

Patient Package Insert in Accordance with the Pharmacists' Regulations (Preparations)- 1986

This medicine can be sold with a doctor's prescription only

Lanoxin® Elixir 0.05 mg/ml

Each 1 ml of Lanoxin Elixir contains digoxin 0.05 mg
Inactive ingredients and allergens in the medicine: see section 2 "Important information about some of the ingredients of this medicine" and section 6 in this leaflet.

Read this entire leaflet carefully before using this medicine.

This leaflet contains concise information about the medicine. If you have any further questions, ask the doctor or pharmacist. This medicine has been prescribed for your treatment. Do not pass it on to others. It may harm them even if you think that their medical condition is the same as yours. If you experience any side effects, including side effects which are not mentioned in section number 4 of this leaflet, inform the doctor or the pharmacist.

1. What is the medicine intended for?

Lanoxin Elixir is indicated whenever digitalis therapy is required for the treatment of congestive heart failure, atrial fibrillation and/or flutter and supra-ventricular tachycardia.

Therapeutic group: cardiac glycosides.

2. Before using the medicine

Do not use Lanoxin Elixir if:

- You are hypersensitive (allergic) to the active ingredient digoxin, to other cardiac glycosides or to any of the other ingredients this medicine contains (see section 6: "Additional information" in this leaflet).
- You have serious heart problems such as: problems with the conduction of the electrical impulses in the heart, especially if you have a history of Stokes-Adams attacks (abrupt, temporary loss of consciousness caused by a sudden change in heart rhythm).
- You have an irregular heartbeat caused by cardiac glycoside intoxication or conditions such as Wolff-Parkinson-White syndrome.
- You have obstructive cardiomyopathy (enlargement of the heart muscle).

Special warnings regarding the use of Lanoxin Elixir

Before the treatment with Lanoxin Elixir, tell the doctor if:

- You are taking this medicine, the doctor may ask you to have regular blood tests to determine the amount of Lanoxin in the blood. This may be useful in the case of patients with kidney problems.

You develop digoxin toxicity, this can lead to various forms of heart rhythm disturbances, some of which resemble the rhythm disturbances for which this medicine was prescribed.

You have an abnormal heart rhythm (heart block) and you are taking Lanoxin Elixir. Refer to your doctor immediately if you feel one or more of the following conditions: fainting, short-term loss of consciousness, dizziness, tiredness, shortness of breath, chest pain, irregular heartbeat or confusion.

You have a sinoatrial disorder (a disorder in the conduction of electrical impulses in the heart, such as Sick Sinus Syndrome), in some patients with a sinoatrial disorder this medicine can cause a slow and/or irregular heartbeat. Sometimes this will cause tiredness, weakness and dizziness and when your heartbeat is very slow you may faint.

You have recently suffered a heart attack.
Your heart failure occurs along with the collection of an abnormal protein in the heart tissue (cardiac amyloidosis). The doctor may prescribe you an alternative therapy.
You have myocarditis (inflammation of the heart muscle), this may cause narrowing of the blood vessels in rare cases. Your doctor may prescribe you a different medicine.

You have Beri-beri disease (caused by a vitamin B1 deficiency).
You have obstructive pericarditis (inflammation of the pericardium).

You are taking diuretics (medicines which induce urine production and help reduce the amount of water in your body), with or without an ACE inhibitor (medicines mainly used to treat high blood pressure), your doctor will prescribe a lower dose of Lanoxin Elixir. Do not stop taking Lanoxin Elixir without consulting the doctor.

You have a heart test called an ECG (electrocardiogram). Tell the person performing the test that you are taking Lanoxin Elixir as it can affect the analysis of the results.

You have a severe respiratory (lung) disease (as you may have an increased sensitivity to Lanoxin).

You have low levels of oxygen reaching certain parts of your body, low levels of potassium, abnormally low levels of magnesium, or increased levels of calcium in your blood.

You have a thyroid disease (such as hypothyroidism or hyperthyroidism) as you might require changes in the dosage of this medicine.

You have a malabsorption syndrome (you cannot absorb minerals from food properly) or if you have ever had a gastrointestinal reconstruction surgery.

You are about to undergo electric shock treatment to correct an abnormal heartbeat. If you are unsure if any of the above conditions apply to you, discuss it with the

doctor or pharmacist before starting to use Lanoxin Elixir.

Tests and follow-up

The doctor may ask you to have regular blood tests to determine the amount of Lanoxin in the blood.

