

# PURINETONE TABLETS MERCAPTOPURINE 50MG

## Mercaptopurine Monohydrate (50mg)

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### 1. What Purinetone is used for

Purinetone tablets contain the active substance called 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.

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

### 2. How Purinetone works

6-Mercaptopurine is sulphhydryl analogue of the purine bases, adenine and hypoxanthine and acts as a cytotoxic antimetabolite.

6-Mercaptopurine is an inactive pro-drug which acts as a purine antagonist but requires cellular uptake and intracellular anabolism to thioguanine nucleotides (TGNs) for cytotoxicity. The TGNs and other metabolites (e.g.6- methyl-mercaptopurine ribonucleotides) inhibit de novo purine synthesis and purine nucleotide interconversions. The TGNs are also incorporated into nucleic acids and this contributes to the cytotoxic effects of the medicinal product.

### 3. Before you use Purinetone

#### When you must not use it

If you are allergic to 6- mercaptopurine

or any of the other ingredients of this medicine. Do not get vaccinated with yellow fever vaccine whilst you are taking 6-mercaptopurine because it may be fatal.

#### Before you start to use it

Talk to your doctor or pharmacist before taking Mercaptopurine

- If you have recently received, or are due to receive, a vaccination (vaccine). If you take Mercaptopurine, 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 Mercaptopurine
- If you have reduced liver function or liver damage
- If you have a genetic condition called TPMT (thiopurine methyltransferase) deficiency
- If you have an inherited mutation in the NUDT15- gene (a gene which is involved in the break- down of Mercaptopurine 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.
- 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 Mercaptopurine could put you at greater risk of:

- Tumors, including skin cancer. Therefore, when taking Mercaptopurine, avoid excessive exposure to sunlight, wear protective clothing and use protective sunscreen with a high

protection factor.

- Lymphoproliferative disorders:
  - Treatment with Mercaptopurine increases your risk of getting a type of cancer called lymphoproliferative disorder. With treatment regimen containing multiple immune suppressants (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 Mercaptopurine 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.

#### Infections

When you are treated with Mercaptopurine 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).

#### Blood tests

Treatment with Mercaptopurine 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.

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### Other laboratory tests

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

### Liver function

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

### Children and adolescents

Low blood sugar levels (sweating more than usual, nausea, dizziness, confusion, etc.) have been reported in some children receiving Mercaptopurine; 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 Mercaptopurine.

### Taking other medicines

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)

## 4. How to use Purinetone

### How much to use

For adults and children the usual dose is 2.5 mg/kg bodyweight per day. The dosage should be carefully adjusted to suit the individual patient. Mercaptopurine has been used in various combination therapy schedules for acute leukemia and the literature should be consulted for details. Consideration should be given to reducing the dosage in patients with impaired hepatic or renal function. When allopurinol and Mercaptopurine are administered concomitantly it is essential that only a quarter of the usual dose of Mercaptopurine is given since allopurinol decreases the rate of catabolism of Mercaptopurine.

### When to use it

You can take Mercaptopurine 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.

### How long to use it

The dose and duration of administration depend on the nature and dosage of other cytotoxic agents given in conjunction with Mercaptopurine.

### If you forget to use it

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

### If you use too much (overdose)

If you take more Purinetone than you

should, tell your doctor immediately or go to a hospital straight away. Take the medicine pack with you.

## 5. While you are using it

### Things you must do

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

- When you take Mercaptopurine, 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 Mercaptopurine. High levels of uric acid may damage your kidneys

- Your doctor may sometimes change your dose of Mercaptopurine as a result of these tests.
- Always take Mercaptopurine 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 m<sup>2</sup> 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

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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.

### **Things you must not do**

*Having vaccines while you are taking Mercaptopurine*

If you are going to have a vaccination speak to your doctor or nurse before you have it. If you take Mercaptopurine, 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 have them whilst you are taking Mercaptopurine.

### *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 Mercaptopurine is not recommended during pregnancy, particularly in the first trimester (three months) because it may cause damage to the fetus. If you are pregnant your doctor will consider the risks and benefits to you and your baby before prescribing Mercaptopurine for you.

If you or your partner are taking Mercaptopurine, you must use a reliable form of contraception to avoid pregnancy for the whole course of Mercaptopurine treatment and for at least 3 months after receiving the last

dose of Mercaptopurine. **This applies to both men and women.**

### *Breast-feeding*

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

### **Things to be careful of**

#### *Pellagra*

Talk to your doctor immediately if you experience diarrhea, 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.

#### *Sun and UV light*

While you are taking Purinetone, 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).

## **6. Side effects**

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

If you get any of the following side effects, talk to your specialist doctor or go to hospital immediately:

- 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 Mercaptopurine.

- Any signs of fever or infection (sore throat, sore mouth or urinary problems) or any unexplained bruising or bleeding. Treatment with Mercaptopurine 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

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### 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 Mercaptopurine; 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, nurse or pharmacist. This includes any possible side effects not listed in this leaflet.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website [npra.gov.my](http://npra.gov.my) [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

### 7.Storage and Disposal of Purinetone

- 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 pack after 'Exp'.
- Do not store your Purinetone tablets above 30°C.
- 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 dispose them according to disposal of dangerous substance guidelines. Only keep the tablets if your doctor tells you to.

### 8.Product Description

#### What it looks like

Pale yellow to yellow, round tablet.

### Ingredients

Mercaptopurine, Lactose monohydrate, Corn starch, Carboxymethyl cellulose calcium, Hydroxypropyl cellulose, Silicon dioxide, Magnesium stearate, Isopropyl alcohol

### MAL number

MALXXXXXX

### 9.Manufacturer and Product Registration Holder

#### Manufacturer

Korea United Pharm. Inc.  
107, Gongdan-ro, Yeonseo-myeon,  
Sejong-si, Republic of Korea

#### Product Registration holder

Averroes Pharmaceuticals Sdn. Bhd.  
03-08-01 & 03-09-01, Block 3, Presint  
Alami, Worldwide business centre II,  
Persiaran Akuatik, Section 13, 40100  
Shah Alam, Selangor, Malaysia

### 10. Date of revision

27 May 2025

### 11. Serial Number

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