

Package Leaflet: Information for the User
Lanoxin-PG® 0.05mg/ml Elixir
(digoxin)

This product is available in the above name but will be referred to as Lanoxin-PG throughout the remainder of this leaflet.

Read all of this leaflet carefully before you start using 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 possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Lanoxin-PG Elixir is and what it is used for
2. What you need to know before you use Lanoxin-PG Elixir
3. How to use Lanoxin-PG Elixir
4. Possible side effects
5. How to store Lanoxin-PG Elixir
6. Contents of the pack and other information

1. What Lanoxin-PG Elixir is and what it is used for

Lanoxin contains the active substance digoxin, which belongs to a group of medicines called cardiac glycosides. It is used to treat arrhythmias and heart failure. An arrhythmia is an irregularity in the heart-beat, which causes the heart to skip a beat, beat irregularly or beat at the wrong speed. This medicine works by correcting irregular heartbeats to a normal rhythm and strengthens the force of the heart-beat, which is why it is useful in heart failure.

2. What you need to know before you use Lanoxin-PG Elixir

Do not use Lanoxin-PG Elixir if you:

- Are allergic to digoxin, other cardiac glycosides or any of the other ingredients of this medicine (listed in section 6).
- Have serious heart problems, such as those 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).
- Have an irregular heart-beat caused by cardiac glycoside intoxication or conditions such as Wolff-Parkinson-White syndrome.
- Have obstructive cardiomyopathy (enlargement of the heart muscle).

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using this medicine:

- If you are taking this medicine, your 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 disorders.
- If you develop digoxin toxicity, this can lead to various forms of heart rhythm disturbances, some of which resemble the rhythm disturbances for which the product was prescribed.
- If you have abnormal heart rhythm (heart block) and you are taking this medicine, contact your doctor immediately if you feel one or more of the following symptoms: fainting, short-lasting loss of consciousness, dizziness or light-headedness, fatigue (tiredness), shortness of breath, chest pain, irregular heart-beat or confusion.
- If 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 heart-beat. Sometimes this will cause tiredness, weakness and dizziness and when your heartbeat is very slow you may faint.
- If you have recently suffered a heart attack.
- When heart failure occurs along with the collection of an abnormal protein in the heart tissue (cardiac amyloidosis), an alternative therapy may be prescribed by the doctor.
- If you have myocarditis (inflammation of the heart muscle) this may cause vasoconstriction (narrowing of the blood vessels) on rare occasions. Your doctor may prescribe you a different medicine.
- If you have Beri-beri disease (caused by a vitamin B1 deficiency).
- If you have constrictive pericarditis (inflammation of the sac which contains the heart).
- If you are taking diuretics (drugs which promote urine production and help reduce the amount of water in your body) with or without an ACE inhibitor (mainly used to treat high blood pressure), your doctor will prescribe a lower dose of Lanoxin. Do not stop taking Lanoxin without talking to your doctor.
- If you have a heart test called an ECG (electrocardiogram), tell the person doing the test that you are taking Lanoxin as it can affect the meaning of the results.
- If you have severe respiratory (lung) disease (as you may have an increased sensitivity to Lanoxin).
- If 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.
- If you have thyroid disease (such as an under-active or over-active thyroid) as you might require changes in the dose of this medicine.
- If you have malabsorption syndrome (you cannot absorb minerals from your food properly) or if you have ever had gastrointestinal reconstruction surgery.
- If you will receive electric shock treatment to correct an abnormal heart-beat.

Other medicines and Lanoxin-PG Elixir

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

Taking several medicines can sometimes have harmful consequences or lead to unwanted interactions.

