

Package Leaflet: Information for the User

Puri-Nethol® 50 mg Tablets

6-mercaptopurine

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 effects not listed in this leaflet. See section 4

What is in this leaflet

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

1. What Puri-Nethol is and what it is used for

Puri-Nethol contains the active substance 6-mercaptopurine. 6-mercaptopurine belongs to a group of medicines called cytotoxics (also called chemotherapy) and works by reducing the number of new blood cells your body makes.

Puri-Nethol is used to treat cancer of the blood (leukaemia) in adults, adolescents and children.

2. What you need to know before you take Puri-Nethol

Do not take Puri-Nethol:

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

Warnings and precautions

Talk to your doctor or pharmacist before taking Puri-Nethol:

- If you have recently received, or are due to receive, a vaccination (vaccine). If you take Puri-Nethol, 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 Puri-Nethol
- If you have reduced liver function or liver damage
- If you have a genetic condition called TPMT (thiopurine methyltransferase) deficiency
- If you have an allergy to a medicine called azathioprine (also used to treat cancer)
- If you have a kidney problem
- Tell your doctor whether you have, or have not, had chicken pox, shingles or hepatitis B (a liver disease caused by a virus)
- If you have a genetic condition called Lesch-Nyhan Syndrome

If you are receiving immunosuppressive therapy, taking Puri-Nethol could put you at greater risk of:

- tumours, including skin cancer. Therefore, when taking Puri-Nethol, avoid excessive exposure to sunlight, wear protective clothing and use protective sunscreen with a high protection factor.
- lymphoproliferative disorders
- treatment with Puri-Nethol 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 Puri-Nethol 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.

Blood tests

- Treatment with Puri-Nethol may 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 carry out blood tests daily when you are at the beginning of your treatment (induction) and at least weekly when you are further along into your treatment (maintenance). This is in order to monitor the levels of these cells in your blood. If you stop treatment early enough, your blood cells will return to normal.

Other laboratory tests

- Additional laboratory tests (urine, blood, etc.) may also be carried out as directed by your doctor.

Liver function

- Puri-Nethol is toxic to your liver. Therefore, your doctor will carry out weekly liver function tests when you are taking Puri-Nethol. 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.

Infections

- When you are treated with Puri-Nethol the risk of viral, fungal and bacterial infections is increased and the infections may be more serious. See also section 4.
- Tell your doctor before starting treatment whether or not you have had chickenpox, shingles or hepatitis B (a liver disease caused by a virus). If you think you have an infection, talk to your doctor immediately.

Sun and UV light

- While you are taking Puri-Nethol, you are more sensitive to the sun and UV light. You must make sure you limit your exposure to sunlight and UV light, wear protective clothing and use a sun cream with a high sun protection factor (SPF).

NUDT15-gene mutation

If you have an inherited mutation in the NUDT15-gene (a gene which is involved in the break-down of Puri-Nethol 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.

Children and adolescents

Low blood sugar levels (sweating more than usual, nausea, dizziness, confusion, etc.) have been reported in some children receiving Puri-Nethol; however, most of the children were under the age of six years old and had a low body weight.

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

Other medicines and Puri-Nethol

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 viruses)
- Other cytotoxic medicines (chemotherapy – used to treat cancer)
- Allopurinol, thiopurinol, oxipurinol or febuxostat (used to treat gout)
- Olsalazine (used to treat a bowel problem called ulcerative colitis)
- Mesalazine (used to treat Crohn's Disease and ulcerative colitis)
- Sulfasalazine (used to treat rheumatoid arthritis or ulcerative colitis)
- Methotrexate (used to treat rheumatoid arthritis or severe psoriasis)
- Infliximab (used to treat Crohn's Disease and ulcerative colitis, rheumatoid arthritis, ankylosing spondylitis or severe psoriasis)
- Warfarin or acenocoumarol (used to 'thin' the blood)

Having vaccines while you are taking Puri-Nethol

If you are due to receive a vaccination (vaccine) speak to your doctor or nurse before you do so. If you take Puri-Nethol, you should not have a live 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 Puri-Nethol.

Puri-Nethol with food and drink

You can take Puri-Nethol with food or on an empty stomach but the choice of method should be consistent from day to day. You should take your medicine at least 1 hour before or 2 hours after having milk or dairy products.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Pregnancy

Treatment with Puri-Nethol is not recommended during pregnancy, particularly in the first trimester (three months) because it may cause damage to the foetus. If you are pregnant your doctor will consider the risks and benefits to you and your baby before prescribing Puri-Nethol for you.

