

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr **LANVIS**[®]

Thioguanine tablets

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 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:

- have been vaccinated, or are planning to be vaccinated, with a live vaccine.
- are deficient in (your body does not make enough of) 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.
- have kidney problems.
- have liver problems.
- 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.
- 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:

- LANVIS may cause:
 - **Intestinal necrosis and perforation.**
 - 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 healthcare professional 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.
- **Increased risk of infections.** Taking LANVIS together with other treatments that weakens your immune system (immunosuppressive or chemotherapeutic agents) could put you at a greater risk of developing viral, fungal and bacterial infections. Your symptoms and complications can be more severe than patients who are not taking these medicines.

Talk to your healthcare professional right away if you notice any signs of infection. They may need to give you medicine to treat your infection.

- **Female patients**

Pregnancy and birth control

- If you are pregnant, or planning on becoming pregnant during treatment with LANVIS, there are specific risks you should discuss with your healthcare professional.
- 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.

Breastfeeding

- Do NOT breastfeed during treatment with LANVIS. It is not known if LANVIS passes into breast milk.
- You and your healthcare professional should discuss whether you will take LANVIS or breastfeed. You should not do both. Talk to your healthcare professional about ways to feed your baby while you are taking LANVIS.

- **Male patients**

- Do NOT father a child during treatment with LANVIS. 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.

- **Driving and using machines:**

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

- **Check-ups and testing:**

You will have regular visits with your healthcare professional before and during treatment with LANVIS. They will do:

- **Blood tests** to check your blood cell counts and monitor how well your liver is working. This will be 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.

- **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 healthcare professional to know if your response to LANVIS may be affected by your genetics. Your healthcare professional 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 dose:

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

- The usual starting dose is 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.
- 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, or a person you are caring for, 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 healthcare professional.
- Never take two doses at the same time to make up for a missed dose.
- If you miss two doses of LANVIS, contact your healthcare professional.

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, tell your healthcare professional.

Side effects may include:

- loss of appetite
- increased sensitivity to sun exposure

LANVIS may cause abnormal blood test results. Your healthcare professional may perform blood tests before you take LANVIS and while you are taking it. Your healthcare professional 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		

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	
Diarrhea (loose or watery and frequent stools)	X		
Stomatitis (mouth sores and swelling): burning sensation and pain in the mouth, difficulty eating, swelling, sores or ulcers in the mouth.	X		
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, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

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.

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>); the Aspen Pharmacare Canada Inc. website (www.aspenpharma.ca), or by calling 1-844-330-1213.

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