Drug interactions

If you are taking or have recently taken other medicines including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. Especially if you are taking the medicines listed below:

Sensitivity to Lanoxin can be increased by using medicines which lower the level of potassium in the blood. These medicines include:

- diuretics
- lithium salts (antidepressants)
- corticosteroid based medicines
- carbinoxolone (a medicine which strengthens the gastric mucosa)

The following medicines increase the level of Lanoxin in the blood, which can increase the risk of toxicity:

- certain medicines which affect the heart: amiodarone, flecainide, prazosin, propafenone, quinidine

- canagliflozin (to treat type 2 diabetes mellitus)
- certain antibiotics: erythromycin, clarithromycin, tetracycline, gentamicin, trimethoprim

- daclatasvir, simeprevir, velpatasvir (in combination with other medications to treat hepatitis C)

- fibanserin (to treat low sexual desire in women who have not gone through menopause)

- isavuconazole, itraconazole (to treat fungal infections)

- ivacaftor (to treat cystic fibrosis)
- spirinolactone (a medicine which increases the amount of urine you produce)

- alprazolam (a sedative which may be used to treat anxiety)
- indometacin (to treat inflammation)
- quinine (may be used to prevent malaria infection)

- propantheline (to prevent muscle spasms)
- mirabegron (to treat overactive bladder that causes a sudden urge to urinate resulting in involuntary loss of urine)

- nefazodone (an antidepressant)
- atorvastatin (to lower blood cholesterol)
- cyclosporine (an immunosuppressant often used to prevent transplant rejection)

- eporostenol (to treat pulmonary hypertension)
- tolvaptan and conivaptan (to treat low blood sodium levels)

- carvedilol (to treat mild to severe heart failure and hypertension)
- ritonavir (to treat HIV infection and AIDS)
- taleprevir (to treat hepatitis C infection)
- dronedarone (to treat irregular heartbeat)
- ranolazine and tiapamil (to treat chest pain)
- telmisartan (to treat high blood pressure)
- lapatinib (to treat breast cancer)

- ticagrelor (to prevent heart attack or stroke)
- verapamil and felodipine (to treat hypertension)
- vandetanib (to treat certain types of thyroid gland cancers)
- p-glycoprotein inhibitors
- venetoclax (to treat patients with chronic lymphocytic leukaemia)
- vemurafenib (to treat adult patients with a type of cancer called melanoma)
- proton pump inhibitors (PPIs) to relieve symptoms of acid reflux, or to treat gastroesophageal reflux disease (GERD)).

The following medicines may increase or have no effect on the level of Lanoxin in the blood:

- nifedipine, diltiazem, angiotensin receptor blockers (ARBs) and ACE inhibitors (to treat hypertension and heart failure)
- non-steroidal anti-inflammatory drugs (NSAIDs) and cyclooxygenase-2 enzyme (COX-2) inhibitors (to treat pain and inflammation).

If you have heart failure and are taking products that contain senna (sennosides – to increase amount of stools, aid in bowel motility) along with Lanoxin, you may have a moderately increased risk of Lanoxin toxicity.

The following medicines reduce the level of Lanoxin in the blood:

- antacids (to treat gastric acidity)
- certain laxatives (create volume and increase the amount of stools that is produced and aid bowel motility)

- kaolin-pectin (to treat diarrhea)
- acarbose (to treat certain types of diabetes)
- certain antibiotics: neomycin, penicillamine, rifampicin

- certain cytostatic medicines (used as chemotherapy for cancer treatment)
- metoclopramide (to treat nausea and vomiting)
- sulfasalazine (a medicine to counteract inflammatory bowel diseases)
- adrenaline (to treat severe allergic reactions)
- salbutamol (to treat asthma)
- cholestyramine (lowers blood cholesterol levels)
- phenytoin (to treat epilepsy)
- St. John's wort (*Hypericum perforatum*) (to treat depression)
- bupropion (to treat depression)
- p-glycoprotein inducers
- supplemental enteral nutrition (being fed by a feeding tube).

If you are taking digoxin along with the following medicines you may have an increased risk of irregular heart rhythm:

- intravenous calcium
- beta blockers
- sympathomimetics (to treat heart attack and low blood pressure)

If you are taking Lanoxin and suxamethonium (used to help muscle relaxation and to treat short-term paralysis), you may have

an increased risk of high potassium levels in the blood.

Use of this medicine and food

This medicine can be taken on an empty stomach or with most meals.

However, you should avoid taking Lanoxin Elixir with foods that are high in fiber, also known as 'dietary fibers', because the level of Lanoxin absorbed in the body can be reduced.

Pregnancy, breastfeeding and fertility

Pregnancy
The doctor will prescribe this medicine with extra caution during pregnancy. You may require a higher dosage of the medicine if you are pregnant.