If you or your partner are taking Puri-Nethol, you must use a reliable form of contraception to avoid pregnancy for the whole course of Puri-Nethol treatment and for at least 3 months after receiving the last dose of Puri-Nethol. **This applies to both men and women.**

Breast-feeding

It is recommended that you do not breast-feed when you are taking Puri-Nethol.

Driving and using machines

It is not expected that Puri-Nethol will affect your ability to drive or use machines, but no studies have been done to confirm this.

Puri-Nethol tablets contain 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 Puri-Nethol

Puri-Nethol should only be prescribed to you by a specialist doctor who is experienced in treating cancers of the blood.

- When you take Puri-Nethol, 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 substance made in your body and levels of uric acid can rise while you are taking Puri-Nethol. High levels of uric acid may damage your kidneys
- Your doctor may sometimes change your dose of Puri-Nethol as a result of these tests.

Always take Puri-Nethol exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. It is important to take your medicine at the right times. The label on your pack will tell you how many tablets to take and how often to take them. If the label does not say or if you are not sure, ask your doctor, nurse or pharmacist.

The usual dose for adults and children is 2.5 mg per kilogram of your body weight each day (or alternatively 50 to 75 mg per m² of your body surface area each day). Your doctor will calculate and adjust your dose based on your body weight, results of your blood tests, whether or not you are taking other chemotherapy medicines and your kidney and liver function.

- Swallow your tablets whole. 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 choice of method should be consistent from day to day. You should take your medicine at least 1 hour before or 2 hours after having milk or dairy products.

If you take more Puri-Nethol than you should

If you take more Puri-Nethol than you should, tell your doctor immediately or go to a hospital straight away. Take the medicine pack with you.

If you forget to take Puri-Nethol

Tell your doctor. Do not take a double dose to make up for a forgotten dose.

If you stop taking Puri-Nethol

If you stop taking Puri-Nethol, tell your doctor immediately. If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

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 medical 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)
- Yellowing of the skin and whites of the eyes. If you get such symptoms, you should stop taking Puri-Nethol.
- Any signs of fever or infection (sore throat, sore mouth or urinary problems) or any unexplained bruising or bleeding. Treatment with Puri-Nethol 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:

Common (may affect up to 1 in 10 people)

- Nausea (you feel sick) or vomiting (being sick)
- Low red blood cell count (anaemia)

Uncommon (may affect up to 1 in 100 people)

- Loss of appetite

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

- Mouth ulcers
- Inflammation of the pancreas (pancreatitis); symptoms may include abdominal pain or feeling or being sick
- Damage to your liver (hepatic necrosis)
- Hair loss
- Various types of cancers including blood, lymph and skin cancers

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

- Blood cancer
- Cancer of the spleen and liver (in patients with a condition called Inflammatory Bowel Disease)
- Ulcers in the intestines; symptoms may include abdominal pain and bleeding
- Low sperm count in men

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

- Increased sensitivity to sunlight and UV light

Additional side effects in children

Low blood sugar levels (sweating more than usual, nausea, dizziness, confusion, etc.) have been reported in some children receiving Puri-Nethol; however, 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, 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 HPRA Pharmacovigilance.

Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

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

5. How to store Puri-Nethol

- 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 bottle label and the carton after 'EXP'. This is printed as month; year and refers to the last date of the month.
- Do not store your Puri-Nethol tablets above 25°C. Store in the original bottle and in the carton in order to protect from light. Keep the bottle tightly closed in order to protect from moisture.
- 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 Puri-Nethol contains

The active substance is 6-mercaptopurine. Each tablet contains 50 mg of 6-mercaptopurine.

The other ingredients are lactose, maize starch, modified maize starch, stearic acid and magnesium stearate.

What Puri-Nethol looks like and contents of the pack

Puri-Nethol tablets are round, pale yellow tablets marked with GX/EX2 on either side of the scorline on one side and plain on the other.

Your Puri-Nethol tablets are in bottles of 25 tablets.

Manufacturer and Parallel Product Authorisation Holder

Manufacturer:

EXCELLA GmbH & Co. KG, Nürnberger Strasse 12, 90537 Feucht, Germany.

Parallel Product Authorisation Holder:

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Other sources of information:

Detailed information on this medicine is available on the European Medicines Agency website: <http://www.ema.europa.eu>

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Is this leaflet hard to see or read?
Phone Primecrown 2010 Ltd,
Tel: + 44 (0)20 8839 3000 to obtain the
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