Azathioprine 50mg Tablets are used to:

- Treat severe inflammation of the gut (Crohn's disease or ulcerative colitis)
- Treat severe rheumatoid arthritis
- Help your body accept a kidney, liver, heart, lung or pancreas transplant.

Taking Azathioprine 50mg 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.

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:

- Allopurinol, oxipurinol or thiopurinol (used mainly to treat gout)
- ACE-inhibitors (used to treat high blood pressure and heart failure)
- Olsalazine, mesalazine or sulfasalazine (used mainly to treat ulcers or chronic inflammation of the colon and anal passage)
- Curare, d-tubocurarine, pancuronium or succinylcholine (used as muscle relaxants during operations).

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

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.

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

Your doctor will monitor how you respond to your medicine and may change your dose if required.
Uncommon side effects (may affect up to 1 in 10 people)

- Increased infections in patients suffering from rheumatoid arthritis
- Blood disorder after transplant surgery
- Poul-smelling stools which are bulky, loose and greasy
- Allergic reactions including dizziness or feeling unwell, low number of white blood cells, low blood pressure, fever, feeling cold, feeling severely sick and vomiting, diarrhoea, rash, rigors, kidney problems, muscle pain (myalgia), pain in the joint (arthralgia), inflammation of blood vessels (vasculitis), high number of liver enzymes
- Hair loss (alopecia)
- Liver problems in patients with rheumatoid arthritis

Rare side effects (may affect up to 1 in 1000 people)

- Paleness, fatigue or shortness of breath caused when the body’s bone marrow is not producing enough blood cells (aplastic anaemia)
- Cough and fever caused by pneumonia or inflammation of the lung
- Following transplantation, stomach ulcers (which can bleed) and disease which may cause heartburn, vomiting, general discomfort in the stomach
- Following transplantation, bowel problems leading to diarrhoea, abdominal pain and constipation
- Blood and bone marrow disorders (including granulocytopenia, pancytopenia, megaloblastic anaemia, erythroid hypoplasia and agranulocytosis)
- Severe liver damage which can be life threatening
- Sensitivity to sunlight which can cause skin discolouration or a rash
- Various types of cancers including blood, lymph and skin cancers.

Very rare side effects (may affect up to 1 in 10,000 people)

- Blood disorders (including acute myeloid leukaemia and myelo-dysplastic syndromes)
- Severe allergic reaction which can be life-threatening
- Severe skin conditions (Stevens-Johnson syndrome and toxic epidermal necrolysis) which can be life threatening

Not known (cannot be estimated from the available data)

- Sudden onset skin condition, which usually affects the head, neck, arms and legs, known as ‘Sweet’s syndrome’ (or acute febrile neutrophilic dermatosis).

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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE AZATHIOPRINE 50MG 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.

Store in the original package in order to protect from light.

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 OTHER INFORMATION

What Azathioprine 50mg Tablets contain

The active substance is azathioprine. Each tablet contains 50mg of azathioprine.

The other ingredients are:

Tablet core: Microcrystalline cellulose, Mannitoll, Maize starch, Povidone K25, Croscarmellose sodium, Sodium stearyl fumarate

Tablet coat: Hypromellose, Macrogol 400.

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

Azathioprine 50mg Tablets are light yellow, round, biconvex tablets, engraved with “AZA’’ and “50” separated by a line on one side and plain on the other side.

Azathioprine 50mg Tablets are available in blister packs containing 50, 56 and 100 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Actavis Group PTC eft, Reykjavikurvegi 76-78, 220 Hafnarfjörður, Iceland

Manufacturer

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Actavis Group PTC eft, Reykjavikurvegi 76-78, 15-220 Hafnarfjörður, Iceland

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