

1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

LANOXIN INJECTION 0,50 mg/2 ml

Digoxin

Contains alcohol: Ethanol 9,98 % v/v

Sugar free

Read all of this leaflet carefully before you are given LANOXIN INJECTION

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.

What is in this leaflet

1. What LANOXIN INJECTION is and what it is used for
2. What you need to know before LANOXIN INJECTION is administered to you
3. How LANOXIN INJECTION will be administered to you
4. Possible side effects
5. How to store LANOXIN INJECTION
6. Contents of the pack and other information



1. What LANOXIN INJECTION is and what it is used for

LANOXIN INJECTION belongs to a group of medicines called cardiac glycosides.

LANOXIN INJECTION works by slowing down the rate while increasing the force of your heart when it beats.

LANOXIN INJECTION is used to treat certain heart problems, such as:

- chronic heart failure,
- certain types of irregular heartbeats, such as atrial fibrillation.

2. What you need to know before LANOXIN INJECTION is administered to you

LANOXIN INJECTION should not be administered to you:

- If you are hypersensitive (allergic) to digoxin or to any of the other ingredients in LANOXIN INJECTION (listed in section 6).
- If you have been told that you have any of the following heart problems:
 - Second degree or total/intermittent complete heart block.
 - Certain types of supraventricular dysrhythmias.
 - Ventricular tachycardia.
 - Hypertrophic obstructive cardiomyopathy.
 - Aortic stenosis.

Warnings and precautions

Tell your doctor or healthcare provider before LANOXIN INJECTION is administered to you:

- If you have recently had a heart attack or other heart problems in the past,

- if you have a heart problem caused by a lack of vitamin B, known as 'Beri-Beri disease,'
- if you have taken or received LANOXIN in the past two weeks in any dosage form,
- if you are elderly, as your dose will have to be adjusted by your doctor,
- if you have problems with your thyroid gland,
- if you have severe breathing problems,
- if you have or have ever had kidney disease,
- if you have digestion problems,
- if you have been told that you have low potassium or magnesium levels in your blood (hypokalaemia or hypomagnesaemia),
- if you have been told that you have low oxygen levels in your body tissue (hypoxia),
- if you have been told that you have high calcium levels in your blood (hypercalcaemia),
- if you have a heart test called an ECG (electrocardiogram), tell the person doing the test that you are receiving LANOXIN INJECTION, as it can affect the interpretation of the results,
- if you will receive electric shock treatment to correct an abnormal heartbeat,
- if you are being treated with LANOXIN INJECTION blood samples may be taken at intervals to check for anything abnormal or to check the amount of digoxin in your blood. Your doctor may change the dose you are receiving. This is particularly important in elderly patients or those who have or ever had kidney disease,

- if you have heart problems, LANOXIN INJECTION may improve the amount of exercise you can withstand before becoming breathless and tired (exercise tolerance).

Children and adolescents

Your child's doctor will decide whether to prescribe LANOXIN INJECTION based on your child's condition, age, weight, and kidney function.

Other medicines and LANOXIN INJECTION

Always tell your healthcare provider if you are taking any other medicines (this includes complementary or traditional medicines).

Tell your doctor if you are taking any of the following medicines:

- P-glycoprotein inhibitors (medicine that can delay the absorption of other medicines).
- Beta-blockers, angiotensin converting enzyme (ACE) inhibitors, angiotensin receptor blocker (ARBs) and other medicines used to treat high blood pressure (such as prazosin, epoprostenol, telmisartan, verapamil, tiapamil, diltiazem, felodipine and nifedipine).
- Lithium (used to treat mood disorders).
- Corticosteroid medicines (used to treat rheumatoid arthritis, lupus, asthma and allergies).
- Carbenoxolone (used to treat gut ulcers) and proton pump inhibitors (PPIs) (used to relieve symptoms of acid reflux, or gastroesophageal reflux disease (GERD)).
- Water tablets (diuretics).

