

Applicant/PHCR: Pharmacare Ltd
Dosage form and strength: Tablets, 50 mg
Product proprietary name: PURI-NETHOL

MODULE 1
1.3.2

1.3.2 Patient Information Leaflet

SCHEDULING STATUS

S4

PURI-NETHOL 50 mg tablets

6-mercaptopurine

Contains sugar: Lactose monohydrate 59 mg

Read all of this leaflet carefully before you start taking PURI-NETHOL.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- PURI-NETHOL has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

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

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The active substance is called 6-mercaptopurine. This belongs to a group of medicines called cytotoxics (also called chemotherapy). PURI-NETHOL is used to treat leukaemia (cancer of the blood). It works by reducing the number of new blood cells your body makes.

PURI-NETHOL is used to treat cancer of the blood:

- Acute lymphoblastic leukaemia (also called acute lymphocytic leukaemia or ALL).
- Acute promyelocytic leukaemia (also called acute myeloid leukaemia or AML).

2. What you need to know before you take PURI-NETHOL

Do not take PURI-NETHOL:

- If you are hypersensitive (allergic) to 6-mercaptopurine, azathioprine or any of the other ingredients of PURI-NETHOL (listed in section 6).

Warnings and precautions

PURI-NETHOL results in profound decrease of blood cells. At the recommended dose, this is the desired effect.

While you are taking PURI-NETHOL you will have regular blood tests. This is to check the number and type of cells in your blood. Your dose of PURI-NETHOL may need to be changed depending on the results of these tests.

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Your doctor will check for and, if necessary, treat for various infections you may carry but the symptoms have not manifested.

Take special care with PURI-NETHOL:

- If you have recently received or are due to receive a vaccination. This is because some vaccines (like flu, polio, measles, mumps and rubella) may give you an infection if you have them whilst you are taking PURI-NETHOL.
- If you are taking a medicine called ribavirin.
- If you are taking other medicines that could cause a shortage of white blood cells or red blood cells in your body. 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 have a kidney problem; your doctor will monitor your kidney function.
- If you already have high uric acid levels in your blood or urine. During a certain phase of treatment when the cancer cells die, the uric acid levels in your blood and urine might rise and you may develop gout.
- You have a liver problem; your doctor will monitor your liver function.
- You have a genetic condition where your body produces too little of something called TPMT or 'thiopurine methyltransferase'.
- If you have an inherited mutated gene called NUDT15.

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- If you have previously taken medicines called 6-thioguanine or azathioprine and have shown resistance to it.
- If you are allergic to a medicine called azathioprine (also used to treat cancer).
- If you are receiving PURI-NETHOL, it 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 (several disorders where lymphocytes are produced in excessive quantities).
 - treatment with PURI-NETHOL increases your risk of getting a type of cancer called lymphoproliferative disorder.
 - PURI-NETHOL in combination with other medicines that also suppresses your immune system, increases the risk of disorders of the lymph system due to a viral infection (Epstein-Barr virus (EBV)).
- Taking PURI-NETHOL puts 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.
- If you are pregnant. PURI-NETHOL could be harmful to the unborn baby (see Pregnancy and breastfeeding).
- If your child is receiving PURI-NETHOL and is under the age of six or is underweight. Your child's blood sugar levels may fall when treated with PURI-NETHOL.

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- If you think you have an infection, talk to your doctor immediately. If you are taking PURI-NETHOL you may be more likely to get infections caused by viruses, bacteria and fungus and your reaction to these infections may be more severe than people who are not taking PURI-NETHOL.
- If you have an inherited disorder where your body builds and breaks down purines and therefore overproduces uric acid. This disorder is called Lesch-Nyhan syndrome.
- If you have a high level of sun-exposure. Treatment with PURI-NETHOL will make you more sensitive to sun. You should wear sunscreen and protective clothing when you are exposed to direct sunlight.
- If you are taking a medicine called allopurinol. You will get a lower dose of PURI-NETHOL if you are taking allopurinol.
- If you are taking medicine called warfarin, to thin your blood. Your blood will have to be closely monitored to ensure that your blood does not clot.
- If you have porphyria.

Other medicines and PURI-NETHOL

Always tell your healthcare provider if you are taking any other medicine (this includes complementary or traditional medicines).

Tell your doctor if you are taking any of the following medicines:

- Any type of vaccination (e.g. measles, mumps, flu).
- Allopurinol or febuxostat (used mainly to treat gout). When used with PURI-NETHOL, only 25 % of the normal dose of PURI-NETHOL should be taken.
- Ribavirin (used to treat viral infections).

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- Other cytotoxic medicines (chemotherapy used to treat cancer).
- Olsalazine (used for a bowel problem called ulcerative colitis).
- Mesalazine (used to treat Crohn's Disease and ulcerative colitis).
- Sulfasalazine (used for rheumatoid arthritis or ulcerative colitis).
- Methotrexate (used to treat cancers, rheumatoid arthritis or severe psoriasis).
- Infliximab (used to treat rheumatoid arthritis, severe psoriasis, ulcerative colitis, Crohn's disease, and ankylosing spondylitis).
- Warfarin (used to thin the blood).

PURI-NETHOL with food and drink

- You can take PURI-NETHOL with food or on an empty stomach. You should, however, take PURI-NETHOL in the same way, every day.
- You should take PURI-NETHOL at least one hour before or two hours after having any milk or dairy products.
- Swallow your tablets whole with a glass of water.

Pregnancy, breastfeeding and fertility

PURI-NETHOL can cause abnormalities in your unborn child.

Do not take PURI-NETHOL if you are pregnant, or if you are planning to have a baby. This applies to both men and women. PURI-NETHOL may harm your sperm or eggs. Reliable contraceptive precautions must be taken during PURI-NETHOL treatment to avoid pregnancy and for at least 3 months after you or your partner have stopped PURI-NETHOL treatment. Ask your doctor for advice.

