

PACKAGE LEAFLET

Package Leaflet: Information for the User

Lanvis 40 mg tablets

Tioguanine

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse..
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any side effects not listed in this leaflet. See section 4.

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1 What Lanvis is and what it is used for

Lanvis tablets contain a medicine called tioguanine. This belongs to a group of medicines called cytotoxics (also called chemotherapy). Lanvis is used for certain blood problems and cancers of the blood. It works by reducing the number of new blood cells your body makes.

Lanvis 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.

2 What you need to know before you take Lanvis

Do not take Lanvis:

- if you are allergic to tioguanine or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

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

- if you have a liver problem so your doctor can monitor your liver function by testing your blood,
- 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,
- if you have a condition where your body produces too little of something called TPMT or ‘thiopurine methyltransferase’,
- if you have a mutation in your NUDT15 gene, you may have a higher risk of developing low levels of white cells in your blood compared to other patients. 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

- 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'.

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

Blood tests

Your doctor may ask you to have a blood test while you are taking Lanvis. This is to check your blood cell count. 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 this medication may be affected by your genetics. Your doctor may change your dose of Lanvis after these tests.

Lanvis and the sun

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.

Other medicines and Lanvis

Tell your doctor, pharmacist or nurse if you are taking, have recently taken or might take any other medicines.

In particular tell your doctor or pharmacist if you are taking any of the following:

- olsalazine or mesalazine – used for a bowel problem called ulcerative colitis.
- sulfasalazine – used for rheumatoid arthritis or ulcerative colitis.
- mercaptopurine - cytotoxic drug (patients with a tumour resistant to mercaptopurine will not respond to Lanvis).
- 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.

Having vaccines while you are taking Lanvis

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.

Pregnancy, breast-feeding and fertility.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine. This applies to both men and women. Lanvis may harm your sperm or eggs. Reliable contraceptive precautions must be taken to avoid pregnancy whilst you or your partner are taking this medicine.

Driving and using machines

There are no data available on the effects of Lanvis on the ability to drive and use machines.

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 tablets.

3 How to take Lanvis

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

Always take this medicine exactly as your doctor has told you. It is important to take your medicine at the right times. The label on your pack will tell you how many tablets to take and how often to take them. Check with your doctor, pharmacist or nurse if you are not sure.

- 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 depending on the result of your blood test.

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.

The usual dose is between 60 and 200 mg/m² body surface area per day. If you have a problem with your kidneys or liver you may be given a lower dose of Lanvis.

If you take more Lanvis than you should

If you take more Lanvis than you should, tell your doctor immediately or go to a hospital straight away. Take the medicine pack with you.

If you forget to take Lanvis

Tell your doctor. **Do not take a double dose to make up for a forgotten dose.**

If you stop taking Lanvis

Do not stop taking Lanvis without your doctor's advice.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse..

4 Possible side effects

Like all medicines, this medicine 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 as you may need to stop taking Lanvis:

- any signs of fever or infection (sore throat, sore mouth or urinary problems),
- treatment with Lanvis can cause a lowering of the white blood cell count. White blood cells fight infection, and when there are too few white blood cells, infections can occur,
- 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).

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

Very common (may affect more than 1 in 10 people)

- a decrease in the number of white blood cells (leucopenia),
- a decrease in number of blood platelets (cells that help blood to clot),
- jaundice (skin and the whites of the eyes turn yellow) and severe liver damage (symptoms include fatigue and nausea followed by itching, dark urine and may include rash or fever) - with long term use or high doses of Lanvis – this may also show up in your blood tests.

Common (may affect up to 1 in 10 people)

- liver damage which can cause jaundice (skin and the whites of the eyes turn yellow) or an enlarged liver (a swelling below your ribcage) – with short term use of Lanvis– this may also show up in your blood tests,
- feeling or being sick (nausea or vomiting), diarrhoea and mouth ulcers,

- increased uric acid concentrations in the blood (hyperuricaemia), which can sometimes lead to decreased kidney function.

Rare (may affect up to 1 in 1,000 people)

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

The following other effects have been rarely reported: rash, sensitivity to light, heart problems, ringing in the ears and deafness and unusual movements of the eye.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:

HPRA Pharmacovigilance.

Earlsfort Terrace

IRL - Dublin 2.

Tel: +353 1 6764971.

Fax: +353 1 6762517.

Website: www.hpra.ie.

e-mail: medsafety@hpra.ie.

By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Lanvis

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the bottle label and the carton after 'Exp'. The expiry date refers to the last day of that month.
- Do not store your Lanvis tablets above 25°C. Store in the original bottle and in the carton in order to protect from light. Keep the bottle tightly closed in order to protect from moisture.
- If your doctor tells you to stop taking the tablets, it is important to return any which are left over to your pharmacist, who will destroy them according to disposal of dangerous substance guidelines. Only keep the tablets if your doctor tells you to.

6 Contents of the pack and other information

What Lanvis contains

The active ingredient is tioguanine. Each Lanvis tablet contains 40 mg of tioguanine.

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

What Lanvis looks like and contents of the pack

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

Your Lanvis tablets are in bottles of 25 tablets.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation holder:

Aspen Pharma Trading Limited

3016 Lake Drive, Citywest Business Campus, Dublin 24, Ireland

Manufacturer: EXCELLA GmbH & Co. KG, Nürnberger Strasse 12, 90537 Feucht, Germany

Medical Information Enquiries

For any Medical Information enquiries about this product, please contact:

Ireland

Tel: 00353 1 630 8400

This leaflet was last revised in December 2021

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