

Lantus®

100 IU/ml solution for injection in a vial

Insulin glargine

†Aventis

PACKAGE LEAFLET

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.

In this leaflet:

1. What Lantus is and what it is used for
2. Before you use Lantus
3. How to use Lantus
4. Possible side-effects

5. Storing Lantus
6. Further information

Lantus 100 IU/ml solution for injection in a vial
Insulin glargine

- The active substance is Insulin glargine. One millilitre of the solution contains 100 IU (International Units) of the active substance insulin glargine.
- Other ingredients of Lantus are: zinc chloride, m-cresol, glycerol, sodium hydroxide, hydrochloric acid and water for injections.

The marketing authorisation holder and manufacturer of Lantus is:
Aventis Pharma Deutschland GmbH, D-65926 Frankfurt am Main, Germany.

1. WHAT LANTUS IS AND WHAT IT IS USED FOR

Lantus is a clear, colourless solution for injection containing insulin glargine. Insulin glargine is a modified insulin, very similar to human insulin. It is made by a recombinant DNA technology process using *Escherichia coli* microorganism. Insulin glargine has a long and steady blood-sugar-lowering action.

Each vial contains 5ml solution (500 IU) or 10ml solution (1000 IU) and they are available in packs of 1, 2, 5 and 10 vials of 5ml or 1 vial of 10ml.

Lantus is used to reduce high blood sugar in patients with diabetes mellitus. Diabetes mellitus is a disease where your body does not produce enough insulin to control the level of blood sugar.

2. BEFORE YOU USE LANTUS

Do not use Lantus:

If you are hypersensitive (allergic) to insulin glargine or to any of the other ingredients of Lantus (see above).

Take special care with Lantus:

Please follow closely the instructions for dosage, monitoring (blood and urine tests), diet and physical activity (physical work and exercise) as discussed with your doctor.

Special patient groups

There is limited experience with the use of Lantus in children less than 6 years old and in patients whose liver or kidneys do not function well.

Travel

Before travelling consult your doctor. You may need to talk about

- the availability of your insulin in the country you are visiting,
- supplies of insulin, syringes etc.,
- correct storage of your insulin while travelling,

- timing of meals and insulin administration while travelling,
- the possible effects of changing to different time zones,
- possible new health risks in the countries to be visited.

Illnesses and injuries

If you are ill or have a major injury then your blood sugar may increase (hyperglycaemia). If you are not eating enough your blood sugar may become too low (hypoglycaemia). In such situations, the management of your diabetes may require a lot of care. In most cases you will need a doctor. **Make sure that you contact a doctor early.** If you have type 1 diabetes (insulin dependent diabetes mellitus), do not stop your insulin and continue to get enough carbohydrates. Always tell people who are caring for you or treating you that you require insulin.

Pregnancy

Ask your doctor or pharmacist for advice before taking any medicine. Inform your doctor if you are planning to become pregnant, or if you are already pregnant. Your insulin dosage may need to be changed during pregnancy and after giving birth. Particularly careful control of your diabetes, and prevention of hypoglycaemia, is important for the health of your baby.

Breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.

If you are breast-feeding consult your doctor as you may require adjustments in your insulin doses and your diet.

Driving and using machines:

Your ability to concentrate or react may be reduced if you have too low (hypoglycaemia) or too high (hyperglycaemia) blood sugar or problems with your sight. Please keep this possible problem in mind in all situations where you might put yourself and others at risk (e.g. driving a car or operating machinery). You should contact your doctor about the advisability of driving if you have:

- frequent episodes of hypoglycaemia,
- reduced or absent warning signs of hypoglycaemia.

Taking/using other medicines:

Some medicines cause the blood sugar level to fall, some cause it to rise, others may have both effects, depending on the situation. In each case, it may be necessary to adjust your insulin dosage to avoid too low or too high blood sugar



levels. Be careful not only when you start another medicine, but also when you stop it.

Tell your doctor about all medicines that you are taking, including those you have bought without a prescription. Before taking a medicine ask your doctor if it can affect your blood sugar level and what action, if any, you need to take.

Medicines that may cause your blood sugar to fall include all other medicines for the treatment of diabetes, ACE inhibitors, disopyramide, fluoxetine, fibrates, MAO inhibitors, pentoxifylline, propoxyphene, salicylates and sulfonamide antibiotics.

