PACKAGE LEAFLET: INFORMATION FOR THE USER

Lanoxin PG 50 micrograms/ml Elixir
(Digoxin)

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 gastro-intestinal 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),
- taleprevir (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 (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 or apalutamide (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.

Driving and using machines
Since dizziness and blurred or yellow vision have been reported, you should exercise caution before driving a vehicle, using machinery or participating in dangerous activities.

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

Methyl parahydroxybenzoate (E218):
- May cause allergic reactions (possibly delayed).

Sucrose:
- If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product. May be harmful to teeth.

Ethanol:

- This medicine contains 10% by volume of ethanol (alcohol) or 0.1ml of ethanol in each 1ml volume (0.05mg digoxin), i.e., up to 82mg of ethanol per 1ml volume (410mg in 5ml), equivalent to approximately 2ml of beer, or less than 1ml of wine.
  The amount of alcohol in this medicine is not likely to have an effect in adults and adolescents, and its side effects in children are not likely to be noticeable. It may have some effects in younger children, for example feeling sleepy.
  The alcohol in this medicine may alter the effects of other medicines. Talk to your doctor or pharmacist if your are taking other medicines.
  If you are pregnant or breastfeeding, talk to your doctor or pharmacist before taking this medicine.
  If you are addicted to alcohol, talk to your doctor or pharmacist before taking this medicine.

Sodium:

- This medicine contains less than 1 mmol sodium (23 mg) per 1 ml of oral solution, that is to say essentially 'sodium-free'.

3. How to take Lanoxin PG Elixir

This medicine is available as an oral solution which is taken orally.

Lanoxin PG Elixir, 0.05 mg in 1 ml, is supplied with a graduated pipette and this should be used for measurement of all doses.

Lanoxin PG Elixir should not be diluted.

Always use this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.

Your doctor will have decided how much of this medicine is right for you:

- It depends on what heart problem you have and how serious it is
- It also depends on your age, weight and how well your kidneys work
- While you are taking this medicine, your doctor will take regular blood tests. This is to determine how you are responding to treatment.
- Your doctor will adjust your dose based on your blood test results and on how you are responding to treatment. This is why you must strictly adhere to the treatment course prescribed by your doctor.
- If you have taken another cardiac glycoside in the past 2 weeks, your doctor may prescribe a lower dose.
- If you feel that the effect of this medicine is too strong or too weak, talk to your doctor or pharmacist.

Taking this medicine
You usually take this medicine in two stages:

- Stage 1 - loading dose

The loading dose gets your Lanoxin levels up to the correct level quickly. You will either:

- take one large single dose and then begin your maintenance dose or
- take a smaller dose each day for a week and then begin your maintenance dose

- Stage 2 - maintenance dose

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

Adults and children over 10 years

- loading dose
  - Usually between 0.75 and 1.5 mg as a single dose
  - For some patients, this may be given in divided doses 6 hours apart
  - Alternatively, between 0.25 and 0.75 mg may be given each day for a week
- maintenance dose
  - Your doctor will decide this, depending on your response to this medicine
  - It is usually between 0.125 and 0.25 mg daily

Children under 10 years

- loading dose
  - This is worked out using your child's weight
  - Usually between 0.025 and 0.045 mg per kg of body weight
  - This should be given in divided doses between 4 and 8 hours apart
- maintenance dose
  - The doctor will decide this, depending on your child's response to Lanoxin
  - It is usually a 1/5 (fifth) or a 1/4 (quarter) of the loading dose, to be taken daily

Elderly

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

If you use more Lanoxin PG Elixir than you should

If you have taken too much Lanoxin PG Elixir or a child has taken the medicine by accident, contact your doctor, hospital or poison centre to evaluate the risks and get more information.

The main symptoms of Lanoxin toxicity are heart rhythm disturbances and gastrointestinal symptoms which may happen before heart rhythm disturbances. Gastrointestinal symptoms include loss of appetite, nausea and vomiting. Other symptoms of Lanoxin toxicity include dizziness, fatigue, a general feeling of being unwell and various neurological disturbances including visual disturbances (more yellow-green than usual). The neurological and visual symptoms may persist even after other signs of toxicity have been resolved. In chronic toxicity, non-heart related symptoms, such as weakness and a general feeling of being unwell, may be the main symptoms.

If you forget to use Lanoxin PG Elixir

Do not take a double dose to make up for the forgotten dose.

If you stop using Lanoxin PG Elixir

Your doctor will tell you how long you should take Lanoxin. Do not stop your treatment early without consulting your doctor.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you get any of the following, talk to your specialist doctor straight away or seek urgent medical advice:

Very rare (may affect up to 1 in 10,000 people)
- palpitations, chest pain, shortness of breath or sweating. These can be symptoms of a serious heart problem caused by new irregular heartbeats

Other side effects may include:

Common (may affect up to 1 in 10 people)
- allergic reactions of the skin may occur (rash, urticaria)
- abnormal heart-beat
- nausea, vomiting, diarrhoea
- central nervous system disturbances such as dizziness
- visual disturbances (blurred or yellow vision)

Uncommon (may affect up to 1 in 100 people)
- depression

Very rare (may affect up to 1 in 10,000 people)
- decrease in blood platelets (symptoms include bruises and nose bleeds)
- loss of appetite (anorexia)
- psychosis, apathy, confusion
- headache
- stomach pain caused by lack of blood supply or damage to your intestines (ischaemia and necrosis)
- enlarged breast tissue in men (gynaecomastia)
- lack of energy (fatigue), a general feeling of being unwell and weakness

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system:
HPRA Pharmacovigilance
Website: www.hpra.ie
By reporting side effects, you can help provide more information on the safety of medicine.

5. How to store Lanoxin PG Elixir

Keep this medicine out of the sight and reach of children.
Do not use this medicine after the expiry date which is stated on the label or carton. The expiry date refers to the last day of that month.
Once opened, use within 12 days.
Do not store above 25°C. Store in the original container in order to protect from light.
Do not use this medicine if you notice any visible signs of deterioration.
Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Lanoxin PG Elixir contains

Each 1 ml of Lanoxin PG Elixir contains 50 micrograms of the active substance digoxin.

The other ingredients are methyl parahydroxybenzoate (E218), syrup (containing sucrose), anhydrous sodium phosphate, citric acid monohydrate, quinoline yellow (E104), ethanol, propylene glycol, lime flavour, purified water.

What Lanoxin PG Elixir looks like and contents of the pack
Lanoxin PG Elixir is a clear, bright yellow, lime flavoured oral solution.
Lanoxin PG Elixir is available in bottles containing 60 ml oral solution.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
Aspen Pharma Trading Limited,
3016 Lake Drive,
Citywest Business Campus,
Dublin 24, Ireland.
+353 1 630 8400

Manufacturer
Aspen Bad Oldesloe GmbH, Industriestrasse 32-36, D-23843 Bad Oldesloe, Germany.

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