ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Insulin lispro Sanofi 100 units/ml solution for injection in vial
Insulin lispro Sanofi 100 units/ml solution for injection in cartridge
Insulin lispro Sanofi 100 units/ml solution for injection in pre-filled pen

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One ml solution contains 100 units (equivalent to 3.5 mg) insulin lispro*.

Insulin lispro Sanofi 100 units/ml solution for injection in vial

Each vial contains 10 ml equivalent to 1,000 units insulin lispro.

Insulin lispro Sanofi 100 units/ml solution for injection in cartridge

Each cartridge contains 3 ml equivalent to 300 units insulin lispro.

Insulin lispro Sanofi 100 units/ml solution for injection in pre-filled pen

Each pre-filled pen contains 3 ml equivalent to 300 units insulin lispro.
Each pre-filled pen delivers 1-80 units in steps of 1 unit.

* Produced in *E.coli* by recombinant DNA technology

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Insulin lispro Sanofi 100 units/ml solution for injection in vial and in cartridge

Solution for injection (injection).

Insulin lispro Sanofi 100 units/ml solution for injection in a pre-filled pen

Solution for injection (injection) in pre-filled pen (SoloStar).

Clear, colourless, aqueous solution.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

For the treatment of adults and children with diabetes mellitus who require insulin for the maintenance of normal glucose homeostasis. Insulin lispro Sanofi is also indicated for the initial stabilisation of diabetes mellitus.

4.2 Posology and method of administration

Posology

The dose should be determined by the physician, according to the requirement of the patient.

Insulin lispro may be given shortly before meals. When necessary insulin lispro can be given soon after meals.

Insulin lispro takes effect rapidly and has a shorter duration of activity (2 to 5 hours) given subcutaneously as compared with regular insulin. This rapid onset of activity allows an Insulin lispro Sanofi injection (or, in the case of administration by continuous subcutaneous infusion, an Insulin lispro Sanofi bolus) to be given very close to mealtime. The time course of action of any insulin may vary considerably in different individuals or at different times in the same individual. The faster onset of action compared to soluble human insulin is maintained regardless of injection site. As with all insulin preparations, the duration of action of insulin lispro is dependent on dose, site of injection, blood supply, temperature, and physical activity.

Insulin lispro Sanofi can be used in conjunction with a longer-acting insulin or oral sulphonylurea medicinal products, on the advice of a physician.

Special populations

Renal impairment
Insulin requirements may be reduced in the presence of renal impairment.

Hepatic impairment
Insulin requirements may be reduced in patients with hepatic impairment due to reduced capacity for gluconeogenesis and reduced insulin breakdown; however, in patients with chronic hepatic impairment, an increase in insulin resistance may lead to increased insulin requirements.

Paediatric population
Insulin lispro Sanofi can be used in adolescents and children (see section 5.1).

Method of administration

Insulin lispro Sanofi solution for injection should be given by subcutaneous injection or by continuous subcutaneous infusion pump (see section 4.2) and may, although not recommended, also be given by intramuscular injection.
If necessary, Insulin lispro Sanofi may also be administered intravenously, for example; for the control of blood glucose levels during ketoacidosis, acute illnesses or during intra and post operative periods.

Subcutaneous administration of Insulin lispro Sanofi

Subcutaneous administration should be in the upper arms, thighs, buttocks, or abdomen. Injection sites should always be rotated within the same region in order to reduce the risk of lipodystrophy and cutaneous amyloidosis (see section 4.4 and 4.8).

When administered subcutaneously care should be taken when injecting Insulin lispro Sanofi to ensure that a blood vessel has not been entered. After injection, the site of injection should not be massaged. Patients must be educated to use the proper injection techniques.

Insulin lispro Sanofi 100 units/ml solution for injection in cartridge
Insulin lispro Sanofi 100 units/ml in cartridges is only suitable for subcutaneous injections from a reusable pen. If administration by syringe, intravenous injection or infusion pump is necessary, a vial should be used (see section 4.4). For further details on handling (see section 6.6).

The Insulin lispro Sanofi cartridges should only be used with the following pens:
- JuniorSTAR which delivers 1-30 units of insulin lispro in 0.5 unit dose increments
- Tactipen which delivers 1-60 units of insulin lispro in 1 unit dose increments
- AllStar and AllStar PRO which all deliver 1-80 units of insulin lispro in 1 unit dose increments.

These cartridges should not be used with any other reusable pen as the dosing accuracy has only been established with the listed pens (see section 6.6).

Insulin lispro Sanofi 100 units/ml solution for injection in pre-filled pen
Insulin lispro in pre-filled pen is available in two strengths (100 units/ml and 200 units/ml). However, Insulin lispro Sanofi in pre-filled pen is available in one strength only: 100 units/ml. For both, the needed dose is dialled in units. **The number of insulin units is shown in the dose window of the pen regardless of strength** and **no** dose conversion should be done when transferring a patient to a new strength or to another insulin lispro pre-filled pen with a different dose step.

Insulin lispro Sanofi in pre-filled pen delivers 1 – 80 units in increments of 1 unit in a single injection. Considering that Insulin lispro Sanofi is only available as 100 units/ml pre-filled pen, if an alternate strength is required, other insulin lispro medicinal products offering such an option should be used. Insulin lispro Sanofi in pre-filled pen is only suitable for subcutaneous injections. If administration by syringe, intravenous injection or infusion pump is necessary, a vial should be used (see section 4.4).

Use of Insulin lispro Sanofi in an insulin infusion pump

Insulin lispro Sanofi 100 units/ml solution for injection in vial
Insulin lispro Sanofi may be used for continuous subcutaneous insulin infusion (CSII) in pump systems suitable for insulin infusion. 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 that accompany the infusion pump. Use the correct reservoir and catheter for the pump. The infusion set (tubing and cannula) should be changed in accordance with 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 health care professional 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 health care professional. When used with an insulin infusion pump, Insulin lispro Sanofi should not be mixed with any other insulin.

Intravenous administration of Insulin lispro Sanofi

Insulin lispro Sanofi 100 units/ml solution for injection in vial
Insulin lispro Sanofi 100 units/ml is available in vials if administration of intravenous injection is necessary. Intravenous injection of insulin lispro should be carried out following normal clinical practice for intravenous injections, for example by an intravenous bolus or by an infusion system. Frequent monitoring of the blood glucose levels is required.
Infusion systems at concentrations from 0.1 units/ml to 1.0 units/ml insulin lispro in 0.9% sodium chloride or 5% glucose are stable at room temperature for 48 hours. It is recommended that the system is primed before starting the infusion to the patient.

4.3 Contraindications

Hypersensitivity to the active substance(s) or to any of the excipients listed in section 6.1.

Hypoglycaemia.

4.4 Special warnings and precautions for use

Traceability

In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.

Transferring a patient to another type or brand of insulin

Transferring a patient to another type or brand of insulin should be done under strict medical supervision. Changes in strength, brand (manufacturer), type (regular, NPH, lente, etc.), species (animal, human, human insulin analogue), and/or method of manufacture (recombinant DNA versus animal-source insulin) may result in the need for a change in dosage. For fast-acting insulins, any patient also on basal insulin must optimise dosage of both insulins to obtain glucose control across the whole day, particularly nocturnal/fasting glucose control.

Injection technique

Patients must be instructed to perform continuous rotation of the injection site to reduce the risk of developing lipodystrophy and cutaneous amyloidosis. There is a potential risk of delayed insulin absorption and worsened glycaemic control following insulin injections at sites with these reactions. A sudden change in the injection site to an unaffected area has been reported to result in hypoglycaemia. Blood glucose monitoring is recommended after the change in the injection site, and dose adjustment of antidiabetic medications may be considered.

Hypoglycaemia or hyperglycaemia

Conditions which may make the early warning symptoms of hypoglycaemia different or less pronounced include long duration of diabetes, intensified insulin therapy, diabetic nerve disease or medications such as beta-blockers.

