

LANOXIN™

Digoxin tablets 62.5µg, 250µg; paediatric elixir 50 µg/mL

Consumer Medicine Information

What is in this leaflet

Please read this leaflet carefully before you start using LANOXIN tablets or paediatric elixir.

This leaflet answers some common questions about LANOXIN. It does not contain all of 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 expected benefits of you taking LANOXIN against the risks this medicine could have for you.

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

Keep this leaflet with your medicine. You may need to read it again.

What LANOXIN is used for

LANOXIN is used in the treatment of chronic heart failure and/or atrial fibrillation and flutter (irregular heart rhythms caused by an electrical problem in the upper chambers of the heart). Heart failure is a disease of the heart which develops when the heart muscle cannot pump blood strongly enough to supply all the blood needed throughout the body.

Heart failure is not the same as a heart attack and does not mean that the heart stops. Heart failure may start off with no symptoms but, as the condition progresses, you may feel short

of breath and may get tired easily after light physical activity, such as walking. Some patients may wake up short of breath at night. Fluid may collect in different parts of the body, often first noticed as swollen ankles and feet.

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

LANOXIN works by slowing down the rate of the heart so that each heartbeat is more effective at pumping blood. In people with heart failure, it also helps to control the symptoms of tiredness, breathlessness and fluid retention.

Use in children and the elderly

LANOXIN may be used in premature and full term babies, infants and children.

It can also be used in elderly people, but because the elderly are more prone to the side effects of LANOXIN, it is usually used in smaller doses than in younger adults.

Before you take LANOXIN

When you must not take it

- Do not use LANOXIN, if you have ever had an allergic (hypersensitivity) reaction to digoxin or to any of the other ingredients in the LANOXIN formulations listed at the end of this leaflet.
- Do not use LANOXIN after the expiry date (EXP) on the packaging. If you use this medicine after the expiry date

has passed it may not work as well. If the pharmacist has repacked the medicine for you, there may not be an expiry date on the packaging.

- Do not take LANOXIN tablets or give LANOXIN paediatric elixir, if the packaging is torn or shows signs of tampering, if the tablets look discoloured or damaged, or if the paediatric elixir looks cloudy or discoloured.

- Do not use LANOXIN if you have any of the following heart problems:

- Irregular heart rhythms (arrhythmias) caused by cardiac glycosides (drugs used to treat heart problems) toxicity
- Certain types of supraventricular arrhythmias
- Ventricular tachycardia or fibrillation
- Second degree or intermittent complete heart block
- Hypertrophic obstructive cardiomyopathy (an enlarged heart muscle).

If you're not sure whether you should be using LANOXIN, talk to your doctor.

Before you start to use LANOXIN

You must tell your doctor if:

- You are pregnant or are planning to become pregnant.

LANOXIN may be used to treat heart failure and/or irregular heart beats in pregnant women and babies. If you are prescribed LANOXIN during pregnancy, your doctor will have weighed up the expected benefits to you and/or your baby against the possible risks.

- You are breastfeeding or are planning to breastfeed.

Only a very small amount of LANOXIN passes into breast milk, so it may be possible for you to breastfeed, if your doctor says it is all right to do so.

- You have other illnesses, especially:
 - Electrical problems in the heart causing a slow heart beat and/or absence of some heart beats
 - A previous heart attack
 - Kidney problems
 - Severe lung disease
 - Low potassium levels in your blood (hypokalaemia)
 - Low magnesium levels in your blood (hypomagnesaemia)
 - High calcium levels in your blood (hypercalcaemia)
 - Hypoxia (not enough oxygen in your blood)
 - An underactive or overactive thyroid gland
 - Digestion problems
- You are allergic to any foods, dyes, preservatives or any other medicines.

Taking other Medicines

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

Tell your doctor if you are taking any of the following medicines:

- Diuretics, including spironolactone (Aldactone™, Spirotone™), used to treat high blood pressure
- Corticosteroids, powerful anti-inflammatory medicines used to relieve inflammation
- Some antibacterial (antibiotic) medicines used to treat infections, including:
 - erythromycin (EMU-V™,

- Eryacne™, Eryc™, Stiemycin™, Eromycin™, EES™, E-Mycin™, ERA™), Tetracycline (Doryx™, Doxine™, Doxy-50™, Doxy-100™, Minomycin™, Minotab 50™, Panmycin™, Helidac™)
- gentamicin (Gentamicin™)
- trimethoprim (TMP™, Triprim™, Apo-Sulfatrim™, Apo-Sulfatrim DS™, Bactrim™, Septrin™, Trimel™, Trisul™).
- neomycin (Neosulf™)
- Anti-arrhythmic medicines used to treat irregular heartbeats, including:
 - amiodarone (Cordarone™, Aratac™), flecainide (Tambacor™), propafenone (Rytmonorm™), quinidine (Kinidin™)
 - Calcium channel blockers, used to treat high blood pressure (hypertension), coronary artery disease (affecting blood vessels in the heart muscle) and irregular heart beats, including:
 - verapamil (Civicor™, Civicor Retard™, Isoptin™, Isoptin SR™, Verpamil™, Verpamil SR™), felodipine (Agon ER™, Plendil ER™), nifedipine (Adalat Oros™, Adalat Retard™, Alpha-Nifedipine Retard™, Nyefax™, Nyefax Retard™), diltiazem (Apo-Diltiazem™, Cardizem™, Dilcard™, Dilzem™, Dilzem LA™, Dilzem SR™), isradipine (Dynacirc™, Dynacirc SRO™)
 - Alpha blockers, used to treat hypertension such as prazosin (Hyprosin™, Pratsiol™)
 - Antacids, used to treat indigestion and heartburn
 - Bulk laxatives, used to treat constipation
 - Some medicines used to stop diarrhoea, including kaolinpectin and diphenoxylate with atropine (Diastop™, Lomotil™)
 - Drugs known as angiotensin converting enzyme (ACE) inhibitors, used to treat high blood pressure
 - Medicines used to treat cancer

