LANTUS SOLOSTAR 100 U/mL

Solution for Injection for Subcutaneous Use · For subcutaneous administration · ATC: A10AE04

Prescription Medicine	Long-Acting Insulin Analog	Sterile	2 Years and Above

COMPOSITION

Active substance: Insulin glargine (Each mL contains 100 U insulin glargine – equivalent to 3.64 mg)

Excipients: Zinc chloride, m-cresol, glycerol, sodium hydroxide, hydrochloric acid, water for injection

Packaging: Ready-to-use prefilled pen (SoloStar)

> **Important information**
>
> Read these INSTRUCTIONS FOR USE carefully before you start using this medicine. It contains important information for you.

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What LANTUS SOLOSTAR is and what it is used for?

LANTUS is an injection solution containing insulin glargine. Insulin glargine is a modified insulin that is very similar to human insulin. It is produced using recombinant DNA technology. Insulin glargine has a long and constant blood glucose-lowering effect.

Indications

AREA OF USE

Diabetes Mellitus

Used to lower high blood sugar in adults, adolescents, and children over 2 years of age.

EFFECT PROPERTY

Long-Lasting Effect

Has a long-lasting and continuous blood sugar-lowering effect.

Diabetes mellitus is a disease in which your body cannot produce enough insulin to control blood sugar.

Things to consider before using LANTUS SOLOSTAR

Do NOT use LANTUS in the following cases

If you are allergic (hypersensitive) to insulin glargine or any of the excipients in the LANTUS formulation.

Use LANTUS with CAUTION in the following cases

Always follow your doctor's instructions regarding dosage, monitoring (blood and urine tests), diet, and physical activity (physical work and exercise), and injection technique. If your blood sugar is too low (hypoglycemia), follow the hypoglycemia instructions at the end of the text.

Hypokalemia (low serum potassium level): All insulins, including LANTUS, may cause a decrease in serum potassium levels. Untreated hypokalemia can cause respiratory paralysis, heart rhythm disorders, and death. If you are taking a medicine that may pose a risk of hypokalemia (potassium-lowering or potassium-sensitive medicines), your potassium levels will be monitored by your doctor if necessary.

Skin changes at the injection site

To prevent skin changes such as the formation of lumps under the skin, the designated injection sites should be rotated at each injection.

If you inject into an area where a lump has formed, the insulin may not work well.

If you are currently injecting into a lumpy area, contact your doctor before injecting into another area.

Travel

Talk to your doctor before you travel. You may need to discuss the following:

Availability of insulin in the country you will be traveling to

Availability of insulin injectors

Proper storage of insulin during travel

Timing of meals and insulin administration during travel

Possible effects related to time zone changes

Possible new health risks in the country you will be traveling to

What to do in emergency situations when you feel unwell or become ill

Illness and injury

In the following situations, your sugar regulation may require very careful attention (e.g., insulin dose adjustment, blood and urine tests):

If you are ill or have a major wound, your blood sugar may increase (hyperglycemia).

If you are not eating enough, your blood sugar may drop too low (hypoglycemia).

In such situations, you will most often need to see a doctor. **Contact a doctor immediately.**

If you have Type 1 diabetes mellitus (insulin-dependent diabetes mellitus), do not stop using insulin and continue to take

enough carbohydrates. Always tell whoever is caring for or treating you that you need insulin.

Insulin therapy may cause your body to produce antibodies (substances that act against insulin) against insulin.

Heart failure has been observed in some patients with long-standing Type 2 diabetes and heart disease or those who have had a previous stroke, treated with pioglitazone and insulin. If you develop symptoms of heart failure such as unusual shortness of breath or rapid weight gain or swelling (edema) in any part of the body, inform your doctor as soon as possible.

To ensure traceability of biotech products, the trade name and batch number of the administered product must be recorded in the patient's file.

If any of these warnings apply to you even in the past, please consult your doctor.

Using LANTUS with food and drinks

If you drink alcohol, your blood sugar level may rise or fall.