A few patients who have experienced hypoglycaemic reactions after transfer from animal-source insulin to human insulin have reported that the early warning symptoms of hypoglycaemia were less pronounced or different from those experienced with their previous insulin. Uncorrected hypoglycaemic or hyperglycaemic reactions can cause loss of consciousness, coma, or death.

The use of doses which are inadequate or discontinuation of treatment, especially in insulin-dependent diabetics, may lead to hyperglycaemia and diabetic ketoacidosis; conditions which are potentially lethal.

Insulin requirements and dosage adjustment

Insulin requirements may be increased during illness or emotional disturbances.
Adjustment of dosage may also be necessary if patients undertake increased physical activity or change their usual diet. Exercise taken immediately after a meal may increase the risk of hypoglycaemia. A consequence of the pharmacodynamics of rapid-acting insulin analogues is that if hypoglycaemia occurs, it may occur earlier after an injection when compared with soluble human insulin.

Combination of Insulin lispro Sanofi with pioglitazone

Cases of cardiac failure have been reported when pioglitazone was used in combination with insulin, especially in patients with risk factors for development of cardiac heart failure. This should be kept in mind, if treatment with the combination of pioglitazone and Insulin lispro Sanofi is considered. If the combination is used, patients should be observed for signs and symptoms of heart failure, weight gain and oedema. Pioglitazone should be discontinued, if any deterioration in cardiac symptoms occurs.

Avoidance of medication errors when using Insulin lispro Sanofi

Patients must be instructed to always check the insulin label before each injection to avoid accidental mix-ups between Insulin lispro Sanofi and other insulin products.

Patients must visually verify the dialled units on the dose counter of the pen. Therefore, the requirement for patients to self-inject is that they can read the dose counter on the pen. Patients who are blind or have poor vision must be instructed to always get help/assistance from another person who has good vision and is trained in using the insulin device.

Insulin lispro Sanofi 100 units/ml solution for injection in vial

When mixing insulin lispro with a longer acting insulin, the shorter-acting Insulin lispro Sanofi should be drawn into the syringe first, to prevent contamination of the vial by the longer-acting insulin. Mixing of the insulins ahead of time or just before the injection should be on advice of the physician. However, a consistent routine must be followed.
For further details on handling, see section 6.6.

Insulin lispro Sanofi 100 units/ml solution for injection in cartridge

Insulin lispro Sanofi 100 units/ml in cartridges is only suitable for subcutaneous injections from a reusable pen. If administration by syringe, intravenous injection or infusion pump is necessary, a vial should be used.

To prevent the possible transmission of disease, each cartridge must be used by one patient only, even if the needle on the delivery device is changed.

Insulin lispro Sanofi 100 units/ml solution for injection in pre-filled pen

Insulin lispro Sanofi 100 units/ml in pre-filled pen is only suitable for subcutaneous injections. If administration by syringe, intravenous injection or infusion pump is necessary, a vial should be used. To prevent the possible transmission of disease, each pen must be used by one patient only, even if the needle is changed.

Excipients

This medicinal product contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially "sodium-free".

4.5 Interaction with other medicinal products and other forms of interaction

Insulin requirements may be increased by medicinal products with hyperglycaemic activity, such as oral contraceptives, corticosteroids, or thyroid replacement therapy, danazol, $beta_2$ stimulants (such as ritodrine, salbutamol, terbutaline).

Insulin requirements may be reduced in the presence of medicinal products with hypoglycaemic activity, such as oral hypoglycaemics, salicylates (for example, acetylsalicylic acid), sulpha antibiotics, certain antidepressants (monoamine oxidase inhibitors, selective serotonin reuptake inhibitors), certain angiotensin converting enzyme inhibitors (captopril, enalapril), angiotensin II receptor blockers, beta-blockers, octreotide or alcohol.

The physician should be consulted when using other medicinal products in addition to Insulin lispro Sanofi (see section 4.4).

4.6 Fertility, pregnancy and lactation

Pregnancy

Data on a large number of exposed pregnancies do not indicate any adverse effect of insulin lispro on pregnancy or on the health of the foetus/new-born.

It is essential to maintain good control of the insulin-treated (insulin-dependent or gestational diabetes) patient throughout pregnancy. Insulin requirements usually fall during the first trimester and increase during the second and third trimesters. Patients with diabetes should be advised to inform their doctor if they are pregnant or are contemplating pregnancy. Careful monitoring of glucose control, as well as general health, is essential in pregnant patients with diabetes.

Breast-feeding

Patients with diabetes who are breast-feeding may require adjustments in insulin dose, diet or both.

Fertility

Insulin lispro did not induce fertility impairment in animal studies (see section 5.3).

4.7 Effects on ability to drive and use machines

The patient's ability to concentrate and react may be impaired as a result of hypoglycaemia. This may constitute a risk in situations where these abilities are of special importance (e.g. driving a car or using machines).

Patients should be advised to take precautions to avoid hypoglycaemia whilst driving, this is particularly important in those who have reduced or absent awareness of the warning signs of hypoglycaemia or have frequent episodes of hypoglycaemia. The advisability of driving should be considered in these circumstances.

4.8 Undesirable effects

Summary of the safety profile

Hypoglycaemia is the most frequent adverse reaction of insulin therapy that a patient with diabetes may suffer. Severe hypoglycaemia may lead to loss of consciousness, and in extreme cases, death. No specific frequency for hypoglycaemia is presented, since hypoglycaemia is a result of both the insulin dose and other factors e.g. a patient`s level of diet and exercise.

Tabulated list of adverse reactions

The following related adverse reactions from clinical investigations are listed below by system organ class and in order of decreasing incidence (very common: ≥1/10; common: ≥1/100 to <1/10; uncommon: ≥1/1,000 to <1/100; rare: ≥1/10,000 to <1/1,000; very rare: <1/10,000) and not known (cannot be estimated from the available data).

Within each frequency grouping, adverse reactions are presented in order of decreasing seriousness.

MedDRA system organ classes	**Common**	**Uncommon**	**Rare**	**Not known**
Immune system disorders				
Local allergy	X			
Systemic allergy			X	
Skin and subcutaneous tissue disorders				
Lipodystrophy		X		
Cutaneous amyloidosis				X

Description of selected adverse reactions

Local allergy

Local allergy in patients is common. Redness, swelling, and itching can occur at the site of insulin injection. This condition usually resolves in a few days to a few weeks. In some instances, this

condition may be related to factors other than insulin, such as irritants in the skin cleansing agent or poor injection technique.

Systemic allergy

Systemic allergy, which is rare but potentially more serious, is a generalised allergy to insulin. It may cause a rash over the whole body, shortness of breath, wheezing, reduction in blood pressure, fast pulse, or sweating. Severe cases of generalised allergy may be life-threatening.

Skin and subcutaneous tissue disorders

Lipodystrophy and cutaneous amyloidosis may occur at the injection site and delay local insulin absorption. Continuous rotation of the injection site within the given injection area may help to reduce or prevent these reactions (see section 4.4).

Oedema

Cases of oedema have been reported with insulin therapy, particularly if previous poor metabolic control is improved by intensified insulin therapy.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system listed in Appendix V.

4.9 Overdose

Insulins have no specific overdose definitions because serum glucose concentrations are a result of complex interactions between insulin levels, glucose availability and other metabolic processes. Hypoglycaemia may occur as a result of an excess of insulin activity relative to food intake and energy expenditure.

Hypoglycaemia may be associated with listlessness, confusion, palpitations, headache, sweating and vomiting.

Mild hypoglycaemic episodes will respond to oral administration of glucose or other sugar or saccharated products.

Correction of moderately severe hypoglycaemia can be accomplished by intramuscular or subcutaneous administration of glucagon, followed by oral carbohydrate when the patient recovers sufficiently. Patients who fail to respond to glucagon must be given glucose solution intravenously.

If the patient is comatose, glucagon should be administered intramuscularly or subcutaneously. However, glucose solution must be given intravenously if glucagon is not available or if the patient fails to respond to glucagon. The patient should be given a meal as soon as consciousness is recovered.

