

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE
PATIENT MEDICATION INFORMATION

PrLANVIS®
Thioguanine tablets, USP

Read this carefully before you start taking **LANVIS®** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **LANVIS®**.

Serious Warnings and Precautions

LANVIS® is a cytotoxic agent. This means it kills cells in your body including cancer cells. LANVIS® must only be given to you by a healthcare professional experienced in the use of drugs to treat cancer.

Side effects of LANVIS® can include:

Bone marrow suppression (neutropenia, thrombocytopenia or anemia): Lanvis® can affect your bone marrow's ability to make blood cells. It can cause you to have low blood cell counts and platelets. This can cause life-threatening infections and bleeding and is especially dangerous if your body does not make enough of the enzyme, thiopurine methyltransferase (TPMT).

Neutropenia is a low white blood cell count.

Thrombocytopenia is low platelets in the blood.

Anemia is a low red blood cell count.

Liver damage.

Severe infection following immunization with a live vaccine. You should not receive a live vaccine when you are taking LANVIS®.

What is LANVIS® used for?

LANVIS® is used to treat acute leukemia. This is a cancer of the blood and bone marrow.

LANVIS® will not be given to you as treatment to help prevent your cancer from coming back after it had disappeared. It will also not be given as a long-term treatment.

How does LANVIS® work?

LANVIS® works by reducing the number of new blood cells your body makes.

What are the ingredients in LANVIS®?

Medicinal ingredients: thioguanine

Non-medicinal ingredients: gum acacia, lactose, magnesium stearate, potato starch and stearic acid

LANVIS® comes in the following dosage forms:

Tablets, 40 mg

Do not use LANVIS® if:

- your disease has previously stopped responding to LANVIS® or to treatment with another drug called PURINETHOL. The active ingredient in this drug is mercaptopurine.
- you are allergic to thioguanine or any of the other ingredients in this medicine, including any non-medicinal ingredient or component of the container.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take LANVIS®. Talk about any health conditions or problems you may have, including if you:

- are pregnant, or you are planning a pregnancy;
Females who are pregnant or plan to become pregnant:
 - LANVIS® may harm your unborn baby.
 - Avoid becoming pregnant while you are taking LANVIS®.
 - Use effective methods of birth control while you are taking LANVIS®.
Talk to your healthcare professional about methods of birth control that may be right for you.
 - If you do become pregnant while taking LANVIS®, stop using it and tell your healthcare professional right away.
- are breastfeeding or are planning to breastfeed. It is not known if LANVIS® passes into breast milk. You and your doctor should discuss whether you will take LANVIS® or breastfeed. You should not do both. Talk to your doctor about ways to feed your baby while you are taking LANVIS®.
- plan to father a child. Your partner should not become pregnant while you are using LANVIS®. You should use birth control to prevent pregnancy in your partner during your treatment. If your partner becomes pregnant while you are receiving LANVIS®, tell your healthcare professional right away.
- you have been vaccinated, or are planning to be vaccinated, with a live vaccine.
- Your body does not make enough of (you are deficient in) the enzyme called thiopurine methyltransferase (TPMT). If you do not have enough of this enzyme, you may get serious side effects if you use LANVIS®.
- you have kidney problems;
- you have liver problems;
- you have a mutation in your NUDT15 gene. If you have this mutation, you may be more likely to develop low levels of white cells in your blood. This may cause you to get infections. The mutation may also put you at a higher risk of losing your hair. Patients of Asian descent may be particularly at risk.
- You are going to be exposed to sunlight, sun lamps or tanning beds. Your treatment with LANVIS® may make you more sensitive to sun and ultraviolet (UV) light. Limit your exposure to the sun and to UV light while you are taking LANVIS®. Be sure to also wear protective clothing and use sunscreen with a high protection factor (spf).

Other warnings you should know about:

Intestinal necrosis and perforation can occur with LANVIS[®] use.

- Intestinal necrosis is a condition that occurs when there is low blood flow to the intestines.
- Intestinal perforation is when a hole forms in the wall of the intestine.
- These are serious and potentially life-threatening side effects of LANVIS[®] use. If you experience bloating or swelling in the abdomen, bloody stools, diarrhea severe abdominal pain and vomiting, call your healthcare professional right away. These may be signs that you are experiencing intestinal necrosis or a perforation.

Bone marrow suppression:

As LANVIS[®] use may cause low white blood cells, low red blood cells and low platelets, you may be at increased risk of infection, bleeding and bruising, be sure to:

- Wash your hands often.
- Keep your mouth and skin clean and healthy.
- Avoid people who are sick.
- Try not to bump into things or cut yourself.
- Blow your nose gently.
- Avoid getting constipated.
- Brush your teeth gently with a soft toothbrush.
- Avoid products containing aspirin or ibuprofen.
- Rest if you need to.
- Call your doctor if you have a fever or other flu-like symptoms or if you have any bleeding, bruising, fatigue, tiny red spots on the skin or weakness.

Risk for cancer and damage to DNA:

Thioguanine, the medicinal ingredient in LANVIS[®], may cause cancer or damage to the genetic material in cells (DNA). Talk to your healthcare professional if you have questions about this.

Driving and operating machines:

Before you do tasks that require special attention, wait until you know how you respond to LANVIS[®] treatment.