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Treatment with PURI-NETHOL should not be used during pregnancy, because it may cause permanent damage to a foetus. If you think you could be pregnant, or if you are planning to become pregnant, check with your doctor before taking PURI-NETHOL. Your doctor will consider the risks and benefits to you and your baby of taking PURI-NETHOL.

Do not breastfeed while taking PURI-NETHOL. Ask your doctor or pharmacist for advice.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking PURI-NETHOL.

Driving and using machines

You should not drive, use machinery or perform any tasks that require concentration until you are certain that PURI-NETHOL does not adversely affect your ability to do so safely (section 4).

It is not always possible to predict to what extent PURI-NETHOL may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which PURI-NETHOL affects you (see section 4).

PURI-NETHOL contains lactose

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If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking PURI-NETHOL.

3. How to take PURI-NETHOL

Do not share medicines prescribed for you with any other person.

PURI-NETHOL should only be given to you by a medical doctor who is experienced in treating blood cancer.

Always take PURI-NETHOL exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are not sure.

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 your uric acid levels and your liver function. Uric acid is a natural body chemical, levels of which can rise while taking PURI-NETHOL.

Your doctor may sometimes change your dose of PURI-NETHOL as a result of these tests.

The usual starting dose for adults and children is 2,5 mg per kilogram of your body weight each day.

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Elderly patients will have their kidney and liver function tested and if ,necessary the dose may need to be reduced.

Children with acute lymphoblastic leukaemia may be asked by their doctor to take PURI-NETHOL in the evening as this may lower the risk of the leukaemia getting worse again in the future.

If you or the caregiver of your child handles broken tablets, the hands should be washed immediately.

If you have a condition where your body produces too little of something called TPMT or 'thiopurine methyltransferase', your dose may be reduced.

If you have an inherited muted NUDT15 gene, your dose of PURI-NETHOL needs to be reduced.

Your doctor will tell you how long your treatment with PURI-NETHOL will last.

Do not stop treatment without your doctor's knowledge.

If you have the impression that the effect of PURI-NETHOL is too strong or too weak, tell your doctor or pharmacist.

If you take more PURI-NETHOL than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

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If you forget to take PURI-NETHOL

Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

PURI-NETHOL can have side effects.

Not all side effects reported for PURI-NETHOL are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking PURI-NETHOL, please consult your healthcare provider for advice.

If any of the following happens, stop taking PURI-NETHOL and tell your doctor immediately or go to the casualty department at your nearest hospital:

- an allergic reaction with swelling of the face and sometimes the mouth and throat (angioedema) which may cause difficulty in swallowing or breathing,
- allergic reaction, the signs may include skin rashes, high temperature, joint pain.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to PURI-NETHOL. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- any unexpected bruising or bleeding, as this could mean that too few blood cells of a particular type are being produced (leukopenia, thrombocytopenia, bone marrow depression),

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- bacterial or viral infections due to low white cell counts that help you fight infections,
- if you suddenly feel unwell (even with a normal temperature),
- abnormal blood cell production in the bone marrow (myelodysplasia),
- if you develop abdominal pain or become sick as this may indicate an inflammation of the pancreas,
- liver problems, damage to liver cells (this may show up in your blood tests) (hepatotoxicity),
- yellow discolouration of your skin or the whites of your eyes (jaundice) and/or pain under your ribs and around the area of your stomach (cholestasis, liver necrosis),
- any signs of fever or infection (cough, sore throat, sore mouth or urinary problems).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- nausea (feeling sick) or vomiting (being sick),
- low red blood cell count (anaemia).

Less frequent side effects:

- loss of appetite,
- sprue-like symptoms, such as diarrhoea, stomach pain and weight loss,

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- mouth ulcers,
- hair loss,
- various types of cancers including blood, lymph, skin, and uterus or cervical cancers,
- cancer of the spleen and liver (in patients with a condition called inflammatory bowel disease),
- ulcers in the intestines,
- diarrhoea,
- increased sensitivity to sunlight and UV light,
- low sperm count in men.

Side effects with an unknown frequency:

- low blood sugar in children.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to:

SAHPRA: <https://www.sahpra.org.za/health-products-vigilance/>

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088

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By reporting side effects, you can help provide more information on the safety of PURI-NETHOL.

5. How to store PURI-NETHOL

Store all medicines out of reach of children.

Store at or below 25 °C.

Protect from light.

Keep dry.

Keep in original packaging until required for use.

Do not store in a bathroom.

Do not use after the expiry date stated on the label.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What PURI-NETHOL contains

The active substance is 50 mg of 6-mercaptopurine.

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

Contains sugar: Lactose monohydrate 59 mg

What PURI-NETHOL looks like and contents of the pack

Pale, yellow, round tablets, biconvex, scored on one side, engraved PT above the score and 50 below the score and plain on the other side.

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25 tablets are packed into an amber glass bottle. The bottle is closed with a child resistant closure with an induction heat seal liner. The bottle is placed in an outer cardboard carton together with a leaflet.

Not all packs or pack sizes may be marketed.

HOLDER OF THE CERTIFICATE OF REGISTRATION

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead

2191

Hotline: 0800 122 912 (South Africa)

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13 February 2022

Registration number:

H2751 (Act 101/1965)

Access to the corresponding Professional Information

SAHPRA Repository of Professional Information and Patient Information

Leaflets:

<https://www.sahpra.org.za/pi-pil-repository/>

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Aspen Pharmacare:

E-mail: Medinfo@aspenpharma.com

Tel: 0800 118 088

Botswana: BOT1703040 S2

Namibia: NS2 14/26/0598