LANVIS TABLET

Thioguanine (40mg)

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What Lanvis Tablet is used for

Lanvis Tablet contains a medicine called thioguanine. This belongs to a group of medicines called cytotoxics (also called chemotherapy). Lanvis Tablet is used for certain blood problems and cancers of the blood.
Lanvis Tablet is used for acute (fast-growing) leukaemias, especially:

- Acute myelogenous leukaemia (also called acute myeloid leukaemia or AML) - a fast-growing disease that increases the number of white blood cells produced by the bone marrow. This can cause infections and bleeding.
- Acute lymphoblastic leukaemia (also called acute lymphocytic leukaemia or ALL) - a fast-growing disease which increases the number of immature white blood cells. These immature white blood cells are unable to grow and function properly and therefore cannot fight infections and may cause bleeding.

Ask your doctor if you would like more explanation about these diseases.

How Lanvis Tablet works

Lanvis Tablet works by reducing the number of new blood cells your body makes.

Before you use Lanvis Tablet

- *<u>When you must not take it</u>*

You must not take Lanvis Tablet if you are allergic (hypersensitive) to thioguanine or any of the other ingredients of Lanvis Tablet (See section 8: Product Description)
Do not take Lanvis Tablet if the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking Lanvis Tablet.

Pregnancy and breast feeding
Do not take Lanvis Tablet if you are planning to have a baby. This applies to both men and women. Lanvis Tablet may harm your sperm or eggs. Reliable contraceptive precautions must be taken to avoid pregnancy whilst you or your partner are taking these tablets. Ask your doctor for advice.
If you are already pregnant, it is important to talk to your doctor before taking Lanvis Tablet.
Do not breast-feed while taking Lanvis Tablet. Ask your doctor or midwife for advice.

Talk to your doctor immediately if you experience intense itching without a rash during your pregnancy. You may also experience nausea, and loss of appetite together with itching, which indicates that you have a condition called cholestasis of pregnancy (condition affecting the liver during pregnancy).

- *<u>Before you start to use it</u>*

Before you take Lanvis Tablet, tell your doctor or pharmacist if:

- you have been taking this medicine for a long period of time. This may increase the chance of side effects, such as liver problems
- you have a condition where your body produces too little of something called TPMT or 'thiopurine methyltransferase'
- you have 'Lesch-Nyhan Syndrome'. This is a rare condition that runs in families caused by a lack of something called HPRT or 'hypoxanthine-guanine-phosphoribosyltransferase'
- you have inherited mutation in the NUDT15-gene (a gene which is involved in the breakdown of thioguanine in the body)
- you need to expose to sunlight and UV light. It is recommended to wear protective clothing and use a sunscreen with high protection factor to reduce exposure to sunlight and UV light.

If you are not sure if any of the above applies to you, talk to your doctor, nurse or pharmacist before taking Lanvis Tablet.

- *<u>Taking other medicines</u>*

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. This includes herbal medicines.
In particular tell your doctor or pharmacist if you are taking any of the following:

- olsalzine or mesalazine – used for a bowel problem called ulcerative colitis
- sulfasalazine – used for rheumatoid arthritis or ulcerative colitis.

- mercaptopurine - cytotoxic drug (patients who no longer respond to mercaptopurine will not respond to Lanvis)
- other cytotoxic drugs or radiation therapy

– *Having vaccines while you are taking Lanvis Tablet*

If you are going to have a vaccination speak to your doctor or nurse before you have it. This is because some vaccines (like polio, measles, mumps and rubella) may give you an infection if you have them whilst you are taking Lanvis.

– *Important information about some of the ingredients of Lanvis Tablet*

Lanvis Tablet contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before you take Lanvis Tablet.

How to use Lanvis Tablet

Lanvis should only be given to you by a specialist doctor who is experienced in treating blood problems.
The label on your pack will tell you how many tablets to take and how often to take them. If the label doesn't say or if you are not sure, ask your doctor, nurse or pharmacist.

- Swallow your tablets whole with a glass of water.
- If you need to break your tablet in half, do not inhale any tablet powder. Wash your hands afterwards.
- When you take Lanvis 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 sometimes change your dose as a result.

