1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

LANOXIN PAEDIATRIC/GERIATRIC ELIXIR 0,05 mg/1 ml

Digoxin

Contains alcohol: Ethanol 9,97 % *v/v*

Contains sugar: Sucrose 300 mg

Read all of this leaflet carefully before you are given/start taking LANOXIN PAEDIATRIC /GERIATRIC ELIXIR

- 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.
- LANOXIN PAEDIATRIC /GERIATRIC ELIXIR has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What LANOXIN PAEDIATRIC /GERIATRIC ELIXIR is and what it is used for
2. What you need to know before you give/take LANOXIN PAEDIATRIC /GERIATRIC ELIXIR
3. How to give/take LANOXIN PAEDIATRIC /GERIATRIC ELIXIR
4. Possible side effects
5. How to store LANOXIN PAEDIATRIC /GERIATRIC ELIXIR
6. Contents of the pack and other information

1. What LANOXIN PAEDIATRIC/GERIATRIC ELIXIR is and what it is used for

LANOXIN PAEDIATRIC/GERIATRIC ELIXIR belongs to a group of medicines called cardiac glycosides. LANOXIN PAEDIATRIC/GERIATRIC ELIXIR works by slowing down the rate while increasing the force of your heart when it beats.
LANOXIN PAEDIATRIC/GERIATRIC ELIXIR 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 you take LANOXIN PAEDIATRIC /GERIATRIC ELIXIR

Do not give/take LANOXIN PAEDIATRIC/GERIATRIC ELIXIR:

- If you are hypersensitive (allergic) to digoxin or to any of the other ingredients LANOXIN PAEDIATRIC/GERIATRIC ELIXIR (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

Take special care with LANOXIN PAEDIATRIC/GERIATRIC ELIXIR:

- 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 taking LANOXIN PAEDIATRIC /GERIATRIC ELIXIR, 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 PAEDIATRIC /GERIATRIC ELIXIR 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 taking. This is particularly important in elderly patients or those who have or ever had kidney disease,

- if you have heart problems, LANOXIN PAEDIATRIC /GERIATRIC ELIXIR 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 PAEDIATRIC/ GERIATRIC ELIXIR based on your child's condition, age, weight, and kidney function.

Other medicines and LANOXIN PAEDIATRIC /GERIATRIC ELIXIR

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, taleprevir, 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)

LANOXIN PAEDIATRIC/GERIATRIC ELIXIR with food and drink

LANOXIN PAEDIATRIC/GERIATRIC ELIXIR can be taken with most foods. However, you should avoid taking it with foods that are high in fibre, also known as 'roughage',

as the amount of LANOXIN PAEDIATRIC/GERIATRIC ELIXIR absorbed into the body may be reduced.

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 taking this medicine.

Pregnancy

Your doctor may prescribe a higher dose of LANOXIN PAEDIATRIC /GERIATRIC ELIXIR if you are pregnant.

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

Breastfeeding

LANOXIN PAEDIATRIC /GERIATRIC ELIXIR is excreted in breast milk, but in very small amounts. Therefore, your doctor can prescribe LANOXIN PAEDIATRIC /GERIATRIC ELIXIR 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 PAEDIATRIC/GERIATRIC ELIXIR, you should not drive, use machinery or perform any tasks that require concentration, until

you are certain that LANOXIN PAEDIATRIC/GERIATRIC ELIXIR does not adversely affect your ability to do so.

It is not always possible to predict to what extent LANOXIN PAEDIATRIC /GERIATRIC ELIXIR 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 PAEDIATRIC /GERIATRIC ELIXIR may affect you.

LANOXIN PAEDIATRIC/GERIATRIC ELIXIR contains sucrose

LANOXIN PAEDIATRIC/GERIATRIC ELIXIR contains sucrose.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking LANOXIN PAEDIATRIC/GERIATRIC ELIXIR.

LANOXIN PAEDIATRIC/GERIATRIC ELIXIR contains alcohol

LANOXIN PAEDIATRIC/GERIATRIC ELIXIR: contains 0,1039 ml of alcohol (ethanol 96 %) in each 1 ml.

