

PURI-NETHOL®

mercaptopurine tablets 50 mg

Consumer Medicine Information (CMI)

What is in this leaflet

This leaflet answers some common questions about PURI-NETHOL tablets. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the expected benefits of you taking PURI-NETHOL against the risks this medicine could have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with your medicine.

You may need to read it again.

What PURI-NETHOL is used for

PURI-NETHOL contains the active ingredient mercaptopurine which belongs to a group of medicines called anti-neoplastic agents. Within this group, PURI-NETHOL belongs to a class of medicines called purine antimetabolites. These medicines are used to treat blood cancers.

PURI-NETHOL is used to treat acute promyelocytic leukaemia (APL)/ acute myeloid leukaemia M3 (AML M3) and acute lymphoblastic leukaemia (ALL). These are different types of cancer affecting the blood. In people with blood cancer, abnormal blood cells are formed in the bone marrow which multiplies uncontrollably, crowding out and interfering with the vital functions of normal healthy blood cells.

PURI-NETHOL is often given in combination with other medicines used to treat cancer of the blood.

It works by interfering with the function of the bone marrow and reducing the number of abnormal blood cells which are causing your illness.

Ask your doctor if you have any questions about why PURI-NETHOL has been prescribed for you.

Your doctor may have prescribed this medicine for another purpose.

PURI-NETHOL is available only with a doctor's prescription.

Before you take it

When you must not take it

Do not take it if:

- you have ever had an allergic reaction before to mercaptopurine or to any of the ingredients in PURI-NETHOL listed at the end of this leaflet
- the packaging is torn or shows signs of interference, or if the tablets appear to be broken, damaged or discoloured
- the expiry date on the packaging has passed. If you take this medicine after the expiry date has passed, it may not work as well. If the pharmacist has repacked the medicine for you, there may not be an expiry date on the pack.

Before you start taking it

Tell your doctor if:

- **you have taken PURI-NETHOL or a medicine called Lanvis™**

(thioguanine) before and it didn't work

- **you have been, or plan to be vaccinated with a 'live' vaccine**
- **you are planning to become pregnant or father a child**
- **you have a NUDT15 Mutation**
- **Lesch-Nyhan Syndrome**
- **Problems with galactose intolerance**
- **Inflammatory Bowel Disease (IBD)**
- **Are TPMT deficient**

As with all cytotoxic drugs, PURI-NETHOL may harm eggs and sperm. Reliable contraception methods must be taken to avoid pregnancy whilst you or your partner is taking this medicine.

- **you are pregnant**

PURI-NETHOL may be harmful to an unborn baby when taken by a pregnant woman. It is recommended that you avoid becoming pregnant while taking PURI-NETHOL.

If you are already pregnant, your doctor will weigh up the expected benefits of PURI-NETHOL to you against the possible risks to your unborn baby.

- **you are breastfeeding or planning to breastfeed.**

It is not recommended for use while breast feeding as it is found in breast milk.

- **you have any other health problems, especially:**

- liver disease
- kidney disease
- thiopurine methyltransferase deficiency (a rare enzyme disorder).

- you are allergic to any other medicines, foods, dyes or preservatives.

If you have not told your doctor about any of the above, tell them before you start taking PURI-NETHOL.

Taking other medicines

Tell your doctor if you are taking any other medicines, including the oral contraceptive pill or medicines you buy without a prescription from a pharmacy, supermarket or health food shop.

Some medicines may be affected by PURI-NETHOL or may affect how well it works. You may need to take different amounts of your medicine or you may need to take different medicines. These include:

- allopurinol, oxipurinol and thiopurinol
- anti-inflammatory medicines used to treat ulcerative colitis and Crohn's disease, such as olsalazine, mesalazine and sulphasalazine
- anticoagulant medicines used to thin the blood, such as warfarin and acenocoumarol
- 6-thioguanine, also used to treat blood cancers
- myelosuppressive agents
- vaccinations with 'live' organism vaccines
- ribavirin
- methotrexate
- infliximab

Your doctor will be able to tell you more about what to do when taking PURI-NETHOL with other medicines.

PURI-NETHOL is often used in combination with other medicines used to treat cancer.

How to take it

How much to take

Take PURI-NETHOL exactly as your doctor has prescribed.

Your doctor will tell you how many PURI-NETHOL tablets to take each day.

Your doctor will calculate the dose based on either your body weight or your body surface area (the area of skin you have). If you have pre-existing liver or kidney problems, your doctor may decide to reduce your PURI-NETHOL dose.

The usual recommended dose is 2.5 mg per kilogram of body weight per day, or 50 mg to 75 mg per square metre of body surface area daily.