Sustained carbohydrate intake and observation may be necessary because hypoglycaemia may recur after apparent clinical recovery.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Drugs used in diabetes, insulins and analogues for injection, fast-acting,

ATC code: A10AB04

Insulin lispro Sanofi is a biosimilar medicinal product. Detailed information is available on the website of the European Medicines Agency http://www.ema.europa.eu

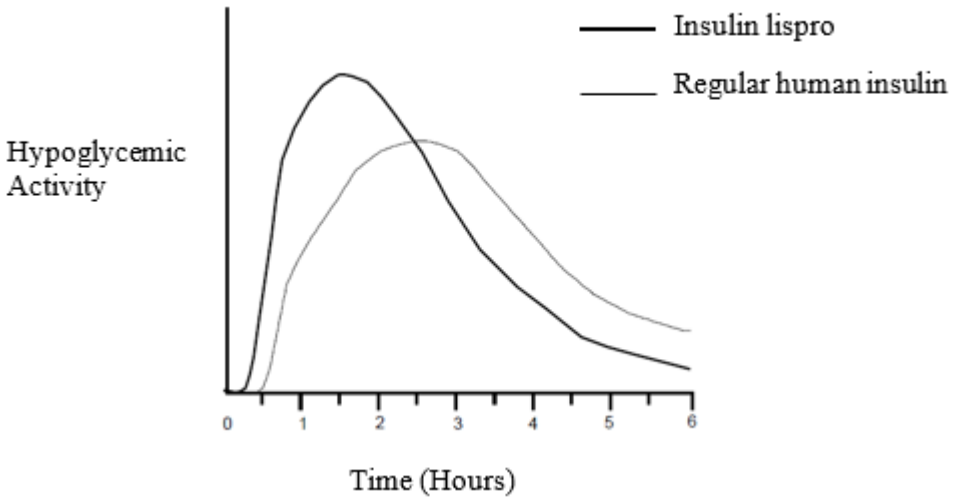
The primary activity of insulin lispro is the regulation of glucose metabolism.

In addition, insulins have several anabolic and anti-catabolic actions on a variety of different tissues. Within muscle tissue this includes increasing glycogen, fatty acid, glycerol and protein synthesis and amino acid uptake, while decreasing glycogenolysis, gluconeogenesis, ketogenesis, lipolysis, protein catabolism and amino acid output.

Insulin lispro has a rapid onset of action (approximately 15 minutes), thus allowing it to be given closer to a meal (within zero to 15 minutes of the meal) when compared to regular insulin (30 to 45 minutes before). Insulin lispro takes effect rapidly and has a shorter duration of activity (2 to 5 hours) when compared to regular insulin.

Clinical trials in patients with type 1 and type 2 diabetes have demonstrated reduced postprandial hyperglycaemia with insulin lispro compared to soluble human insulin.

As with all insulin preparations, the time course of insulin lispro action may vary in different individuals or at different times in the same individual and is dependent on dose, site of injection, blood supply, temperature and physical activity. The typical activity profile following subcutaneous injection is illustrated below.



The above representation reflects the relative amount of glucose over time required to maintain the subject's whole blood glucose concentrations near fasting levels and is an indicator of the effect of these insulins on glucose metabolism over time.

Clinical trials have been performed in children (61 patients aged 2 to 11) and children and adolescents (481 patients aged 9 to 19 years), comparing insulin lispro to human soluble insulin. The pharmacodynamic profile of insulin lispro in children is similar to that seen in adults.

When used in subcutaneous infusion pumps, treatment with insulin lispro has been shown to result in lower glycosylated haemoglobin levels compared to soluble insulin. In a double-blind, crossover study, the reduction in glycosylated haemoglobin levels after 12 weeks dosing was 0.37 percentage points with insulin lispro, compared to 0.03 percentage points for soluble insulin ($p = 0.004$).

In patients with type 2 diabetes on maximum doses of sulphonyl urea agents, studies have shown that the addition of insulin lispro significantly reduces HbA1c compared to sulphonyl urea alone. The reduction of HbA1c would also be expected with other insulin products e.g. soluble or isophane insulins.

Clinical trials in patients with type 1 and type 2 diabetes have demonstrated a reduced number of episodes of nocturnal hypoglycaemia with insulin lispro compared to soluble human insulin. In some studies, reduction of nocturnal hypoglycaemia was associated with increased episodes of daytime hypoglycaemia.

The glucodynamic response to insulin lispro is not affected by renal or hepatic function impairment. Glucodynamic differences between insulin lispro and soluble human insulin, as measured during a glucose clamp procedure, were maintained over a wide range of renal function.

Insulin lispro has been shown to be equipotent to human insulin on a molar basis but its effect is more rapid and of a shorter duration.

5.2 Pharmacokinetic properties

The pharmacokinetics of insulin lispro reflect a compound that is rapidly absorbed, and achieves peak blood levels 30 to 70 minutes following subcutaneous injection. When considering the clinical relevance of these kinetics, it is more appropriate to examine the glucose utilisation curves (as discussed in section 5.1).

Insulin lispro maintains more rapid absorption when compared to soluble human insulin in patients with renal impairment. In patients with type 2 diabetes over a wide range of renal function the pharmacokinetic differences between insulin lispro and soluble human insulin were generally maintained and shown to be independent of renal function. Insulin lispro maintains more rapid absorption and elimination when compared to soluble human insulin in patients with hepatic impairment.

5.3 Preclinical safety data

In *in vitro* tests, including binding to insulin receptor sites and effects on growing cells, insulin lispro behaved in a manner that closely resembled human insulin. Studies also demonstrate that the dissociation of binding to the insulin receptor of insulin lispro is equivalent to human insulin. Acute, one month and twelve month toxicology studies produced no significant toxicity findings.

Insulin lispro did not induce fertility impairment, embryotoxicity or teratogenicity in animal studies.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Metacresol
Glycerol
Disodium hydrogen phosphate heptahydrate
Zinc oxide
Water for injections
Hydrochloric acid (for pH adjustment)
Sodium hydroxide (for pH adjustment).

6.2 Incompatibilities

Insulin lispro Sanofi 100 units/ml solution for injection in vial

This medicinal product must not be mixed with other medicinal products except those mentioned in section 6.6.

Insulin lispro Sanofi 100 units/ml solution for injection in cartridge and in pre-filled pen

This medicinal product should not be mixed with any other insulin or any other medicinal product.

6.3 Shelf life

Before first use

3 years.

After first use

Dispose of after 4 weeks.

6.4 Special precautions for storage

Insulin lispro Sanofi 100 units/ml solution for injection in vial

Store in a refrigerator (2°C - 8°C). Do not freeze.
Keep the vial in the outer carton in order to protect from light.

After first use

Store below 30°C. Do not refrigerate.
Keep the vial in the outer carton in order to protect from light.

Insulin lispro Sanofi 100 units/ml solution for injection in cartridge

Store in a refrigerator (2°C - 8°C). Do not freeze.
Keep the cartridge in the outer carton in order to protect from light.

After first use

Store below 30°C and protect from direct heat and light. Do not refrigerate.
Keep the pen cap on the pen in order to protect from light

Insulin lispro Sanofi 100 units/ml solution for injection in pre-filled pen

Store in a refrigerator (2°C - 8°C). Do not freeze.
Keep the pre-filled pen in the outer carton in order to protect from light.

After first use

Store below 30°C. Do not refrigerate.
The pen cap must be put back on the pen after each injection in order to protect from light.

6.5 Nature and contents of container

Insulin lispro Sanofi 100 units/ml solution for injection in vial

Type I colourless glass vial with a flanged cap (aluminium) with a sealing disk (chlorobutyl rubber) and a tear-off cap (polypropylene) containing 10 ml of solution.
Pack sizes: 1 or 5 vials.

Not all packs sizes may be marketed.

Insulin lispro Sanofi 100 units/ml solution for injection in cartridge

Type 1 colourless glass cartridge with a black plunger (bromobutyl rubber) and a flanged cap (aluminium) with a sealing disk (laminate of isoprene and bromobutyl rubber). Each cartridge contains 3 ml of solution.
Pack sizes: 5 or 10 cartridges
Not all packs sizes may be marketed.

