

SCHEDULING STATUS: S4

MERCAPTOPURINE EQUITY, 50 mg 6-mercaptopurine, Tablets

6-mercaptopurine

Contains sugar (59,00 mg lactose anhydrous per tablet)

Read all of this leaflet carefully before you take MERCAPTOPURINE EQUITY

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist, nurse or other healthcare provider.
- MERCAPTOPURINE EQUITY 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 MERCAPTOPURINE EQUITY is and what it is used for
2. What you need to know before you take MERCAPTOPURINE EQUITY
3. How to take MERCAPTOPURINE EQUITY
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5. How to store MERCAPTOPURINE EQUITY
6. Contents of the pack and other information

1. What MERCAPTOPURINE EQUITY is and what it is used for

The active ingredient is 6-mercaptopurine.

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

MERCAPTOPURINE EQUITY 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 MERCAPTOPURINE EQUITY

Do not take MERCAPTOPURINE EQUITY:

If you are allergic (hypersensitive) to 6-mercaptopurine or any of the other ingredients of MERCAPTOPURINE EQUITY (listed in section 6).

Warnings and precautions

Take special care with MERCAPTOPURINE EQUITY:

- If you have recently received, or are due to receive, a vaccination (vaccine). If you take MERCAPTOPURINE EQUITY, 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 EQUITY
- If you have reduced liver function or liver damage
- If you have a genetic condition where your body produces too little of the enzyme called TPMT (thiopurine methyltransferase).
- If you have an inherited mutation in the NUDT15-gene (a gene which is involved in the breakdown of MERCAPTOPURINE EQUITY 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 EQUITY could put you at greater risk of:

- tumours, including skin cancer. Therefore, when taking MERCAPTOPURINE EQUITY, avoid excessive exposure to sunlight, wear protective clothing and use protective sunscreen with a high protection factor

- lymphoproliferative disorders:
 - treatment with MERCAPTOPURINE EQUITY 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 MERCAPTOPURINE EQUITY 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.
- Sensitivity to the sun, you must wear protective clothing and use a sunscreen with a high protection factor.

Infections

When you are treated with MERCAPTOPURINE EQUITY the risk of viral, fungal and bacterial infections is increase 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 EQUITY 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

MERCAPTOPURINE EQUITY is toxic to your liver. Therefore, your doctor will carry out weekly liver function tests when you are taking 6-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 EQUITY; 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 EQUITY.

Other medicines and MERCAPTOPURINE EQUITY

Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary or traditional 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 MERCAPTOPURINE EQUITY

If you are going to have a vaccination speak to your doctor or nurse before you have it. If you take MERCAPTOPURINE EQUITY, 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 EQUITY.

MERCAPTOPURINE EQUITY with food and drink

You can take MERCAPTOPURINE EQUITY 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, breastfeeding and fertility

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 MERCAPTOPURINE EQUITY.

Do not take MERCAPTOPURINE EQUITY during pregnancy or if you are planning to have a baby. This applies to both men and women. MERCAPTOPURINE EQUITY may harm your sperm or eggs. Reliable contraception must be used to avoid pregnancy whilst you or your partner are taking MERCAPTOPURINE EQUITY. Women should continue to use effective contraception for at least 8 months after stopping treatment. Men should continue to use effective contraception for at least 5 months after stopping treatment. Ask your doctor for advice.

Do not take MERCAPTOPURINE EQUITY while breastfeeding your infant.

Driving and using machines

It is not always possible to predict to what extent MERCAPTOPURINE EQUITY may interfere with the daily activities of a patient. You should ensure that you do not engage in activities requiring driving a vehicle or use machines until you are aware of the measure to which MERCAPTOPURINE EQUITY affects you.

MERCAPTOPURINE EQUITY contains lactose anhydrous

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before you take MERCAPTOPURINE EQUITY tablets.

3. How to take MERCAPTOPURINE EQUITY

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

Always take MERCAPTOPURINE EQUITY exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

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

When you take MERCAPTOPURINE EQUITY, 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 6-mercaptopurine. High levels of uric acid may damage your kidneys.

Your doctor may sometimes change your dose of MERCAPTOPURINE EQUITY as a result of these tests.

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.

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 MERCAPTOPURINE EQUITY in the evening as this may lower the risk of the leukaemia getting worse again in the future.

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.

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 MERCAPTOPURINE EQUITY needs to be reduced.

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 have the impression that the effect of MERCAPTOPURINE EQUITY is too strong or too weak, talk to your doctor.

If you take more MERCAPTOPURINE EQUITY than you should

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

If you forget to take MERCAPTOPURINE EQUITY

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

4. Possible side effects

MERCAPTOPURINE EQUITY can have side effects.

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

If any of the following happens, stop using MERCAPTOPURINE EQUITY and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or

breathing,

- rash or itching,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to MERCAPTOPURINE EQUITY. 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:

- an allergic reaction with joint pain, skin rashes, high temperature (fever),
- any signs of fever or infection (sore throat, sore mouth or urinary problems) or any unexplained bruising or bleeding. Treatment with MERCAPTOPURINE EQUITY affects your bone marrow and will cause a reduction in your white blood cells and platelets (this is a very frequent side effect),
- yellowing of the skin and whites of the eyes. If you get such symptoms, you should stop taking MERCAPTOPURINE EQUITY.

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:

- low red blood cell count (anaemia)
- nausea (you feel sick) or vomiting (being sick)
- inflammation of the pancreas (pancreatitis); symptoms may include abdominal pain or feeling or being sick

Less frequent side effects:

- loss of appetite
- mouth ulcers
- damage to your liver (hepatic necrosis)
- hair loss
- various types of cancers including blood, lymph and skin cancers
- 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
- mild diarrhoea (loose stool) and severe, chronic diarrhoea with substantial weight loss, abdominal pain, fatigue, bloating, nausea, vomiting and low iron (Sprue-like symptoms)

Side effects with unknown frequency:

- 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 6-mercaptopurine; however, most of the children were under the age of six years old and had a low body weight

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. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of MERCAPTOPURINE EQUITY.

5. How to store MERCAPTOPURINE EQUITY

Store all medicines out of reach of children.

Store MERCAPTOPURINE EQUITY at or below 25 °C.

Keep the bottle tightly closed.

Do not use after the expiry date stated on the label / carton / bottle.

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 MERCAPTOPURINE EQUITY contains

Each tablet contains 50 mg 6-mercaptopurine.

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

What MERCAPTOPURINE EQUITY looks like and contents of the pack

MERCAPTOPURINE EQUITY is a round, yellowish scored tablet.

MERCAPTOPURINE EQUITY tablets are presented in 20 ml amber glass type III bottles and child-proof propylene cap with silica gel.

Pack sizes

25 tablets/carton box

50 (2 x 25) tablets/carton box

Bottles are packed in a carton box.

Holder of Certificate of Registration

Equity Pharmaceuticals (Pty) Ltd

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An electronic copy of the translated Patient Information Leaflet (PIL) is available on the Equity website:

<http://www.equitypharmaceuticals.co.za> or <http://www.sahpra.org.za>