– *How much to use*

Always take Lanvis Tablet exactly as your doctor has told you.
The dose of Lanvis Tablet you are given will be worked out by your doctor based on:

- your body size (surface area)
- the results of your blood test
- the disease being treated.
- The usual dose is between 60 and 200 mg/m^2 body surface area per day. If you have a problem with your kidneys or liver you may be given a lower dose of Lanvis Tablet.

– *When to use it*

The administration depends on your condition. Always take Lanvis Tablet exactly as your doctor has told you. It is important to take your medicine at the right times.

– *How long to use it*

The administration depends on your condition. Always take Lanvis Tablet exactly as your doctor has told you.

– *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 Lanvis Tablet than you should, tell your doctor immediately or go to the Emergency Department of your nearest hospital. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using Lanvis Tablet

– *Things you must do*

Tell your doctor if, for any reason, you have not taken your medicine exactly as directed.
Otherwise, your doctor may think that it was not working as it should and change your treatment unnecessarily.
Do not take a double dose to make up for the one you have missed.

Visit your doctor regularly so they can check your progress and make sure your medicine is working.
Tell any other specialist, doctor, dentist or pharmacist that you are on Lanvis Tablet, especially if you are about to be started on any new medicines, immunisations, vaccinations or radiotherapy.
Tell your doctor if you become pregnant, are trying to become pregnant or trying to father a child.

– *Things you must not do*

Do not give this medicine to anyone else even if their symptoms seem similar to yours.
Do not use Lanvis Tablet to treat any other complaints unless your doctor says to.

– *Things to be careful of*

Do not have any vaccinations without your doctor's approval. Lanvis Tablet can lower the number of white blood cells and platelets in your blood. This means that you have an increased chance of getting an infection or bleeding.

Side Effects

Like all medicines, Lanvis Tablet can cause side effects, although not everybody gets them.
If you get any of the following, talk to your specialist doctor or go to hospital straight away:

- any signs of fever or infection (sore throat, sore mouth or urinary problems)

- any **unexpected** bruising or bleeding, as this could mean that too few blood cells of a particular type are being produced
- if you **suddenly** feel unwell (even with a normal temperature)
- any yellowing of the whites of the eyes or skin (jaundice).
- if you experience severe chills, fever, sore throat, cough, flu-like symptoms and headache accompanied by nausea, rash, and/or confusion, while you are taking Lanvis Tablet with other cancer treatments as these symptoms may suggest that you have a bacterial, viral or fungal infection. Your doctor may prescribe antiviral therapy and other supportive treatments.

Talk to your doctor if you have any of the following side effects which may also happen with this medicine:

Very common (affects more than 1 in 10 people)

- a drop in the number of your blood cells
- jaundice and severe liver damage - with long term use or high doses of Lanvis Tablet.

Common (affects less than 1 in 10 people)

- liver damage which can cause jaundice or an enlarged liver (a swelling below your ribcage) – with short term use of Lanvis.
- feeling or being sick (nausea or vomiting), diarrhoea and mouth ulcers.
- High uric acid

Uncommon (may affect up to 1 in 100 people)

- cholestasis of pregnancy, which can cause intense itching, especially on the hands and feet.

Rare (affects less than 1 in 1,000 people)

- a problem with your bowels, called necrotising colitis which can cause severe stomachache, being sick, diarrhoea, bloody stool and fever
- severe liver damage when used with other chemotherapy drugs, oral contraceptives and alcohol.

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 [Consumers--> Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Lanvis Tablet

– *Storage*

- Keep out of the reach and sight of children.
- Do not use Lanvis Tablet after the expiry date which is stated on the pack after 'Exp'.
- Store your Lanvis Tablet below 30°C.

– *Disposal*

- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

– *What it looks like*

Lanvis Tablets are white to off-white tablet, round, biconvex scored and imprinting 'T40' on upper side, without score and debossing on lower side.

– *Ingredients*

- *Active ingredient*

  Thioguanine.

- *Inactive ingredients*

  lactose monohydrate, potato starch, acacia, stearic acid, magnesium stearate and purified water.

– *MAL number*

MAL13065045ACZ

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Product Registration Holder

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