Insulin lispro Sanofi 100 units/ml solution for injection in pre-filled pen

Type 1 colourless glass cartridge with a black plunger (bromobutyl rubber) and a flanged cap (aluminium) with a sealing disk (laminate of isoprene and bromobutyl rubber) sealed in a disposable pen injector. Each pre-filled pen contains 3 ml of solution.
Pack sizes: 1, 3, 5 or 10 pre-filled pens.
Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

Insulin lispro Sanofi 100 units/ml solution for injection in vial

Instructions for use and handling

The vial is to be used in conjunction with an appropriate syringe (100 units markings).

Preparing a dose
Inspect the Insulin lispro Sanofi solution. It should be clear and colourless. Do not use the medicinal product if it appears cloudy, thickened, or slightly coloured or if solid particles are visible.

If the therapeutic regimen requires the injection of basal insulin and Insulin lispro Sanofi at the same time, the two can be mixed in the syringe. If mixing insulins, see section “Mixing Insulin lispro Sanofi with longer-acting human insulins” below and section 6.2.

1. Wash your hands.

2. If using a new vial, flip off the plastic protective cap, but **do not** remove the stopper.

3. Draw air into the syringe equal to the prescribed Insulin lispro Sanofi dose. Wipe the top of the vial with an alcohol swab. Put the needle through the rubber top of the Insulin lispro Sanofi vial and inject the air into the vial.

4. Turn the vial and syringe upside down. Hold the vial and syringe firmly in one hand.

5. Making sure the tip of the needle is in the Insulin lispro Sanofi; withdraw the correct dose into the syringe.

6. Before removing the needle from the vial, check the syringe for air bubbles that reduce the amount of Insulin lispro Sanofi in it. If bubbles are present, hold the syringe straight up and tap its side until the bubbles float to the top. Push them out with the plunger and withdraw the correct dose.

7. Remove the needle from the vial and lay the syringe down so that the needle does not touch anything.

Mixing Insulin lispro Sanofi with longer-acting human insulins (see section 6.2)
1. Insulin lispro Sanofi should be mixed with longer-acting human insulins only on the advice of a doctor. Insulin in vials must not be mixed with insulin in cartridges.

2. Draw air into the syringe equal to the amount of longer-acting insulin being taken. Insert the needle into the longer-acting insulin vial and inject the air. Withdraw the needle.

3. Now inject air into the Insulin lispro Sanofi vial in the same manner, but **do not** withdraw the needle.

4. Turn the vial and syringe upside down.

5. Making sure the tip of the needle is in the Insulin lispro Sanofi, withdraw the correct dose of Insulin lispro Sanofi into the syringe.

6. Before removing the needle from the vial, check the syringe for air bubbles that reduce the amount of Insulin lispro Sanofi in it. If bubbles are present, hold the syringe straight up and tap its side until the bubbles float to the top. Push them out with the plunger and withdraw the correct dose.

7. Remove the needle from the vial of Insulin lispro Sanofi and insert it into the vial of the longer-acting insulin. Turn the vial and syringe upside down. Hold the vial and syringe firmly in one hand and shake gently. Making sure the tip of the needle is in the insulin; withdraw the dose of longer-acting insulin.

8. Withdraw the needle and lay the syringe down so that the needle does not touch anything.

Injecting a dose
1. Choose a site for injection.

2. Clean the skin as instructed.

3. Stabilise the skin by spreading it or pinching up a large area. Insert the needle and inject as instructed.

4. Pull the needle out and apply gentle pressure over the injection site for several seconds. Do not rub the area.

5. Dispose of the syringe and needle safely.

6. Use of the injection sites should be rotated so that the same is not used more than approximately once a month.

<u>Insulin lispro Sanofi 100 units/ml solution for injection in cartridge</u>

<u>Instructions for use and handling</u>

Insulin lispro Sanofi 100 units/ml in cartridge is only suitable for subcutaneous injections from a reusable pen. If administration by syringe, intravenous injection or infusion pump is necessary, a vial should be used. To prevent the possible transmission of disease, each cartridge must be used by one patient only, even if the needle on the delivery device is changed.

Insulin lispro Sanofi cartridges are to be used with JuniorSTAR, Tactipen, AllStar or AllStar PRO pens as recommended in the user manual (see section 4.2).
Not all of these pens may be marketed in each country.
The pen with the inserted cartridge should not be stored with the needle attached.

Preparing a dose

Inspect the Insulin lispro Sanofi solution. It should be clear and colourless. Do not use the medicinal product if it appears cloudy, thickened, or slightly coloured or if solid particles are visible.

The following is a general description. The manufacturer's instructions with each individual pen must be followed for loading the cartridge, attaching the needle and administering the insulin injection

Injecting a dose
1. Wash your hands.

2. Choose a site for injection.

3. Clean the skin as instructed.

4. Remove outer needle cap.

5. Stabilise the skin by spreading it or pinching up a large area. Insert the needle as instructed.

6. Press the knob.

7. Pull the needle out and apply gentle pressure over the injection site for several seconds. Do not rub the area.

8. Using the outer needle cap, unscrew the needle and dispose of it safely.

9. Use of injection sites should be rotated so that the same site is not used more than approximately once a month.

Insulin lispro Sanofi 100 units/ml solution for injection in pre-filled pen

Instructions for use and handling

Insulin lispro Sanofi 100 units/ml in pre-filled pen is only suitable for subcutaneous injections. If administration by syringe, intravenous injection or infusion pump is necessary, a vial should be used. To prevent the possible transmission of disease, each pen must be used by one patient only, even if the needle is changed.

Inspect the Insulin lispro Sanofi solution. It should be clear and colourless. Do not use it if it appears cloudy, thickened, or slightly coloured or if solid particles are visible.

Before using the pre-filled pen, the user manual included in the package leaflet must be read carefully.
The pre-filled pen has to be used as recommended in the user manual.
The pre-filled pen should not be stored with the needle attached.
A new needle should always be used for each injection.
Needles are not included in the pack.

7. MARKETING AUTHORISATION HOLDER

Sanofi Winthrop Industrie
82 avenue Raspail
94250 Gentilly
France

8. MARKETING AUTHORISATION NUMBER(S)

EU/1/17/1203/001

EU/1/17/1203/002
EU/1/17/1203/003
EU/1/17/1203/004
EU/1/17/1203/005
EU/1/17/1203/006
EU/1/17/1203/007
EU/1/17/1203/008

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 19 july 2017
Date of latest renewal: 28 March 2022

10. DATE OF REVISION OF THE TEXT

Detailed information on this medicinal product is available on the website of the European Medicines Agency http://www.ema.europa.eu.

ANNEX II

A. MANUFACTURER OF THE BIOLOGICAL ACTIVE SUBSTANCE AND MANUFACTURERS RESPONSIBLE FOR BATCH RELEASE

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

C. OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

D. CONDITIONS OR RESTRICTIONS WITH REGARD TO THE SAFE AND EFFECTIVE USE OF THE MEDICINAL PRODUCT

A. MANUFACTURER OF THE BIOLOGICAL ACTIVE SUBSTANCE AND MANUFACTURERS RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer of the biological active substance

Sanofi-Aventis Deutschland GmbH
Brüningstrasse 50
Industriepark Höchst
65926 Frankfurt am Main
Germany

Name and address of the manufacturers responsible for batch release

Sanofi-Aventis Deutschland GmbH
Brüningstrasse 50
Industriepark Höchst
65926 Frankfurt am Main
Germany

Sanofi-Aventis Private Co. Ltd.,
Budapest Logistics and Distribution Platform
Bdg. DC5, Campona utca 1.,
Budapest, 1225, Hungary

The printed package leaflet of the medicinal product must state the name and address of the manufacturer responsible for the release of the concerned batch.

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Medicinal product subject to medical prescription.

C. OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

- **Periodic safety update reports (PSURs)**

The requirements for submission of PSURs for this medicinal product are set out in the list of Union reference dates (EURD list) provided for under Article 107c(7) of Directive 2001/83/EC and any subsequent updates published on the European medicines web-portal.