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

These include:

- diuretics,
- lithium salts (antidepressants),
- corticosteroid based products,
- carbenoxolone (a product which strengthens the gastric mucosa),

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

- certain products which affect the heart: amiodarone, flecainide, prazosin, propafenone, quinidine,
- canagliflozin (used to treat of type 2 diabetes mellitus),
- certain antibiotics: erythromycin, clarithromycin, tetracycline, gentamicin, trimethoprim,
- daclatasvir (used in combination with other medications to treat hepatitis C),

- flibanserin (used to treat low sexual desire in women who have not gone through menopause),
- medicines used for fungal infections (isavuconazole, itraconazole, posaconazole),
- ivacaftor (used to treat cystic fibrosis),
- spironolactone (a drug which increases the amount of urine you produce),
- alprazolam (a sedative which may be used to treat anxiety),
- indomethacin (used to treat inflammation),
- quinine (may be used to prevent malaria infection),
- propantheline (used to prevent muscle spasms),
- mirabegron (used to treat overactive bladder that causes a sudden urge to urinate resulting in involuntary loss of urine),
- nefazodone (an antidepressant),
- atorvastatin (lowers blood cholesterol),
- cyclosporine (an immunosuppressant often used to prevent transplant rejection),
- epoprostenol (used to treat pulmonary arterial hypertension),
- tolvaptan (used to treat low blood sodium levels),
- conivaptan (used to treat low blood sodium levels),
- carvedilol (used to treat mild to severe congestive heart failure and high blood pressure),
- ritonavir (used to treat HIV infection and AIDS),
- telaprevir (used to treat hepatitis C infection),
- dronedarone (used to treat irregular heart-beat),
- ranolazine (used to treat chest pain),
- simeprevir (used in combination with other medications to treat hepatitis C),
- telmisartan (used to treat high blood pressure),
- medicines used for cancer (lapatinib, vandetanib, Vemurafenib, osimertinib),
- ticagrelor (used to prevent heart attack or stroke),
- verapamil (used to treat high blood pressure),
- felodipine (used to treat high blood pressure),
- tiapamil (used to treat chest pain),
- velpatasvir (used in combination with other medications to treat hepatitis C),
- P-glycoprotein inhibitors.
- Venetoclax (is used to treat patients with chronic lymphocytic leukaemia)
- Proton pump inhibitors (PPIs) (used to relieve symptoms of acid reflux, or gastroesophageal reflux disease (GERD))

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

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

If you have heart failure and are taking sennosides (increase the amount of stools you produce to help you have bowel movements) 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 (used to treat gastric acidity),
- some bulk-forming laxatives (increase the amount of stools you produce to help you have bowel movements),
- kaolin-pectin (used to treat diarrhoea),
- acarbose (used to treat some types of diabetes),
- certain antibiotics: neomycin, penicillamine, rifampicin,
- some cytostatic drugs (used as chemotherapy for cancer treatment),
- metoclopramide (a product for treating nausea and vomiting),
- sulfasalazine (a product to counteract inflammatory diseases of the intestine),
- adrenaline (used to treat severe allergic reactions),
- salbutamol (a product used to treat asthma),
- colestyramine (lowers blood cholesterol),
- phenytoin (used to treat epilepsy),
- St. John's wort (*Hypericum perforatum*) (used to treat depression),
- bupropion (used 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
- betablockers
- sympathomimetics (used to treat heart attack and low blood pressure)

If you are taking Lanoxin and suxamethonium (used to help muscle relaxation and treat short-term paralysis), you may have an increased risk of high potassium levels in the blood.

Tell your doctor if you take a medicine containing enzalutamide (for the treatment of prostate cancer).

It may interfere with your digoxin tests.

Lanoxin-PG Elixir with food and drink

This medicine may be taken on an empty stomach or with most meals. However, you should avoid taking Lanoxin-PG Elixir with foods that are high in fibre, also known as 'dietary fibre', because the level of Lanoxin absorbed by the body can be reduced.

Pregnancy, breastfeeding and fertility

Pregnancy

Your doctor will prescribe this medicine with caution during pregnancy.

You may require a higher dose of this medicine if you are pregnant.

This medicine could be given to the mother to treat abnormally high heart rate and congestive heart failure in the unborn child.

Side effects of Lanoxin treatment affecting the mother may also affect the unborn child.

Breastfeeding

This medicine is excreted in breast milk, but in very small amounts. Therefore, this medicine can be used by women who are breast-feeding.

Fertility

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

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.