

## PACKAGE LEAFLET: INFORMATION FOR THE USER

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### Lanibos

0.25 mg Tablets

DIGOXIN

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*• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.*

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*• Keep this leaflet • You may need to read it again • If you have any further questions, ask your doctor or pharmacist • This medicine has been prescribed for you only • Do not pass it on to others • It may harm them, even if their signs of illness are the same as yours • If you get any side effects, talk to your doctor or pharmacist • This includes any possible side effects not listed in this leaflet •*

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#### What is in this leaflet?

1. What Lanibos is and what it is used for
2. Before you take Lanibos
3. How to take Lanibos
4. Possible side effects
5. How to store Lanibos

#### 1. WHAT LANIBOS IS AND WHAT IT IS USED FOR

Lanibos contains a medicine called digoxin. This belongs to a group of medicines called '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:

- heart failure

This is when your heart muscle can't pump strongly enough to supply blood around your whole body. It is not the same as a heart attack and does not mean that your heart stops.

- certain types of irregular heart beats

These include 'atrial flutter' or 'fibrillation'. They are caused by problems in the way the upper chambers of your heart send electrical signals. They cause your heart to beat too fast or in an uneven way.

#### 2. BEFORE YOU TAKE LANIBOS

##### **Do not take Lanibos if:**

- you are allergic (hypersensitive) to digoxin, digitoxin or any of the other ingredients of Lanibos
- you have been told that you have any of the following heart problems:

- 'Second degree' or 'intermittent complete heart block'
- Certain types of 'supraventricular arrhythmias'
- 'Ventricular tachycardia' or 'Ventricular fibrillation'
- 'Hypertrophic obstructive cardiomyopathy'

Your doctor should have checked your heart problem and decided that this medicine will help you. If you are not sure, talk to your doctor or pharmacist before taking Lanibos.

### ***Take special care with Lanibos***

Check with your doctor or pharmacist before using your medicine if:

- you have recently had a heart attack (myocardial infarction)
- you have been told that you have low potassium or magnesium levels in your blood (hypokalaemia or hypomagnesaemia)
- you have been told that you have high calcium levels in your blood (hypercalcaemia)
- you have a heart problem caused by a lack of vitamin B, known as 'Beri-Beri disease'
- you have kidney problems
- you have a lung problem
- you have thyroid problems
- you have digestion problems.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking this medicine. Your doctor may change your dose or you may need a different medicine.

### ***Taking other medicines***

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines.

This includes medicines obtained without a prescription and herbal products. In particular tell your doctor or pharmacist if:

- you have taken either digoxin or digitoxin in the last 2 weeks. Your doctor may need to change your dose.

Taking Lanibos with other medicines can change how they work or how Lanibos works. Tell your doctor or pharmacist if you are taking any of the following:

- medicines for stomach problems, including indigestion, diarrhoea and being sick (vomiting)
- medicines for heart problems, including high blood pressure (hypertension) and irregular heart beat (arrhythmia)
- medicines for breathing problems, like asthma
- medicines for cancer
- medicines for epilepsy
- medicines for anxiety or depression
- medicines for bacterial infections (antibiotics)
- medicines for fungal infections (antifungals)
- medicines for high cholesterol
- medicines for preventing organ transplant rejection
- medicines for problems with your immune system
- medicines for preventing blood clots during kidney dialysis
- water tablets (diuretics)
- laxatives
- steroids
- anaesthetics
- the herbal remedy St John's wort (*Hypericum perforatum*). This should not be taken, when taking Lanibos. If you already take St John's wort, speak to your doctor, as soon as possible, before you stop taking St John's wort.

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before taking Lanibos.

### ***Taking Lanibos with food***

Lanibos can be taken with most foods. However, you should avoid taking it with foods that are high in fibre (e.g. brown bread, cereals, fruit, vegetables and pulses), also known as 'roughage', as the amount of Lanibos absorbed into the body may be reduced.

### ***Pregnancy and breast-feeding***

Talk to your doctor before taking this medicine if you are pregnant, might become pregnant or are breast-feeding.