D. CONDITIONS OR RESTRICTIONS WITH REGARD TO THE SAFE AND EFFECTIVE USE OF THE MEDICINAL PRODUCT

- **Risk management plan (RMP)**

The marketing authorisation holder (MAH) shall perform the required pharmacovigilance activities and interventions detailed in the agreed RMP presented in Module 1.8.2 of the marketing authorisation and any agreed subsequent updates of the RMP.

An updated RMP should be submitted:
- At the request of the European Medicines Agency;
- Whenever the risk management system is modified, especially as the result of new information being received that may lead to a significant change to the benefit/risk profile or as the result of an important (pharmacovigilance or risk minimisation) milestone being reached.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

OUTER CARTON (10 ml vial)

1. NAME OF THE MEDICINAL PRODUCT

Insulin lispro Sanofi 100 units/ml solution for injection in vial
insulin lispro

2. STATEMENT OF ACTIVE SUBSTANCE(S)

One ml solution contains 100 units (equivalent to 3.5 mg) insulin lispro.
Each vial contains 10 ml equivalent to 1,000 units insulin lispro.

3. LIST OF EXCIPIENTS

Excipients: metacresol, glycerol, zinc oxide, disodium hydrogen phosphate heptahydrate, hydrochloric acid and sodium hydroxide (for pH adjustment), water for injections. See leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

Solution for injection
1 x 10 ml
5 x 10 ml

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
Subcutaneous and intravenous use

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

Before first use:
Store in a refrigerator.

Do not freeze.
Keep the vial in the outer carton in order to protect from light.

After first use:
Store below 30°C.
Do not refrigerate.
Keep the vial in the outer carton in order to protect from light.
Dispose of after 4 weeks.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Sanofi Winthrop Industrie
82 avenue Raspail
94250 Gentilly
France

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/17/1203/007 1 vial
EU/1/17/1203/008 5 vials.

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

Insulin lispro Sanofi 100

17. UNIQUE IDENTIFIER – 2D BARCODE

2D barcode carrying the unique identifier included.

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

PC
SN
NN

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

LABEL (10 ml vial)

1. NAME OF THE MEDICINAL PRODUCT AND ROUTE(S) OF ADMINISTRATION

Insulin lispro Sanofi 100 units/ml injection
insulin lispro
SC/IV use

2. METHOD OF ADMINISTRATION

Subcutaneous or intravenous use

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Lot

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

10 ml

6. OTHER

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

OUTER CARTON (cartridge)

1. NAME OF THE MEDICINAL PRODUCT

Insulin lispro Sanofi 100 units/ml solution for injection in cartridge
insulin lispro

2. STATEMENT OF ACTIVE SUBSTANCE(S)

One ml solution contains 100 units (equivalent to 3.5 mg) insulin lispro.
Each cartridge contains 3 ml equivalent to 300 units insulin lispro.

3. LIST OF EXCIPIENTS

Excipients: metacresol, glycerol, zinc oxide, disodium hydrogen phosphate heptahydrate, hydrochloric acid and sodium hydroxide (for pH adjustment), water for injections. See leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

Solution for injection
5 x 3 ml
10 x 3 ml

5. METHOD AND ROUTE(S) OF ADMINISTRATION

The cartridges are to be used only with the pens: Tactipen, AllStar, AllStar PRO, JuniorSTAR.
Not all of these pens may be marketed in your country.

Read the package leaflet before use.
Subcutaneous use

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

For single patient use only.

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

Before first use:
Store in a refrigerator.
Do not freeze.
Keep the cartridge in the outer carton in order to protect from light.

After first use:
Store below 30°C.
Do not refrigerate.
Keep the pen cap on the pen in order to protect from light.
Dispose of after 4 weeks.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Sanofi Winthrop Industrie
82 avenue Raspail
94250 Gentilly
France

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/17/1203/001 5 cartridges
EU/1/17/1203/002 10 cartridges.

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

Insulin lispro Sanofi 100

17. UNIQUE IDENTIFIER – 2D BARCODE

2D barcode carrying the unique identifier included.

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

PC
SN
NN

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

LABEL (cartridge)

1. NAME OF THE MEDICINAL PRODUCT AND ROUTE(S) OF ADMINISTRATION

Insulin lispro Sanofi 100 units/ml injection in cartridge
insulin lispro
SC use

2. METHOD OF ADMINISTRATION

Use specific pens.
Subcutaneous use

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Lot

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

3 ml

6. OTHER

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

OUTER CARTON (3 ml pre-filled pen)

1. NAME OF THE MEDICINAL PRODUCT

Insulin lispro Sanofi 100 units/ml solution for injection in a pre-filled pen
insulin lispro

2. STATEMENT OF ACTIVE SUBSTANCE(S)

One ml solution contains 100 units (equivalent to 3.5 mg) insulin lispro.
Each pre-filled pen contains 3 ml equivalent to 300 units insulin lispro.

3. LIST OF EXCIPIENTS

Excipients: metacresol, glycerol, zinc oxide, disodium hydrogen phosphate heptahydrate, hydrochloric acid and sodium hydroxide (for pH adjustment), water for injections. See leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

Solution for injection in pre-filled pen SoloStar
1 pen of 3 ml
3 pens of 3 ml
5 pens of 3 ml
10 pens of 3 ml

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Open here
Read the package leaflet before use.
Subcutaneous use

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

Always use a new needle for each injection.
For single patient use only.

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

Before first use:
Store in a refrigerator.
Do not freeze.
Keep the pre-filled pen in the outer carton in order to protect from light.

After first use:
Store below 30°C.
Do not refrigerate.
Put the pen cap back on the pen after each injection in order to protect from light.
Dispose of after 4 weeks.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Sanofi Winthrop Industrie
82 avenue Raspail
94250 Gentilly
France

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/17/1203/003 1 pen.
EU/1/17/1203/004 3 pens.
EU/1/17/1203/005 5 pens.
EU/1/17/1203/006 10 pens.

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

Insulin lispro 100 SoloStar

17. UNIQUE IDENTIFIER – 2D BARCODE

2D barcode carrying the unique identifier included.

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

PC
SN
NN

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

PEN LABEL (Pre-filled pen)

1. NAME OF THE MEDICINAL PRODUCT AND ROUTE(S) OF ADMINISTRATION

Insulin lispro Sanofi 100 units/ml injection
insulin lispro
SC use

2. METHOD OF ADMINISTRATION

Subcutaneous use

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Lot

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

3 ml

6. OTHER

SoloStar

B. PACKAGE LEAFLET

Package leaflet: information for the user

Insulin lispro Sanofi 100 units/ml solution for injection in vial
insulin lispro

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.

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.

<u>Skin changes at the injection site</u>

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.

Talk to your doctor, pharmacist or nurse before using Insulin lispro Sanofi:

- 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

Insulin lispro Sanofi contains sodium
This medicine contains less than 1 mmol (23 mg) sodium per dose, that is to say 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.

Dose
- 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 or are unsure how much you have injected, 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 or are unsure how much you have injected, a high blood sugar may occur. Check your blood sugar.

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
Lipodystrophy is uncommon (it may affect up to 1 in 100 people). If you inject insulin too often at the same place, the fatty tissue may either shrink (lipoatrophy) or thicken (lipohypertrophy). 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.

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 national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

Common problems of diabetes

A. 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.

B. 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.**

C. 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 (see section 2 "Insulin lispro Sanofi contains sodium").

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
Sanofi Winthrop Industrie, 82 avenue Raspail, 94250 Gentilly, France

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

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

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This leaflet was last revised in

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

Package leaflet: information for the user

Insulin lispro Sanofi 100 units/ml solution for injection in cartridge
insulin lispro

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.

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
Insulin lispro Sanofi in cartridges is only suitable for injecting just under the skin using a reusable pen (see also section 3). Speak to your doctor if you need to inject your insulin by another method.

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.

