Azathioprine 50mg Tablets

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.

What is in this leaflet:
1. What Azathioprine 50mg Tablets are and what they are used for
2. What you need to know before you take Azathioprine 50mg Tablets
3. How to take Azathioprine 50mg Tablets
4. Possible side effects
5. How to store Azathioprine 50mg Tablets
6. Contents of the pack and other information

1. WHAT AZATHIOPRINE 50MG TABLETS ARE AND WHAT THEY ARE USED FOR

Azathioprine 50mg Tablets contain the active substance azathioprine which belongs to a group of medicines called immunosuppressants. This means that they reduce the strength of your immune system.

Immunosuppressant medicines are sometimes necessary to help your body accept an organ transplant, or to treat some diseases where your immune system is reacting against your own body (autoimmune diseases).

Azathioprine 50mg Tablets are used to:
- Help your body accept a kidney, liver, heart, lung or pancreas transplant (Azathioprine Tablets are usually used together with other medicines in order to enhance their effect).
- Treat severe rheumatoid arthritis.
- Treat severe inflammation of the gut (Crohn’s disease or ulcerative colitis).
- Treat some diseases where your immune system is reacting against your own body (autoimmune diseases) including severe inflammatory diseases of the skin, liver, arteries and some blood disorders.

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

Do not take Azathioprine 50mg Tablets:
- If you are allergic to azathioprine, 6-mercaptopurine or any of the other ingredients of this medicine (listed in section 6).
- If you have a severe infection.
- If you have severe liver disease or severe bone marrow disease.
- If you have an inflamed pancreas.
- If you need or are going to have a vaccination containing a living virus or bacteria, such as BCG, smallpox or yellow fever vaccine.
- If you are pregnant, unless your doctor thinks it is absolutely necessary (see “Pregnancy, breast-feeding and fertility”).
- If you are breast-feeding.

Warnings and precautions
Talk to your doctor or pharmacist before taking Azathioprine 50mg Tablets:
- If you have or have ever had any liver or kidney problems.
- If you have a condition where your body produces too little of a natural chemical called thiopurine methyltransferase (TPMT).
- If you have had any type of operation. You should inform your anaesthesiologist of your treatment with Azathioprine Tablets.
- If you have a rare genetic disorder called “Lesch-Nyhan syndrome”.
- If you are receiving immunosuppressive therapy, taking Azathioprine Tablets 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.

You should take care to avoid too much sun (including sunbeds) whilst taking Azathioprine Tablets.

You must use contraceptive methods whilst taking these tablets and for up to 3 months after you have finished taking them. Suitable methods of contraception should be discussed with your doctor. Women using intrauterine devices (IUDs) should use additional contraceptive methods while taking Azathioprine Tablets.

NUDT15-gene mutation
If you have an inherited mutation in the NUDT15-gene (a gene which is involved in the break-down of Azathioprine 50mg Tablets in the body), you have a higher risk of infections and hair loss and your doctor may give you a lower dose.

Other medicines and Azathioprine 50mg Tablets
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. The following medicines may interact with Azathioprine Tablets:
- Cytotoxic medicines - also called “chemotherapy” (used to treat cancer).
- Indometacin (used as a painkiller and to treat inflammation).
- Trimethoprim/sulfamethoxazole (used to treat bacterial infections).
- ACE-inhibitors (used to treat high blood pressure and heart failure).
- Warfarin or phenprocoumon (used to prevent blood clots).
- Olsalazine, mesalazine or sulfasalazine (used mainly to treat ulcers or chronic inflammatory bowel disease).
- Infliximab (used to treat inflammation of the bowels [Crohn’s disease]).
- Ciclosporin or tacrolimus (also used as immunosuppressant medicines).
- Influenzal (used to treat inflammation of the bowels [Crohn’s disease]).
- Glucocorticosteroids (used to treat ulcers or chronic inflammatory bowel disease).
- Mesalazine (used as an anti-inflamatory therapy).
- Anti-thyroid medicines - also called “chemotherapy” (used to treat cancer).
- Vaccines (such as hepatitis B vaccine).

Currently, there is no long-term safety information on other immunosuppressive therapies, but this is likely to be safe.

You should inform your anaesthesiologist of your treatment with Azathioprine 50mg Tablets prior to surgery.

Pregnancy, breast-feeding and fertility
Azathioprine 50mg Tablets should only be taken if your doctor thinks it is absolutely necessary. If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Women of childbearing potential and men must use effective contraception during treatment with Azathioprine and for at least 3 months after the treatment is discontinued. Azathioprine has been reported to interfere with the effectiveness of intrauterine contraceptive devices (IUCD) therefore additional contraceptive measures are recommended. Do not take the tablets if you are breast-feeding.

Driving and using machines
Studies on the effects of azathioprine on the ability to drive and use machines have not been performed. This product may cause dizziness, which could affect a patient’s ability to drive.

3. HOW TO TAKE AZATHIOPRINE 50MG 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.

The label on the carton will tell you how many tablets to take and when.

Azathioprine tablets should be swallowed whole with one full glass of water (about 200ml). Take your tablets during meals.

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Colours

1. Black
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3. 2
4. 3
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Non Printing Colours

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You should stop taking your medicine unless the doctor tells you because stopping your medicine can make your condition worse.

If your doctor does not see an improvement in your condition within three to six months, your doctor may wish to gradually reduce your dose and finally stop giving you this medicine.

It is important that you stop your treatment gradually. You should stop taking the tablets slowly, over a period of time.

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