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Package leaflet:
information for the user

Insulin lispro Sanofi®

100 units/ml solution for injection in vial

Insulin lispro

SANOFI

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- 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. See section 4.

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What is in this leaflet

1. What Insulin lispro Sanofi is and what it is used for

Insulin lispro Sanofi is used to treat diabetes. It works more quickly than normal human insulin because the insulin molecule has been changed slightly.

You get diabetes if your pancreas does not make enough insulin to control the level of glucose in your blood. Insulin lispro Sanofi is a substitute for your own insulin and is used to control glucose in the long term. It works very quickly and lasts a shorter time than soluble insulin (2 to 5 hours). You should normally use Insulin lispro Sanofi within 15 minutes of a meal.

Your doctor may tell you to use Insulin lispro Sanofi as well as a longer-acting insulin. Each kind of insulin comes with another patient information leaflet to tell you about it. Do not change your insulin unless your doctor tells you to. Be very careful if you do change insulin.

Insulin lispro Sanofi is suitable for use in adults and children.

2. What you need to know before you use Insulin lispro Sanofi

Do not use Insulin lispro Sanofi
- if you think **hypoglycaemia** (low blood sugar) is starting. Further in this leaflet it tells you how to deal with mild hypoglycaemia (see section 3: If you use more Insulin lispro Sanofi than you need).
- if you are **allergic** to insulin lispro or to any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Record the brand name ("Insulin lispro Sanofi") and Lot number (included on the outer cartons and labels of each vial, cartridge and pre-filled pen) of the product you are using and provide this information when reporting any side effects.

Skin changes at the injection site
The injection site should be rotated to prevent skin changes such as lumps under the skin. The insulin may not work very well if you inject into a lumpy area (see How to use Insulin lispro Sanofi). Contact your doctor if you are currently injecting into a lumpy area before you start injecting in a different area. Your doctor may tell you to check your blood sugar more closely, and to adjust your insulin or your other antidiabetic medications dose.

- If your blood sugar levels are well controlled by your current insulin therapy, you may not feel the warning symptoms when your blood sugar is falling too low. Warning signs are listed later in this leaflet. You must think carefully about when to have your meals, how often to exercise and how much to do. You must also keep a close watch on your blood sugar levels by testing your blood glucose often.
- A few people who have had hypoglycaemia after switching from animal insulin to human insulin have reported that the early warning symptoms were less obvious or different. If you often have hypoglycaemia or have difficulty recognising it, please discuss this with your doctor.
- If you answer YES to any of the following questions, tell your doctor, pharmacist or diabetes nurse
  - Have you recently become ill?
  - Do you have trouble with your kidneys or liver?
  - Are you exercising more than usual?
- You should also tell your doctor, pharmacist or diabetes nurse if you are planning to go abroad. The time difference between countries may mean that you have to have your injections and meals at different times from when you are at home.
- Some patients with long-standing type 2 diabetes mellitus and heart disease or previous stroke who were treated with pioglitazone and insulin experienced the development of heart failure. Inform your doctor as soon as possible, if you experience signs of heart failure such as unusual shortness of breath or rapid increase in weight or localised swelling (oedema).

Other medicines and Insulin lispro Sanofi
Your insulin needs may change if you are taking
- the contraceptive pill,
- steroids,
- thyroid hormone replacement therapy,
- oral hypoglycaemics,
- acetyl salicylic acid,
- sulpha antibiotics,
- octreotide,
- "beta$_2$ stimulants" (for example ritodrine, salbutamol or terbutaline),
- beta-blockers, or
- some antidepressants (monoamine oxidase inhibitors or selective serotonin reuptake inhibitors),
- danazol,
- some angiotensin converting enzyme (ACE) inhibitors (for example captopril, enalapril), and
- angiotensin II receptor blockers.

Tell your doctor if you are taking, have recently taken or might take any other medicines (see also section "Warnings and precautions").

Insulin lispro Sanofi with alcohol
Your blood sugar levels may change if you drink alcohol. Therefore the amount of insulin needed may change.

Pregnancy and breast feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.The amount of insulin you need usually falls during the first three months of pregnancy and increases for the remaining six months.
If you are breast-feeding, you may need to alter your insulin intake or diet.

Driving and using machines
Your ability to concentrate and react may be reduced if you have hypoglycaemia. 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 using machines). You should contact your doctor about the advisability of driving if you have:
- frequent episodes of hypoglycaemia
- reduced or absent warning signs of hypoglycaemia

Important information about some of the ingredients of Insulin lispro Sanofi
This medicine contains less than 1 mmol (23 mg) sodium per dose, i.e. it is essentially "sodium-free".

3. How to use Insulin lispro Sanofi

Always check the pack and the vial label for the name and type of the insulin when you get it from your pharmacy. Make sure you get the Insulin lispro Sanofi that your doctor has told you to use.