Talk to your doctor, pharmacist or nurse before using Insulin lispro Sanofi:

- 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

Insulin lispro Sanofi contains sodium
This medicine contains less than 1 mmol (23 mg) sodium per dose, that is to say essentially "sodium-free".

3. How to use Insulin lispro Sanofi

Always check the pack and the label cartridge 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. To prevent the possible transmission of disease, each cartridge must be used by you only, even if the needle on the delivery device is changed.

Dose
- 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.

Getting the pen ready to use
- First wash your hands. Disinfect the rubber membrane of the cartridge.
- The 3 ml cartridge only fits the 3 ml pen. Insulin lispro Sanofi in cartridges is only suitable for injecting just under the skin using a reusable pen. Speak to your doctor if you need to inject your insulin by another method. To ensure you get the accurate dose, the Insulin lispro Sanofi cartridges are to be used only with the following pens:
    - JuniorSTAR which delivers doses in steps of 0.5 units
    - Tactipen, AllStar and AllStar PRO which deliver doses in steps of 1 unit.

  Not all of these pens may be marketed in your country.
- Follow the instructions that come with the pen. The manufacturer's instructions for using the pen must be followed carefully for loading the cartridge, attaching the needle, and administering the insulin injection.
- Always perform a safety test before each injection.

Injecting Insulin lispro Sanofi

- Before you make an injection, clean your skin as you have been instructed. 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 ten 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.
- 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.

After injecting

- As soon as you have done the injection, take the needle off the pen using the outer needle cap. **Do not share your needles**. Do not share your pen. Replace the cap on your pen. Leave the cartridge in the pen.

Further injections Always use a new sterile needle for each injection. Always perform a safety test before each injection.

Do not mix any other insulin in an Insulin lispro Sanofi cartridge. Once the cartridge is empty, do not use it again.

If you use more Insulin lispro Sanofi than you should

If you use more Insulin lispro Sanofi than you need or are unsure how much you have injected, 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 or are unsure how much you have injected, a high blood sugar may occur. Check your blood sugar.

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, or a spare pen and cartridges, in case you lose your pen or cartridges or they get damaged.
- 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
Lipodystrophy is uncommon (it may affect up to 1 in 100 people). If you inject insulin too often at the same place, the fatty tissue may either shrink (lipoatrophy) or thicken (lipohypertrophy). 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.

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 national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

Common problems of diabetes

A. 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.

B. 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.**

C. 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 Insulin lispro Sanofi in a refrigerator (2°C – 8°C). Do not freeze. Keep the cartridge in the outer carton in order to protect from light.

Keep your cartridge in use at room temperature (below 30°C) and dispose of after 4 weeks. Do not put it near heat or in the sun. Keep the pen cap on the pen in order to protect from light. Do not keep your pen or the cartridges you are using in the fridge. The pen with the inserted cartridge should not be stored with the needle attached.

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 cartridge contains 3 ml of solution for injection, equivalent to 300 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 (see section 2 "Insulin lispro Sanofi contains sodium").

What Insulin lispro Sanofi looks like and contents of the pack
Insulin lispro Sanofi, solution for injection is a clear, colourless, aqueous solution.
Each cartridge contains 3 ml.
The Insulin lispro Sanofi cartridges come in a pack of 5 or 10 cartridges. Not all pack sizes may be marketed.

Marketing Authorisation Holder
Sanofi Winthrop Industrie, 82 avenue Raspail, 94250 Gentilly, France

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

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

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United Kingdom (Northern Ireland)
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This leaflet was last revised in

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

Package leaflet: information for the user

Insulin lispro Sanofi 100 units/ml solution for injection in pre-filled pen
insulin lispro
Each pre-filled pen delivers 1-80 units in steps of 1 unit.

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.

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.

Insulin lispro Sanofi SoloStar is a disposable pre-filled pen containing 3 ml (300 units, 100 units/ml) of insulin lispro. One Insulin lispro Sanofi pre-filled pen contains multiple doses of insulin. The Insulin lispro Sanofi pre-filled pen dials 1 unit at a time. **The number of units are displayed in the dose window, always check this before your injection.** You can give from 1 to 80 units in a single injection. **If your dose is more than 80 units, you will need to give yourself more than one injection.**

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
Insulin lispro Sanofi in pre-filled pen is only suitable for injecting just under the skin (see also section 3). Speak to your doctor if you need to inject your insulin by another method.

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.

Talk to your doctor, pharmacist or nurse before using Insulin lispro Sanofi:
- 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).
- This pen is not recommended for use by the blind or visually impaired without the help of someone trained to use the pen.

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

Insulin lispro Sanofi contains sodium
This medicine contains less than 1 mmol (23 mg) sodium per dose, that is to say essentially “sodium-free”.

3. How to use Insulin lispro Sanofi

Always check the pack and the label of the pre-filled pen 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. To prevent the possible transmission of disease, each pen must be used by you only, even if the needle is changed.

Dose
- 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.

Getting the SoloStar pre-filled pen ready to use (Please see user manual)
- Insulin lispro Sanofi in pre-filled pen is only suitable for injecting just under the skin. Speak to your doctor if you need to inject your insulin by another method.
- First wash your hands.
- Read the instructions on how to use your pre-filled insulin pen. Please follow the instructions carefully. Here are some reminders.

- Use a clean needle. (Needles are not included).
- Always perform a safety test before each injection.

Injecting Insulin lispro Sanofi
- Before you make an injection, clean your skin as you have been instructed. 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 ten 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.
- 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.

After injecting
- As soon as you have done the injection, unscrew the needle from the pre-filled pen using the outer needle cap. **Do not share your needles**. Do not share your pen. Replace the cap on your pen.

Further injections
- Every time you use pre-filled pen you must use a new needle. Always perform a safety test before each injection. You can see roughly how many units of insulin are left by looking at where the plunger is on the insulin scale.
- Do not mix any other insulin in your pre-filled pen. Once the pre-filled pen is empty, do not use it again. Please get rid of it carefully - your pharmacist or diabetes nurse will tell you how to do this.

If you use more Insulin lispro Sanofi than you should
If you use more Insulin lispro Sanofi than you need or are unsure how much you have injected, 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 or are unsure how much you have injected, a high blood sugar may occur. Check your blood sugar.

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, or a spare pen and cartridges, in case you lose your SoloStar pre-filled pen or it gets damaged.
- 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
Lipodystrophy is uncommon (it may affect up to 1 in 100 people). If you inject insulin too often at the same place, the fatty tissue may either shrink (lipoatrophy) or thicken (lipohypertrophy). 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.

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 national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

Common problems of diabetes

A. 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.

B. 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.**

C. 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 in pre-filled pen 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 pre-filled pen in a refrigerator (2°C – 8°C). Do not freeze. Keep the pre-filled pen in the outer carton in order to protect from light.

Keep your Insulin lispro Sanofi pre-filled pen in use at room temperature (below 30°C) and dispose of after 4 weeks. Do not keep the pre-filled pen that you are using in the fridge. The pre-filled pen should not be stored with the needle attached. Always keep the cap on the pre-filled pen when you are not using it in order to protect from light.

Do not use Insulin lispro Sanofi pre-filled pen if the solution 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. Each ml of the solution contains 100 units (equivalent to 3.5 mg) of insulin lispro. Each pre-filled pen contains 3 ml of solution for injection, equivalent to 300 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 (see section 2 "Insulin lispro Sanofi contains sodium").

What Insulin lispro Sanofi looks like and contents of the pack

Insulin lispro Sanofi, solution for injection is a clear, colourless, aqueous solution.
Each pre-filled pen contains 3 ml.
The Insulin lispro Sanofi in pre-filled pen (SoloStar) comes in a pack of 1, 3, 5 or 10 pre-filled pens.
Not all pack sizes may be marketed.
The Insulin lispro Sanofi in your pre-filled pen is the same as the Insulin lispro Sanofi, which comes in separate Insulin lispro Sanofi cartridges. The pre-filled pen simply has a built in cartridge. When the pre-filled pen is empty you cannot use it again.

