

Please refer to this leaflet

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PACKAGE LEAFLET: INFORMATION FOR THE USER

# Ozathuia® 75mg, 100mg 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.

**What is in this leaflet:**

1. What Ozathuia® Tablets are and what they are used for
2. What you need to know before you take Ozathuia® Tablets
3. How to take Ozathuia® Tablets
4. Possible side effects
5. How to store Ozathuia® Tablets
6. Contents of the pack and other information

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## 1. WHAT OZATHUIA® TABLETS ARE AND WHAT THEY ARE USED FOR

Ozathuia® 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).

Ozathuia® Tablets are used to:

- Help your body accept a kidney, liver, heart, lung or pancreas transplant. (Ozathuia® is 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 OZATHUIA® TABLETS

**Do not take Ozathuia® 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 (see "Pregnancy, breast-feeding and fertility")

**Warnings and precautions**

Talk to your doctor or pharmacist before taking Ozathuia® 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 an infection for which you have not yet received treatment
- If you are pregnant or trying to become pregnant (see "Pregnancy, breast-feeding and fertility")
- If you have a rare genetic disorder called "Lesch-Nyhan syndrome".
- If you are receiving immunosuppressive therapy, taking Ozathuia® Tablets could put you at greater risk of:
  - tumours, including skin cancer. Therefore, when taking Ozathuia® Tablets, avoid excessive exposure to sunlight, wear protective clothing and use protective sunscreen with a high protection factor.
  - lymphoproliferative disorders
    - treatment with Ozathuia® 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 viral infection (Epstein-Barr virus (EBV)-associated lymphoproliferative disorders).

**Vitamin B3 deficiency (pellagra)**

Talk to your doctor immediately if you experience diarrhoea, localised pigmented rash, decline in your memory, reasoning or other thinking skills as these symptoms may suggest vitamin B3 deficiency (nicotinic acid deficiency/pellagra).

**Liver damage**

Treatment with Azathioprine Tablets may affect the liver and your doctor will monitor your liver function regularly. Tell your doctor if you experience symptoms of liver damage (see section 4 'Possible side effects').

Taking Ozathuia® 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 Ozathuia® Tablets.

**You must use effective 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.

**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.

**Other medicines and Ozathuia® 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 Ozathuia® Tablets:

- Allopurinol, oxipurinol, thiopurinol or other xanthine oxidase inhibitors, such as febuxostat (mainly used to treat gout)
- Ciclosporin or tacrolimus (also used as immunosuppressant medicines)
- Infliximab (used to treat inflammation of the bowels [Crohn's disease])
- Olsalazine, mesalazine or sulfasalazine (used mainly to treat ulcers or chronic inflammation of the colon and anal passage)
- Warfarin or phenprocoumon (used to prevent blood clots)
- ACE-inhibitors (used to treat high blood pressure and heart failure)
- Furosemide (used mainly to treat high blood pressure)
- Trimethoprim/sulfamethoxazole (used to treat bacterial infections)
- Cimetidine (used to treat stomach ulcers and indigestion)
- Indometacin (used as a painkiller and to treat inflammation)
- Cytotoxic medicines - also called "chemotherapy" (used to treat cancer)
- Vaccines (such as hepatitis B vaccine)
- Before a surgical procedure tell the anaesthetist that you are taking azathioprine because muscle relaxants used during anaesthesia may interact with Ozathuia.

**Pregnancy, breast-feeding and fertility**

Talk to your doctor immediately if you experience intense itching without a rash during your pregnancy. You may also experience nausea, and loss of appetite together with itching, which indicates that you have a condition called cholestasis of pregnancy (condition affecting the liver during pregnancy). This condition can cause harm to your unborn child.

Ozathuia® 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 Ozathuia® Tablets and for at least 3 months after the treatment is discontinued. Azathioprine has been reported to interfere with the effectiveness of intrauterine contraceptive devices (IUD) 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.

**Ozathuia® Tablets contain sodium**

This medicine contain less than 1 mmol sodium (23 mg) per film-coated tablet, that is to say essentially 'sodium-free'.

## 3. HOW TO TAKE OZATHUIA® 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.

Whilst you are taking Ozathuia® Tablets, your doctor will want you to have a complete blood test performed, at least once a week, during the first 8 weeks of treatment. In certain situations, your doctor may decide to carry out blood tests more frequently.

After 8 weeks, the frequency of the testing may be reduced and your doctor may ask you to repeat the complete blood test every month or at least at intervals of no longer than 3 months.

**After organ transplant**

A dose of 5mg per kilogram of your bodyweight per day may be given on the 1st day of your treatment. However, the usual maintenance dose is between 1 and 4mg per kilogram of your bodyweight per day. Your doctor may adjust this dose according to your body's response to your medicine.

