# LANOXIN TABLETS / PG TABLETS

Digoxin (250mcg, PG 62.5mcg)

#### What is in the leaflet

- 1. What Lanoxin Tablet is used for
- 2. How Lanoxin Tablet works
- 3. Before you use Lanoxin Tablet
- 4. How to use Lanoxin Tablet
- 5. While you are using it
- 6. Side effects
- 7. Storage and Disposal of Lanoxin Tablet
- 8. Product Description
- 9. Manufacturer and Product Registration Holder
- 10. Date of Revision

#### What Lanoxin Tablet is used for

Lanoxin Tablet 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 Tablet works**

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

Lanoxin Tablet 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 Tablet

# - When you must not use it

You must not take Lanoxin Tablet if you are allergic to digoxin, to other cardiac glycosides or to any of the other ingredients in this medicine.

Lanoxin Tablet 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.

#### - <u>Before you start to use it</u>

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 Tablet. This can cause Lanoxin Tablet not to work properly, can increase your chance of getting side effects, or can make side effects more severe.

#### **How to use Lanoxin Tablet**

# - How much to use

Your doctor will work out the right dose of Lanoxin Tablet 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 Tablet at the same time every day.

Lanoxin Tablet 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 Tablet for as long as your doctor recommends.

#### - If you forget to use it

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 Tablet. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Taking too many tablets 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 Tablet 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 Tablet. 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 Tablet 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 Tablet, as it can affect the meaning of the results.

#### - Things you must not do

Do not stop taking Lanoxin Tablet 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 Tablet to treat any other complaints unless your doctor tells you to.

Do not give Lanoxin Tablet 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 Tablet 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 Tablet 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 Tablet.

**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 Tablet

# - <u>Storage</u>

Keep out of the reach and sight of children.

Store below 30°C.

# - <u>Disposal</u>

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 250 Micrograms Tablets

 White, round, biconvex tablets, bisected and debossed "D025" on the same side and plain on the other side. Each tablet contains 250mcg (0.250mg) of Digoxin BP.

# Lanoxin PG 62.5mcg Tablets

- Blue, round, biconvex tablets, debossed "D06" on the one side and plain on the other side. Each tablet contains 62.5mcg (0.0625mg) of Digoxin BP.
- Ingredients

Lanoxin 250 Micrograms Tablets

Active ingredient:

• Digoxin

Inactive ingredients:

- Purified water
- Magnesium stearate
- Rice starch
- Oxidised Starch
- Maize starch
- Lactose monohydrate

Lanoxin PG 62.5mcg Tablets

Active ingredient:

• Digoxin

Inactive ingredients:

- Purified water
- Indigo carmine FD&C Blue No. 2
- Povidone
- Rice starch
- Magnesium stearate
- Oxidised Starch
- Lactose monohydrate
- Maize starch

# - MAL number

Lanoxin 250 Micrograms Tablets

MAL19983999AZ

Lanoxin PG 62.5mcg Tablets

• MAL19973575AZ

#### 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 (R1/2) 21072020/126