LANOXIN PG ELIXIR

Digoxin (50mcg/ml)

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What Lanoxin PG Elixir is used for

Lanoxin PG Elixir is used to treat arrhythmias and heart failure. An arrhythmia is an irregularity in the heartbeat, which causes the heart to skip a beat, beat irregularly or beat at the wrong speed.

How Lanoxin PG Elixir works

Lanoxin PG Elixir contains the active ingredient digoxin which belongs to a group of medicines called cardiac glycosides.

Lanoxin PG Elixir works by correcting irregular heartbeats to a normal rhythm and strengthens the force of the heartbeat, which is why it is useful in heart failure.

Before you use Lanoxin PG Elixir

- When you must not use it

You must not take Lanoxin PG Elixir if you are allergic to digoxin, to other cardiac glycosides or to any of the other ingredients in this medicine. Lanoxin PG Elixir must not be used in patients with certain heart problems. Your doctor will have checked your medical history before treating you with this medicine. If you have any concerns you should discuss these with your doctor.

- Before you start to use it

If you are pregnant or are intending to become pregnant or breastfeeding you must discuss this with your doctor. Your doctor will discuss the possible risks and benefits involved.

- Taking other medicines

You **must** tell your doctor or pharmacist about all the medicines you are taking, even those which you have bought for yourself without a doctor's prescription, including herbal remedies such as St John's wort and vitamins. Digoxin interacts with lots of different medicines. The other medicines that you may be taking may increase or decrease the effect of Lanoxin PG Elixir. This can cause Lanoxin PG Elixir not to work properly, can increase your chance of getting side effects, or can make side effects more severe

How to use Lanoxin PG Elixir

- How much to use

Your doctor will work out the right dose of Lanoxin PG Elixir for you, and how often you should take it.

Follow all directions given to you by your doctor carefully. These directions may differ from the information contained in this leaflet. If you do not understand the instructions on the pack, ask your doctor or pharmacist for help.

- When to use it

You should try to take Lanoxin PG Elixir at the same time every day.

Lanoxin PG Elixir can be taken with most foods. However, you should avoid taking it with foods that are high in fibre, as the amount of Lanoxin absorbed into the body may be reduced.

- How long to use it

Continue taking Lanoxin PG Elixir for as long as your doctor recommends.

- <u>If you forget to use it</u>

If you forget to take a dose, take it as soon as you remember, and then continue as before. Do not take a double dose to make up for forgotten individual doses. If more than one dose is missed, contact your doctor or pharmacist for advice.

- If you use too much (overdose)

Contact your doctor immediately or go to Emergency Department of your nearest hospital if you think that you or anyone else may have taken too much Lanoxin PG Elixir. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Taking too much may cause severe dizziness, blurring of vision, irregular heartbeat, feeling sick, diarrhoea and skin rashes.

While you are using it

- Things you must do

Some illnesses can affect how well Lanoxin PG Elixir will work for you. In some cases you may be more likely to get side effects, which can be serious. You may need to be checked more often or need a reduction in your dose of Lanoxin PG Elixir. Tell your doctor if any of these apply to you:

- if you have recently had a heart attack or other heart problems in the past;
- if you have problems with your thyroid gland;
- if you have severe breathing problems;
- if you have or have ever had kidney disease.

While you are being treated with Lanoxin PG Elixir blood samples may be taken at intervals to check for anything abnormal or to check the amount of digoxin in your blood. It may be necessary to 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 a heart test called an ECG (electrocardiogram), tell the person doing the test that you are taking Lanoxin PG Elixir, as it can affect the meaning of the results.

- Things you must not do

Do not stop taking Lanoxin PG 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.

Do not take any new medicines without consulting your doctor.

Do not take Lanoxin PG Elixir to treat any other complaints unless your doctor tells you to.

Do not give Lanoxin PG Elixir to anyone else, even if they have the same condition as you.

- Things to be careful of

This medicine may cause dizziness, confusion and eyesight problems in some people. It may affect your ability to drive or use machines.

If Lanoxin PG Elixir make you feel sick, dizzy or tired, or give you a headache, do not drive or use machine and contact your doctor immediately.

Side effects

Like all medicines, Lanoxin PG Elixir can cause side effects. However, many of these occur because the dose is too high. Therefore your doctor may need to adjust this. The expected benefit of your medicines will usually be greater than the risk of you suffering any harmful side effects. These are the side effects reported from patients taking Lanoxin PG Elixir.

Common effects: this means that between 1 in 10 and 1 in 100 people may be affected.

- Disorientation, dizziness, problems with eyesight (blurred or yellow vision).
- Changes in the rhythm or rate of your heartbeat. Your heart may beat more slowly or irregularly.
- Feeling sick or being sick, diarrhoea.
- Skin rash.

Uncommon effects: this means that between 1 in 100 and 1 in 1,000 people may be affected.

• Depression.

If any side effects become serious, or if you notice any side effects not listed in this leaflet please tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers > Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Lanoxin PG Elixir

- Storage

Keep out of the reach and sight of children.

Store below 25°C.

- <u>Disposal</u>

Discard any unused portion 12 days after opening.

Medicines should not be disposed of via wastewater or household waste. If your doctor or pharmacist tells you to stop taking this medicine or it has passed its expiry date, ask your pharmacist what to do with any medicine that is left over. These measures will help to protect the environment.

Product Description

- What it looks like

Lanoxin PG Elixir is a clear, yellow, lime-flavoured solution containing 50mcg (0.050mg) Digoxin BP in each 1ml of sweetened, aqueous-alcoholic vehicle.

- <u>Ingredients</u>

Active ingredient:

• Digoxin

Inactive ingredients:

- Propylene Glycol
- Ethanol 96%
- Colour Quinoline Yellow No. 10 E104
- Syrup
- Citric Acid Monohydrate
- Lime flavour No. 1
- Methyl Parahydroxybenzoate
- Anhydrous sodium phosphate
- Purified water
- *MAL number* MAL19861532AZ

Manufacturer

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

Product Registration Holder

Aspen Medical Products Malaysia Sdn Bhd (1004761-W) Unit 1302A, Level 13A, Uptown 1, 1 Jalan SS21/58, Damansara Uptown, 47400 Petaling Jaya, Selangor, Malaysia.

Date of Revision

15/06/2020

Serial Number

NPRA (R1/3) 21072020/127