PACKAGE LEAFLET: INFORMATION FOR THE USER

LANITOP

0.1 mg tablet

METILDIGOXIN

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • 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 or pharmacist • 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 or pharmacist • This includes any possible side effects not listed in this leaflet •

What is in this leaflet?

1. What Lanitop is and what it is used for
2. Before you take Lanitop
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1. What Lanitop is and what it is used for

Lanitop is used is in the form of tablets and contains the active substance metildigoxin.
Lanitop belongs to the group of medicines called digitalis glycosides, and are used in the treatment of heart disease.

Lanitop is used in the treatment of acute and chronic Cardiac decompensation (the inability of the heart to pump a sufficient amount of blood).
Lanitop is also used in the treatment of supraventricular arrhythmia (rhythm disorders of the heart).

2. BEFORE YOU TAKE LANITOP

Do not take Lanitop:

- If you are hypersensitive to metildigoksin, other cardiac glycosides or to any of the excipients in the medicinal product
- In case of Digitalis poisoning
- Without prior consultations with your doctor if you have other heart disease

• If you have lack of potassium, calcium or magnesium in the blood

Be careful and consult with a doctor before starting treatment with Lanitop:

• If you have impaired kidney and liver function
• If you have had any kind of surgery on the digestive system
• If you are a previous heart attack, heart failure or you have a different heart disease
• If you have high blood pressure
• If you have myxedema
• If you have hypoxia or severe lung disease
• If you suffer from malabsorption
• If you have a disorder of electrolytes in the blood
• If you have cardiac arrhythmias.
• If you have reduced or increased values of thyroid hormones in the blood (hipotireiza or hyperthyroidism)
• If you are older

Excipients

Patients with rare hereditary problems of Galactose intolerance, the Lapp lactase deficiency or glucose-Galactose malabsorption should not take this medicine.

Taking other medicines with Lanitop

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Lanitop can make interaction with the following medicines:

• preparations containing calcium
• Preparations of the herb Rauwolfia
• Rezerpin, Guanethidine-medicines used to treat high blood pressure
• Beta-blockers – medicines used in the treatment of high blood pressure
• Diuretics-medications that stimulate urination
• Corticosteroids-medicines used in the treatment of allergies, inflammation and skin diseases
• Some pituitary hormones
• medicines used to treat high blood pressure (calcium channel blockers, ACE inhibitors)
• Itraconazole, amphotericin B – medication for the treatment of fungal diseases
• Quinine – medications for the treatment of malaria
• Atropine
• Anti-arrhythmic agents – medicines used in the treatment of heart rhythm disorders (quinidine, flecainide, propafenone)
• Indomethacin — anti-inflammatory medicines

Alprazolam, prazosin – medications for the treatment of diseases of the nervous system

• Antibiotics-medications used in the treatment of bacterial infections (e.g., tetracyclines, erythromycin, gentamycine, trimethoprim)
• Antituberculotics (rifampicin, rifapentin)
• Antacids – medications that reduce acidity
• some medicines used in the treatment of epilepsy (phenytoin and phenobarbital)
• medicines used in the treatment of thyroid disease (levothyroxine, metamizol)
• Products containing our Lady's weed

Pregnancy and breastfeeding

This medicine should be avoided because of the potential adverse effects on the fetus or infant during pregnancy and breast-feeding; it should be used only if the benefit exceeds the possible risk.

Driving and using machines
Lanitop have no influence on the ability to drive and use machines.

Other warnings
It is necessary to regularly monitor the values of electrolytes in the blood and kidney function.
If you have been told by your doctor that you have intolerance to some sugars, before you start taking this medicine, consult your doctor.

3. HOW TO TAKE LANITOP

Your doctor will determine what dose of Lanitop tablet you will take and how often. Follow your doctor's instructions and take this medicine exactly as you were told.

The recommended doses are average and can be customized to your sensitivity, or condition. Therefore, the dose of Lanitop Tablet is determined by your doctor. Treatment begins with higher doses until saturation, when it switches to the maintenance dose.