Medicines that may cause your blood sugar to rise include corticosteroids (“cortisone”), danazol, diazoxide, diuretics, glucagon, isoniazid, oestrogens and progestogens (e.g. in the contraceptive pill), phenothiazine derivatives, somatropin, sympathomimetic medicines (e.g. epinephrine, salbutamol, terbutaline), thyroid hormones, clozapine, olanzapine and protease inhibitors.

Your blood sugar level may either rise or fall if you take beta-blockers, clonidine or lithium salts or drink alcohol. Pentamidine may cause hypoglycaemia which may sometimes be followed by hyperglycaemia.

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Beta-blockers like other sympatholytic medicines (e.g. clonidine, guanethidine, and reserpine) may weaken the warning symptoms of a hypoglycaemic reaction or suppress them entirely.

If you are not sure whether you are taking one of those medicines ask your doctor or pharmacist.

3. HOW TO USE LANTUS

Based on your life-style and the results of blood sugar (glucose) tests and your previous insulin usage, your doctor will:

- determine how much Lantus per day you will need and at what time.
- tell you when to check your blood sugar level, and whether you need to carry out urine tests,
- tell you when you may need to inject a higher or lower dose of Lantus,
- show you in which skin area to inject Lantus.

Lantus is a long-acting insulin. Your doctor may tell you to use it in combination with a short-acting insulin or with tablets against high blood sugar. Many factors may influence your blood sugar level. You should know these factors to be able to react correctly to changes in your blood sugar level and to prevent it from becoming too high or too low. See the box at the end of section 4 for further information.

You need one injection of Lantus every day, at the same time of the day. In children, only evening injection has been studied.

Lantus is injected under the skin. Do NOT inject Lantus in a vein, since this will change its action and may cause hypoglycaemia.

Your doctor will advise you in which area of the skin you should inject Lantus. With each injection, change the puncture site within the particular area of skin that you are using.

How to handle the vials

Look at the vial before you use it. Only use it if the solution is clear, colourless and waterlike, and has no visible particles in it. Lantus is a solution and does not require shaking or mixing before use.

Make sure that neither alcohol nor other disinfectants or other substances contaminate the insulin. Do not mix Lantus with any other insulins or medicines. Do not dilute it. Mixing or diluting may change the action of Lantus.

Mistakes in dosage:

Please discuss in advance with your doctor what you should do if you inject too much Lantus, if you miss a dose or if you inject too low a dose.

If you take more Lantus than you should:

If you **have injected too much Lantus**, you may develop hypoglycaemia. Check your blood sugar frequently. In general, to prevent hypoglycaemia you must eat more food and monitor your blood sugar. For information on the treatment of hypoglycaemia, see box at the end of section 4.

If you forget to take Lantus:

If you **have missed a dose of Lantus** or if you **have injected too low a dose**, your blood sugar level may become too high. Check your blood sugar frequently. See the end of section 4 for further information on hyperglycaemia.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Lantus can have side effects.

Too low blood sugar levels (hypoglycaemia)

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. Please see the box at the end of this section for important further information about hypoglycaemia and its treatment.

Too high blood sugar levels (hyperglycaemia)

Too high a blood sugar level tells you that you could have needed more insulin than you injected. Please see the box at the end of this section for further information.

Eye reactions

A marked change (improvement or worsening) in your blood sugar control can cause a temporary worsening of your vision. If you have proliferative retinopathy (an eye disease related to diabetes) severe hypoglycaemic attacks may cause transient loss of vision.

Skin side-effects and allergic reactions

If you inject your insulin too often at the same skin site, fatty tissue under the skin at this site may shrink or thicken (called lipodystrophy). Thickening of fatty tissue may occur in 1 to 2% of patients while shrinking may occur uncommonly. Insulin that you inject in such a site may not work very well. Changing the site with each injection may help to prevent such skin changes.

3 to 4% of patients may experience reactions at the injection site (e.g. reddening, unusually intense pain on injection, itching, hives, swelling or inflammation). They can also spread

around the injection site. Most minor reactions to insulins usually resolve in a few days to a few weeks.

Severe allergic reactions to insulins are rare. Such reactions to insulin or to the excipients can cause large-scale skin reactions, severe swelling of skin or mucous membranes (angio-oedema), shortness of breath, a fall in blood pressure and circulatory breakdown and may become life-threatening.

Other side-effects

Insulin treatment can cause the body to produce antibodies to insulin (substances that act against insulin). Rarely, this may require a change to your insulin dosage. In rare cases, insulin treatment may also cause temporary build-up of water in the body, with swelling in the calves and ankles.

Tell your doctor or pharmacist if you notice any of the side-effects listed above or any other unwanted or unexpected effects. To prevent serious reactions, speak to a doctor immediately if a side-effect is severe, occurred suddenly or gets worse rapidly.

