

LANOXIN® Injection

digoxin

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about LANOXIN Injection. 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 being given LANOXIN Injection 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 Injection

LANOXIN Injection 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 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 Injection has been prescribed for you.

Your doctor may have prescribed it for another reason.

There is no evidence that LANOXIN Injection is addictive.

Before you are given it

When you must not be given it

Do not use LANOXIN Injection 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 this medicine 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 use LANOXIN Injection 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 be given LANOXIN Injection, talk to your doctor or pharmacist.

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

Do not use 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 use 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 this medicine during pregnancy. It 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 Injection 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 Injection
- 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 being given LANOXIN Injection.

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 I Injection 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 Injection 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 using LANOXIN Injection.

How to use it

How much is given

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

How LANOXIN Injection is given

Except under unusual circumstances, LANOXIN Injection is given as a slow injection into a vein by a doctor or nurse.

How long LANOXIN Injection is given

LANOXIN injection should be administered for as long as recommended by your doctor.

After you begin using LANOXIN Injection, your doctor may

sometimes check its level in your blood. This will help your doctor find out if your dose needs to be changed.

If you are given too much (overdose)

As LANOXIN Injection is given to you under the supervision of your doctor, it is unlikely that you will receive too much. However, if you experience any side effects after being given LANOXIN Injection, tell your doctor immediately or go to Accident and Emergency at your nearest hospital.

You may need urgent medical attention.

Symptoms of an overdose to LANOXIN Injection 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 using it

Things you must do

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

Tell any other doctors, dentists and pharmacists who are treating you that you are being given LANOXIN Injection.

Tell your doctor, dentist or pharmacist that you are being given LANOXIN Injection 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 being given LANOXIN Injection.

If you become pregnant while using this medicine, tell your doctor immediately.

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

LANOXIN Injection 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 to be careful of

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

LANOXIN Injection 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.

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 Injection that may be 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 Injection 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 this medicine 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 using it

Storage

Store LANOXIN Injection in the original packaging until it is time to use them.

If you take them out of the pack, they may not keep as well.

Keep your medication in a cool place, protected from light, where the temperature stays below 30°C.

Do not store it 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.

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.

Disposal

If your doctor tells you to stop using LANOXIN Injection 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 Injections are clear, colourless solutions, free from particulate matter, in clear glass ampoules. Available in boxes of 5.

Ingredients

LANOXIN INFANTS Injection

Active ingredient:

Each 2 mL ampoule contains digoxin 50 micrograms.

Other ingredients:

- propylene glycol
- ethanol
- citric acid-anhydrous
- sodium phosphate-dibasic anhydrous
- water for injections.

LANOXIN ADULT Injection

Active ingredient:

Each 2 mL ampoule contains digoxin 500 micrograms.

Other ingredients:

- propylene glycol
- ethanol
- citric acid-anhydrous
- sodium phosphate-dibasic anhydrous
- water for injections.

The Australian Product Registration Numbers for:

LANOXIN INFANTS digoxin 50 micrograms/2 mL injection ampoule: AUST R 11105

LANOXIN ADULT digoxin 500 micrograms/2 mL injection ampoule: AUST R 11106.

Sponsor

Aspen Pharma Pty Ltd
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Australia

This leaflet was revised in September 2017.