

PACKAGE LEAFLET: INFORMATION FOR THE USER

Azapress Tablets 50mg

[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 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:

- 1. What Azapress Tablets are and what they are used for**
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1. WHAT AZAPRESS TABLETS ARE AND WHAT THEY ARE USED FOR

Azapress Tablets contain the active ingredient Azathioprine which belongs to a group of medicines called immunosuppressants. It is most commonly used for protection against organ transplant rejection. It is also used for treatment of various conditions in which the usual treatment (with steroids) is not working properly or is causing problems, or where steroids cannot be used. These include hepatitis (liver disease), rheumatoid arthritis, a condition called systemic lupus erythematosus (SLE), various blood and bleeding disorders and skin disorders.

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

Do not take this medicine if:

- You are pregnant, or may become pregnant or if you are breast-feeding
- You have been given Azathioprine before and had an allergic reaction
- You have had an allergic reaction before to 6-mercaptopurine (6-MP) as you are more likely to be hypersensitive to Azathioprine.

Warnings and precautions

Talk to your doctor or pharmacist or nurse before taking Azapress Tablets if:

- You have the inherited deficiency of the enzyme thiopurine methyltransferase (TPMT) or Lesch-Nyhan Syndrome (hypoxanthine-guanine-phosphoribosyltransferase deficiency)
- You have kidney or liver disease.

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

- Tumours, including skin cancer. Therefore, when taking Azapress Tablets, avoid excessive exposure to sunlight, wear protective clothing and use protective sunscreen with a high protection factor
- Lymphoproliferative disorders
 - ▶ Treatment with Azapress Tablets 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 Azapress 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.

Since many of the effects of Azathioprine cause changes in the blood, your doctor will probably want to take regular blood samples whilst you are taking this medicine to look out for any such changes.

Whilst undergoing treatment with Azathioprine, avoid excessive exposure to the sun. In addition, examine your skin regularly for any skin reactions or lumps. If you experience any changes in your skin or develop any lumps (especially if you have had an organ transplant) tell your doctor immediately.

You should contact your doctor immediately if you notice any evidence of infection, unexpected bruising or bleeding as this may indicate a serious blood disorder (bone marrow depression).

Azathioprine has been known to cause alterations to chromosomes (the sites for genes) in body cells, which is reversible on withdrawal of the drug. Further advice should be obtained from your doctor.

Use of Azathioprine in renal transplant patients may lead to an increase in fertility in both males and females.

Whilst taking Azathioprine patients are at an increased risk of developing non-Hodgkin's lymphomas and other malignancies particularly skin cancers, sarcomas, uterine or cervical cancer.

Patients receiving multiple immunosuppressants may be at risk of over-immunosuppression.

You should talk to your doctor if you have ever suffered with chicken pox or shingles.

Other medicines and Azapress Tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

In particular tell your doctor if you are taking any of the following:

- Medicines for gout such as allopurinol, oxipurinol and thiopurinol
- Neuromuscular blocking agents such as succinylcholine and tubocurarine
- Warfarin which is a medicine used to prevent blood clots
- Penicillamine used to treat rheumatoid arthritis
- Co-trimoxazole used to treat infections
- Captopril used to treat high blood pressure
- Cimetidine used to treat excess stomach acid
- Indomethacin used for pain and inflammation
- Medicines that inhibit the TPMT enzyme such as olsalazine, mesalazine and sulfasalazine
- Furosemide used to treat heart failure
- Vaccination with live vaccines is not advised.

Having vaccines whilst taking Azapress Tablets

Speak to your doctor or nurse before you have it. This is because vaccines may not work properly while you are taking Azapress Tablets.

Pregnancy, breast-feeding and fertility

Do not take Azapress Tablets if you are a man trying to have a baby. This is because it may affect the baby.

Do not take Azapress Tablets 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 Azapress Tablets 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.

Driving and using machines

Do not drive or use machines if you are affected by this medication.

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Azapress Tablets contain lactose

This medicine contains lactose (a type of sugar), if you have been told by your doctor that you have an intolerance to some sugars talk to your doctor before taking this medicine.

3. HOW TO TAKE AZAPRESS TABLETS

Always take Azapress Tablets exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

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.

Swallow tablets with water, with meals. Do not chew the tablets.

The usual dose is:-

To stop your body rejecting an organ transplant:

On the first day

- The usual dose is up to 5mg 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.

The exact dosage for treatment for other conditions where steroids cannot be used or when steroids are not working properly may vary. This includes hepatitis (liver disease), rheumatoid arthritis, systemic lupus erythematosus (SLE), skin disorders, various blood and bleeding disorders.

This will normally be between 1mg to 3mg/kg body weight per day.

Exactly how many tablets and how often you must take them will be written on the label. Please read the label carefully.

If you are unsure of the dosage check with your doctor.

If you take more Azapress Tablets than you should

This medicine is to be taken at regular intervals, as determined by the physician. If you take too many tablets by mistake contact your nearest hospital casualty department or tell your doctor immediately. Take your tablet pack with you.

If you stop taking Azapress Tablets

You should finish all the tablets your doctor has prescribed. Even if you feel better, you should still take all the tablets you have been given. It may be dangerous to stop taking the medicine without your doctor's advice.

If you forget to take Azapress Tablets

If you forget to take a dose, take the missed dose as soon as you remember, unless it is nearly time to take the next one. Never take two doses together. Take the remaining tablets at the correct times.

4. POSSIBLE SIDE EFFECTS

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

If you experience any of the following then STOP taking the medicine and contact a doctor immediately

- Allergic reactions may occur rarely, with symptoms such as rash, itching, swelling of the face, wheeziness, shortness of breath, tightness in the chest, fever, low blood pressure and feeling dizzy particularly when standing up
- Pancreatitis (inflammation of the pancreas) with symptoms of stomach pain, nausea and vomiting
- 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 feel extremely tired
- You notice lumps anywhere on your body
- You notice any changes in 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 these tablets and see a doctor straightaway.

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.

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
- Liver problems, which may cause pale stools, itchiness and yellowing of your skin and eyes.

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

- Problems with your bowel leading to diarrhoea, abdominal pain, constipation, feeling sick and being sick
- Hair loss which may get better even though you continue to take Azapress
- 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.

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 AZAPRESS TABLETS

Check the expiry date printed on the label or side of the box. Do not use after the expiry date stated on the label. Store in a dry place, below 25°C. Store in the original package to protect from light.

In case of any visible signs of deterioration, you should discard the package.

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

Keep out of the sight and reach of children

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Azapress Tablets contain:

Each tablet contains 50mg of azathioprine.

The other ingredients are: lactose, starch maize, microcrystalline cellulose, magnesium stearate, purified talc and sodium starch glycollate.

What Azapress Tablets look like and contents of the pack

Azapress Tablets are pale yellow biconvex tablets scored on one side and engraved with 'A10' on the other side. The scoreline is not intended for breaking the tablet.

These tablets are supplied in packs of 28, 50, 56, 100 or 250 tablets or in securitainers of 50 or 100 tablets. Not all pack sizes may be marketed.

Manufacturer and Marketing Authorisation Holder:

Ennogen Pharma Limited
Unit G4, Riverside Industrial Estate,
Riverside Way, Dartford, DA1 5BS, UK.

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