

Package leaflet: Information for the user

Purimmun 50 mg tablets mercaptopurine monohydrate

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, 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, pharmacist or nurse. This includes any possible side effects not listed in the leaflet. See section 4.

What is in this leaflet

1. What Purimmun is and what it is used for
2. What you need to know before you take Purimmun
3. How to take Purimmun
4. Possible side effects
5. How to store Purimmun
6. Contents of the pack and other information

1. What Purimmun is and what it is used for

Purimmun tablets contain a medicine called mercaptopurine. This belongs to a group of medicines called cytotoxics (also called chemotherapy). It works by reducing the number of new blood cells your body makes.

Purimmun tablets are used to treat a certain type of blood cancer, (acute promyelocytic leukaemia) in adults, adolescents and children. This is a fast-growing disease which increases the number of new white blood cells. These new white blood cells are immature (not fully formed) and unable to grow and work properly. They therefore cannot fight infections and may cause bleeding. Ask your doctor if you would like more explanation about this disease.

2. What you need to know before you take Purimmun

Do not take Purimmun:

- if you are allergic to mercaptopurine or any of the other ingredients of this medicine (listed in section 6).

Do not get vaccinated with yellow fever vaccine whilst you are taking Purimmun because it may be fatal.

Warnings and precautions

Talk to your doctor before taking Purimmun:

- If you have been vaccinated with yellow fever vaccine or if you have recently been or should be vaccinated.

- If you take Purimmin, you should not have a live organism vaccine (for example: flu vaccine, measles vaccine, BCG vaccine, etc.) until advised it is safe to do so by your doctor. This is because some vaccines may give you an infection if you receive them while you are taking Purimmin.
- If you have kidney or liver problems, as your doctor will need to check that they are working properly.
- If you have a condition where your body produces too little of the enzyme called TPMT (thiopurine methyltransferase) as your doctor may need to adjust the dose.
- If you are allergic to a medicine called azathioprine (also used to treat cancer).
- If you have, or have not, had chicken pox, shingles or hepatitis B (a liver disease caused by a virus)
- If you have a genetic disease called Lesch-Nyhan syndrome.
- If you are planning to have a baby. This applies to both men and women. Purimmin may harm your sperm or your eggs (see “Pregnancy, breast-feeding and fertility” below).

The tablets should be handled carefully.

Women who are pregnant, planning to be or breast-feeding should not handle Purimmin. Please see “Safe handling of the tablets” in section 3 How to take Purimmin.

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

- Tumours, including skin cancer. Therefore, when taking Purimmin, avoid excessive exposure to sunlight, wear protective clothing and use protective sunscreen with a high protection factor.
- Lymphoproliferative disorders:
 - o treatment with Purimmin 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.
 - o 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 Purimmin could put you at greater risk of:

- Developing a serious condition called Macrophage Activation Syndrome (MAS, excessive activation of white blood cells associated with inflammation), which usually occurs in people who have certain types of arthritis.
- Some patients with inflammatory bowel disease who have received mercaptopurine have developed a rare and aggressive type of cancer called Hepatosplenic T-cell Lymphoma (see section 4 Possible side effects).

The use of Purimmin for the treatment of inflammatory bowel disease (IBD) is an unlicensed indication.

Blood tests

Purimmin can affect your bone marrow. This means you may have a reduced number of white blood cells, platelets and (less commonly) red blood cells in your blood. Your doctor will take daily blood tests at the beginning of your treatment (induction) and at least once a week in your treatment (maintenance). This is to check the levels of these blood cells in your blood. If the treatment is completed, the number of blood cells in your blood return to normal.

Hepatic function

Purimmin is toxic to your liver. Therefore, your doctor will carry out weekly liver function tests when you are taking Purimmin. If you already have liver disease, or if you are taking other medications which may affect your liver, your doctor will carry out more frequent tests. If you notice the whites of your eyes or your skin turn yellow (jaundice) tell your doctor immediately as you may need to stop your treatment immediately.

Vitamin B3 deficiency (pellagra)

Talk to your doctor immediately if you experience diarrhoea, localized pigmented rash (dermatitis), decline in your memory, reasoning or other thinking skills (dementia) as these symptoms may suggest vitamin B3 deficiency (nicotinic acid deficiency/pellagra). Your doctor will likely prescribe vitamin supplements (niacin/nicotinamide) to help treat this condition.

Infections

When you take Purimmin you may be more prone to suffer infections and your reaction to these infections may be more serious than people not being treated with Purimmin. Tell your doctor immediately if you think you have an infection.

NUDT15-gene mutation

If you have an inherited mutation in the NUDT15-gene (a gene which is involved in the breakdown of Purimmin 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.

