

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

The medicine is dispensed 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 preparation: see section 2 "Important information about some of the ingredients of the medicine" and section 6 "Further information" in the leaflet.

Read the leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have 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 it seems to you that their medical condition is similar.

If you experience any side effects, including side effects which are not mentioned in section 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 sensitive (allergic) to the active ingredient digoxin, to other cardiac glycosides or to any of the additional ingredients this medicine contains (see section 6 "Further information" in the leaflet).
 - You suffer from 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, short-lived loss of consciousness caused by a sudden change in heart rate or rhythm).
 - You suffer from an irregular heartbeat caused by cardiac glycoside intoxication or conditions such as Wolff-Parkinson-White syndrome.
 - You suffer from obstructive cardiomyopathy (enlargement of the heart muscle).

Special warnings regarding the use of Lanoxin Elixir

Before treatment with Lanoxin Elixir, tell the doctor if:

- You are taking this medicine, the doctor can ask you to have regular blood tests to determine the amount of digoxin in the

blood. This can 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 a doctor immediately if you experience one or more of the following symptoms: fainting, short-term loss of consciousness, dizziness or light-headedness, tiredness, shortness of breath, chest pains, 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 suffering from 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.
- Heart failure occurs along with an accumulation of an abnormal protein in the heart tissue (cardiac amyloidosis). The doctor may prescribe you an alternative therapy.
- You suffer from myocarditis (inflammation of the heart muscle); this can 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 constrictive pericarditis (inflammation of the sac which contains the heart).

- You are taking diuretics (medicines which promote 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 dosage 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 meaning of the results.
- You are suffering from a severe respiratory (lung) disease (as you may have an increased sensitivity to Lanoxin Elixir).
- You suffer from 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 the blood.
- You suffer from a thyroid disease (such as an under-active or over-active thyroid), as you might require changes in the dosage of the 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 due 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 can ask you to have regular blood tests to determine the amount of digoxin 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 Elixir can be increased as a result of using medicines which lower the level of potassium in the blood. These medicines include:

- diuretics
- lithium salts (antidepressants)
- corticosteroid-based preparations
- carbenoxolone (a preparation which strengthens the gastric mucosa)

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

- certain medicines which affect the heart: amiodarone, flecainide, prazosin, propafenone, quinidine
- canagliflozin (to treat type 2 diabetes)
- certain antibiotics: erythromycin, clarithromycin, tetracycline, gentamicin, trimethoprim

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

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- You suffer from a thyroid disease (such as an under-active or over-active thyroid), as you might require changes in the dosage of the medicine.

- sodium levels)
- carvedilol (to treat mild to severe heart failure and high blood pressure)
- ritonavir (to treat HIV infection and AIDS)
- telaprevir (to treat hepatitis C infection)
- dronedarone (to treat irregular heartbeat)
- ranolazine and tiapamil (to treat chest pains)
- telmisartan (to treat high blood pressure)
- lapatinib (to treat breast cancer)
- ticagrelor (to prevent heart attack or stroke)

- verapamil and felodipine (to treat high blood pressure)
- vandetanib (to treat certain types of thyroid gland cancers)
- p-glycoprotein inhibitors

- venetoclax (to treat patients suffering from chronic lymphocytic leukemia)
- 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 can **increase or have no effect on the level of Lanoxin Elixir** in the blood:

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

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

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

- antacids (to treat gastric acidity)
- some bulk-forming laxatives (increase the amount of stools you produce to help you have bowel movements)
- 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 Elixir and suxamethonium (used for muscle relaxation and to treat short-term paralysis), you may have an **increased risk of high potassium level in the blood**.

Use of the medicine and food

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

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

Pregnancy, breastfeeding and fertility

Pregnancy
The doctor will prescribe you 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 can also affect the fetus.

Breastfeeding

This medicine is excreted in breast milk, but in very small amounts. Therefore, breastfeeding women 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 are pregnant or are planning to become pregnant, consult with the doctor or pharmacist before using the 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, using machines or participating in dangerous activities.

Important information about some of the ingredients of the medicine

Lanoxin Elixir contains methyl parahydroxybenzoate, sucrose, ethanol and sodium.

Methyl parahydroxybenzoate:

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

Sucrose:

Lanoxin Elixir contains less than 0.3 g of sucrose per 1 ml of solution, i.e., 1.5 g 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 the 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 g 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 the 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 diseases or epilepsy.