Pregnancy

Inform your doctor if you are pregnant or planning to become pregnant. Your insulin dose may need to be adjusted during pregnancy and after childbirth. Careful control of your diabetes and prevention of low blood sugar is important for your baby's health. *If you realize you are pregnant during your treatment, consult your doctor or pharmacist immediately.*

Breastfeeding

If you are breastfeeding, consult your doctor as your insulin dose or diet may need to be adjusted.

Driving and operating machinery

Your ability to concentrate and react may be impaired in the following situations: hypoglycemia (low blood sugar level), hyperglycemia (high blood sugar level), vision problems. Consider this potential problem in all situations that may put you and others at risk (such as driving and operating machinery). Contact your doctor for advice on driving in the following situations: if you have frequent hypoglycemic episodes, if the early warning signs of hypoglycemia are reduced or absent.

Important information about some excipients in LANTUS

This medicinal product contains less than 1 mmol (23 mg) sodium per mL. No effects due to sodium are expected.

Use with other medicines

Some medicines may cause blood sugar to drop, some may cause it to rise, and some may cause either effect depending on the situation. In each case, your insulin dose may need to be adjusted to protect you from blood sugar levels that are too high or too low. Be careful not only when starting a new medicine but also when stopping a medicine.

These medicines may cause your blood sugar to drop (hypoglycemia):

Other medicines used in the treatment of diabetes

Angiotensin-converting enzyme (ACE) inhibitors

Disopyramide

Fluoxetine and monoamine oxidase (MAO) inhibitors

Fibrates

Pentoxifylline

Pentoxifylline, propoxyphene, and salicylates (e.g., aspirin)

Sulfonamide antibiotics (such as sulfamethoxazole, sulfacetamide)

These medicines may cause your blood sugar to rise (hyperglycemia):

- Corticosteroids (cortisone)
- Danazol
- Diazoxide
- Diuretics (water pills)
- Glucagon
- Isoniazid
- Estrogens and progestogens (e.g., birth control pills)
- Phenothiazine derivatives
- Growth hormone somatropin
- Medicines that stimulate the sympathetic nervous system (e.g., salbutamol, terbutaline, epinephrine)
- Thyroid hormones
- Medicines used in the treatment of psychosis (e.g., olanzapine and clozapine)
- Protease inhibitors

When taking these medicines, your blood sugar may drop or rise:

- Beta blockers (e.g., nebivolol, carvedilol)
- Clonidine
- Lithium salts

Pentamidine, used in the treatment of some infections caused by parasites, may cause hypoglycemia and sometimes may be followed by hyperglycemia.

Beta blocker medicines, like other medicines that stimulate the sympathetic nervous system (e.g., clonidine, guanethidine, and reserpine), may also cause the early warning signs of low blood sugar to weaken or disappear completely.

If you are currently using or have recently used any prescription or non-prescription medicine, please inform your doctor or pharmacist about this.

How to use LANTUS SOLOSTAR?

Instructions for correct use and dose/frequency of administration

Always use this medicine exactly as your doctor has recommended. If you are not sure how to use it, consult your doctor or pharmacist.

Based on your lifestyle, blood glucose (sugar) test results, and your previous insulin dose, your doctor will:

- Tell you how much LANTUS you need each day and when
- Tell you when to check your blood sugar level and whether you need to do urine tests
- Tell you when you need a higher or lower dose of LANTUS

.

LANTUS is a long-acting insulin. Your doctor may tell you to use it together with a short-acting insulin or a tablet for high blood sugar.

You need one injection of LANTUS every day at the same time each day.

Many factors can affect your blood sugar level. You need to know what these factors are so that you can react correctly to changes in your blood sugar level and prevent it from rising or falling too much.

Method and route of administration

LANTUS is administered by injection under the skin. **Do not inject into a vein** as this will change the effect of this medicine and may cause hypoglycemia.

Your doctor will show you the skin area where LANTUS should be injected. Change the skin area you use for each injection.

When switching from other insulins to LANTUS, the dose of diabetes medicines being used may need to be adjusted. Close monitoring is recommended during the switch from other insulins to LANTUS and during the first weeks following the switch.

Mixing insulins

Always check the insulin label before each injection to prevent mixing errors between LANTUS and other insulins.