Sun and UV light

During your treatment with Purimmin you are more sensitive to the sun and UV light. You must be sure to limit your exposure to sunlight and UV light, wear protective clothing and use sunscreen with a high SPF.

Children and adolescents

Low blood sugar (sweating more than usual, nausea, dizziness, confusion, etc.) has sometimes been seen in children, mainly in children under the age of six or with a low body mass index. Talk to your child's doctor if this happens.

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before taking Purimmin.

Other medicines and Purimmin

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

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

- Ribavirin (used to treat viral infections)
- Other cytotoxic drugs (used to treat cancer)
- Allopurinol thiopurinol, oxypurinol or febuxostat (used mainly to treat gout)
- Olsalazine (used to treat bowel problems called ulcerative colitis)
- Mesalazine (used to treat bowel problems called Crohn's disease and ulcerative colitis)
- Sulfasalazine (used for rheumatoid arthritis or ulcerative colitis)
- Methotrexate (used to treat cancer, rheumatoid arthritis or skin disease (severe psoriasis))
- Infliximab (used to treat bowel disorders (Crohn's disease and ulcerative colitis), rheumatoid arthritis, inflammation of the spinal column (ankylosing spondylitis) or severe psoriasis (skin))

- Warfarin or acenocoumarol (anticoagulants)
- Anti-epileptic medicines such as phenytoin, carbamazepine. Blood levels of anti-epileptic medicines may need to be monitored, and doses adjusted if necessary.

Having vaccines

If you are going to have a vaccination during or after treatment, speak to your doctor or nurse before you have it. This is because live vaccines (like polio, measles, mumps and rubella) may give you an infection if it is given before your immune system has recovered.

Do not get vaccinated with yellow fever vaccine whilst you are taking Purimmin because it may be fatal.

Purimmin tablets with food and drink

You can take Purimmin with food or on an empty stomach, but the way you choose should be the same, day to day. You should take Purimmin at least 1 hour before or 2 hours after ingestion of milk or dairy products.

Pregnancy, breast-feeding and fertility

If you think you could be pregnant, or if you are planning to become pregnant, check with your doctor before taking Purimmin.

Treatment with Purimmin is not recommended during pregnancy, particularly in the first three months, because it may cause permanent damage to a foetus.

Your doctor will consider the risks and benefits to you and your baby of taking Purimmin.

Taking Purimmin during pregnancy may cause severe, excessive itching without a rash. You may also experience nausea and loss of appetite at the same time, which may indicate a condition called cholestasis of pregnancy (a disease of the liver during pregnancy). Talk with your doctor immediately, as this condition can cause harm to your unborn child.

Do not take Purimmin if you are planning to have a baby. This applies to both men and women. Purimmin may harm your sperm or eggs. Reliable contraceptive precautions must be taken to avoid pregnancy during the treatment and for at least 3 months after end of treatment with Purimmin, if you or your partner are taking Purimmin.

Do not breast-feed while taking Purimmin. Ask your doctor, pharmacist or midwife for advice.

Driving and using machines

There is no data about the effects of mercaptopurine on the ability to drive vehicles and use machines and such effects could not be attributed to the pharmacological properties of Purimmin.

Purimmin contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Purimmin

Purimmin will be prescribed to you by a specialist doctor who is experienced in treating blood problems.

- During treatment with Purimmun tablets your doctor will take regular blood tests. This is to check the number and type of cells in your blood and to ensure your liver is working correctly.
- Your doctor may also ask for other blood and urine tests to monitor how your kidneys are working and to measure uric acid levels. Uric acid is a natural body chemical, levels of which can rise while taking Purimmun. High levels of uric acid may damage your kidneys.
- Your doctor may sometimes change your dose of Purimmun as a result of these tests.

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

Your doctor will calculate and adjust your dose based on your weight, or your body surface area and the results of your blood tests, if you take other chemotherapy drugs, as well as your kidney and liver function.

Swallow the tablets whole with some water. Do not chew the tablets. The tablets should not be broken or crushed. If you or your caregiver does handle broken tablets, wash the hands immediately. You can take your medicine with food or on an empty stomach, but the way you choose should be the same day to day. You should take Purimmun at least 1 hour before or 2 hours after ingestion of milk or dairy products. It is important to take Purimmun in the evening to make the medicine more effective.

Safe handling of the tablets

If you are a parent or carer who provides the medicine, wash your hands before and after you give a dose. Spilled medicine should be collected immediately. In order to reduce the risk of exposure you should wear disposable gloves when handling Purimmun.

Immediately and thoroughly rinse with soap and water if Purimmun comes into contact with skin, eyes or nose.

