to monitor you closely throughout your treatment. You should therefore visit your doctor regularly whilst taking Azathioprine so your condition can be checked. You will need to have your blood count checked at least once a week for the first two months of treatment and then monthly.

Other medicines and Azathioprine

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription, or the following:

- other immunosuppressants e.g. ciclosporin, methotrexate, tacrolimus
- medicines to treat cancer e.g. doxorubicin
- allopurinol, oxipurinol or thiopurinol (for gout or kidney stones)
- cimetidine (for gut or stomach ulcers)
- furosemide ('water tablets')
- penicillamine (for rheumatoid arthritis)
- warfarin (to 'thin' the blood)

- captopril (for blood pressure or heart failure)
- indomethacin (an anti-inflammatory)
- co-trimoxazole (an antibiotic)
- mesalazine, olsalazine, sulfasalazine or balsalazide (mainly used to treat ulcerative colitis).

If you are going to have an operation, tell your doctor or the hospital staff as Azathioprine can interact with medicines called muscle relaxants (e.g. succinylcholine or tubocurarine), which you might be given during your operation.

If you are going to have a vaccination, tell your doctor as some vaccines should not be given or may be less effective, when given together with Azathioprine.

Pregnancy and breast-feeding

Do not take Azathioprine if you are pregnant, become pregnant, or suspect you may already be pregnant as the product could harm your baby (see section 2 "Do not take Azathioprine" above). Contact your doctor as soon as possible for advice. Do not take Azathioprine if you are planning to have a baby. This applies to both men and women.

You and your partner must use a reliable method of contraception whilst taking Azathioprine.

Do not breast-feed your baby. Azathioprine may pass into breast milk.

Driving and using machines do not drive or

operate machinery if you feel dizzy while taking this medicine

3. HOW TO TAKE AZATHIOPRINE TABLETS

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Adults, adolescents and children
Your dose will be adjusted depending on your weight. The recommended doses are:

To prevent organ rejection

The recommended starting dose is up to 5 mg per kg of body weight per day. Your doctor will then assess your response to Azathioprine and choose the best dose for you. This may take weeks or months. After this assessment your dose will usually be between 1 and 4 mg per kg of body weight per day.

Other conditions

The recommended starting dose is between 1 and 3 mg per kg of body weight per day. Your doctor will adjust the dose until it is right for you. Your doctor will prescribe the lowest dose that is effective to treat your condition. If there is no improvement within three months, your doctor may stop giving you this medicine.

Older people or people with kidney or liver disease If you are elderly or you have kidney

or liver disease, you may be started on a lower dose of Azathioprine. Your doctor will monitor your blood and liver function carefully. Your dose may be reduced further if there are any signs that your blood or liver is affected.

Taking Azathioprine

- Swallow the tablets whole with a glass of water. Do not break, chew or crush them.
- The 50 mg tablets have a score line but this is not intended for breaking the tablet.
- If you feel sick after taking your Azathioprine, it should help to take your tablets after meals

If you take more Azathioprine than you should

Contact your doctor or nearest hospital emergency department immediately. Take the container and any remaining tablets with you. Symptoms of overdose include nausea (feeling sick), vomiting and diarrhoea, lack of white blood cells which may cause frequent infections such as fever, severe chills, sore throat or mouth ulcers, disturbances of your liver function, bruising and bleeding.

If you forget to take Azathioprine

If you forget to take your tablets, take the missed dose as soon as you remember. If it is nearly time for your next dose and if you take only one dose a day, do not double your next dose, carry on as usual and check with your doctor. If you miss a dose, check with your doctor.

If you stop taking Azathioprine
Do not stop taking this medicine without talking to your doctor. You may need to take it indefinitely to help stop transplant rejection.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist

4. POSSIBLE SIDE EFFECT

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If any of the following happen **stop taking Azathioprine and tell your doctor immediately** or go to your nearest hospital emergency department:

Very common (may affect more than 1 in 10 people):

- you have any signs of a viral, fungal or bacterial infection or fever. Infections are very common if you are taking Azathioprine after an organ transplant, and with another immunosuppressant or corticosteroid.
- low levels of white blood cells that means you are more likely to catch infections.

Common (may affect up to 1 in 10 people):

- reduction in blood platelets which increase the risk of bleeding or bruising

Uncommon (may affect up to 1 in 100

people):

- allergic reactions which may cause: feeling generally unwell, dizziness, nausea (feeling sick), vomiting (being sick), diarrhoea, fever, chills, rash or red spots, muscle or joint pain, problems with your kidneys (which may cause changes in the amount and colour of your urine), problems with your liver (which may cause yellowing of your skin and whites of your eyes), or a fall in blood pressure (hypotension) which may cause light-headedness or sweating. Your doctor may tell you to stop taking Azathioprine if you develop these symptoms.
- inflamed pancreas which causes severe pain in the abdomen and back.
- cholestasis (when the flow of bile is blocked) or abnormal liver enzyme levels in the blood. The symptoms of these conditions include dark urine, pale stools, itchy skin and yellowing of your skin and whites of your eyes.

Rare (may affect up to 1 in 1,000 people):

- various types of cancers including blood, lymph and skin cancers
- Stomach pain and swelling; yellowing of the skin or whites of the eyes. These may be due to problems with your liver. Azathioprine can cause a rare but severe form of liver disease which can be fatal.

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- Disturbances of the bowel such as inflammation which causes abdominal pain, fever, discomfort, vomiting or diarrhoea. This is more likely to happen if you also take high doses of corticosteroids. Also, severe diarrhoea may happen, especially if you are being treated for inflammatory bowel disease.

severe reduction of all types of blood cells which can cause weakness, bruising or make infections more likely.

- severe blistering of the skin, mouth, throat, nose, genitals and conjunctivitis (red and swollen eye)

Very rare (may affect up to 1 in 1,000 people):

- inflammation of the lungs which can cause weakness, breathlessness, cough and fever.

Stop taking Azathioprine and tell your doctor immediately if you come into contact with anyone who is suffering from chickenpox or shingles.

**Other side effects include:
Rare side effects (may affect up to 1 in 1,000 people):**

Hair loss, especially if you are also taking another immunosuppressant. Your hair will usually grow back even when you carry on taking Azathioprine.

Increased sensitivity of the skin to sunlight.

Not known (frequency cannot be estimated from the available data):

Nausea (feeling sick) especially when first taking Azathioprine. This can be relieved if you take your tablets after meals.

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.

5. HOW TO STORE AZATHIOPRINE TABLETS

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment



6. CONTENTS OF THE PACK AND FURTHER INFORMATION

What Azathioprine contains

a) Each tablet contains:

Azathioprine USP.....25mg
Excipients.....q.s.

b) Each tablet contains:

Azathioprine USP.....50mg
Excipients.....q.s.

The other ingredients are maize starch, microcrystalline cellulose, mannitol, povidone K25, croscarmellose sodium and stearyl fumarate sodium. The film-coating contains hypromellose and macrogol.

What Azathioprine looks like and contents of the pack: your medicine comes as a pale yellow, round, film-coated tablet.

Azathioprine is available in blister packs or plastic containers of 28, 30, 50, 56, 60, 84, 90, 100, 112, 168, 500 and 1,000 tablets. Not all pack sizes may be marketed.

7. MANUFACTURED IN INDIA BY:

TAJ PHARMACEUTICALS LTD.

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