- Sennoside and bulk laxatives (used to treat constipation).
- Suxamethonium (used in anaesthesia).
- Calcium containing medicines.
- Mirabegron (used to treat the sudden and urgent need to urinate).
- Ivacaftor (used to treat cystic fibrosis).
- Isavuconazole and itraconazole (used to treat fungal infections).
- Sympathomimetics (used to treat heart attack and low blood pressure).
- Lapatinib (used to treat certain breast cancers).
- Medicines used to treat depression (such as bupropion and nefazodone).
- Supplemental enteral nutrition (a specialised liquid food mixture administered into the stomach or small intestine through tube-feeding).
- Medicines used to treat heart disorders (such as amiodarone, captopril, flecainide, propafenone, quinidine or quinine, carvedilol, dronedarone, ranolazine and ticagrelor).
- Canagliflozin (used to treat type 2 diabetes).
- Flibanserin (used to increase sexual desire in women).
- Certain antibiotics (such as tetracycline, macrolide antibiotics e.g. erythromycin, clarithromycin (and possibly other antibiotics), gentamicin, trimethoprim, neomycin, rifampicin and penicillamine).
- Cytostatics (medicines that slows or stops the growth of cells, including cancer cells, without killing them).
- Alprazolam (used to treat anxiety).
- Anti-inflammatory medicines (NSAIDs and COX-2 inhibitors, such as indomethacin and aspirin).
- Propantheline (used to treat excessive sweating).

- Atorvastatin and cholestyramine (used to treat high cholesterol).
- Ciclosporin (used in organ transplants).
- Conivaptan and tolvaptan (used to treat low levels of sodium in the blood).
- Velpatasvir, sofosbuvir, simeprevir, and daclatasvir, (used to treat hepatitis C).
- Venetoclax, Vemurafenib, Vandetanib (used to treat cancers).
- Antiretroviral medicines (such as ritonavir).
- Medicines used to treat heartburn (antacids).
- Kaolin-pectin and diphenoxylate (used to treat diarrhoea).
- Acarbose (used to treat high blood sugar).
- Adrenaline (used to treat allergic reactions).
- Salbutamol (used to treat asthma).
- Phenytoin (used to treat epilepsy).
- Metoclopramide (used to treat nausea).
- St. John's wort (herbal remedy).
- Sulphasalazine (used to treat certain kind of bowel diseases).
- Milrinone (used during cardiac surgeries in patients with heart problems)

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your healthcare provider for advice before receiving LANOXIN INJECTION.

Pregnancy

Your doctor may prescribe a higher dose of LANOXIN INJECTION if you are pregnant.



Your doctor may prescribe LANOXIN INJECTION to you during pregnancy to treat abnormally high heart rate and congestive heart failure in your unborn baby.

Breastfeeding

LANOXIN INJECTION is passed into breast milk, but in very small amounts. Therefore, your doctor can prescribe LANOXIN INJECTION to you while you are breastfeeding.

Driving and using machines

Since adverse reactions such as dizziness and visual disturbances have been reported in patients receiving LANOXIN INJECTION, you should not drive, use machinery or perform any tasks that require concentration, until you are certain that LANOXIN INJECTION does not adversely affect your ability to do so.

It is not always possible to predict to what extent LANOXIN INJECTION may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which LANOXIN INJECTION may affect you.

LANOXIN INJECTION contains alcohol

LANOXIN INJECTION contains 0,208 ml of alcohol (ethanol 96 %) in each 2 ml ampoule.

The small amount of alcohol in this medicine will not have any noticeable effects.

3. How LANOXIN INJECTION will be administered to you

Your doctor will tell you how long your treatment with LANOXIN INJECTION will last.



You will not be expected to give yourself LANOXIN INJECTION. It will be given to you by a person who is qualified to do so. You should check with your doctor or pharmacist if you are unsure.

Your doctor will work out the right dose of LANOXIN INJECTION for you. This will depend on:

- what heart problem you have and how serious it is,
- your age, weight, and how well your kidneys and liver work.

Your doctor will take regular blood tests, to determine how you are responding to treatment.

If you have the impression that the effect of LANOXIN INJECTION is too strong or too weak, tell your doctor or pharmacist.