- Metoclopramide (Maxolon™, Metamide™, Paramax™), used for nausea (feeling sick) and vomiting
- Salbutamol (Asmol™, Respolin™, Respox™, Salbuvent™, Salbuvent Forte™, Ventodisk™, Ventolin™, Ventolin Forte™, Volmax™), used mainly to treat asthma and other breathing difficulties
- Phenytoin (Dilantin™), used to treat epilepsy
- Quinine (Q200, Q300, Quinoc-F, Quinoc-S), used to treat malaria
- Adrenaline (Medihaler Epi™) used to treat breathing problems
- Lithium (Lithicarb™, Priadel™), used to treat some mental illnesses
- Cholestyramine (Questran™), used to lower blood cholesterol levels
- Indomethacin (Arthrexin™, Indocid™, Indocid-R™, Rheumacin™, Rheumacin-R™), a non-steroidal antiinflammatory medicine used to treat pain, inflammation and stiffness
- Sulphasalazine (Colizine™, Colizine E™, Salazopyrin™, Salazopyrin-EN™) used to treat some bowel problems
- Alprazolam (Xanax™), used to treat anxiety and depression
- Itraconazole (Sporanox™), used to treat some types of fungal infection
- Propantheline (Pro-Banthine™), a muscle relaxant, used in people with peptic ulcers, irritable bowel syndrome and renal colic
- St John's wort (also called *Hypericum perforatum*), a natural remedy for depression

Your doctor or pharmacist will be able to tell you more about what to do when taking LANOXIN tablets or paediatric elixir while you are taking other medicines.

How to take LANOXIN

Your doctor will tell you how many LANOXIN tablets or how much LANOXIN paediatric elixir to give and how often.

Do not take or give an extra LANOXIN dose. Do not take or give LANOXIN or any medicine more often than you have been told.

Your doctor will calculate your LANOXIN dose according to your age, body weight and how well your kidneys are working.

How much to take

For adults and children over 10 years of age:

LANOXIN tablets and paediatric elixir: Depending on your condition and how quickly your heart failure and/or irregular heartbeats need to be treated, you may be given a rapid or slow loading (bulk) dose of LANOXIN:

The usual rapid loading dose is 750µg to 1500µg, taken as one dose.

In elderly people and those likely to be very sensitive to the side effects of LANOXIN, the total starting dose may be given in smaller amounts six hours apart.

The usual slow loading dose is 250µg to 750µg daily for one week.

After the loading dose, the usual maintenance (long term) dose is 125µg to 750µg of LANOXIN daily. In elderly people and those with poor kidney function, a dose as low as 62.5µg may be given.

For newborn babies, infants and children up to 10 years:

LANOXIN paediatric elixir : The usual loading dose is 25µg to 45µg per kilogram of bodyweight for the paediatric elixir.

Your doctor will calculate the dose according to the age and weight of the child.

If your child has been treated with LANOXIN within the past two weeks, the doctor will prescribe smaller dose of LANOXIN than usual.

The maintenance dose of LANOXIN paediatric elixir for premature babies is usually 20% of the loading dose given in the first 24 hours. For full term babies, infants and children up to 10 years, the maintenance dose is usually 25% of the loading dose given in the first 24 hours.

Your doctor may adjust your child's dose of LANOXIN according to his or her response to treatment, as well as blood levels of digoxin, the active ingredient in LANOXIN.

How to take it

LANOXIN tablets should be swallowed with a drink of water. LANOXIN paediatric elixir should be swallowed. A measuring syringe or cup should be used, so you can measure the dose correctly.

How long to take it

The length of time you need to take LANOXIN will depend on the reason why it has been prescribed for you. Many people need treatment with LANOXIN lifelong.

Do not stop taking LANOXIN without first talking to your doctor, or your underlying condition could worsen.

If you forget to take it

If it is almost time for the next dose of LANOXIN tablets or paediatric elixir, skip the missed dose and take or give the next dose when you are meant to. Otherwise, take or give it as soon as you remember, then go back to using it as you would normally.

Do not take or give a double dose to make up for the one that you missed.

If you take or give too much (overdose)

Immediately telephone your doctor or Poisons Information Centre (0800 POISON or 0800 764 766) or go to the accident and emergency department 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 poisoning or discomfort. Urgent medical attention could be needed.