Women who are pregnant, planning to be or breast-feeding should not handle Purimmun.

Accidental ingestion can be lethal for children. Keep Purimmun out of the reach and sight of children, preferably in a locked cupboard.

If you take more Purimmun than you should

If you take too many Purimmun tablets or if someone else took your medication by mistake, please immediately contact your doctor for advice or contact the nearest hospital or call the poison control center. You may feel sick, vomit or have diarrhoea. Take the medicine package and this leaflet with you.

If you forget to take Purimmun

If you forget to take a dose, inform your doctor. Do not take a double dose to make up for a forgotten dose.

If you stop taking Purimmun

Do not stop taking your medicine unless your doctor tells you to or you may get a relapse of your condition.

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, talk to your specialist doctor straight away or seek urgent medicinal advice:

- An allergic reaction with swelling of the face and sometimes mouth and throat (this is a very rare side effect)
- An allergic reaction with joint pain, skin rashes, high temperature (fever) (this is a rare side effect)
- An allergic reaction with skin nodules (erythema nodosum) (the frequency is unknown)
- Yellowing of the skin and whites of the eyes. If you get such symptoms, you should stop taking Purimmun.
- Any signs of a high temperature or infection (feeling very tired or unwell, sore throat, sore mouth or urinary problems) or any unexplained bruising or bleeding. Treatment with Purimmun affects your bone marrow and will cause a reduction in your white blood cells and platelets (this is a very common side effect)

Talk to your doctor if you have any of the following side effects, which may also happen with this medicine:

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

- A drop in the number of white blood cells and platelets (may show up in blood tests).

Common (may affect up to 1 in 10 people)

- Nausea (you feel sick) or vomiting (being sick)
- Low red blood cell count (anemia)
- Liver damage – this may show up in blood tests
- Loss of appetite
- Inflammation of the pancreas (pancreatitis) in inflammatory bowel disease patients.

Uncommon (may affect up to 1 in 100 people)

- Joint pain, skin rash, fever due to hypersensitivity
- Severe liver damage (hepatic necrosis)
- Infections, general malaise, tendency to sore throat and fever. Can get serious. If you get a fever, consult a doctor or emergency room.

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

- Hair Loss
- Mouth ulcers
- In men: low sperm count
- Swollen face due to hypersensitivity
- Various types of cancers including cervix, lymph, supporting tissue and skin cancers
- Inflammation of the pancreas (pancreatitis) in patients with leukaemia (cancer of the blood).

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

- A different type of leukaemia to that being treated
- Ulcers in the intestines, with symptoms such as abdominal pain and bleeding.

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

- A rare type of cancer (hepatosplenic T-cell lymphoma, in patients with a disease called inflammatory bowel disease) (see section 2 Warnings and Precautions)
- Burning or tingling sensation in the mouth or lips (inflammation of the mucosa, stomatitis)
- Cracked or swollen lips (cheilitis)
- Vitamin B3 deficiency (pellagra) associated with a localised pigmented skin rash, diarrhoea or decrease in memory, reasoning or other thinking skills
- Increased sensitivity to sunlight and UV light causing skin reactions
- Skin nodules (erythema nodosum)
- A decrease in clotting factors.

Additional side effects in children – frequency is not known

Low blood sugar levels (sweating more than usual, nausea, dizziness, confusion, etc.) have been reported in some children receiving Purimmun. The frequency is not known. Most of the children were under the age of six years old and had a low body weight.

Reporting of side effects

If you get any side effects or if the side effects get worse, 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 national reporting system listed in [Appendix V](#).^{*} By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Purimmun

Keep this medicine out of the sight and reach of children, preferably in a locked cupboard. Accidental ingestion can be lethal for children.

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

This medicine does not require any special temperature storage conditions. Store in the bottle in order to protect from light.

If your doctor tells you to stop taking the tablets, it is important to return any which are left over to your pharmacist, who will destroy them according to disposal of dangerous substance guidelines. Only keep the tablets if your doctor tells you to.

6. Contents of the pack and other information

What Purimmun contains

- The active ingredient is mercaptopurine monohydrate. One tablet contains 50 mg of mercaptopurine monohydrate.
- The other ingredients are lactose, maize starch, maltodextrin, stearic acid and magnesium stearate.

What Purimmun looks like and contents of the pack

Purimmun is a round 6 mm yellowish tablet.

Purimmun is packed in amber glass container and a child-proof propylene cap with silica gel.

Pack sizes: 25 tablets, 50 (2x25) tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

<To be completed nationally>

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Detailed information on this medicine is available on the website of (name of MA Agency
(hyperlink))