> #### Using the pen
>
> Carefully read the "How to Use SoloStar" section at the end of these instructions. Use the pen as described in How to Use SoloStar.

Different age groups

Use in children

LANTUS can be used in adolescents and children 2 years of age and older.

Use in the elderly

Your doctor will apply the appropriate treatment for you by evaluating your kidney function.

Special use conditions

Kidney impairment

Your doctor will adjust the appropriate dose for you based on the severity of your kidney disease.

Liver impairment

Your doctor will adjust the appropriate dose for you based on the severity of your liver disease.

> #### If you have used more LANTUS than you should
>
> If you have injected more LANTUS than you should, your blood sugar level may drop too low (hypoglycemia). In such a case, check your blood sugar frequently. In general, to prevent hypoglycemia, you should eat more and check your blood sugar. *If you have used more LANTUS than you should, talk to a doctor or pharmacist.*

> #### If you forget to use LANTUS
>
> **Do not take a double dose to make up for forgotten doses.** If you missed your LANTUS dose or injected too low a dose, your blood sugar level will rise too high (hyperglycemia). In such a case, check your blood sugar frequently.

Effects that may occur when LANTUS treatment is stopped

Stopping treatment will lead to severe hyperglycemia (high blood sugar) and ketoacidosis (a buildup of acid in the blood because the body is using fat instead of sugar). Do not stop using LANTUS without talking to your doctor who will tell you what needs to be done.

What are the possible side effects?

If any of the following occurs, stop using LANTUS and tell your doctor IMMEDIATELY or go to the emergency department of your nearest hospital:

Low blood sugar level (hypoglycemia) can be very serious. If your blood sugar drops too much, you may lose consciousness. Severe hypoglycemia can cause brain damage and may be life-threatening. If you have symptoms of hypoglycemia, you must act immediately to raise your blood sugar.

Severe allergic reactions to insulins: Widespread skin reactions (rash and itching all over the body), severe swelling of the skin or mucous membranes (angioedema), difficulty breathing, heart palpitations with drop in blood pressure and sweating. These may be symptoms of severe allergic reactions that can develop against insulins and may become life-threatening.

Skin changes at the injection site

If you inject insulin into the same skin area too often, fat tissue under the skin may become trapped and shrink (lipodystrophy) (may affect up to 1 in 100 people), or may thicken (lipohypertrophy) (may affect up to 1 in 10 people). Lumps can also form under the skin due to the buildup of a protein called amyloid (cutaneous amyloidosis, frequency unknown). If you inject into an area where these changes have occurred, the insulin may not work well. Changing the injection site with each injection may help prevent these skin changes.

Very common side effects (≥1/10)

Hypoglycemia

As with all insulins, hypoglycemia is the most common side effect. Low blood sugar (hypoglycemia) means there is not enough sugar in your blood. See the box at the end of this section for more information about hypoglycemia and its treatment.

Common side effects (≥1/100)

Skin changes at the injection site

If you inject into the same skin area frequently, the fat tissue under the skin in that area may shrink (lipodystrophy) or thicken (lipohypertrophy). Insulin injected into such an area may not work properly. Changing the injection site with each injection may help prevent these skin changes.

Skin and allergic reactions

Reactions may occur at the injection site in patients (e.g., redness, unusually intense pain during injection, itching, hives, swelling, or inflammation). They may also spread to the surrounding area of the injection site. Most minor reactions usually resolve within a few days to a few weeks.

Rare side effects (≥1/10000)

Serious allergic reactions to insulin

These reactions include widespread skin reactions (rash and itching all over the body), severe swelling of the skin or mucous membranes (angioedema), difficulty breathing, heart palpitations with drop in blood pressure, and sweating. These may be symptoms of severe allergic reactions that can develop against insulins and may become life-threatening.

Eye reactions

A significant change (improvement or worsening) in your blood sugar control may cause a temporary worsening of your vision. If you have progressive retinopathy (an eye disease related to diabetes), severe hypoglycemic attacks may cause temporary vision loss.

General disorders

Rarely, insulin therapy may also cause temporary fluid retention in your body, resulting in swelling in the joints and ankles.

