

## Patient Information

**LANTUS® SOLOSTAR® 3 mL disposable insulin delivery device (300 units per device)**

**100 units per mL (U-100)**

**(insulin glargine [recombinant DNA origin] injection)**

- What is the most important information I should know about LANTUS?
- What is LANTUS?
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- How should I use LANTUS?
- Mixing with LANTUS
- Instructions for Use
- What can affect how much insulin I need?
- What are the possible side effects of LANTUS and other insulins?
- How should I store LANTUS?
- General Information about LANTUS

Read this “Patient Information” that comes with LANTUS (LAN-tus) before you start using it and each time you get a refill because there may be new information. This leaflet does not take the place of talking with your healthcare provider about your condition or treatment. If you have questions about LANTUS or about diabetes, talk with your healthcare provider.

### **What is the most important information I should know about LANTUS?**

- **Do not change the insulin you are using without talking to your healthcare provider.** Any change of insulin should be made cautiously and only under medical supervision. Changes in insulin strength, manufacturer, type (for example: Regular, NPH, analogs), species (beef, pork, beef-pork, human) or method of manufacture (recombinant DNA versus animal-source insulin) may need a change in the dose. This dose change may be needed right away or later on during the first several weeks or months on the new insulin. Doses of oral anti-diabetic medicines may also need to change, if your insulin is changed.
- **You must test your blood sugar levels while using an insulin, such as LANTUS.** Your healthcare provider will tell you how often you should test your blood sugar level, and what to do if it is high or low.
- **Do NOT dilute or mix LANTUS with any other insulin or solution.** It will not work and you may lose blood sugar control, which could be serious.
- **LANTUS** comes as U-100 insulin and contains 100 units of LANTUS per milliliter (mL). One milliliter of U-100 insulin contains 100 units of insulin. (1 mL = 1 cc).

### **What is Diabetes?**

- Your body needs insulin to turn sugar (glucose) into energy. If your body does not make enough insulin, you need to take more insulin so you will not have too much sugar in your blood.

- Insulin injections are important in keeping your diabetes under control. But the way you live, your diet, careful checking of your blood sugar levels, exercise, and planned physical activity, all work with your insulin to help you control your diabetes.

### **What is LANTUS?**

- LANTUS (insulin glargine [recombinant DNA origin]) is a long-acting insulin. . Because Lantus is made by recombinant DNA technology (rDNA) and is chemically different from the insulin made by the human body, it is called an insulin analog. LANTUS is used to treat patients with diabetes for the control of high blood sugar. It is used once a day to lower blood glucose.
- LANTUS is a clear, colorless, sterile solution for injection under the skin (subcutaneously).
- The active ingredient in LANTUS is insulin glargine. The concentration of insulin glargine is 100 units per milliliter (mL), or U-100. LANTUS also contains zinc, metacresol, glycerol, and water for injection as inactive ingredients. Hydrochloric acid and/or sodium hydroxide may be added to adjust the pH.
- You need a prescription to get LANTUS. Always be sure you receive the right insulin from the pharmacy.

### **Who should NOT take LANTUS?**

**Do not take LANTUS if you are allergic to insulin glargine** or any of the inactive ingredients in LANTUS. Check with your healthcare provider if you are not sure.

- **Before starting LANTUS, tell your healthcare provider about all your medical conditions including if you:**
  - **have liver or kidney problems.** Your dose may need to be adjusted.
  - **are pregnant or plan to become pregnant.** It is not known if LANTUS may harm your unborn baby. It is very important to maintain control of your blood sugar levels during pregnancy. Your healthcare provider will decide which insulin is best for you during your pregnancy.
  - **are breast-feeding or plan to breast-feed.** It is not known whether LANTUS passes into your milk. Many medicines, including insulin, pass into human milk, and could affect your baby. Talk to your healthcare provider about the best way to feed your baby.
  - **are taking any other medicines including** prescription and non-prescription medicines, vitamins and herbal supplements.

### **How should I use LANTUS?**

See the "**Instructions for SoloStar<sup>®</sup> Use**" section for additional information.

- Follow the instructions given by your healthcare provider about the type or types of insulin you are using. Do not make any changes with your insulin unless you have talked to your healthcare provider. Your insulin needs may change because of illness, stress,

other medicines, or changes in diet or activity level. Talk to your healthcare provider about how to adjust your insulin dose.

