LANOXIN tablets & oral liquid

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I being given LANOXIN?

LANOXIN contains the active ingredient digoxin. It is used to treat certain heart problems like chronic heart failure, and certain types of irregular heartbeats.

For more information, see Section 1. Why am I being given LANOXIN? in the full CMI.

2. What should I know before I receive LANOXIN?

Do not use if you have ever had an allergic reaction to digoxin, other cardiac glycosides, or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I receive LANOXIN? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with LANOXIN and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How is LANOXIN given?

- Tablets: Swallow LANOXIN tablets with a glass of water.
- Oral liquid: Accurately measure the dose with the calibrated dropper provided. Do not dilute.
- Your doctor will tell you how much LANOXIN to take and how long you use it for.
- It does not matter if you take LANOXIN before or after food.

More instructions can be found in Section 4. How is LANOXIN given? in the full CMI.

5. What should I know while using LANOXIN?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using LANOXIN • If you need to have any medical tests while you are being given it, tell your doctor. • Be sure to keep all your doctor's appointments so that your progress can be checked. • Tell your doctor immediately if you become pregnant while using LANOXIN.
Driving or using machines	• Be careful driving or operating machinery until you know how LANOXIN affects you. LANOXIN may cause dizziness, blurred vision, and faintness in some patients.
Drinking alcohol	• Tell your doctor if you drink alcohol. Alcohol may increase the likelihood of side effects
Looking after your medicine	• Store LANOXIN in the original packaging until it is time to use it. • Keep LANOXIN-PG tablets in a cool dry place, away from moisture, heat, or sunlight where the temperature stays below 30°C. • Keep LANOXIN tablets and LANOXIN PAEDIATRIC ELIXIR oral liquid in a cool dry place, away from moisture, heat, or sunlight where the temperature stays below 25°C.

For more information, see Section 5. What should I know while using LANOXIN? in the full CMI.

6. Are there any side effects?

Side effects of LANOXIN generally occur when using higher doses than needed. Tell your doctor immediately if you notice any side effects while using LANOXIN.

Side effects include nausea, vomiting or loss of appetite; diarrhoea; lower stomach pain; slow or irregular heart beats (may be fast in children); unusual tiredness or extreme weakness.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

LANOXIN tablets & oral liquid

Active ingredient: *digoxin*

Consumer Medicine Information (CMI)

This leaflet provides important information about using LANOXIN tablets & oral liquid.

You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using LANOXIN.

Where to find information in this leaflet:

1. Why am I being given LANOXIN?
2. What should I know before I use LANOXIN?
3. What if I am taking other medicines?
4. How do I use LANOXIN?
5. What should I know while using LANOXIN?
6. Are there any side effects?
7. Product details

1. Why am I being given LANOXIN?

LANOXIN contains the active ingredient digoxin. It belongs to a group of medicines known as cardiac glycosides. They work by slowing down the rate while increasing the force of your heart when it beats.

It is used to treat certain heart problems, such as:

Chronic heart failure
Heart failure is when your heart can't pump strongly enough to supply blood needed throughout the whole body. It is not the same as a heart attack and does not mean that your heart stops.

Certain types of irregular heartbeats
Irregular heart rhythms caused by an electrical problem in the upper chamber of your heart. They cause your heart to beat too fast or in an uneven way.

Ask your doctor if you have any questions about why LANOXIN has been prescribed for you.

Your doctor may have prescribed it for another reason.

There is no evidence that LANOXIN is addictive.

2. What should I know before I use LANOXIN?

Warnings

You must not be given LANOXIN if:

- **you are allergic to digoxin, other cardiac glycosides, or any of the ingredients listed at the end of this leaflet.** Symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty in breathing; swelling of the face, lips, tongue, or any other parts of the body; rash, itching or hives on the skin.
- **you have or have had any of the following medical conditions:**
  - intermittent or complete heart block or second degree atrioventricular block, (conditions where the heart misses beats) especially if there is a history of Stokes-Adams attacks
  - ventricular tachycardia and ventricular fibrillation (a type of irregular heart rhythm)
  - irregular heart rhythm caused by cardiac glycoside overdose.
  - certain other irregularities of heart rhythm.
- **the expiry date printed on the pack has passed.**
- **the packaging is torn or shows signs of tampering.**