Very rare side effects (<1/10000)

Taste disturbance (dysgeusia) and muscle pain (myalgia) may occur.

Frequency unknown

Cutaneous amyloidosis (lumps under the skin) may occur.

Pediatric population

In general, side effects observed in patients 18 years of age and under are similar to those in patients over 18 years of age.

In patients 18 years of age and under, injection site reactions and skin reactions are reported relatively more frequently than in adults.

No clinical study safety data are available for patients under 2 years of age.

If you experience any side effect not mentioned in these instructions for use, inform your doctor or pharmacist.

> **Reporting side effects**
>
> If you experience any side effects, whether or not listed in these instructions for use, talk to your doctor, pharmacist, or nurse. You can also report side effects to the Turkish Pharmacovigilance Center (TÜFAM) by clicking the "Drug Side Effect Reporting" icon on www.titck.gov.tr or by calling the side effect reporting line 0 800 314 00 08.

How to store LANTUS SOLOSTAR

Store LANTUS SOLOSTAR in its original packaging, out of the sight and reach of children.

Do not use LANTUS after the expiry date printed on the packaging.

Pens not in use

Store in the refrigerator at temperatures between 2-8°C.

Do not freeze.

Prevent SOLOSTAR from coming into direct contact with the freezer compartment or cooling packs in the refrigerator.

Store the ready-to-use prefilled pens in their carton to protect from light.

Pens in use

Ready-to-use prefilled injection pens in use or carried as spares can be stored for a maximum of 4 weeks below 30°C, away from direct light and heat.

Do not store the pen in use in the refrigerator.

Do not use after this period.

Expiry date

Use before the expiry date. Do not use LANTUS after the expiry date printed on the packaging.

Disposal

Do not throw away LANTUS SOLOSTAR in the city water or waste to protect the environment. Ask your pharmacist about this. Do not throw away expired or unused medicines in the waste! Give them to the collection system determined by the Ministry of Environment and Urbanization.

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Hyperglycemia and Hypoglycemia

Important

Always carry sugar (at least 20 grams) with you. Carry a card indicating you have diabetes.

HYPERGLYCEMIA (high blood sugar level)

If your blood sugar is too high (hyperglycemia), you may not have injected enough insulin.

Your blood sugar may be too high for the following reasons:

- You may not have injected your insulin or may not have injected enough, or its effect may have decreased due to improper storage.
- Your insulin pen may not be working properly.
- You may have been less physically active, may be under stress (emotional stress, excitement), or may have an injury, surgery, feverish illness, or some other illness.
- You may be taking or may have taken some other medicines.

Warning signs of hyperglycemia

Thirst, increased urination, tiredness, dry skin, flushing, loss of appetite, drop in blood pressure, palpitations, and increased sugar and ketone bodies in urine are signs that your blood sugar is too high.

Stomach pain, rapid and deep breathing, drowsiness, or even loss of consciousness may be signs of a serious condition (ketoacidosis) resulting from insulin deficiency.

What to do when hyperglycemia occurs?

Check your blood sugar and ketone bodies in urine immediately. Severe hyperglycemia or ketoacidosis should always be treated by a doctor and normally in a hospital.

HYPOGLYCEMIA (low blood sugar level)

If your blood sugar drops too much, you may lose consciousness. Severe hypoglycemia can cause a heart attack or brain damage; it can be life-threatening. You need to know when your blood sugar drops too low so that you can take the right action.

Your blood sugar may drop too low for the following reasons:

- You may have injected too much insulin.
- You may have missed or delayed a meal.
- You may not have eaten enough or may have eaten food with lower carbohydrates than normal (sugar and sugar-like substances are called carbohydrates; artificial sweeteners are NOT carbohydrates).
- You may have lost carbohydrates due to vomiting or diarrhea.
- You may have drunk alcohol without eating enough.
- Your physical activity may have been more than usual or a different type than usual.
- You may be recovering from injury, surgery, or stress.
- You may be recovering from a feverish illness or another illness.
- You may have taken or stopped taking some other medicines.