Always use this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.

Dosage
- You should normally inject Insulin lispro Sanofi within 15 minutes of a meal. If you need to, you can inject soon after a meal. But your doctor will have told you exactly how much to use, when to use it, and how often. These instructions are only for you. Follow them exactly and visit your diabetes clinic regularly.
- If you change the type of insulin you use (for example from a human or animal insulin to an Insulin lispro Sanofi product), you may have to use more or less than before. This might just be for the first injection or it may be a gradual change over several weeks or months.
- Inject Insulin lispro Sanofi under the skin (subcutaneous use or "SC"). You should only inject it into a muscle if your doctor has told you to.

Preparing Insulin lispro Sanofi
- Insulin lispro Sanofi is already dissolved in water, so you do not need to mix it. But you must use it **only** if it looks like water. It must be clear, have no colour and no solid pieces in it. Check each time you inject yourself.

Injecting Insulin lispro Sanofi
- First wash your hands.
- Before you make an injection, clean your skin as you have been instructed. Clean the rubber stopper on the vial, but do not remove the stopper.
- Use a clean, sterile syringe and needle to pierce the rubber stopper and draw in the amount of Insulin lispro Sanofi you want. Your doctor or clinic will tell you how to do this. **Do not share your needles and syringes.**
- Inject under the skin, as you were taught. Do not inject directly into a vein. After your injection, leave the needle in the skin for five seconds to make sure you have injected the whole dose. Do not rub the area you have just injected. Make sure you inject at least half an inch (1 cm) from the last injection and that you 'rotate' the places you inject, as you have been taught. It doesn't matter which injection site you use, either upper arm, thigh, buttock or abdomen, your Insulin lispro Sanofi injection will still work quicker than soluble human insulin.
- Your doctor will tell you if you have to mix Insulin lispro Sanofi with one of the human insulins. For example if you do need to inject a mixture, draw the Insulin lispro Sanofi into the syringe before the long acting insulin. Inject the liquid as soon as you have mixed it. Do the same thing every time.
- You should not normally mix Insulin lispro Sanofi with one of the mixtures of human insulins. You should never mix Insulin lispro Sanofi with insulins produced by other manufacturers or animal insulins.
- You must not administer Insulin lispro Sanofi by the intravenous route (IV). Inject Insulin lispro Sanofi as your physician or nurse has taught you. Only your physician can administer Insulin lispro Sanofi by the intravenous route. He will only do this under special circumstances such as surgery or if you are ill and your glucose levels are too high.

Using Insulin lispro Sanofi in an infusion pump
- Only certain CE-marked insulin infusion pumps may be used to infuse insulin lispro. Before infusing insulin lispro, the manufacturer's instructions should be studied to ascertain the suitability or otherwise for the particular pump. Read and follow the instructions in the product literature supplied with the infusion pump.
- Be sure to use the correct reservoir and catheter for your pump.
- Changing of the infusion set (tubing and needle) must be done according to the instructions in the product information supplied with the infusion set.
- In the event of a hypoglycaemic episode, the infusion should be stopped until the episode is resolved. If repeated or severe low blood glucose levels occur, notify your doctor or clinic and consider the need to reduce or stop your insulin infusion.
- A pump malfunction or obstruction of the infusion set can result in a rapid rise in glucose levels. If an interruption to insulin flow is suspected, follow the instructions in the product literature and if appropriate, notify your doctor or clinic.
- When used with an insulin infusion pump, Insulin lispro Sanofi should not be mixed with any other insulin.

If you use more Insulin lispro Sanofi than you should
If you use more Insulin lispro Sanofi than you need, a low blood sugar may occur. Check your blood sugar. If your blood sugar is low (**mild hypoglycaemia**), eat glucose tablets, sugar or drink a sugary drink. Then eat fruit, biscuits, or a sandwich, as your doctor has advised you and have some rest. This will often get you over mild hypoglycaemia or a minor insulin overdose. If you get worse and your breathing is shallow and your skin gets pale, tell your doctor at once. A glucagon injection can treat quite severe hypoglycaemia. Eat glucose or sugar after the glucagon injection. If you do not respond to glucagon, you will have to go to hospital. Ask your doctor to tell you about glucagon.

If you forget to use Insulin lispro Sanofi
If you use less Insulin lispro Sanofi than you need, a high blood sugar may occur. Check your blood sugar.

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If hypoglycaemia (low blood sugar) or hyperglycaemia (high blood sugar) is not treated, they can be very serious and cause headaches, feeling sick (nausea), being sick (vomiting), loss of fluids (dehydration), unconsciousness, coma or even death (see Hypoglycaemia and Hyperglycaemia and diabetic ketoacidosis in section 4 "Possible Side Effects").