Check with your doctor if:

- **you have allergies to any other medicines, foods, preservatives or dyes.**
- **you have or have had any other medical conditions, especially the following:**
  - heart disease
  - heart disease caused by lack of vitamin B, known as 'Beri-Beri disease'
  - lung problems
  - liver or kidney problems – effect of LANOXIN may be increased because of slower removal from the body
  - thyroid disease – patients with low or high thyroid gland activity may be more or less sensitive to the effects of LANOXIN
  - high or low levels of calcium, potassium in your blood
  - low level of magnesium in your blood
  - digestion problems.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Tell your doctor if you are pregnant or intend to become pregnant.

Pregnant women may require an adjustment of the dose of this medicine during pregnancy. It may have harmful effects on the developing baby if the dose is too high.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with LANOXIN and affect how it works. These include:

- amphetamine, appetite suppressants, medicines for colds, sinus problems, hay fever or other allergies – may increase the risk of heart rhythm problems
- medicines for heart problems, including high blood pressure (hypertension) and irregular heartbeat (arrhythmia)
- diuretics (water tablets)
- potassium supplements
- medicines to treat all types of cancer (e.g. enzalutamide or apalutamide for prostate cancer)
- medicines for depression
- medicines for bacterial infection (antibiotics)
- medicines for fungal infections (antifungals)
- medicines for stomach problems, including for nausea, vomiting, diarrhoea or indigestion
- some laxatives
- medicines for relieving asthma attacks or other breathing problems
- corticosteroids (e.g. hydrocortisone, dexamethasone, prednisolone, prednisone)
- medicines for diabetes (e.g. insulin, glucagon)
- cholestyramine, a medicine used for high cholesterol
- phenytoin, a medicine used to control epilepsy
- indomethacin – medication used for inflammation, gout or arthritis
- St John's Wort.

These medicines may be affected by LANOXIN or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines. You doctor will advise you.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect LANOXIN.

4. How do I use LANOXIN?

How much to take

Your doctor will tell you how much LANOXIN you will receive. This depends on your condition and other factors such as your weight, age and other medicines you may be taking.

How to take it

Tablets:
Swallow LANOXIN tablets with a glass of water.

Oral liquid:
Accurately measure the dose with the calibrated dropper provided. Do not dilute.
Using the dropper will make sure that you get the correct dose.

Do not change your dose of LANOXIN unless your doctor tells you to do so.
After you begin taking LANOXIN, your doctor may sometimes check its level in your blood. This will help your doctor find out if your dose needs to be changed.

When to take it

Take LANOXIN at the same time each day.
This will have the best effect. It will also help you remember when to take it.

It does not matter if you take LANOXIN before or after food.

How long to take it

Continue taking LANOXIN for as long as your doctor tells you.

LANOXIN helps control your condition but does not cure it. Therefore, you must take LANOXIN every day.

If you forget to take it

Take it as soon as you remember. However, if it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose that you missed.
This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you take too much

If you think that you or someone you know has taken too much LANOXIN, medical attention may be needed.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or

- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

Symptoms of an overdose to LANOXIN include loss of appetite, nausea, vomiting, diarrhoea, or extremely slow heartbeat. In infants and small children, the earliest signs of overdose are changes in the rate and rhythm of the heartbeat. Carers should be aware that children may not show symptoms as soon as adults.

5. What should I know while using LANOXIN?

Things you should do

Remind any other doctors, dentists and pharmacists you visit that you are being given LANOXIN.

If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are being given LANOXIN.

If you need to have any medical tests while you are being given it, tell your doctor.

This medicine may affect the results of some tests.

Be sure to keep all your doctor's appointments so that your progress can be checked.

Your doctor will check your progress and may want to take some blood tests from time to time. This helps to prevent unwanted side effects.

Call your doctor straight away if you:

- **become pregnant while using LANOXIN.**
- **notice any side effects from this medicine.**

Things you should not do

Do not give LANOXIN to anyone else, even if their symptoms seem similar or they have the same condition as you.

Do not take LANOXIN to treat any other complaints unless your doctor tells you to.