Low blood sugar may occur more frequently in the following situations:

- If you have just started insulin therapy or have switched to LANTUS from another insulin preparation (if hypoglycemia occurs when switching from previous basal insulin therapy to LANTUS, this is expected to occur more in the morning than at night).
- If your blood sugar level is almost normal or unstable (variable).
- If you have changed the area where you inject insulin (e.g., from thigh to upper arm).
- If you have other illnesses such as severe kidney or liver disease or hypothyroidism.

Warning signs of hypoglycemia

In your body: Sweating, clammy skin, anxiety, rapid heartbeat, elevated blood pressure, palpitations, and irregular heartbeat. These symptoms often develop before the signs of low blood sugar in the brain.

In your brain: Headache, intense hunger, nausea, vomiting, weakness, drowsiness, sleep disturbances, restlessness, aggressive behavior, lack of concentration, unresponsiveness, depression, mental confusion, speech disorder (sometimes loss of speech), visual disturbances, tremor, paralysis, sensory disturbances (paresthesia), numbness, and sensory disturbances in the mouth area, dizziness, loss of control, inability to care for yourself, seizures, and loss of consciousness.

The early warning signs ("warning signs") of hypoglycemia may change, be milder, or both in the following situations:

- If you are elderly, have had diabetes for a long time, or have a specific nervous system disease related to diabetes (autonomic neuropathy)
- If you have had hypoglycemia recently (e.g., the day before) or if it developed slowly
- If your blood sugar level is almost normal or close to normal
- If you have recently switched from animal insulin to human insulin such as LANTUS
- If you are taking or have taken other medicines

In such cases, hypoglycemia (even loss of consciousness) may develop before you realize there is a problem. Be careful about the warning signs. More frequent blood sugar testing, if needed, helps recognize mild hypoglycemic episodes that might otherwise be missed. If you are not confident about recognizing warning signs, avoid situations that may put you and

others at risk from hypoglycemia (such as driving).

What to do when hypoglycemia occurs?

1. **Do not inject insulin.** Immediately take 10-20 grams of sugar in the form of glucose, lump sugar, or sugary drink. (Measure how much sugar a tablespoon or glucose tablets contain.) *Note: Remember that artificial sweeteners and foods sweetened with them (e.g., diet drinks) do not correct hypoglycemia.*
2. After that, take foods that will raise your blood sugar over a longer period (e.g., bread or pasta). Your doctor will have discussed this with you. Since LANTUS is a long-acting medicine, it may take time for hypoglycemia to resolve.
3. If hypoglycemia recurs, take another 10-20 grams of sugar.
4. If you cannot control hypoglycemia or if it recurs, talk to your doctor immediately.

> **Tell your relatives, friends, and colleagues the following**
>
> If you are unable to swallow sugar or are unconscious, you will need an injection of glucose or glucagon (a medicine that raises blood sugar). These injections should be given even if hypoglycemia has not been confirmed. It is recommended to check blood sugar immediately after taking sugar to confirm hypoglycemia.

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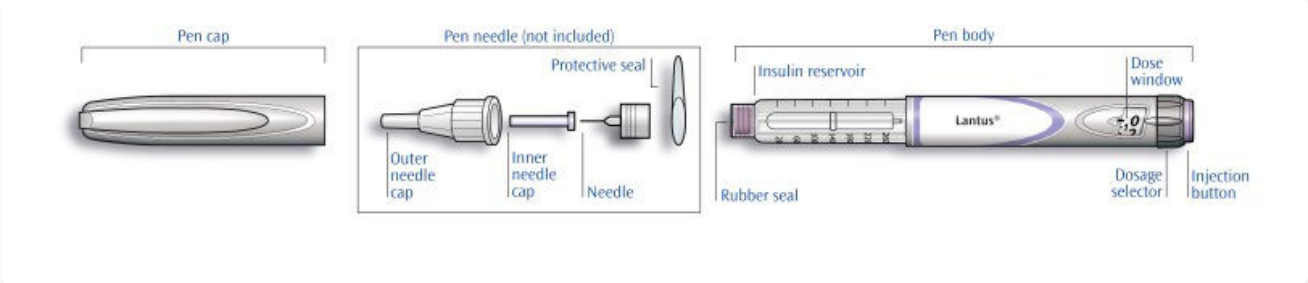
How to Use the SoloStar Pen

SoloStar is a ready-to-use prefilled pen for insulin injection. Your doctor has decided that SoloStar is suitable for you based on your ability to use it. Before using SoloStar, talk to your doctor, pharmacist, or nurse about proper injection technique.