Your doctor will calculate your PURI-NETHOL dose for you. Your doctor may adjust the dose depending on the type of blood cancer you have, your response to treatment and other medicines being used to treat your illness.

Never take more tablets than your doctor has prescribed.

Your doctor may do regular blood and urine tests to make sure that PURI-NETHOL is working for you.

How to take it

Swallow tablets whole with a glass of water. Do not take the tablets with milk or dairy products. The tablets may be taken with food or on an empty stomach.

If halving of a tablet is required, care should be taken not to contaminate the hands or inhale the drug.

When to take it

Take your dose at least 1 hour before or 2 hours after milk and dairy products

If you forget to take it

Do not take an extra dose. Wait until the next dose and take your normal dose then.

Do not try to make up for the dose that you missed by taking more than one dose at a time.

If you are not sure what to do, ask your doctor or pharmacist.

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Information Centre (0800 POISON or 0800 764 766) for advice, or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else has taken too much PURI-NETHOL. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Symptoms of overdose include nausea, vomiting, diarrhoea and loss of appetite. It could have serious effects on your bone marrow, blood cells and the way your liver functions.

While you are taking it

Things you must do

Tell all doctors, dentists and pharmacists treating you that you are taking PURI-NETHOL.

Tell your doctor if you become pregnant while taking PURI-NETHOL.

As with many medicines used to treat cancer, you should use reliable contraception when taking PURI-NETHOL, whether you are male or female.

Exposure to sunlight and UV light must be limited. Wear protective clothing and use a sunscreen with a high protection factor.

Tell your doctor if, for any reason, you have not taken PURI-NETHOL exactly as prescribed.

Otherwise, your doctor may think it is not working for you and change your medicine unnecessarily.

Tell your doctor if you feel that PURI-NETHOL is not helping your condition.

Things you must not do

Do not stop taking PURI-NETHOL or change the dose without first checking with your doctor.

Do not let yourself run out of medicine over the weekend or on holidays.

Do not give PURI-NETHOL to anyone else even if they have the same condition as you.

Do not take any other medicines whether they require a prescription or not without first asking your doctor or a pharmacist.

Do not drive a vehicle or operate machinery until you know how PURI-NETHOL affects you.

- frequent infections such as fever, severe chills, sore throat or mouth ulcers
- bleeding or bruising more easily than normal
- a stiff and tender abdomen, possibly with chest pain (this may be caused by pancreatitis).

Your doctor can prescribe helpful medication if you develop any of the above side effects.

PURI-NETHOL can also have side effects which affect your kidney and liver function, bone marrow and blood count. This may make you feel tired and weak. It will also affect how well your blood clots. Your doctor will do regular blood and urine tests to check for these problems.

Your doctor may also recommend that you change your dose of PURI-NETHOL if you experience any of these side effects.

Tell your doctor if you notice anything else that is making you feel unwell, even if you think the problems are not connected with this medicine and are not referred to in this list.

Other side effects not listed above may also occur in some people.

Do not be alarmed by this of possible side effects.

You might not experience any of them.

Side-Effects

Tell your doctor as soon as possible if you do not feel well while you are taking PURI-NETHOL.

All medicines can have unwanted side effects. Sometimes they may be serious, but often they are not. You may need medical treatment if you get some of the side effects.

If you think PURI-NETHOL is causing you to have an allergic (hypersensitivity) reaction, TELL YOUR DOCTOR IMMEDIATELY.

Symptoms include:

- severe skin rash, itching or hives
- swelling of the face, lips, mouth or throat
- difficulty breathing or swallowing
- fever
- low blood pressure (feeling dizzy and faint).

Tell your doctor if you notice any of the following:

- jaundice (yellowing of the skin and/or eyes)
- nausea
- vomiting
- weight loss
- skin rash

take any other medicine, in a bathroom or near a sink.

Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it.

A locked cupboard at least one and a half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking PURI-NETHOL, or the medicine has passed its expiry date, ask your pharmacist what to do with any tablets that are left over.

Product description

What it looks like

PURI-NETHOL tablets are Pale yellow, round, biconvex tablets, marked PT above the line and 50 below the line on one side and plain on the other

Ingredients

Active ingredient:

Each tablet contains 50 mg mercaptopurine.

Inactive ingredients:

- lactose
- hydrolysed starch
- maize
- stearic acid
- magnesium stearate.

After taking it

Storage

Keep your tablets in the bottle until it is time to take them.

If you take the tablets out of the bottle they may not keep as well.

Keep it in a cool dry place, protected from light, where the temperature stays below 25°C.

Do not leave it in a car or on windowsills. Do not store it, or

Distributor

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