Adults:
Fast digitization (saturation) can be achieved by oral administration of 0.2 mg Lanitop tablet three times a day for 2-4 days. Slower digitization (saturation) is achieved with smaller doses metildigoxin (0.4 mg daily) for 3 to 5 days.
The maintenance dose is 0.05 to 0.3 mg per day (usually 0.15 to 0.2 mg per day) in a single dose or in divided doses.

Atrial fibrillation

Metildigoxin 0.2 to 0.3 milligrams per day (orally) was effective in controlling the ventricular response in patients with atrial fibrillation. The dose can be administered either once a day or in two divided doses.
Congestive heart failure (decompensation)
a) The effective oral dose for rapid digitization (saturation) is 0.2 mg three times daily for 1 to 5 days. In most patients digitization is achieved in 2-3 days.
b) The effective maintenance dose is 0.05 to 0.4 milligrams per day, for most patients however it is 0.15 to 0.2 milligrams per day. The maintenance dose may be administered either once a day or in two divided doses.

Children
In children Lanitop is applicable according to their weight.
The saturation dose amounts to 0.01 mg/kg every 6 hours (2 to 4 doses). It continues with a dose of maintenance of 0.01 mg/kg/day.
The tablets are an appropriate form of administration in children with adequate weight and who are able to swallow them. For other children the medicine should be administered in the form of a solution.

Dosing in elderly patients and patients with impaired renal function
If you are older and you have impaired kidney function, your doctor will adjust the dose to suit your needs.

What if you take too many tablets?
Too many tablets at once can harm you. In case of overdose, contact your doctor to give you immediate assistance.

What if you forget to take a tablet?
If you forget to take a dose of Lanitop, take it as soon as you remember. However if it's been a long time and it's close to the time for the next dose, do not take your missed dose and take the next dose at the usual time.

If you have any further questions on the use of Lanitop, please contact your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Lanitop can cause side effects.

Adverse reactions with Lanitop tablets usually occur because of the small boundaries between therapeutic and toxic doses. Therefore, some adverse reactions may be symptoms of overdose.
The most serious adverse reactions are heart response. All types of heart rhythm disorders can occur. Described adverse effects are typical of digitalis intoxication.

Use of Lanitop tablets may be accompanied by loss of appetite, nausea (occurrence of nausea should be considered early signs of excessive high doses), vomiting, and in rare cases, abdominal pain and diarrhea. In individual cases there was mesenteric infarction (infarction of intestines).

Headache, weakness, dizziness, drowsiness, insomnia and mental changes that rarely occur (e.g., nightmares, restlessness, confusion), and also depression, hallucinations and psychosis. In individual cases, there was the loss of the ability of speech. There are also reports of weakness, apathy. Visual disturbances (blurred vision, altered perception of color) may occasionally occur. Lanitop can rarely cause a lack of platelets in the blood, renal impairment, and Gynecomastia (breast enlargement with men).
Hypersensitivity reactions (skin rashes) are rare.

If you notice any side effects talk to your doctor or pharmacist.

5. HOW TO STORE LANITOP

KEEP OUT OF REACH AND SIGHT OF CHILDREN.
Store at temperature up to 25°C, in original packaging.
The shelf life of the medicine is 4 years.
Lanitop should not be used after the expiry date stated on the carton.

6. FURTHER INFORMATION

What does Lanitop contain?
The active substance of Lanitop is metildigoksin.
One Lanitop tablet contains 0.1 mg metildigoksin.
It containes excipients: lactose monohydrate; povidone K30; silicon dioxide, colloidal anhydrous; cellulose, microcrystalline, magnesium stearate; sodium starch glycolate, type A.

Contents of the Pack
50 (5 x 10) tablets in the blister, in a box.

Regime of dispensing
The medicine is issued on doctor`s prescription.

Manufacturer
Pliva Hrvatska d.o.o.
Prilaz baruna Filipovića 25, Zagreb, Croatia

Manufacturer of the medicinal product
Pliva Hrvatska d.o.o.
Prilaz baruna Filipovića 25, Zagreb, Croatia