Before using the SoloStar injection pen, read the following instructions carefully. If you cannot follow all instructions, use SoloStar with the help of someone who can follow them. Hold the pen as described in these instructions. To read the dose correctly, hold the pen horizontally with the needle on the left side and the dose selector on the right side, as shown below.

You can select a dose between 1 and 80 units in increments of 1 unit. Each pen contains more than one dose.

Keep these instructions for future reference. If you have any questions about SoloStar or diabetes, ask your doctor.



SoloStar Injection Pen Schematic Drawing
(Pen body, Pen cap, Insulin reservoir, Dose window, Dose selector, Injection button, Needle)

Important information for using SoloStar

- Attach a new needle before each use. Use only needles compatible with the SoloStar injection pen.
- Do not select a dose and/or press the injection button before attaching the needle.
- Always perform the safety test before each injection.

- Make sure that alcohol or other disinfectants or other substances do not mix with the insulin.
- This pen is for your use only. Do not share it with anyone else.
- If someone else is giving you the injection, this person should take necessary precautions to avoid needle-stick injuries and transmission of infection.
- Do not use the pen if it is damaged or if you are not sure it is working properly.
- Do not refill empty pens and dispose of them properly.
- Always keep a separate spare SoloStar pen in case your SoloStar injection pen is lost or damaged.
- If you notice that your blood sugar level is unexpectedly worsening, always use a new pen.

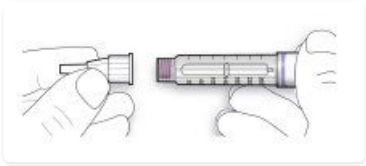
Step 1: Check the insulin

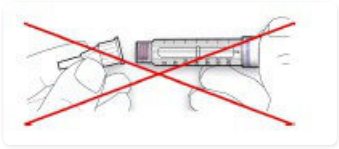
1. **A.** Check the label on SoloStar to make sure it is the correct insulin. LANTUS SoloStar is grey-colored and has a purple injection button.
2. **B.** Remove the pen cap.
3. **C.** Check the appearance of the insulin. LANTUS is a clear insulin. Do not use the insulin if it is cloudy, colored, or contains particles. You do not need to shake or mix it before use.

Step 2: Attach the needle

Always use a new sterile needle for each injection. This helps prevent contamination and potential needle blockage.

1. **A.** Remove the protective seal from the new needle.
2. **B.** Keep the needle and pen aligned and attach the needle to the pen (attach by turning or pushing depending on the needle type).





> **Caution**
>
> If the needle is not attached correctly, the rubber disc may be damaged causing leakage, or the needle may break.

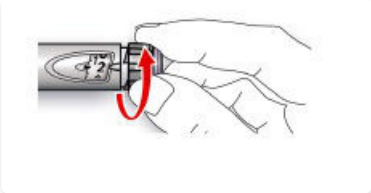
Step 3: Perform the safety test

Always perform the safety test before each injection. This ensures:

- That the pen and needle are working correctly.
- That air bubbles are removed.

This guarantees that you receive the correct dose.

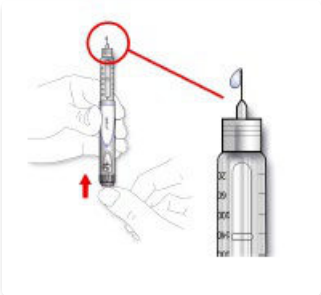
1. **A.** Select 2 units by turning the dose selector.



2. **B.** Remove the outer needle cap and set it aside; you will use this cap to remove the used needle after injection. Remove and discard the inner needle cap.



3. **C.** Hold the pen with the needle pointing upward.
4. **D.** Tap the insulin reservoir to make air bubbles collect toward the needle.
5. **E.** Press the injection button all the way in. Check that insulin comes out of the needle tip.