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

LANOXIN PAEDIATRIC/GERIATRIC ELIXIR contains propylene glycol

LANOXIN PAEDIATRIC/GERIATRIC ELIXIR contains 0,05 ml of propylene glycol in each 1 ml.

3. How to give/take LANOXIN PAEDIATRIC/GERIATRIC ELIXIR

Do not share medicines prescribed for you with any other person.

Your doctor will work out the right dose of LANOXIN PAEDIATRIC/GERIATRIC ELIXIR for you, and how often you should take it. 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.

You should try to take LANOXIN PAEDIATRIC/GERIATRIC ELIXIR at the same time every day.

LANOXIN PAEDIATRIC/GERIATRIC ELIXIR is supplied with a graduated pipette. You should use this to measure out the correct dose your doctor has prescribed.

LANOXIN PAEDIATRIC/GERIATRIC ELIXIR should not be diluted.

Always take LANOXIN PAEDIATRIC/GERIATRIC ELIXIR as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Your doctor will tell you how long your treatment with LANOXIN PAEDIATRIC /GERIATRIC ELIXIR will last. Do not stop treatment early because you may experience undesirable effects. If you have the impression that the effect of LANOXIN PAEDIATRIC/GERIATRIC ELIXIR is too strong or too weak, tell your doctor or pharmacist.

If you give/take more LANOXIN PAEDIATRIC/GERIATRIC ELIXIR than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

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 to give/take a dose of LANOXIN PAEDIATRIC/GERIATRIC ELIXIR

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

If you have missed a dose of LANOXIN PAEDIATRIC/GERIATRIC ELIXIR, give/take the missed dose as soon as you remember. However, if it is nearly time for the next dose, skip the missed dose. If you have forgotten to give/take several doses, contact your doctor without delay.

If you stop giving/taking LANOXIN PAEDIATRIC/GERIATRIC ELIXIR

Do not stop giving/taking LANOXIN PAEDIATRIC/GERIATRIC ELIXIR without first checking with your doctor. Stopping suddenly could make your heart condition worse. Even if you feel better, you need to keep taking this medicine to help the heart work properly.

4. Possible side effects

LANOXIN PAEDIATRIC/GERIATRIC ELIXIR can have side effects.

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

If any of the following happens, stop taking LANOXIN PAEDIATRIC/GERIATRIC ELIXIR 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 PAEDIATRIC/GERIATRIC ELIXIR. 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 interest, emotion, 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 PAEDIATRIC/GERIATRIC ELIXIR

5. How to store LANOXIN PAEDIATRIC/GERIATRIC ELIXIR

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 PAEDIATRIC/GERIATRIC ELIXIR contains

The active substance in each 1 ml of elixir is 0,05 mg of digoxin.

The other ingredients are citric acid monohydrate (for pH adjustment), disodium phosphate anhydrous (for pH adjustment), ethanol, lime flavour, methyl parahydroxybenzoate, propylene glycol, purified water, quinolone yellow (C.I. 47005), sucrose.

Preservative: Methyl parahydroxybenzoate 0,1 % *m/v*

Contains sugar: Sucrose 300 mg

Contains alcohol: Ethanol 9,97 % *v/v*

What LANOXIN PAEDIATRIC/GERIATRIC ELIXIR looks like and contents of the pack

LANOXIN PAEDIATRIC/GERIATRIC ELIXIR is a clear bright yellow fluid with a characteristic odour.

LANOXIN PAEDIATRIC/GERIATRIC ELIXIR: 50 ml or 60 ml is packed into an amber, glass bottle and sealed with a white polypropylene or metal roll-on pilfer proof cap, fitted with a sealing wad. The bottle is packed together with a graduated 1 ml polyethylene dropper into an outer cardboard carton.

Not all packs and pack sizes may be marketed.

Holder of Certificate of Registration

PHARMACARE LIMITED

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Registration number

G2847 (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

Namibia: NS2 14/6.3/0131

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