Children and adults over the age of 10 years
Sodium:

- Adults and children over the age of 10 years: Lanoxin Elixir contains 38.019 mg of sodium (the main ingredient in 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 SHOULD YOU USE THE MEDICINE?

Always use the preparation according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and the treatment regimen of the preparation. The dosage and treatment regimen will be determined by the doctor only:

- The dosage depends on what heart problem you suffer from and how serious it is.
- The dosage also depends on your age, weight and kidney function.

While you are taking the medicine, the 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 the doctor.

- If you are taking or have taken another medicine of the glycoside family for cardiac treatment in the last two weeks, the doctor may prescribe a lower dosage for you.
- If you feel that the effect of the medicine is too strong or too weak, refer to the doctor.

Method of administration

Lanoxin Elixir is an oral solution which is taken orally.

Lanoxin Elixir is supplied with a graduated dropper. Use it to measure out all of the doses.

- 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 quickly bring your Lanoxin Elixir level to the correct blood level, in one of two ways:

- You will receive a large single dose and then begin to receive your maintenance dose or
- You will receive a smaller dose each day for one week and then begin to receive your maintenance dose.

- Stage 2- maintenance dose**

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

Children and adults 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 hours apart.
 - Alternatively, taking a dose of 0.25-0.75 mg each day for one week.

- Maintenance dose
 - Your doctor will decide on the dose, depending on your response to Lanoxin Elixir.
 - 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-hour intervals.
- Maintenance dose
 - The doctor will decide on the dose, depending on your child's response to Lanoxin Elixir.
 - 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 dosage than the usual adult dosage. This is because elderly people may have reduced kidney function. The doctor will check the level of Lanoxin Elixir in your blood and may change your dosage if necessary.

Do not exceed the dose recommended by the doctor.

If you have accidentally taken a higher dosage

If you have taken an overdose or if a child has accidentally swallowed the medicine, refer immediately to a doctor or proceed 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 digoxin toxicity are heart rhythm disturbances and gastrointestinal symptoms which can 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 signs of toxicity have passed. In chronic toxicity, non-heart-related symptoms, such as weakness and a general feeling of illness, will be the main symptoms.

If you forgot to take the medicine at the designated time, do not take a double dose to compensate for the forgotten dose. Take the next dose at the regular time and consult a doctor. Adhere to the treatment regimen 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 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 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. **Refer to a specialist immediately or seek urgent medical advice if the following signs occur:**

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

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

Additional side effects can include:

Common side effects – (occur in up to 1 in 10 users)

- allergic reactions of the skin may occur (rash, urticaria)
- abnormal heartbeat
- nausea, vomiting, diarrhea
- central nervous system disturbances, such as dizziness

- visual disturbances (blurred or yellow vision)
- Uncommon side effects (occur in less than 1 in 100 users)**

- depression
- Very rare side effects (occur in less than 1 in 10,000 users)**
 - decrease in the amount of blood platelets (symptoms include bruises and nosebleeds)
 - loss of appetite (anorexia)
 - psychosis, apathy, confusion
 - headache
 - stomach pains caused by lack of blood supply or damage to the 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 occurs, if one of the side effect worsens, or if you suffer from a side effect not mentioned in the leaflet, consult the doctor.

Reporting of 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 to the online form for reporting side effects, or by clicking on the following link: <https://sideeffects.health.gov.il>

Additionally, side effects can be reported to Padagis via the following address:

recomended by the doctor.
5. HOW SHOULD THE MEDICINE BE STORED

- Avoid poisoning! This medicine and any other medicine must be stored in a safe place out of the reach and sight of children and/or infants in order 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.
- After first opening the bottle, the preparation can be used for 12 days and no later than the expiry date of the medicine, the earlier of the two.
- 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. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains the following inactive ingredients:

- Purified Water, Disodium Phosphate Anhydrous, Methyl Parahydroxybenzoate, Citric Acid Monohydrate, Syrup, Quinoline Yellow E104 (Colourant), Ethanol, Propylene Glycol, Lime Flavour.

What the medicine looks like and the content of the package:

Lanoxin Elixir is a yellow, lime-flavored liquid, packaged in an amber glass bottle containing 60 ml of liquid with a plastic 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 May 2023 according to MOH guidelines.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 126.96.30673.