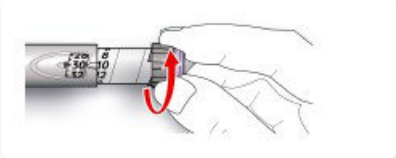


- You may need to perform the safety test several more times until insulin appears at the needle tip.
- If no insulin comes out of the needle tip, check for air bubbles and repeat the safety test twice to remove air bubbles.
- If still no insulin comes out, the needle tip may be blocked. In this case, change the needle and try the same steps again.
- If insulin still does not come out after changing the needle, SoloStar may be faulty. Do not use this SoloStar injection pen.

Step 4: Select the dose

Dose adjustment can be done in increments of 1 unit. A minimum of 1 unit and a maximum of 80 units can be selected. If you need a dose higher than 80 units, you can administer it in two or more injections.

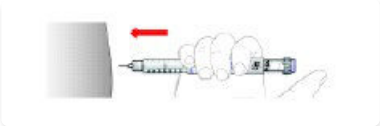
1. **A.** After performing the safety test, check that the dose window shows "0".
2. **B.** Select the dose recommended by your doctor. If you pass your intended units while adjusting your dose, you can turn back.



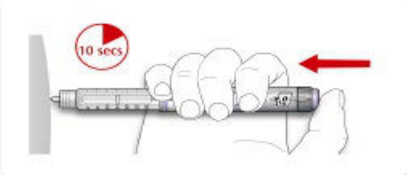
- Do not press the injection button while turning, otherwise insulin will come out of the needle tip.
- You cannot set the dose selector to a number higher than the units remaining in the pen. Do not force the dose selector to turn. In this case, you can inject the remaining amount in the pen and complete the remaining amount using a new SoloStar injection pen, or you can take your entire dose using a new SoloStar injection pen.

Step 5: Inject the insulin dose

1. **A.** Use the injection technique recommended by your doctor or nurse.
2. **B.** Pierce the needle into your skin.



3. **C.** Inject the dose by pressing the injection button all the way in. The number in the dose window will return to "0" when the injection is complete.



4. **D.** Keep the injection button pressed. Count slowly to **10** before removing the needle from the injection site. This ensures that the full dose has been delivered under the skin.

The pen's piston will advance with each dose. The piston will reach the end of the cartridge after a total of 300 units of insulin have been used.

Step 6: Remove and dispose of the needle

Always remove the needle after each injection and store the SoloStar injection pen without the needle. This way:

- You prevent contamination and/or infection,
- You prevent air from entering the insulin reservoir and insulin leakage. These can lead to incorrect dosing.

1. **A.** Remove the needle by reattaching the outer needle cap to the needle and then unscrewing the needle from the pen. Never reattach the inner needle cap to reduce the risk of accidental needle-stick injury.
   If someone else is giving you the injection, this person should also take special precautions during needle removal and disposal. Follow the recommended safety precautions for needle removal and disposal to reduce the risk of needle-stick accidents and disease transmission.
2. **B.** Dispose of needles safely as instructed by healthcare personnel.
3. **C.** Always put the pen cap back on the pen and store it this way until your next injection.

Storage

See the "5. How to store LANTUS SOLOSTAR" section in the Instructions for Use.

If you store SoloStar in a cool place, take your pen out of the cool place 1-2 hours before the injection so that it reaches normal room temperature. Cold insulin is more painful when injected.

Never use empty pens and dispose of them properly.

Care

Protect your SoloStar injection pen from dirt and dust. You can clean the outside of your pen with a damp cloth.

Do not soak, wash, or lubricate your pen. These actions may damage the pen.

Your SoloStar injection pen is designed to work accurately and safely. Handle with care; avoid situations where your pen may be damaged. If you suspect your pen is damaged, use a new SoloStar injection pen.

Marketing Authorization Holder:

Sanofi Health Products Ltd. Co.

Şişli-Istanbul

Manufacturing Site:

Sanofi Aventis Pharma Deutschland GmbH

D-65926 Frankfurt am Main, Germany

These instructions for use were approved on 27.05.2022.