Read all of this leaflet carefully before you start using this medicine because it contains important information for you. The instructions for using the insulin pen are provided with your insulin. Refer to them before using your medicine. Keep this leaflet. You may need to read it again.

1. What is Lantus and what is it used for?

Lantus contains insulin glargine. This is a modified insulin, very similar to human insulin in aged adults.

Lantus is used to treat diabetes mellitus in adults, adolescents and children aged 2 years and above. Diabetes mellitus is a disease where your body does not produce enough insulin to control the level of blood sugar in your blood. Lantus helps to control your blood sugar level and to prevent it from becoming too high or low.

2. What you need to know before you use Lantus

3. How to use Lantus

4. If you have missed a dose of Lantus or if you start or stop taking another medicine.

5. What you should do in emergency situations

6. There is no experience with the use of Lantus in children aged below the age of 2 years.

7. Children

8. Do not use Lantus

9. Do not use Lantus in patients with poorly controlled diabetes, or those who have been recently treated with insulin.

10. Life-threatening reactions

11. Severe allergic reactions (rare, may affect up to 1 in 1,000 people) - the signs may include breathing difficulties (including itching all over the body), severe swelling of skin or mucous membranes (angioedema), shortness of breath, a fall in blood pressure with rapid heart beat and sweating. Severe allergic reactions to insulin may become life-threatening. Tell a doctor straight away if you notice signs of severe allergic reaction.

Common reported side effects (may affect up to 1 in 100 people)

Skin changes at the injection site

If you inject your insulin too often at the same site, you may get skin changes under the skin at this site may either shrink (lipoatrophy, may affect up to 1 in 10 people) or thicken (lipohypertrophy). The insulin may not work well. Change the injection site with each injection to avoid these changes.

Skin and allergic reactions at the injection site

The most common side effects include reddening, unusual intense pain when injecting, itching, hives, redness, swelling, pain or tenderness around the injection site. Most minor reactions to insulin usually disappear in a few hours.

Rare reported side effects (may affect up to 1 in 1,000 people)

• A marked change (improvement or worsening) in your blood sugar control may occur during or after minor surgery. If you have proliferative retinopathy (an eye disease related to diabetes) severe hypoglycaemic attacks may cause permanent loss of vision.

General disorders

It is not known whether treatment may also cause temporary build-up of water in the body, with swelling in the calves and ankles.

Very rare reported side effects (may affect less than 1 in 10,000 people)

In very rare cases, dyspnea (taste disorders) and myalgia (muscular pain) can occur.

Use in children and adolescents

In general, the effects of treatment in children and adolescents of 18 years of age or less are similar to those in adults.

Complaints of injection site reactions (injection site pain, injection site reaction) are reported relatively more frequently in children and adolescents of 18 years of age or less than in adults.
HYPERGLYCAEMIA AND HYPOGLYCAEMIA

HYPERGLYCAEMIA (High blood sugar level)
If your blood sugar is too high (hyperglycaemia), you may have injected enough insulin.

Why does hyperglycaemia occur?
Examples include:
- you have not injected your insulin or not injected enough, or it has become less effective, for example through incorrect storage,
- you did not eat after you had injected insulin, or you ate less than usual, or you ate a less healthy meal,
- you ate more carbohydrates than usual, or you ate too much food, or you ate food with a high sugar content.
- you are elderly, if you have had diabetes for a long time or if you suffer from a certain type of nervous disease (diabetic autonomic neuropathy),
- you have recently changed from a human insulin to a human insulin such as Lantus, or if you inject insulin incorrectly,
- you are pregnant.

What you should do if you experience hyperglycaemia?
Test your blood sugar level and your urine for ketones as soon as any of the above symptoms occur. Severe hyperglycaemia or ketonuria must always be treated by a doctor, normally in a hospital.

HYPOGLYCAEMIA (Low blood sugar levels)
If your blood sugar level falls too much you may become unconscious. Serious hypoglycaemia may cause a heart attack or brain damage and may be life-threatening. You normally should be able to recognise when your blood sugar is falling too much so that you can take the right actions.