- You may take LANTUS at any time during the day but you must take it at the same time every day.
- Only use LANTUS that is clear and colorless. If your LANTUS is cloudy or slightly colored, return it to your pharmacy for a replacement.
- Follow your healthcare provider's instructions for testing your blood sugar.
- Inject LANTUS under your skin (subcutaneously) in your upper arm, abdomen (stomach area), or thigh (upper leg). Never inject it into a vein or muscle.
- Change (rotate) injection sites within the same body area.
- **NEEDLES AND SOLOSTAR® MUST NOT BE SHARED.**
- Disposable needles should be used only once. Used needle should be placed in sharps containers (such as red biohazard containers), hard plastic containers (such as detergent bottles), or metal containers (such as an empty coffee can). Such containers should be sealed and disposed of properly.

### **Mixing with LANTUS**

- **Do NOT dilute or mix LANTUS with any other insulin or solution.** It will not work as intended and you may lose blood sugar control, which could be serious.

### **Instructions for SoloStar® Use**

**It is important to read, understand, and follow the step-by-step instructions in the “SoloStar® Instruction Leaflet” before using SoloStar® disposable insulin Pen. Failure to follow the instructions may result in getting too much or too little insulin.** If you have lost your leaflet or have a question, go to [www.lantus.com](http://www.lantus.com) or call 1-800-633-1610.

The following general notes should be taken into consideration before injecting Lantus:

- Always wash your hands before handling the SoloStar® disposable insulin Pen.
- Always attach a new needle before use. BD Ultra-Fine™ needles† are compatible with SoloStar. These are sold separately and are manufactured by BD.
- Always perform the safety test before use.
- Check the insulin solution in the pen to make sure it is clear, colorless, and free of particles. If it is not, throw it away.
- Do NOT mix or dilute LANTUS with any other insulin or solution. LANTUS will not work if it is mixed or diluted and you may lose blood sugar control, which could be serious.
- Decide on an injection area - either upper arm, thigh, or abdomen. Do not use the same injection site as your last injection.
- After injecting LANTUS, leave the needle in the skin for an additional 10 seconds. Then pull the needle straight out. Gently press on the spot where you injected yourself for a few seconds. **Do not rub the area.**
- Do not drop the SoloStar® disposable insulin Pen.

If your blood glucose reading is high or low, tell your healthcare provider so the dose can be adjusted.

### **What can affect how much insulin I need?**

**Illness.** Illness may change how much insulin you need. It is a good idea to think ahead and make a "sick day" plan with your healthcare provider in advance so you will be ready when this happens. Be sure to test your blood sugar more often and call your healthcare provider if you are sick.

**Medicines. Many medicines can affect your insulin needs.** Other medicines, including prescription and non-prescription medicines, vitamins, and herbal supplements, can change the way insulin works. You may need a different dose of insulin when you are taking certain other medicines. **Know all the medicines you take**, including prescription and non-prescription medicines, vitamins and herbal supplements. You may want to keep a list of the medicines you take. You can show this list to your healthcare provider and pharmacists anytime you get a new medicine or refill. Your healthcare provider will tell you if your insulin dose needs to be changed.

**Meals.** The amount of food you eat can affect your insulin needs. If you eat less food, skip meals, or eat more food than usual, you may need a different dose of insulin. Talk to your healthcare provider if you change your diet so that you know how to adjust your LANTUS and other insulin doses.

**Alcohol.** Alcohol, including beer and wine, may affect the way LANTUS works and affect your blood sugar levels. Talk to your healthcare provider about drinking alcohol.

**Exercise or Activity level.** Exercise or activity level may change the way your body uses insulin. Check with your healthcare provider before you start an exercise program because your dose may need to be changed.

**Travel.** If you travel across time zones, talk with your healthcare provider about how to time your injections. When you travel, wear your medical alert identification. Take extra insulin and supplies with you.

**Pregnancy or nursing.** The effects of LANTUS on an unborn child or on a nursing baby are unknown. Therefore, tell your healthcare provider if you planning to have a baby, are pregnant, or nursing a baby. Good control of diabetes is especially important during pregnancy and nursing.

### **What are the possible side effects of LANTUS and other insulins?**

Insulins, including LANTUS, can cause hypoglycemia (low blood sugar), hyperglycemia (high blood sugar), allergy, and skin reactions.

**Hypoglycemia (low blood sugar):**

Hypoglycemia is often called an "insulin reaction" or "low blood sugar". It may happen when you do not have enough sugar in your blood. Common causes of hypoglycemia are illness, emotional or physical stress, too much insulin, too little food or missed meals, and too much exercise or activity.