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

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This leaflet was last revised in

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

Insulin lispro Sanofi solution for injection in pre-filled pen (SoloStar)
INSTRUCTIONS FOR USE

Read this first

Important information

- Never share your pen – it is only for you.
- Never use your pen if it is damaged or if you are not sure that it is working properly.
- Always perform a safety test
- Always carry a spare pen and spare needles in case they got lost or stop working.
- **Never re-use needles.** If you do you might not get your dose (underdosing) or get too much (overdosing) as the needle could block.

Learn to inject

- Talk with your doctor, pharmacist or nurse about how to inject, before using your pen.
- Ask for help if you have problems handling the pen, for example if you have problems with your sight.
- This pen is not recommended for use by the blind or visually impaired without the help of someone trained to use the pen.
- Read all of these instructions before using your pen. If you do not follow all of these instructions, you may get too much or too little insulin.

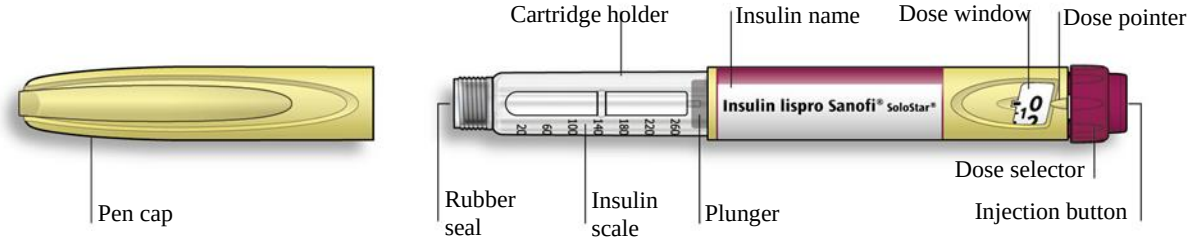
Need help?

If you have any questions about your pen or about diabetes, ask your doctor, pharmacist or nurse or contact the local representative of the Marketing Authorization Holder mentioned on the front of this leaflet.

Extra items you will need:

- a new sterile needle (see STEP 2).
- a puncture resistant container for used needles and pens (see **Throwing your pen away**).

Get to know your pen



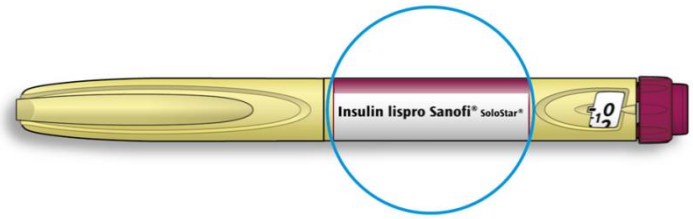
* You will not see the plunger until you have injected a few doses.

STEP 1: Check your pen

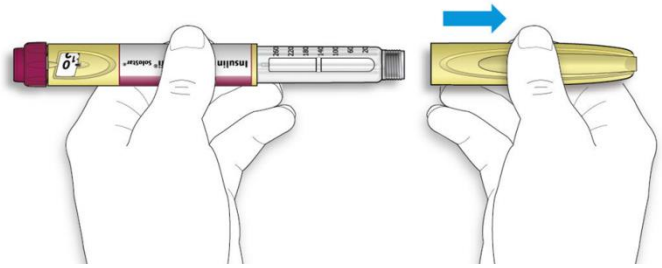
- Take a new pen out of the fridge at least 1 hour before you inject. Cold insulin is more painful to inject.

A Check the name and expiration date on the label of your pen.

- Make sure you have the correct insulin. This is especially important if you have other injector pens.
- Never use your pen after the expiration date.



B Pull off the pen cap.



C Check that the insulin is clear.

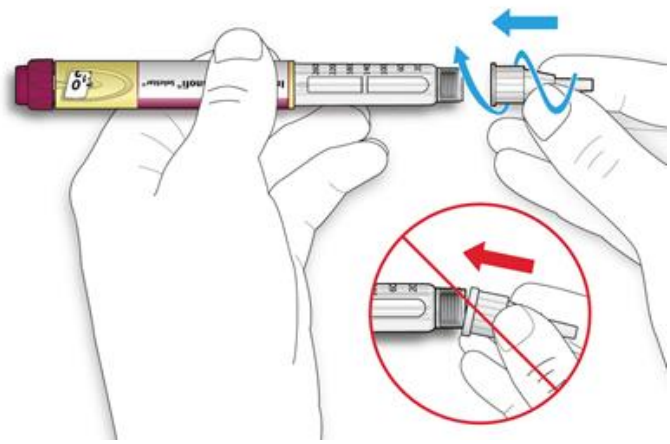
- Do not use the pen if the insulin looks cloudy, coloured or contains particles.

STEP 2: Attach a new needle

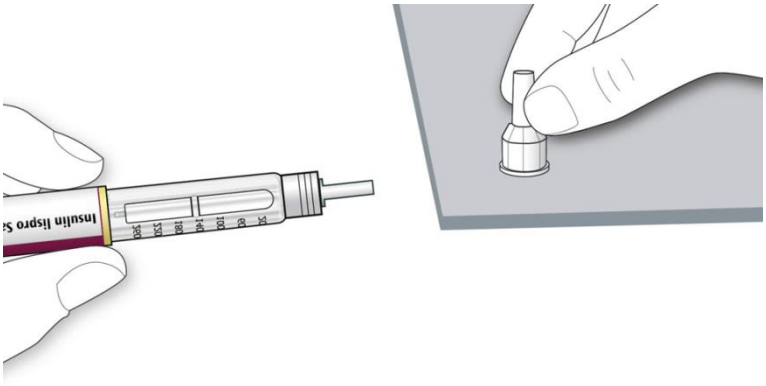
- Always use a new sterile needle for each injection. This helps stop blocked needles, contamination and infection.
- Only use needles that are compatible for use with Insulin lispro Sanofi.

A Take a new needle and peel off the protective seal.

B Keep the needle straight and screw it onto the pen until fixed. Do not overtighten.



C Pull off the outer needle cap. Keep this for later.



D Pull off the inner needle cap and throw away.

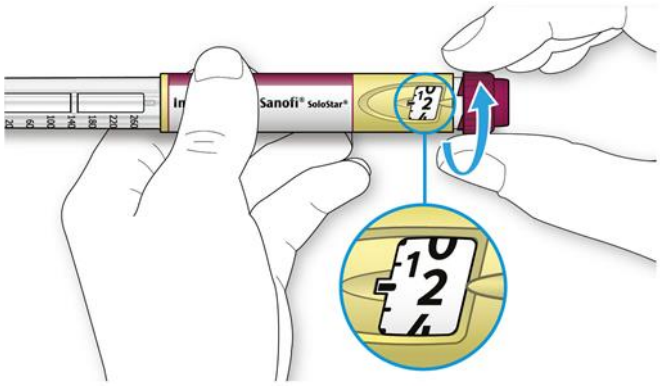
Handling needles

- Take care when handling needles – this is to prevent needle injury and cross-infection.

STEP 3: Do a safety test

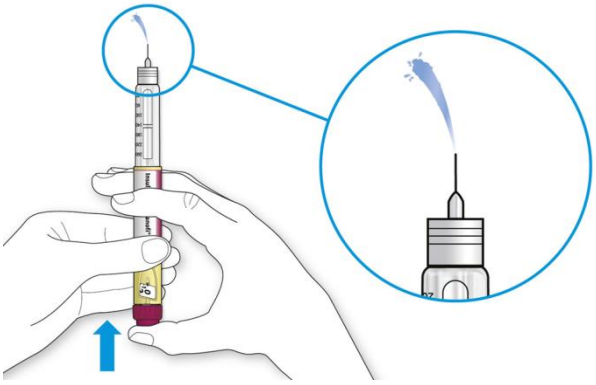
- Always do a safety test before each injection – this is to:
  - check your pen and the needle are working properly.
  - make sure that you get the correct insulin dose.

A Select 2 units by turning the dose selector until the dose pointer is at the 2 mark.



B Press the injection button all the way in.