If you receive more LANOXIN INJECTION than you should

Since a healthcare provider will administer LANOXIN INJECTION, he/she will control the dosage. However, in the event of overdose your doctor will manage the overdose.

The main symptoms toxicity (overdose) are problems with the speed that your heart beats and gastrointestinal (stomach) symptoms. You may experience loss of appetite, feeling sick and being sick.

You may also experience dizziness, fatigue (tiredness), a general feeling of being unwell and blurred or yellowed vision (more yellow than usual). These symptoms may still be present even after other symptoms have been treated.

In long term toxicity you may experience non-heart related symptoms, such as weakness and a general feeling of being unwell.

If you forget a dose of LANOXIN INJECTION

Since a healthcare provider will administer LANOXIN INJECTION, it is unlikely that the dose will be missed.

4. Possible side effects

LANOXIN INJECTION can have side effects.

Not all side effects reported for LANOXIN INJECTION are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking LANOXIN INJECTION, please consult your doctor, pharmacist or other health care provider for advice.

If any of the following happens, stop receiving LANOXIN INJECTION and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to LANOXIN INJECTION. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Changes in pulse rate or palpitations. Your heart may beat more slowly, faster or irregularly (bradycardia, dysrhythmia, tachycardia, electrocardiogram ST segment depression),
- a decrease in blood components called platelets, which help your blood

to clot. This may cause unusual bruising or bleeding under the skin (these are symptoms of thrombocytopenia),

- loss of contact with reality, hallucinations, (psychotic disorder),
- severe stomach pain, nausea, vomiting, bloody stools (gastrointestinal necrosis and intestinal ischaemia),
- pain and swelling of the skin on the arms and legs (eosinophilia).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Disorientation lack of co-ordination, memory loss (nervous system disorders),
- irregular heartbeat, palpitations (trigeminy, bigeminy, ventricular extrasystoles),
- dizziness,
- blurred or yellow vision,
- feeling sick or being sick, diarrhoea,
- bright red rash that feels like sandpaper (scarlatiniform).

Less frequent side effects:

- Depression.

Side effects with unknown frequency:

- Decreased appetite,
- lack of emotion, interest, enthusiasm, or concern,
- confusion, headache,
- extreme tiredness or weakness,
- enlarged breasts in men following long-term treatment,
- general feeling of discomfort or illness.



If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to:

SAHPRA: via the “6.04 Adverse Drug Reactions Reporting Form”, found online under SAHPRA’s publications:

<https://www.sahpra.org.za/Publications/Index/8>

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088/+27 (0)11 239 -6200

By reporting side effects, you can help provide more information on the safety of LANOXIN INJECTION.

5. How to store LANOXIN INJECTION

Store all medicines out of reach of children.

Store at or below 25 °C.

Protect from light.

Keep in original packaging until required for use.

Do not store in a bathroom.

Do not use after the expiry date stated on the label.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).



6. Contents of the pack and other information

What LANOXIN INJECTION contains

The active substance in each 2 ml ampoule is 0,50 mg digoxin.

The other ingredients are:

Citric acid monohydrate (for pH adjustment), ethanol, propylene glycol, sodium phosphate dodecahydrate (for pH adjustment), water for injection.

Contains alcohol: Ethanol 9,98 % v/v; Propylene glycol: 0,8 ml/2 ml

Sugar free

What LANOXIN INJECTION looks like and contents of the pack

LANOXIN INJECTION is a clear, colourless liquid, practically free from particles.

LANOXIN INJECTION is packed into Type I, clear, glass ampoules. Five ampoules are packed together in a printed cardboard carton.

Holder of Certificate of Registration

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

Hotline: 0800 122 912

Tel: +27 11 239 6200

This leaflet was revised in



06 October 2023

Registration number

G2848 (Act 101/1965)

Access to the corresponding Professional Information

SAHPRA Repository of Professional Information and Patient Information Leaflets:

<https://www.sahpra.org.za/pi-pil-repository/>

Aspen Pharmacare:

E-mail: Medinfo@aspenpharma.com

Tel: 0800 118 088

Botswana: B9317290 S2

Namibia: NS2 14/6.3/0271

ZA_LANOINJ_2310_00