Keep telephone numbers for these places handy.

An overdose of LANOXIN may cause symptoms similar to those listed later under "Side effects", and include abnormal potassium levels in the blood, and slow and/or irregular heart rhythms. An overdose of LANOXIN can sometimes be fatal.

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

While you are taking LANOXIN

Things you must do

Tell all doctors and pharmacists involved in your health care that you are taking LANOXIN if you are about to be started on any new medicines.

You must also tell your doctor or

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

Tell your doctor if you become pregnant while taking LANOXIN.

If you are taking LANOXIN tablets or giving the paediatric elixir, tell your doctor if, for any reason, you have not used the medicine exactly as prescribed. Otherwise your doctor may think that it is not working for you and change your treatment unnecessarily.

Tell your doctor if you feel that LANOXIN is not helping your condition.

Things you must not do

If you are taking LANOXIN tablets or giving paediatric elixir to a child, do not stop using this medicine or change the dose, without first checking with your doctor.

Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

Do not use LANOXIN to treat any other complaints unless your doctor says so.

Things to be careful of

Do not drive or operate machinery until you know how LANOXIN affects you. As with many other medicines, LANOXIN may cause headache and tiredness in some people.

Side-Effects

All medicines can have unwanted side effects. Sometimes they may be serious, but often they are not. You may need medical treatment if you get some of these side effects.

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

Be sure that your doctor knows as soon as possible if you do not feel well while you are taking LANOXIN.

If you think that LANOXIN is causing you to have an allergic (hypersensitivity) reaction, TELL YOUR DOCTOR IMMEDIATELY. Symptoms

include:

- Severe skin rash, itching and hives
- Swelling of the face, lips, mouth or throat
- Difficulty breathing or swallowing
- Fever
- Low blood pressure (feeling faint or dizzy).

Tell your doctor if you notice any of the following:

- Loss of appetite
- Nausea (feeling as if you are about to vomit), vomiting
- Diarrhoea
- Weakness
- Feeling indifferent
- Tiredness
- Headache
- Visual disturbances
- Depression
- Palpitations (irregular heart beats)
- Confusion
- A general feeling of "unwellness"
- Pains in the lower stomach (caused by lack of blood supply or damage to the intestines)
- Skin rash
- Unusual bleeding or bruising
- Breast enlargement in men

In both adults and children, LANOXIN can cause new irregular heart rhythms of a different type to those caused by atrial fibrillation (which LANOXIN is often used to treat). Your doctor may perform 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.

This is not a complete list of side effects. Ask your doctor or pharmacist if you have any questions about the side effects of LANOXIN.

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

Ask your doctor or pharmacist if you don't understand something on this list.

Do not be alarmed by this list of side effects. You may not experience any of them. Your doctor may reduce your LANOXIN dose if some of these side effects occur. The more common ones tend to become less troublesome as your treatment progresses. If anything worries you, please talk to your doctor.

After taking LANOXIN

Storage

Keep this medicine where young children cannot reach it. A locked cupboard at least one and a half metres off the ground is a good place to store medicines.

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

Keep your LANOXIN tablets in their pack until it is time to take them. If you take LANOXIN tablets out of their pack they may not work as well.

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

If you are using LANOXIN

paediatric elixir, always screw the lid on the bottle after taking or giving the medicine, otherwise it may not work as well.

Disposal

If your doctor tells you to stop using LANOXIN tablets or paediatric elixir, or your medicine has passed its expiry date, ask your pharmacist what to do with any leftover medicine.

Product description

What LANOXIN looks like

LANOXIN 62.5µg tablets are blue, round, biconvex tablets debossed "DO6". They are packed in a bottle or blister pack.

LANOXIN 250µg tablets are white, round, biconvex tablet debossed "DO25". They are packed in a bottle or blister pack.

LANOXIN paediatric elixir is a clear, yellow, lime-flavoured, sweetened liquid. It comes in a 60ml bottle.

Ingredients

LANOXIN 62.5µg tablets contain Digoxin, Rice starch, Lactose, Maize starch, Maize starch (hydrolysed), Magnesium stearate, Povidone (K90), Indigo Carmine E132, Purified water

LANOXIN 250µg tablets contain Digoxin, Rice starch, Lactose, Maize starch, Maize starch (hydrolysed), Magnesium stearate, Purified water

LANOXIN paediatric elixir contains Digoxin, Methylhydroxybenzoate, Syrup, Anhydrous sodium phosphate, Citric acid monohydrate, Quinoline yellow, Ethanol (96%), Propylene glycol

Lime flavour No 1, Purified water

Manufacturer

Your LANOXIN medicine is distributed by:
Pharmacy Retailing (NZ) Limited
trading as Healthcare Logistics
58 Richard Pearse Drive
Airport Oaks
Auckland
New Zealand

Further information

This is not all the information that is available on LANOXIN tablets and oral solution. If you have any more questions or are not sure about anything, ask your doctor or pharmacist.

Your doctor and pharmacist are the best people to give you advice on the treatment of your condition. You may also be able to find general information about your disease and its treatment from books in public libraries, or on the Internet.

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