Blood tests:

Your doctor will ask you to have blood tests done before you take LANVIS[®] for the first time. Some of these tests will be repeated every week and others will be repeated every month while you are taking LANVIS[®]. This is to check your blood cell counts and to monitor how well your liver is working.

Your doctor may also perform genetic testing before or during your treatment. These tests will determine if you have the NUDT15 gene mutation and if you are deficient in the enzyme, TPMT. The results of these tests will help your doctor to know if your response to LANVIS[®] may be affected by your genetics. Your doctor may change your dose of LANVIS[®] after these tests.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

Serious Drug Interactions

- Vaccines containing live viruses. There is a risk for serious infections if these are given with LANVIS®.
- Other cytotoxic drugs or radiation therapy. The risk for bone marrow suppression is increased when these are used with LANVIS®.
- Olsalazine, mesalazine or sulphasalazine. These are medicines that prevent inflammation and are used in the treatment of inflammatory bowel disease.

The following may also interact with LANVIS®:

- Busulfan. This is a medicine used to treat a type of cancer.

How to take LANVIS®:

- Take this medicine exactly as your healthcare professional has told you to.
- Take it once per day by mouth.
- Check with your healthcare professional if you are not sure how to take it.
- Your healthcare professional will tell you how much LANVIS® to take and when to take it.

Usual starting dose: 2 mg / kg of body weight

If, after one month of treatment, your condition has not improved, your dose may be increased to 3 mg / kg of body weight.

The amount of LANVIS® you will take will depend on your weight and how you respond to treatment.

Your healthcare professional may interrupt or stop your treatment, or reduce your dose of LANVIS®. This will depend on how you are feeling or if your disease has gotten worse.

Overdose:

If you think you have taken too much LANVIS®, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

- If you miss a dose of LANVIS®, take it as soon as possible.
- If it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule as prescribed by your doctor.
- Never take two doses at the same time to make up for a missed dose.
- If you miss two doses of LANVIS®, contact your doctor.

What are possible side effects from using LANVIS?

These are not all the possible side effects you may feel when taking LANVIS®. If you experience any side effects not listed here, contact your healthcare professional.

Side effects may include:

- loss of appetite

- increased sensitivity to sun exposure

LANVIS® may cause abnormal blood test results. Your doctor may perform blood tests before you take LANVIS® and while you are taking it. Your doctor will interpret the results.

| Serious side effects and what to do about them | | | |
|---|--------------------------------------|--------------|---|
| Symptom / effect | Talk to your healthcare professional | | Stop taking drug and get immediate medical help |
| | Only if severe | In all cases | |
| VERY COMMON | | | |
| Neutropenia (decreased white blood cells): aches, feeling tired, fever, flu-like symptoms, any signs of infections (sore throat, sore mouth or urinary problems) | | X | |
| Thrombocytopenia (decreased platelets in the blood): bruising, fatigue, tiny red dots on the skin, weakness. | | X | |
| Anemia (decreased red blood cells): dizziness, feeling tired and weak, loss of energy, shortness of breath. | | X | |
| Liver damage: abdominal pain, dark urine, fatigue, itching, loss of appetite, nausea, rash, swelling in the abdomen, vomiting, weight loss, yellowing of the skin or eyes (jaundice). | | X | |
| COMMON | | | |
| Veno-occlusive disease (a condition where liver veins are blocked): enlargement of liver which causes abdomen to swell and fluid to accumulate there, yellowing of the skin or eyes (jaundice), vomiting of blood. | | X | |
| Nausea | X | | |
| Vomiting | X | | |
| Diarrhea (loose or watery and frequent stools) | X | | |
| Stomatitis (mouth sores and swelling): burning sensation and pain in the mouth, difficulty | X | | |

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| eating, swelling, sores or ulcers in the mouth. | | | |
| Esophageal varices (swollen veins in the lower section of the esophagus that can bleed): vomiting blood, black or bloody stools, lightheadedness and loss of consciousness in severe cases. | | X | |
| Hyperuricemia (high level of uric acid in the blood): fever, pain in a joint, swelling of a joint, or kidney problems. | | X | |
| RARE | | | |
| Intestinal necrosis or perforation (potentially life threatening conditions where intestines are damaged): bloating or swelling in the abdomen, bloody stools, diarrhea (loose or watery and frequent stools), severe abdominal pain, vomiting. | | | X |
| Severe liver damage: confusion, disorientation, coma, pain in upper right side of the abdomen, sleepiness, yellowing of the skin or eyes (jaundice). | | | X |

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

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| <p>Reporting Side Effects</p> <p>You can report any suspected side effects associated with the use of health products to Health Canada by:</p> <ul style="list-style-type: none"> • Visiting the Web page on Adverse Reaction Reporting (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html) for information on how to report online, by mail or by fax; or • Calling toll-free at 1-866-234-2345. <p><i>NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.</i></p> |
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Storage:

Store LANVIS® in a dry place between 15° and 25°C. Protect it from light.

LANVIS® is cytotoxic. Be careful not to contaminate your hands or inhale the drug when you are handling LANVIS®.

Return unused tablets to your healthcare professional. Be cautious when you are packaging your leftover LANVIS® for transportation.

Keep out of reach and sight of children.

If you want more information about LANVIS®:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>) or the Aspen Pharmacare Canada Inc. website (www.aspenpharma.ca), or by calling 1-844-330-1213.

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