This medicine can be given to the mother to treat abnormally high heart rate and heart failure in the fetus.

Side effects of Lanoxin Elixir treatment affecting the mother may also affect the fetus.

Breastfeeding

This medicine is excreted in breast milk, but in very small amounts. Therefore, a breastfeeding woman can use this medicine.

Fertility

There is no information on the effect of Lanoxin Elixir on fertility.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to become pregnant, consult with your doctor or pharmacist before using this medicine.

Driving and using machines

Since dizziness, blurred vision and yellow vision have been reported during treatment with Lanoxin Elixir, you should exercise extreme caution when driving, operating machines or participating in dangerous activities.

Important information about some of the ingredients of this medicine

Lanoxin Elixir contains methyl parahydroxybenzoate (E218), sucrose, ethanol and sodium.

Methyl parahydroxybenzoate (E218): May cause allergic reactions (it is possible that these will appear after a while).

Sucrose:

Lanoxin Elixir contains less than 0.3 grams of sucrose per 1 ml of solution, i.e., 1.5 grams of sucrose in a 5 ml (0.25 mg digoxin) dose. The amount of sucrose varies depending on the dose. If you have an intolerance to certain sugars, consult the doctor before using this medicine. Refer to the doctor for further explanation if your child is taking this medicine. The medicine may be harmful to teeth.

Ethanol:

Lanoxin Elixir contains less than 0.1 ml of ethanol (alcohol) per 1 ml of the medicine, i.e., up to 0.44 grams of ethanol in a 5 ml (0.25 mg

digoxin) dose, which is equivalent to less than 12.5 ml (less than 3 teaspoons) of beer, less than 4.5 ml (less than one teaspoon) of wine per 0.25 mg digoxin dose. The amount of ethanol varies depending on the dose. Refer to the doctor for further explanation if your child is taking this medicine. The medicine is harmful to those suffering from alcoholism. This is to be taken into consideration in pregnant women or breastfeeding women, children and high-risk groups such as patients with liver disease, or epilepsy.

Sodium:
Adults and children over the age of 10 years: Lanoxin Elixir contains 38.019 mg of sodium (cooking salt), or less per dose. This is equivalent to 1.9% of the recommended maximum daily dietary intake of sodium for an adult.

Children under the age of 10 years: Lanoxin Elixir contains less than 1 millimole (23 mg) of sodium per 1 ml of medicine, which is considered 'sodium free'.

3. How to use the medicine

Always use the medicine according to the doctor's instructions. Check with the doctor or pharmacist if you are not sure about the dosage and the treatment regimen with the medicine. The dosage and treatment regimen will be determined by the doctor only.

The dosage depends on what health problem you have and how serious it is.

The dosage also depends on your age, weight and kidney function.

While you are taking the medicine, your doctor will instruct you to have regular blood tests to determine your response to Lanoxin Elixir.

The dosage will be adjusted by your doctor based on the blood test results and your response to the treatment. Therefore, you must strictly adhere to the treatment prescribed by your doctor.

If you are taking or have taken another medicine of the glycoside family for cardiac treatment in the last two weeks, your doctor may prescribe a lower dosage for you.

If you feel that the effect of this medicine is too strong or too weak, refer to the doctor.

Method of administration

• Lanoxin Elixir is a drinking solution for oral administration.

• Lanoxin Elixir is supplied with a graduated dropper.

• Be sure to measure the dose with the dropper supplied with the package. **Do not dilute the medicine.**

How to take the medicine

The medicine is usually taken in two stages:

• Stage 1- loading dose

The loading dose will bring your Lanoxin level to the correct blood level quickly, in one of two ways:

- You will receive a large single dose and

then begin to receive your maintenance dose

○ You will receive a smaller dose each day for a week and then begin to receive your maintenance dose.

• Stage 2- maintenance dose

After taking your loading dose you will take a much smaller dose each day, until the doctor tells you to stop.

Children and adolescents over the age of 10 years:

• Loading dose

○ Usually a single dose of 0.75 - 1.5 mg. For certain patients, this dose will be given in divided doses 6 hour apart.

○ Alternatively, taking a dose of 0.25 - 0.75 mg each day for a week.

• Maintenance dose

○ Your doctor will decide your dose, depending on your response to Lanoxin.

○ It is usually a dose of 0.125 - 0.25 mg per day.

Children under the age of 10 years:

• Loading dose

○ Calculated according to the weight of the child.

○ Usually a dose of 0.025 - 0.045 mg/kg body weight.

○ This dose is given in divided doses at 4 to 8 hours intervals.

