

LANOXIN®

Tablets & Liquid

digoxin

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about LANOXIN. It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist. All medicines have risks and benefits.

Your doctor has weighed the risks of you taking LANOXIN against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What is LANOXIN

LANOXIN 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 through out the whole body. It is not the same as a heart attack and does not mean that your heart stops.

Certain type of irregular heart beats

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 LANOXIN for another reason.

There is no evidence that LANOXIN is addictive.

Before you take it

When you must not take it

Do not take LANOXIN if you have an allergy to:

- digoxin or other cardiac glycosides
- any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction to LANOXIN may include:

- shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- skin rash, itching or hives

Do not take LANOXIN if 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.

If you are not sure whether you should start taking LANOXIN, talk to your doctor or pharmacist.

Do not take LANOXIN after the expiry date (EXP) printed on the pack.

Do not take it if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

Before you start to take it

Tell your doctor if you have allergies to:

- any other medicines
- any other substances, such as foods, preservatives or dyes.

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

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

Tell your doctor if you are breast-feeding or plan to breast-feed.

Tell your doctor if you have or have had any 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.

If you have not told your doctor or pharmacist about any of the above, it is important to tell them before you start taking LANOXIN.

Taking other medicines

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

Some medicines and LANOXIN may interfere with each other.

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 heart beat (arrhythmia)
- diuretics (water tablets)
- potassium supplements
- medicines for 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. Your doctor will advise you.

If you not sure if any of the above apply to you, talk to your doctor or pharmacist before taking LANOXIN.

How to take it

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

How much to take

Your doctor will tell you how much LANOXIN you will need to take each day. 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.

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 same time each day.

Taking LANOXIN at the same time each day 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.

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.

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 take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at your nearest hospital if you think that you or

anyone else may have taken too much LANOXIN. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Symptoms of an overdose to LANOXIN include some of the side effects listed below.

Some early warning signs of overdose are loss of appetite, nausea, vomiting, diarrhoea, or extremely slow heart beat.

In infants and small children, the earliest signs of overdose are changes in the rate and rhythm of the heart beat.

Carers should be aware that children may not show symptoms as soon as adults.

While you are taking it

Things you must do

Tell your doctor immediately if you notice any side effects from LANOXIN.

Tell any other doctors, dentists and pharmacists who are treating you that you are taking LANOXIN.

Tell your doctor, dentist or pharmacist that you are taking LANOXIN before you start taking any medicines you buy from a pharmacy, health food shop or supermarket.

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

If you become pregnant while taking LANOXIN, tell your doctor immediately.

If you need to have any medical tests while you are taking LANOXIN, tell your doctor. LANOXIN may affect the results of some tests.

Be sure to keep all of 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.

Things you must 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.

Things to be careful of

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 LANOXIN, before you drive a car, operate machinery, or do anything else that could be dangerous if this happens.

Side effects

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

If any of the following happen, tell your doctor or pharmacist immediately:

- nausea or vomiting, loss of appetite
- diarrhoea
- lower stomach pain
- slow or irregular heart beats (may be fast in children)

- 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
- mental disturbances, such as confusion or feeling indifferent
- skin rash
- painful, swollen breasts, or breast enlargement in men
- bleeding or bruising more easily than normal.

These may be serious side effects. You may need urgent medical attention. Serious side effects are rare or are caused by a dose of LANOXIN that is too high for you.

Tell your doctor immediately if you have:

- palpitations
- chest pain
- shortness of breath or sweating.

These can be symptoms of a serious heart problem caused by new irregular heart beats of a different type to those caused by atrial fibrillation (which LANOXIN is often used to treat).

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

Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on this list.

Other side effects not listed above may also occur in some people.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

After taking it

Storage

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Keep your LANOXIN tablets in the pack and the liquid in the bottle until it is time to take them.

If you take the tablets or liquid out of the pack, they will not keep well.

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

Store LANOXIN tablets and paediatric elixir in a cool, dry place away from light and where the temperature stays below 25°C.

Do not store LANOXIN or any other medicine in the bathroom or near a sink. Do not leave it in the car on hot days or on windowsills.

Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop taking LANOXIN or the medicine has passed its expiry date, ask your pharmacist what to do with any that is left over.

Product description

What it looks like

LANOXIN-PG Tablet

Blue, biconvex, round tablet coded "U3A" on the upper face, bottom face plain; in bottles of 200.

LANOXIN Tablet

White, biconvex, uncoated round tablet scored and marked "X3A" on one side. Blister packs of 100 tablets.

LANOXIN Paediatric Elixir

Clear, bright yellow liquid with a characteristic odour, in 60 mL

bottles with calibrated dropper. Do not dilute.

Ingredients

LANOXIN-PG tablet

Active ingredient:

Each tablet contains digoxin 62.5 micrograms.

Other ingredients:

- lactose
- starch-oxidised maize
- starch-maize
- starch-rice
- magnesium stearate
- povidone
- indigo carmine – CI73015.

LANOXIN-PG tablets do not contain sucrose, gluten, tartrazine or any other azo dyes.

LANOXIN tablet

Active ingredient:

Each tablet contains digoxin 250 micrograms.

Other ingredients:

- lactose
- starch-oxidised maize
- starch-maize
- starch-rice
- magnesium stearate.

LANOXIN tablets do not contain sucrose, gluten, tartrazine or any other azo dyes.

LANOXIN Paediatric Elixir

Active ingredient:

Each mL of oral liquid contains digoxin 50 micrograms.

Other ingredients:

- sucrose
- sodium phosphate - dibasic
- citric acid - anhydrous
- ethanol
- propylene glycol
- quinoline yellow – CI47005
- lime flavour D20673
- methyl hydroxybenzoate
- water-purified.

LANOXIN Paediatric Elixir does not contain lactose, gluten, tartrazine or any other azo dyes.

The Australian Product Registration Numbers for:

LANOXIN-PG digoxin 62.5 microgram tablet bottle: AUST R 11108

LANOXIN digoxin 250 microgram tablet blister pack: AUST R 15333

LANOXIN PAEDIATRIC ELIZIR digoxin 50 microgram/mL oral liquid bottle: AUST R 42757.

Sponsor

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Australia

This leaflet was revised in February 2021.