**Patients with chronic active hepatitis**

The usual dose is between 1 and 1.5mg per kilogram of your bodyweight per day.

**Other conditions**

The usual starting dose is between 1 and 3mg per kilogram of your bodyweight per day. Your doctor will adjust the dose until it is right for you.

**Use in children and adolescents**

Where treatment is recommended, the dosage for children and adolescents is the same as the adult dose.

**Elderly patients or patients with kidney or liver disease**

A smaller adult dose may be required.

**If you have taken more Ozathuia® Tablets than you should**

In the event of overdose the most likely effect is bone marrow suppression reaching its maximum 9-19 days after dosing. You may get a sore throat, fever or infection. You may also feel tired or experience bruising and bleeding. If you have taken too many tablets, contact your doctor or go the nearest hospital casualty department immediately. Remember to take the pack and any remaining tablets with you to show the doctor.

**If you forget to take Ozathuia® Tablets**

Do not take a double dose to make up for a forgotten tablet. Wait and take your next dose at the usual time. If you have missed more than one dose, contact your doctor for advice.

**If you stop taking Ozathuia® Tablets**

Do not 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.

**4. POSSIBLE SIDE EFFECTS**

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

**If you get any of the following serious side effects, talk to your doctor immediately, you may need urgent medical treatment:**

- **Reversible swelling of the brain with symptoms including severe headache, vision changes, seizures, confusion and reduced consciousness, with or without high blood pressure (Posterior Reversible Encephalopathy Syndrome or PRES).**
- **Get any ulcers in the throat, fever, bruises or bleeding, or you think you have an infection.**
- **Allergic reactions, 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, skin nodules, or a skin rash, pain in the muscles or joints, changes in the colour of your urine (kidney problems), chest pain, shortness of breath or swollen legs (heart problems), confusion, feeling light headed or weak (caused by low blood pressure).**
- **You may develop a rash (raised red, pink or purple lumps which are sore to touch), particularly on your arms, hands, fingers, face and neck, which may also be accompanied by a fever (Sweet's syndrome, also known as acute febrile neutrophilic dermatosis). The rate at which these side effects occur is not known (cannot be estimated from available data).**
- **Severe liver damage which can be life threatening, especially in patients who receive long-term treatment (like liver injury, non-cirrhotic portal hypertension, portosinusoidal vascular disease). Tell your doctor if you experience any of the following symptoms: yellowing of the skin and whites of the eyes (jaundice), bruising easily, abdominal discomfort, loss of appetite, fatigue, nausea, or vomiting. The rate at which these side effects occur is Rare (may affect up to 1 in 1,000 people).**

The following side effects have been reported. Tell your doctor if any of these side effects become troublesome:

**Very common side effects** (may affect more than 1 in 10 people)

- Infections (in kidney transplant patients)
- Reduction in number of white blood cells which makes infections more likely
- Feeling and being sick (nausea and vomiting)
- Loss of appetite (anorexia).

**Common side effects** (may affect up to 1 in 10 people)

- Increased infections in patients with bowel inflammation
- Reduction in blood platelets which increases risk of bleeding or bruising
- Decrease in red blood cells in the blood (anaemia)
- Decrease in white blood cells in patients with rheumatoid arthritis
- Liver disease
- Certain types of cancer (lymphomas, cancer of the cervix, vulva and skin (especially on areas of the skin exposed to the sun)) are common in patients after kidney transplant
- Inflammation of the pancreas, which causes severe pain in the abdomen and back.

**Uncommon side effects** (may affect up to 1 in 100 people)

- Increased infections in patients suffering from rheumatoid arthritis
- Blood disorder after transplant surgery
- Foul 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 1,000 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** (frequency cannot be derived from the available data):

- Tremor
- Inflammation of a salivary gland (sialoadenitis)
- Vitamin B3 deficiency (pellagra) associated with a localised pigmented skin rash, diarrhoea and decrease in memory, reasoning or other thinking skills.

**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](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

**5. HOW TO STORE OZATHUIA® 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 Ozathuia® Tablets contain**

The active substance is azathioprine. Each film-coated tablet contains 75mg or 100 mg of azathioprine.

The other ingredients are:

- Tablet core:** Microcrystalline cellulose, Mannitol, Maize starch, Povidone K25, Croscarmellose sodium, Sodium stearyl fumarate.
- Tablet coating:** Hypromellose, Macrogol 400.

**What Ozathuia® Tablets look like and contents of the pack**

Ozathuia® Tablets are light yellow, round, biconvex tablets, engraved with "AZA" and the tablet strength ("75 or 100") on one side and plain on the other side.

The tablets are available in blister packs containing 30, 50 and 100 tablets.

Not all pack sizes may be marketed.

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