• Maintenance dose

○ Your doctor will decide your dose, depending on your child's response to Lanoxin.

○ Usually 1/5 (one fifth) or 1/4 (one quarter) of the loading dose, taken once a day.

Elderly

Elderly people may be given a lower dose than the usual adult dose. This is because elderly people may have reduced kidney function. The doctor will check the level of Lanoxin in your blood and may change your dose if necessary.

Do not exceed the dose recommended by your doctor.

If you have accidentally taken a higher dosage

If you have taken an overdose or if a child has accidentally swallowed this medicine, refer immediately to a hospital emergency room or to a poison center to evaluate the risks and receive information and bring the package of the medicine with you.

The main symptoms of Lanoxin toxicity are heart rhythm disturbances and gastrointestinal symptoms which may appear before heart rhythm disturbances. Gastrointestinal symptoms include: loss of appetite, nausea and vomiting.

Other symptoms of digoxin toxicity include: dizziness, fatigue, a general feeling of illness and various neurological disturbances, including visual disturbances (vision is more

yellow-green than usual). The neurological and visual symptoms may persist even after the other symptoms of toxicity have passed. In chronic toxicity, non-heart related symptoms, such as weakness and a general feeling of illness, may be the main symptoms.

If you forgot to take the medicine at the designated time, do not take a double dose to make up for the forgotten dose. Take the next dose at the regular time and consult a doctor. Continue with the treatment as recommended by the doctor.

If you stop taking the medicine
Your doctor will tell you how long you should take Lanoxin Elixir. Do not stop taking this medicine without consulting the doctor.

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.

If you have further questions on the use of this medicine, consult the doctor or pharmacist.

4. Side effects

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

You should refer to a specialist immediately or seek urgent medical advice if the following signs occur:

Very rare side effects (appear in less than 1 out of 10,000 users)

- palpitations, chest pain, shortness of breath or sweating. These can be symptoms of a serious heart problem caused by new irregular heartbeats.

Additional side effects:
Common side effects (appear in up to 1 out of 10 users)

- allergic reactions of the skin may occur (rash, urticaria)
- irregular heart rate
- nausea, vomiting, diarrhea
- central nervous system disturbances, such as dizziness
- visual disturbances (blurred or yellow vision)

Uncommon side effects (appear in less than one out of 100 users)

- depression

Very rare side effects (appear in less than one out of 10,000 users)

- decrease in the amount of blood platelets (symptoms include bruises and nose bleed)
- loss of appetite (anorexia)
- psychosis, apathy, confusion
- headache
- stomach pain caused by lack of blood supply or damage to your intestines (ischemia and necrosis)
- enlarged breast tissue in men (gynecomastia)

• lack of energy (tiredness), a general feeling of illness and weakness.

If a side effect appears, if one side effect gets worse or if you suffer from a side effect which is not mentioned in this leaflet, consult the doctor.

Reporting of side effects:

Side effects can be reported to the Ministry of Health by clicking on the link "Report adverse effects and problems associated with medications" that can be found on the home page of the Ministry of Health website (www.health.gov.il) directing to the online form of adverse events reporting or by clicking on the following link: <https://sideeffects.health.gov.il>

Additionally, side effects can be reported to Padagis via the following address: www.perrigo-pharma.co.il

5. How to store the medicine

• Avoid poisoning! This medicine and any other medicine must be stored in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.

• Do not use the medicine after the expiry date (exp. date) that appears on the carton box and the bottle. The expiry date refers to the last day of that month.

• Store below 25°C.

• The medicine can be used for 12 days after first opening the bottle.

• Do not dispose of medicines via wastewater or household waste. Ask the pharmacist how to dispose of medicines no longer in use. These measures will help to protect the environment.

6. Additional information

In addition to the active ingredient, the medicine also contains the following excipients: Disodium Phosphate Anhydrous, Methyl Parahydroxybenzoate, Citric Acid Monohydrate, Syrup, Quinoline Yellow E104 (Colour), Ethanol Propylene Glycol, Lime flavour and Purified Water.

• What does the medicine look like and what is the content of the package:
Lanoxin Elixir is a yellow, lime flavored liquid, in an amber glass bottle containing 60 ml of liquid with a plastic or metal cap. Each bottle is packaged in a carton box containing a dropper.

• Registration holder and address: Padagis Israel Agencies Ltd., 1 Rakefet St., Shoham.

• Manufacturer and address: Aspen Bad Oldesloe GmbH, Bad Oldesloe, Germany.

• Revised in September 2021 according to MOH guidelines.

• Registration number of the medicine at the National Drug Registry of the Ministry of Health: 126-96-30673

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