If your blood sugar is too high (hyperglycaemia)

Your blood sugar level may be too high if, for example,

- you have not injected your insulin or not injected enough, or if it has become less effective, e.g. through incorrect storage,
- you are doing less physical exercise, you are under stress (emotional distress, excitement), or if you have an injury, operation, feverish illness or certain other diseases,
- you are taking or have taken certain other medicines (see section 2, “Taking/using other medicines”).

Thirst, increased need to pass water, tiredness, dry skin, reddening of the face, loss of appetite, low blood pressure, fast heart beat, and glucose and ketone bodies in urine may be signs of too high blood sugar. Stomach pain, fast and deep breathing, sleepiness or even loss of consciousness may be signs of a serious condition (ketoacidosis) resulting from lack of insulin.

Test your blood sugar level and your urine for ketones as soon as any such symptoms occur. Severe hyperglycaemia or ketoacidosis must always be treated by a doctor, normally in a hospital.

If your blood sugar is too low (hypoglycaemia)

Your blood sugar levels may fall too much if, for example:

- 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 lose carbohydrates due to vomiting or diarrhoea,
- you drink alcohol, particularly if you are not eating much,
- you take more physical 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 a feverish illness or from another illness,
- you are taking or have stopped taking certain other medicines (see section 2, “Taking/using other medicines”).

Too low blood sugar levels are also more likely to occur if

- 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 (e.g. from the thigh to the upper arm),
- you suffer from severe kidney or liver disease, or some other disease such as hypothyroidism.

Symptoms that tell you that your blood sugar level is falling too much or too fast may be, for example: sweating, clammy skin, anxiety, fast heart beat, high blood pressure, palpitations and irregular heartbeat, chest pain (angina pectoris). These symptoms often develop before the symptoms of a low sugar level in the brain. The following symptoms indicate a low sugar level in the brain: headaches, intense hunger, nausea, vomiting, tiredness, sleepiness, sleep disturbances, restlessness, aggressive behaviour, lapses in concentration, impaired reactions, depression, confusion, speech disturbances (sometimes total loss of speech), visual disorders, trembling, paralysis, tingling sensations (paraesthesia), numbness 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 (“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, due to diabetes, suffer from a certain type of nervous disease (autonomic neuropathy),
- you have recently suffered hypoglycaemia (e.g. 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 an animal insulin to a human insulin such as Lantus,
- you are taking or have taken certain other medicines (see section 2, “Taking/using other medicines”).

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

What to do in case of hypoglycaemia?

1. Do not inject insulin. Immediately take about 10 to 20 g sugar, e.g. as glucose, sugar cubes or a sugar-sweetened beverage. (Measure once as spoonfuls or lumps of sugar or glucose tablets to see how much this means.) Caution: please remember that artificial sweeteners and foods with artificial sweeteners (e.g. diet drinks) are of no help in hypoglycaemia.
2. Then eat something that has a long-acting effect in raising your blood sugar (e.g. bread). Your doctor or nurse will have discussed this with you. The recovery of hypoglycaemia may be delayed because Lantus has a long action.
3. If the hypoglycaemia comes back again take another 10 to 20 g sugar.
4. Speak to a doctor immediately if you are not able to control the hypoglycaemia or if it recurs.

Always carry some sugar (at least 20 grams) with you. Carry some information with you to show you are diabetic.

If you are not able to swallow or if you are unconscious, you will require an injection of glucose or glucagon (a medicine which increases blood sugar). These injections are justified even if it is not certain that you have hypoglycaemia.

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

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

5. STORING LANTUS

Keep out of the reach and sight of children.

Do not use Lantus after the expiry date printed on the carton and on the label of the vial.

Store at 2°C–8°C (in a refrigerator). Keep the container in the outer carton in order to protect from light. Do not allow it to freeze. Do not put Lantus next to the freezer compartment of your refrigerator or next to a freezer pack.

Once in use, you can keep the vial at a temperature of up to 25°C for up to 4 weeks in the outer carton. Do not use it after this time. It is helpful to note on the label the date of the first withdrawal from the vial.

Always use a new vial if you notice that your blood sugar control is unexpectedly getting worse. This is because the insulin may have lost some of its effectiveness. If you think you may have a problem with Lantus, have it checked by your doctor or pharmacist.

Do not use Lantus if you notice particles in it. Only use Lantus if the solution is clear, colourless and waterlike.

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6. FURTHER INFORMATION

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

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