Three simple steps to avoid hypoglycaemia or hyperglycaemia are:
- Always keep spare syringes and a spare vial of Insulin lispro Sanofi.
- Always carry something to show you are diabetic.
- Always carry sugar with you.

If you stop using Insulin lispro Sanofi
If you use less Insulin lispro Sanofi than you need, a high blood sugar may occur. Do not change your insulin unless your doctor tells you to.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Systemic allergy is rare (may affect up to 1 in 1,000 people). The symptoms are as follows:
- rash over the whole body
- difficulty in breathing
- wheezing
- blood pressure dropping
- heart beating fast
- sweating

If you think you are having this sort of insulin allergy with Insulin lispro Sanofi, tell your doctor at once.

Local allergy is common (may affect up to 1 in 10 people). Some people get redness, swelling or itching around the area of the insulin injection. This usually clears up in anything from a few days to a few weeks. If this happens to you, tell your doctor.

Skin changes at the injection site
If you inject insulin too often at the same place, the fatty tissue may either shrink (lipoatrophy) or thicken (lipohypertrophy) (may affect up to 1 in 100 people). Lumps under the skin may also be caused by build-up of a protein called amyloid (cutaneous amyloidosis; how often this occurs is not known). The insulin may not work very well if you inject into a lumpy area. Change the injection site with each injection to help prevent these skin changes.

Oedema (e.g. swelling in arms, ankles; fluid retention) has been reported, particularly at the start of insulin therapy or during a change in therapy to improve control of your blood glucose.

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Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

Common problems of diabetes

Hypoglycaemia
Hypoglycaemia (low blood sugar) means there is not enough sugar in the blood. This can be caused if:
- you inject too much Insulin lispro Sanofi or other insulin;
- you miss or delay meals or change your diet;
- you exercise or work too hard just before or after a meal;
- you have an infection or illness (especially diarrhoea or vomiting);
- there is a change in your need for insulin; or
- you have trouble with your kidneys or liver which gets worse.

Alcohol and some medicines can affect your blood sugar levels (see section 2).

The first symptoms of low blood sugar usually come on quickly and include the following:
- tiredness
- nervousness or shakiness
- headache
- rapid heartbeat
- feeling sick
- cold sweat

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.

Hyperglycaemia and diabetic ketoacidosis
Hyperglycaemia (too much sugar in the blood) means that your body does not have enough insulin. Hyperglycaemia can be brought about by:
- not using your Insulin lispro Sanofi or other insulin;
- using less insulin than your doctor tells you to;
- eating a lot more than your diet allows; or
- fever, infection or emotional stress.

Hyperglycaemia can lead to diabetic ketoacidosis. The first symptoms come on slowly over many hours or days. The symptoms include the following:
- feeling sleepy
- flushed face
- thirst
- no appetite
- fruity smell on the breath
- feeling or being sick

Severe symptoms are heavy breathing and a rapid pulse.
Get medical help immediately.

Illness
If you are ill, especially if you feel sick or are sick, the amount of insulin you need may change. **Even when you are not eating normally, you still need insulin.** Test your urine or blood, follow your 'sick rules', and tell your doctor.

5. How to store Insulin lispro Sanofi

Keep out of the reach and sight of children.

Do not use Insulin lispro Sanofi after the expiry date which is stated on the label and the carton. The expiry date refers to the last day of that month.

Before the first use store your medicine in a refrigerator (2°C – 8°C). Do not freeze. Keep the vial in the outer carton in order to protect from light.

Keep your vial in use at room temperature (below 30°C) and dispose of after 4 weeks. Do not store the vial in a refrigerator. Keep the vial in the outer carton in order to protect from light.

Do not use Insulin lispro Sanofi if it is coloured or it has solid pieces in it. You must use it **only** if it looks like water. Check this each time you inject yourself.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Insulin lispro Sanofi contains
- The active substance is insulin lispro. One ml of the solution contains 100 units (equivalent to 3.5 mg) of insulin lispro. Each vial contains 10 ml of solution for injection, equivalent to 1,000 units.
- The other ingredients are: metacresol, glycerol, disodium hydrogen phosphate heptahydrate, zinc oxide and water for injection. Sodium hydroxide or hydrochloric acid may have been used to adjust the acidity.

What Insulin lispro Sanofi looks like and contents of the pack
Insulin lispro Sanofi, solution for injection in a vial is a clear, colourless, aqueous solution.
Each vial contains 10 ml.
The Insulin lispro Sanofi in a vial comes in a pack of 1 vial or 5 vials. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
Marketing Authorisation Holder:
sanofi-aventis groupe, 54 rue La Boétie,
F - 75008 Paris, France

Manufacturer:
Sanofi-Aventis Deutschland GmbH,
D-65926 Frankfurt am Main, Germany.

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Other source of information
Detailed information on this medicine is available on the European Medicines Agency web site: http://www.ema.europa.eu/

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

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