Do not stop taking LANOXIN or change the dose even if you are feeling better, without checking with your doctor.

Driving or using machines

Be careful driving or operating machinery until you know how LANOXIN affects you.

LANOXIN may cause dizziness, blurred vision, and faintness in some patients. Make sure you know how you react to it before you drive a car, operate machinery, or do anything else that could be dangerous if this happens.

Looking after your medicine

Store LANOXIN-PG 62.5 microgram tablets in the bottle in a cool, dry place away from light where the temperature stays below 30°C.

Store LANOXIN 250 microgram tablets in the blister pack and LANOXIN oral liquid in the glass bottle in a cool, dry place away from light where the temperature stay below 25°C.

For example, do not store LANOXIN:
- in the bathroom or near a sink, or
- in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Serious side effects	What to do
• nausea or vomiting, loss of appetite • diarrhoea • lower stomach pain • unusual tiredness or extreme weakness • general feeling of 'unwellness' • blurred vision or visual disturbances (e.g. coloured halos around objects i.e. yellow, green, or white) • depression • headache.	**Tell your doctor if you have any of these less serious side effects.** They may be caused by a dose of LANOXIN that is too high for you.

Serious side effects

Serious side effects	What to do
• slow or irregular heartbeats (may be fast in children) • mental disturbances, such as confusion or feeling indifferent	**Tell your doctor immediately or go straight to the Emergency**

• skin rash • painful, swollen breasts, or breast enlargement in men • bleeding or bruising more easily than normal.	**Department at your nearest hospital if you notice any of these serious side effects.** Serious side effects are rare.
• palpitations • chest pain • shortness of breath or sweating. These can be symptoms of a serious heart problem caused by new irregular heartbeats of a different type to those caused by atrial fibrillation (which LANOXIN is often used to treat).	**Tell your doctor immediately or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

Your doctor may do regular checks on your blood levels of digoxin and body salts, as well as your kidney function to make sure this medicine is working safely for you

Tell your doctor if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What LANOXIN-PG 62.5 microgram tablets contain

Active ingredient (main ingredient)	digoxin 62.5 microgram/tablet
Other ingredients (inactive ingredients)	• indigo carmine • lactose monohydrate • magnesium stearate • maize starch • oxidized maize starch • povidone • rice starch.
Potential allergens	• sugars as lactose.

What LANOXIN 250 microgram tablets contain

Active ingredient (main ingredient)	digoxin 250 microgram/tablet
Other ingredients (inactive ingredients)	• lactose monohydrate • magnesium stearate • maize starch • oxidized maize starch • rice starch.
Potential allergens	• sugars as lactose.

What LANOXIN PAEDIATRIC ELIXIR oral liquid contains

Active ingredient (main ingredient)	digoxin 250 microgram/1 mL
Other ingredients (inactive ingredients)	• citric acid • dibasic sodium phosphate heptahydrate • ethanol • lime flavour oil D20673 • methyl hydroxybenzoate • propylene glycol • purified water • quinoline yellow • sucrose.
Potential allergens	• sugars, as sucrose • alcohol, as ethanol (10.6% v/v) • hydroxybenzoates.

Do not take this medicine if you are allergic to any of these ingredients.

What LANOXIN tablets & oral liquid look like

LANOXIN-PG 62.5 microgram tablets

Blue, biconvex, round tablet coded “U3A” on the upper face, bottom face plain. Available in glass bottles of 200 tablets.

LANOXIN 250 microgram tablets

White, biconvex, round tablet scored and marked “X3A” on one side. Available in blister packs of 100 tablets.

LANOXIN PAEDIATRIC ELIXIR 50 microgram/mL oral liquid

Clear, bright yellow liquid with a characteristic odour. Available in a 60 mL bottle with a calibrated dropper.

Do not dilute.

Australian Registration numbers:

- LANOXIN-PG 62.5 microgram tablets: AUST R 11108
- LANOXIN 250 microgram tablets: AUST R 15333
- LANOXIN PAEDIATRIC ELIXIR 50 microgram/mL oral liquid: AUST R 42757.

Who distributes LANOXIN

Aspen Pharmacare Australia Pty Ltd
Sydney NSW
Australia

www.aspenpharma.com.au

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