- When insulin comes out of the needle tip, your pen is working correctly.



If no insulin appears:

- You may need to repeat this step up to 3 times before seeing insulin.
- If no insulin comes out after the third time, the needle may be blocked. If this happens:
  - change the needle (see STEP 6 and STEP 2),
  - then repeat the safety test (STEP 3).
- Do not use your pen if there is still no insulin coming out of the needle tip. Use a new pen.
- Never use a syringe to remove insulin from your pen.

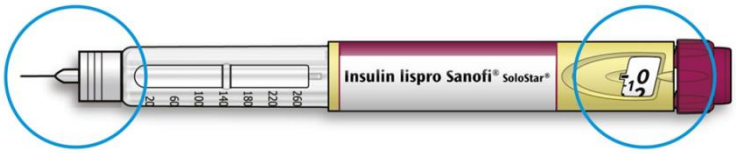
If you see air bubbles

- You may see air bubbles in the insulin. This is normal, they will not harm you.

STEP 4: Select the dose

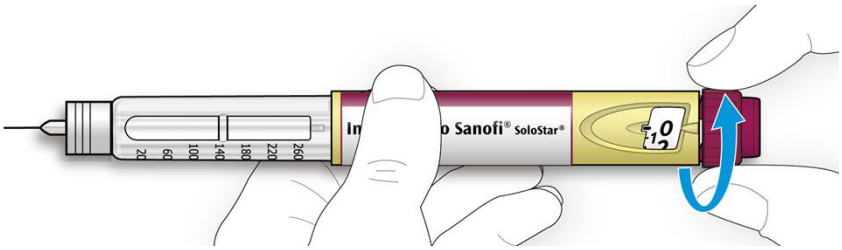
- Never select a dose or press the injection button without a needle attached. This may damage your pen.

A Make sure a needle is attached and the dose is set to '0'.



B Turn the dose selector until the dose pointer lines up with your dose.

- If you turn past your dose, you can turn back down.
- If there are not enough units left in your pen for your dose, the dose selector will stop at the number of units left.
- If you cannot select your full prescribed dose, use a new pen or inject the remaining units and use a new pen to complete your dose.



How to read the dose window

Even numbers are shown in line with the dose pointer:

20 units selected

Odd numbers are shown as a line between even numbers:

21 units selected

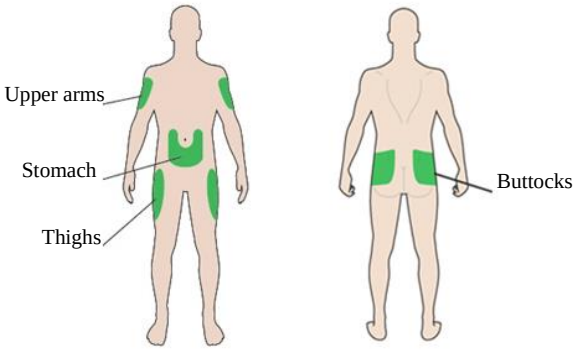
Units of insulin in your pen

- Your pen contains a total of 300 units of insulin. You can select doses from 1 to 80 units in steps of 1 unit. Each pen contains more than one dose.
- You can see roughly how many units of insulin are left by looking at where the plunger is on the insulin scale.

STEP 5: Inject your dose

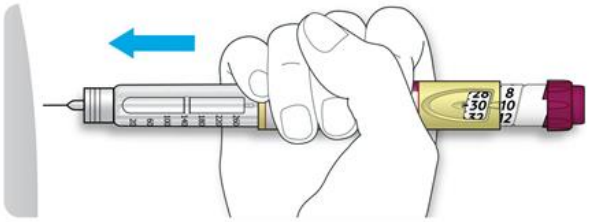
- If you find it hard to press the injection button in, do not force it as this may break your pen. See the section below for help.

A Choose a place to inject as shown in the picture



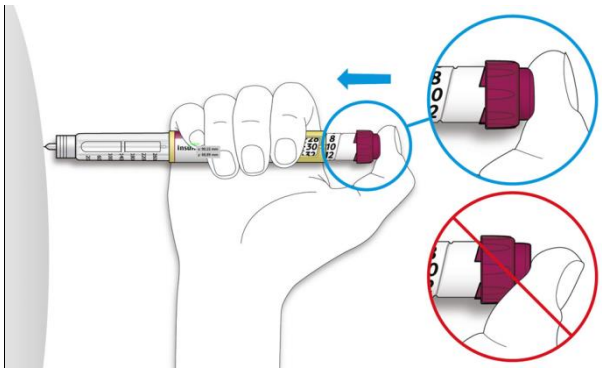
B Push the needle into your skin as shown by your doctor, pharmacist or nurse.

- Do not touch the injection button yet

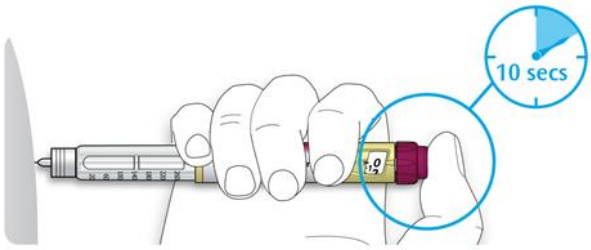


C Place your thumb on the injection button. Then press all the way in and hold.

- Do not press at an angle – your thumb could block the dose selector from turning.



D Keep the injection button held in and when you see "0" in the dose window, slowly count to 10.
This will make sure you get your full dose.



E After holding and slowly counting to 10, release the injection button. Then remove the needle from your skin.

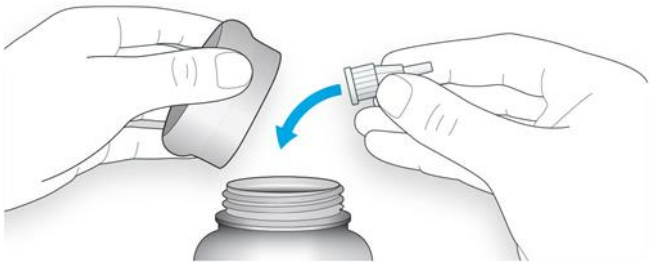
If you find it hard to press the button in:
- Change the needle (see STEP 6 and STEP 2) then do a safety test (see STEP 3).
- If you still find it hard to press in, get a new pen.
- Never use a syringe to remove insulin from your pen.

STEP 6: Remove the needle

- Take care when handling needles – this is to prevent needle injury and cross-infection.
- Never put the inner needle cap back on.

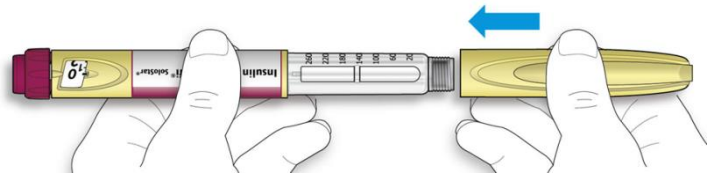
A Put the outer needle cap back on the needle, and use it to unscrew the needle from the pen.
- To reduce the risk of accidental needle injury, never replace the inner needle cap.
- If your injection is given by another person, or if you are giving an injection to another person, special caution must be taken by this person when removing and disposing of the needle.
- Follow recommended safety measures for removal and disposal of needles (contact your doctor, pharmacist or nurse) in order to reduce the risk of accidental needle injury and transmission of infectious diseases.

B Throw away the used needle in a puncture resistant container, or as told by your pharmacist or local authority.



C Put the pen cap back on.

- Do not put the pen back in the fridge.



How to care for your pen

Handle your pen with care

- Do not drop your pen or knock it against hard surfaces.
- If you think that your pen may be damaged, do not try to repair it, use a new one.

Protect your pen from dust and dirt

- You can clean the outside of your pen by wiping it with a damp cloth (water only). Do not soak, wash or lubricate your pen – this may damage it.

Throwing your pen away

- Remove the needle before throwing your pen away.
- Throw away your used pen as told by your pharmacist or local authority.

For further information on the storage and use of your pen, please refer to sections 2 and 5 of the package leaflet