PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

The medicine is dispensed with a doctor's prescription only

Lanvis Tablets 40 mg

The active ingredient and its quantity:
Thioguanine 40 mg

A list of inactive ingredients is detailed in section 6.

Read the leaflet carefully in its entirety before using the medicine as it contains important information for you. Keep the leaflet. You may need to read it again. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor, nurse or pharmacist.
This medicine has been prescribed for you only. Do not pass it on to others. It may harm them even if it seems to you that signs of their ailment are similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

Lanvis is a medicine for treating acute nonlymphocytic leukemia.

Therapeutic group: A cytotoxic medicine (also called chemotherapeutic) from the family of purine analogs.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:
- You are sensitive (allergic) to thioguanine (the active ingredient) or to any of the other ingredients contained in the medicine (see section 6).
- You are pregnant or breastfeeding.

Special warnings regarding use of the medicine

Before treatment with Lanvis, consult the doctor if:
- You have been using the medicine for a prolonged period. Prolonged use may increase the risk of side effects, such as liver problems.
- You suffer from low levels of the thiopurine methyltransferase (TPMT) enzyme.
- You suffer from Lesch-Nyhan Syndrome – a rare hereditary condition caused by deficiency of HPRT (hypoxanthine-guanine-phosphoribosyltransferase).

If you are uncertain if one of the above sections applies to you, please consult the doctor, nurse or pharmacist before taking Lanvis.

If you are taking or have recently taken, or there is a chance you may take other medicines, including non-prescription medicines, nutritional supplements, vitamins and herbal supplements, tell the doctor or pharmacist. In particular, inform the doctor or pharmacist before starting treatment with Lanvis, if you are taking any of the following medicines:
- Certain medicines for treatment of ulcerative colitis (e.g., olsalazine or mesalazine).
- Certain medicines for treatment of rheumatoid arthritis or ulcerative colitis (e.g., sulfasalazine).
- Certain medicines that may have a harmful effect on the bone marrow, such as other chemotherapy or radiotherapy. In this case it may be necessary to reduce the dosage of the medicine Lanvis.

Use of the medicine and sun exposure

During use of the medicine Lanvis, there may be hypersensitivity to sunlight which can lead to skin discoloration or a rash may appear.
Avoid prolonged exposure to the sun as much as possible, wear long clothing and use sunscreen.

Use of the medicine and vaccinations

Consult the doctor or nurse before receiving a vaccination. Certain vaccinations (e.g., polio, measles, mumps and rubella) may give you an infection if given during the course of treatment with Lanvis.

Pregnancy, breastfeeding and fertility

If you are pregnant or planning to become pregnant, consult the doctor before using Lanvis. If one of the partners is taking the medicine Lanvis, pregnancy should be avoided during this period. Lanvis may harm the egg or sperm. A reliable contraceptive must be used to prevent pregnancy during use of these tablets by you or by your partner.
Do not breastfeed during the course of treatment with Lanvis. Consult a doctor.

Important information on some of the ingredients of the medicine

The medicine Lanvis contains lactose.
Consult the doctor before taking the medicine if you know that you have an intolerance to certain sugars.

3. HOW SHOULD YOU USE THE MEDICINE?

This medicine must only be given by a doctor specializing in blood problems.
Always use precisely according to the doctor's instructions. It is important to take the medicine at the right time.
Check with the doctor, nurse or pharmacist if you are uncertain.
- Swallow the tablet whole with a glass of water.
- If you want to split the tablet into two, do not inhale the tablet powder. Wash your hands thoroughly afterwards. The score line is intended to enable tablet breakage and to ease swallowing, and not to split it into two equal doses. There is no information about crushing the tablet.
- During the course of treatment with Lanvis, the doctor will instruct you to have blood tests performed, in order to check the number and type of cells in your blood and to ensure that your liver function is normal; the doctor may change the dosage instructions accordingly.

The dosage and the treatment regimen will be determined by your doctor only.
The doctor will calculate the appropriate dosage for you according to the surface area of your body, your blood test results and the disease from which you are suffering.
Cytotoxic medicine – the dosage will be determined by a doctor only!
The recommended daily dose is between 100-200mg/m^2 body surface area per day. If you suffer from a kidney or liver problem, you may receive a lower dosage of Lanvis.

Do not exceed the recommended dose.

If you accidentally took a higher dosage (overdose) or if a child accidentally swallowed the medicine, immediately refer to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you.

If you forgot to take the medicine at the required time, consult the doctor. **Do not take a double dose to compensate for a missed dose.**
Adhere to the treatment regimen as recommended by the doctor.
Even if there is an improvement in your health, do not discontinue treatment with the medicine without consulting the doctor.
Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.
If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Lanvis may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them.

Immediately refer to a doctor or proceed to an emergency room if any of the following side effects occur:
- Fever or other signs of infection, such as: sore throat, sore mouth or urinary tract problems.
- **Unexpected** bruising or bleeding.
- Sudden sick feeling (even if temperature is normal).
- Yellowing of the skin or whites of the eyes (jaundice).

Consult a doctor if any of the following side effects occur:
Very common side effects (occur in more than one user in 10):
- A drop in the number of blood cells and platelets.
- Jaundice (yellowing of the skin and whites of the eyes) and severe liver damage (the symptoms include fatigue and nausea accompanied by itching, dark urine and may include rash or fever) during long-term use or high dosages of Lanvis; these may appear in blood test results.

Common side effects (occur in less than one user in 10):
- Liver damage which may cause jaundice (yellowing of the skin or whites of the eyes) or enlarged liver (swelling under the ribcage) – with short-term use of Lanvis; these may appear in blood test results.
- Feeling of nausea or vomiting, diarrhea, mouth ulcers.
- High level of uric acid in the blood (hyperuricemia), which may lead in certain conditions to impaired kidney function.

Rare side effects (appear in less than one user in 1,000):
- Necrotizing enterocolitis, which may cause severe abdominal pain, nausea, diarrhea, vomiting and fever.
- Severe liver damage when used with other cytotoxic (chemotherapeutic) medicines, oral contraceptives and alcohol.

Side effects of unknown frequency:
- Sensitivity to light.

If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.

Reporting side effects:
Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il), which directs you to the online form for reporting side effects, or at the following link:
https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType= AdversEffectMedic@moh.gov.il
Additionally, you can report to Perrigo via the following address:
www.perrigo-pharma.co.il

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine and any other medicine should be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without explicit instruction from the doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- Store below 25°C.
- Store in a dark and dry place.
- Protect from light.
- After first opening the bottle, use the medicine within 25 days.

If the doctor decides to discontinue treatment, return the remaining tablets to the pharmacy. Keep the tablets only if the doctor instructed you to do so.

6. FURTHER INFORMATION

- In addition to the active ingredient, the medicine also contains:
  Lactose, potato starch, acacia, stearic acid, magnesium stearate.
  The amount of lactose in each tablet is 150 mg.
- What the medicine looks like and the contents of the pack: a glass bottle with a plastic, child-resistant screw cap. The bottle contains 25 tablets. The tablets are white-almost white, rounded and biconvex, with a score line and 'T40' imprinted on one side.
- Registration holder: Perrigo Israel Agencies Ltd., 29 Lehi St., Bnei Brak 51200.
- Manufacturer: Excella GmbH, Feucht, Germany.
- This leaflet was checked and approved by the Ministry of Health in December 2016.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 058-23-20936-05.