Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about LANVIS. It does not contain all of the available information

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of giving you this medicine against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What LANVIS is used for

LANVIS contains tioguanine as the active ingredient. It belongs to a group of medicines called cytotoxics.

LANVIS is used solely or in combination with other medicines to treat certain types of blood disorders (leukaemia).

LANVIS acts by inhibiting the growth of cancer cells.

Ask your doctor if you have any questions about why LANVIS has been prescribed for you.

Your doctor may have prescribed it for another purpose.

This medicine is only available with a doctor's prescription.

There is no evidence that it is addictive.

Before you take it

When you must not take it

Do not take LANVIS if you have ever had an allergic reaction to:

- tioguanine
- any of the tablet ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty in breathing; swelling of the face, lips, tongue or any other parts of the body; rash, itching or hives on the skin.

Do not take it if:

- · you have severe liver or kidney disease
- you have leucopenia, a lack of white blood cells
- you have anaemia, a lack of red blood cells
- you have fever and chills caused by a virus (viraemia)
- the expiry date (EXP) printed on the pack has passed
- the packaging is torn or shows signs of tampering.

Before you start to take it

Tell your doctor if you are allergic to any other medicines or any other foods, dyes or preservatives.

Tell your doctor if you have or have had any of the following conditions:

- you have recently been vaccinated or are planning to be vaccinated
- · kidney or liver disease
- blood disorders
- Lesch-Nyhan Syndrome

- NUDT15 variant (mutated NUDT15 gene)
- a condition where your body produces too little of a natural chemical called thiopurine methyltransferase (TPMT).

Tell your doctor if you are planning to become pregnant or intending to father a child.

As with all cytotoxic drugs, LANVIS may harm eggs and sperm. You or your partner should take adequate contraceptive precautions while you are taking this medicine.

Do not take LANVIS if you are pregnant or breast feeding unless you and your doctor have discussed the risks and benefits involved.

If you have not told your doctor about any of the above, tell them before you start taking LANVIS.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from your supermarket, pharmacy or health food shop.

Some medicines may be affected by LANVIS or may affect how well it works. You may need to take different amounts of your medicine or you may need to take different medicines. These include:

- busulphan
- allopurinol
- aminosalicylate derivatives e.g. olsalazine,mesalazine or sulphasalazine
- vaccinations with 'live' organism vaccines.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking this medicine.

How to take it

How much to take

Take LANVIS exactly as directed by your doctor.

Your doctor will decide what dose and for how long you will be taking LANVIS. This depends on factors such as your weight, any pre-existing conditions and your response to the treatment. Your doctor may change the dose and frequency of your medicine as your condition changes.

Your doctor may order regular blood cell count and liver function tests while you are taking LANVIS in order to monitor your condition and to change your dose if necessary.

How long to take it for

Your doctor will tell you how long to take LANVIS for.

Do not stop taking LANVIS or change the dose without first checking with your doctor

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 131126) for advice, if you think you or anyone else may have taken too much LANVIS, even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are taking it

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, 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.

Patients taking LANVIS are more sensitive to the sun. Limit your exposure to sunlight and UV light. Wear protective clothing and use a sunscreen with a high SPF.

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 to treat any other complaints unless your doctor says to.

Things to be careful of

Be careful driving or operating machinery until you know how LANVIS affects you.

Do not have any vaccinations without your doctor's approval. Wait until at least 3 months after chemotherapy treatment has been completed before receiving a vaccine and only after consultation with your doctor.

LANVIS 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. Your doctor will monitor your blood count while you are undergoing chemotherapy.

Side effects

Tell your doctor as soon as possible if you do not feel well while you are taking LANVIS.

All medicines can cause some side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Tell your doctor if you notice any of the following:

- nausea and vomiting
- diarrhoea
- jaundice (yellowing of the whites of the eyes or skin)
- · weight gain due to fluid retention
- swelling due to build-up of fluid around the stomach
- frequent infections such as fever, severe chills, sore throat or mouth ulcers
- bleeding or bruising more easily than normal

- · blood in the urine
- lowered resistance to disease (immunosuppression)

Tell your doctor immediately if you notice any of the following allergic-type symptoms:

 wheezing, swelling of the lips or mouth, difficulty in breathing, hayfever, lumpy rash (hives) or fainting.

Tell your doctor if you notice anything else that is making you feel unwell, even if you think the problems are not connected with this medicine and are not referred to in this leaflet.

Other side effects not listed above may also occur in some people.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

After taking it

Storage

Keep your tablets in the bottle until it is time to take them.

If you take the medicine out of the bottle it may not keep as well.

Keep it in a cool, dry place, protected from light, where the temperature stays below 25°C.

Do not leave it in a car, on window sills, near a sink or in the bathroom.

Heat and dampness can affect some medicines

Keep it where children cannot reach it. A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Product description

What it looks like

LANVIS tablets are white to off-white, round, biconvex, scored and imprinted 'T40' on one side and plain on the other.

Available in bottles of 25 tablets.

Ingredients

Active ingredient:

Each tablet contains 40 mg of tioguanine.

Inactive ingredients:

- acacia
- lactose monohydrate
- · magnesium stearate
- · starch-potato
- stearic acid

LANVIS tablets do not contain sucrose, tartrazine or any other azo dyes.

Sponsor

Aspen Pharmacare Australia Pty Ltd

34-36 Chandos Street St Leonards NSW 2065 Phone: +61 2 8436 8300 Web: www.aspenpharma.com.au

Australian Registration Number: AUST R

11110

This leaflet was revised in March 2022