### ***Driving and using machines***

You may feel dizzy, tired, have a headache or get blurred vision while taking Lanibos. If this happens, do not drive or use any tools or machines.

### ***Important information about some of the ingredients of Lanibos***

This medicine contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, talk to your doctor before taking Lanibos.

## **3. HOW TO TAKE LANIBOS**

Always take Lanibos exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Your doctor will have decided how much Lanibos is right for you:

- It depends on what heart problem you have and how serious it is.
- It also depends on your age, weight and how well your kidneys work.
- Your dose may go up or down depending on how you respond to the medicine. Your doctor will do checks to see how well the medicine is working. These may involve blood and urine tests.

### ***Taking this medicine***

- Tablets should be swallowed whole.
- You usually take this medicine in two stages:

Stage 1 - loading dose

The loading dose gets your Lanibos levels up to the correct level quickly. You will either:

- take one large single dose and then begin your maintenance dose or
- take a smaller dose each day for a week and then begin your maintenance dose.

Stage 2 - maintenance dose

After your loading dose you will take a much smaller dose every day, until your doctor tells you to stop.

Adults and children over 10 years

- loading dose
  - Usually between 0.75 and 1.5 mg (3 and 6 tablets) as a single dose.
  - For some patients, this may be given in divided doses 6 hours apart.
  - Alternatively, between 0.25 and 0.75 mg (1 and 3 tablets) may be given each day for a week.
- maintenance dose
  - Your doctor will decide this, depending on your response to Lanibos.
  - It is usually between 0.125 and 0.25 mg daily.
  - You may take a lower strength tablet for the maintenance dose.

Children under 10 years

- loading dose
  - This is worked out using your child's weight
  - Usually between 0.025 and 0.045 mg per kg of body weight.

- This should be given in divided doses between 4 and 8 hours apart.
- maintenance dose
- The doctor will decide this, depending on your child's response to Lanibos.
- It is usually a 1/5 (fifth) or a 1/4 (quarter) of the loading dose, to be taken daily.

***If you use more Lanibos than you should***

If you take too much or if somebody else takes your medicine by mistake, go to the hospital immediately. You may get any of the side effects and symptoms listed in Section 4, but these can be serious.

***If you forget to use Lanibos***

- If you forget to take a dose, take it as soon as you remember. However, if it is almost time for the next dose, skip the missed dose.
- Do not take a double dose to make up for the one that you missed.

***If you stop using Lanibos***

Do not stop taking this medicine, as your heart problem may get worse. Talk to your doctor if you want to stop.

If you have any further questions on taking this medicine, ask your doctor or pharmacist.

***4. POSSIBLE SIDE EFFECTS***

Like all medicines, Lanibos can cause side effects, although not everybody gets them. In general, the side effects tend to happen if the dose you are taking is too high, your doctor may adjust your dose.

***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. If these happen, tell your doctor immediately.

Other side effects that you should tell your doctor about, include:

**Common** (affects less than 1 in 10 people)

- slow or irregular heart rate
- feeling sick, being sick or diarrhoea
- skin rash that may be itchy
- drowsiness or dizziness
- visual disturbances, with blurred or yellow-green sight.

**Uncommon** (affects less than 1 in 100 people)

- depression.

**Very Rare** (affects less than 1 in 10,000 people)

- bruising or bleeding more easily than normal
- stomach pain caused by lack of blood supply or damage to your intestines
- mental disturbances, you may feel confused, indifferent or unable to judge clearly
- weakness, tiredness or a general feeling of being unwell
- breast enlargement in men
- loss of appetite
- headache.

Lanibos can very rarely cause serious irregular heart rates. Your doctor may do regular checks to make sure Lanibos is working safely for you.

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

## *5. HOW TO STORE LANIBOS*

Keep out of the reach and sight of children.

Do not use Lanibos after the expiry date on carton or bottle label (Exp.). The expiry date refers to the last day of that month.

Store below 25°C

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

***Leaflet date: August 2014***