Why does hypoglycaemia occur?
Examples include:
- you inject too much insulin,
- you miss meals or delay them,
- you do not eat enough, or eat food containing less carbohydrate than normal (sugar and substances similar to sugar are called carbohydrates; however, artificial sweeteners are NOT carbohydrates),
- you are pregnant.
- you are doing more exercise than usual or a different type of physical activity,
- you are recovering from an injury or operation or other stress,
- you are recovering from an illness or from fever,
- you are taking or have stopped taking certain other medicines (see section 2, "Other medicines and Lantus").

What if you have hypoglycaemia?
If your blood sugar level falls too much (hypoglycaemia), you may lose consciousness. Examples of symptoms that indicate a low sugar level in the brain:
- stomach pain, fast and deep breathing, and glucose and ketone bodies in urine,
- diarrhea, vomiting, dizziness, loss of consciousness.

Examples of symptoms that tell you that your blood sugar level is falling too much:
- headache, sweating, trembling, weakness, shakiness, hunger, anxiety, fast heart beat, high blood pressure, palpitations and irregular heart beat. These symptoms often develop before the symptoms of a low sugar level in the brain.
- in your brain:
- Examples of symptoms that indicate a low sugar level in the brain:
- headaches, intense hunger, nausea, vomiting, tiredness, dizziness, sleeplessness, restlessness, aggressiveness, elevated temperature, palpitations, and tingling sensations in the area of the mouth, dizziness, loss of self-control, inability to look after yourself, convulsions, loss of consciousness.

If your blood sugar is too high (hyperglycaemia), you may have injected enough insulin.

What you should do if you experience hyperglycaemia?
- you have just begun insulin treatment or changed to another insulin preparation (when changing from your previous basal insulin to Lantus hypoglycaemia, if it occurs, may be more likely to occur in the morning than at night),
- your blood sugar levels are almost normal or are unstable.
- you change the area of skin where you inject insulin (for example from the thigh to the upper arm).
- you suffer from severe kidney or liver disease, or some other disease such as hypothyroidism.

Warning symptoms of hypoglycaemia
- In your body
Examples of symptoms that tell you that your blood sugar level is falling too much or too fast:
- sweating, clamminess, hunger, anxiety, fast heart beat, high blood pressure, palpitations and irregular heart beat. These symptoms often develop before the symptoms of a low sugar level in the brain.

In your brain
Examples of symptoms that indicate a low sugar level in the brain:
- headaches, intense hunger, nausea, vomiting, tiredness, dizziness, sleeplessness, restlessness, aggressiveness, elevated temperature, palpitations, and tingling sensations in the area of the mouth, dizziness, loss of self-control, inability to look after yourself, convulsions, loss of consciousness.

The first symptoms which alert you to hypoglycaemia are:
- you are looking unwell, or you feel unwell,
- you feel tired or weak, or you do not feel well,
- you are having difficulty concentrating, or you are finding it difficult to think,
- you are white in the face, pale, sweating, shaggy, thirsty, or in a cold sweat,
- you have an unusual appetite.

The second symptoms which alert you to hypoglycaemia are:
- you feel dizzy, faint, or you feel you are going to faint.

The third symptoms which alert you to hypoglycaemia are:
- you start to feel sick, or you vomit.

In such a case, you may develop severe hypoglycaemia (“warning symptoms”), may change, be weaker or may be missing altogether if:
- you are elderly, if you have had diabetes for a long time or if you suffer from a certain type of nervous disease (diabetic autonomic neuropathy),
- you have recently suffered hypoglycaemia (for example the day before) or if it develops slowly,
- you have almost normal or, at least, greatly improved blood sugar levels,
- you have recently changed from a human insulin to a human insulin such as Lantus, you are taking or have taken certain other medicines (see section 2, “Other medicines and Lantus”).

In such a case, you may develop severe hypoglycaemia (and even faint) before you are aware of the problem. Be familiar with your warning symptoms. If necessary, more frequent blood sugar testing can help to identify mild hypoglycaemic episodes that may otherwise be overlooked. If you are not confident about recognising your warning symptoms, avoid situations (such as driving a car) in which you or others would be put at risk by hypoglycaemia.

It is advisable to test your blood sugar immediately after taking glucose to check that you really have hypoglycaemia.

Other source of information
Detailed information on this medicine is available on the European Medicines Agency (EMA) website: http://www.ema.europa.eu/

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder.

Marketing Authorisation Holder and Manufacturer
Sanofi-Aventis Deutschland GmbH,
D-65926 Frankfurt am Main, Germany.

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