PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

LANVIS 40 mg tablets

Thioguanine

Contains sugar: Lactose monohydrate 150,0 mg

Read all of this leaflet carefully before you start taking LANVIS

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

1. What LANVIS is and what it is used for

LANVIS belongs to a group of medicines called cytotoxics (also called chemotherapy). LANVIS is used for treatment of cancers of the blood. It works by reducing the number of new blood cells your body makes.

LANVIS is used for acute:

- **Acute myelogenous leukaemia** (also called acute myeloid leukaemia or AML).
- **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.

2. What you need to know before you take LANVIS

Do not take LANVIS:

- if you are hypersensitive (allergic) to thioguanine or to any of the other ingredients of LANVIS (listed in section 6).
- Do not receive live vaccines while on LANVIS.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking LANVIS:

- If 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', a product produced by the body. This condition is characterised by neurological and behavioral abnormalitites and the overproduction of uric acid in the body which can cause gout, kidney stones, bladder stones.

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

- You should not receive vaccines when taking LANVIS. 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.
- if you have been taking LANVIS for a long period of time. This may increase the chance of side effects, such as liver problems.
- if you have a condition where your body produces too little 'thiopurine methyltransferase' (TPMT), a product your body uses to break down or inactivate LANVIS.
- if you have an inherited mutation in the NUDT15-gene (a gene which is involved in the break-down of LANVIS 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. Your doctor may also perform genetic testing (i.e. looking at your TPMT and/or NUDT15 genes) before or during your treatment to determine if your response to LANVIS may be affected by your genetics. Your doctor may change your dose of LANVIS after these tests.
- while taking LANVIS you may become sensitive to the sunlight which can cause skin discolouration or a rash. Take care to avoid too much sun, cover up and use sunscreen.
- if you suffer from bone marrow depression (decreased production of blood cells).
- if you suffer from chickenpox (type of viral infection).
- if you suffer from herpes zoster (type of viral infection).
- if you suffer from gout (joint disease due to increased production of uric acid).
- if you have kidney stones.
- if you have severe liver dysfunction.
- if you have an infection.
- if you suffer from kidney function impairment or renal failure.
- if you have had cytotoxic medicine therapy or radiation therapy within 4 to 6 weeks prior to treatment with LANVIS.

- if you have septicaemia, marrow aplasia, severe anaemia, leucopenia, bleeding states.
- if you have intolerance to LANVIS.

Other medicines and LANVIS

Always tell your healthcare provider if you are taking any other medicine (this includes complementary or traditional medicines).

Tell your doctor if you are taking any of the following:

- Other medicines used to treat cancer e.g. busulphan.
- Aminosalicylate derivates, medicine used to treat inflammation of the colon and small intestine e.g. olsalazine, mesalazine or sulphasalazine.
- Medicines that cause the presence of abnormal material in the blood e.g. ACE-inhibitors (used primarily for the treatment of hypertension), anticonvulsants, antidepressants, NSAIDs, chloramphenicol.
- Medicines that can have a harmful effect on the bone marrow, like other chemotherapy or radiotherapy. This can lead to bone marrow damage and the dose of LANVIS may need to be reduced.
- Killed virus vaccines e.g. hepatitis A virus vaccine.
- Live virus vaccines e.g. chicken pox vaccine, yellow fever vaccine, measles vaccine.

Pregnancy, breastfeeding and fertility

You should not use LANVIS if you are pregnant.

If you are taking LANVIS you should not breastfeed your baby.

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 LANVIS.

Reliable contraceptive precautions must be used to avoid pregnancy whilst you or your partner are taking LANVIS.

Driving and using machines

LANVIS is not expected to influence your ability to drive and use machinery.

It is not always possible to predict to what extent LANVIS may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which LANVIS affects you (see section 4).

LANVIS contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking LANVIS.

3. How to take LANVIS

LANVIS should only be given to you by a specialist doctor who is experienced in treating blood problems.

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

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

The dose of LANVIS 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.

Adult and adolescent dose

For adults, the usual dosage of LANVIS 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.

Paediatric dose

Similar dosages to those used in adults, with appropriate correction for body surface area.

Your doctor will advise you on how much LANVIS to give your child.

Elderly patients

Your doctor will prescribe the lowest dose of LANVIS that best controls your condition.

If you have liver problems or kidney problems

Your doctor will prescribe the lowest dose of LANVIS that best controls your condition.

If you have the impression that the effect of LANVIS is too strong or too weak for you, tell your doctor or pharmacist.

If halving a tablet is required, care should be taken not to contaminate your hands or inhale the medicine.

If you take more LANVIS than you should

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

If you forget to take LANVIS

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

4. Possible side effects

LANVIS can have side effects.

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

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

- swelling of the hands, feet, ankles, face, lips, mouth, tongue or throat, which may cause difficulty in swallowing or breathing,
- rash or itching.

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

- if you are feeling tired, you bruise easily as well as being more prone to infections,
- reduction in blood platelets, which increases risk of bleeding or bruising (thrombocytopaenia),
- problem with your bowels, causing severe stomach ache, being sick, diarrhoea, bleeding, vomiting and fever,
- liver damage which can cause jaundice (skin and the whites of the eyes turn yellow) or an enlarged liver (a swelling below your ribcage), symptoms include nausea, weakness and stomach pain,

- kidney damage with symptoms such as swelling of your ankles, painful urination (urate nephropathy).

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:

- feeling or being sick (nausea or vomiting), diarrhoea, mouth ulcers (stomatitis), discomfort in the digestive system, indigestion, loss of appetite,
- abnormal enlargement of the spleen (splenomegaly), which may cause symptoms such as pain or fullness in the left upper stomach area, feeling full after eating, abnormal tiredness, easy bleeding,
- too much bilirubin in the blood (hyperbilirubinaemia), which may cause symptoms such as stomach pain or swelling, fever, chest pain, weakness, light-headedness,
- abnormal enlarged tender liver, symptoms including nausea, fatigue, itching (tender hepatomegaly),
- weight gain due to fluid retention including in the stomach (ascites).

Side effects with an unknown frequency:

- sensitivity to light.

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. You can also report side effects to:

SAHPRA: https://www.sahpra.org.za/health-products-vigilance/

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088

By reporting side effects, you can help provide more information on the safety of LANVIS.

5. How to store LANVIS

Store all medicines out of reach of children.

Store at or below 25° C.

Protect from light.

Keep dry.

Keep in original packaging until required for use.

Do not store in a bathroom.

Do not use after the expiry date stated on the label.

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 LANVIS contains

The active substance is 40 mg thioguanine.

The other ingredients are acacia, lactose monohydrate, magnesium stearate, potato starch and stearic acid.

Contains sugar: Lactose monohydrate 150,0 mg

What LANVIS looks like and contents of the pack

LANVIS is a white to off-white tablet, round, biconvex scored and imprinted “T40” on upper side, without score and debossing on lower side.

Amber glass bottles of 25 tablets, sealed with plastic caps. Each bottle is packed into a preprinted carton together with a leaflet.

Holder of certificate of registration

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead, 2191

Hotline: 0800 122 912

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C/26/119

Access to the corresponding Professional Information

SAHPRA Repository of Professional Information and Patient Information Leaflets:

https://www.sahpra.org.za/pi-pil-repository/

Aspen Pharmacare:

E-mail: Medinfo@aspenpharma.com

Tel: 0800 118 088

Namibia: NS2 90/26/00582

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