Early warning signs of hypoglycemia may be different, less noticeable or not noticeable at all in some people. That is why it is important to check your blood sugar as you have been advised by your healthcare provider.

**Hypoglycemia can happen with:**

- **Taking too much insulin.** This can happen when too much insulin is injected.
- **Not enough carbohydrate (sugar or starch) intake.** This can happen if a meal or snack is missed or delayed.
- **Vomiting or diarrhea** that decreases the amount of sugar absorbed by your body.
- **Intake of alcohol.**
- **Medicines that affect insulin.** Be sure to discuss all your medicines with your healthcare provider. **Do not start any new medicines until you know how they may affect your insulin dose.**
- **Medical conditions that can affect your blood sugar levels or insulin.** These conditions include diseases of the adrenal glands, the pituitary, the thyroid gland, the liver, and the kidney.
- **Too much glucose use by the body.** This can happen if you exercise too much or have a fever.
- **Injecting insulin the wrong way or in the wrong injection area.**

Hypoglycemia can be mild to severe. Its onset may be rapid. Some patients have few or no warning symptoms, including:

- patients with diabetes for a long time
- patients with diabetic neuropathy (nerve problems)
- or patients using certain medicines for high blood pressure or heart problems.

Hypoglycemia may reduce your ability to drive a car or use mechanical equipment and you may risk injury to yourself or others.

Severe hypoglycemia can be dangerous and can cause temporary or permanent harm to your heart or brain. **It may cause unconsciousness, seizures, or death.**

Symptoms of hypoglycemia may include:

- anxiety, irritability, restlessness, trouble concentrating, personality changes, mood changes, or other abnormal behavior
- tingling in your hands, feet, lips, or tongue

- dizziness, light-headedness, or drowsiness
- nightmares or trouble sleeping
- headache
- blurred vision
- slurred speech
- palpitations (fast heart beat)
- sweating
- tremor (shaking)
- unsteady gait (walking).

If you have hypoglycemia often or it is hard for you to know if you have the symptoms of hypoglycemia, talk to your healthcare provider.

Mild to moderate hypoglycemia is treated by eating or drinking carbohydrates such as fruit juice, raisins, sugar candies, milk or glucose tablets. Talk to your healthcare provider about the amount of carbohydrates you should eat to treat mild to moderate hypoglycemia.

Severe hypoglycemia may require the help of another person or emergency medical people. A person with hypoglycemia who is unable to take foods or liquids with sugar by mouth, or is unconscious needs medical help fast and will need treatment with a glucagon injection or glucose given intravenously (IV). Without medical help right away, serious reactions or even death could happen.

### **Hyperglycemia (high blood sugar):**

Hyperglycemia happens when you have too much sugar in your blood. Usually, it means there is not enough insulin to break down the food you eat into energy your body can use. Hyperglycemia can be caused by a fever, an infection, stress, eating more than you should, taking less insulin than prescribed, or it can mean your diabetes is getting worse.

### **Hyperglycemia can happen with:**

- **Insufficient (too little) insulin.** This can happen from:
  - injecting too little or no insulin
  - incorrect storage (freezing, excessive heat)
  - use after the expiration date.
- **Too much carbohydrate intake.** This can happen if you eat larger meals, eat more often, or increase the amount of carbohydrate in your meals.
- **Medicines that affect insulin.** Be sure to discuss all your medicines with your healthcare provider. **Do not start any new medicines until you know how they may affect your insulin dose.**
- **Medical conditions that affect insulin.** These medical conditions include fevers, infections, heart attacks, and stress.

- **Injecting insulin the wrong way or in the wrong injection area.**

Testing your blood or urine often will let you know if you have hyperglycemia. If your tests are often high, tell your healthcare provider so your dose of insulin can be changed.

Hyperglycemia can be mild or severe. It can **progress to diabetic ketoacidosis (DKA) or very high glucose levels (hyperosmolar coma) and result in unconsciousness and death.**

Although diabetic ketoacidosis occurs most often in patients with type 1 diabetes, it can also happen in patients with type 2 diabetes who become very sick. Because some patients get few symptoms of hyperglycemia, it is important to check your blood sugar/urine sugar and ketones regularly.

**Symptoms of hyperglycemia include:**

- confusion or drowsiness
- increased thirst
- decreased appetite, nausea, or vomiting
- rapid heart rate
- increased urination and dehydration (too little fluid in your body).

**Symptoms of DKA also include:**

- fruity smelling breath
- fast, deep breathing
- stomach area (abdominal) pain.

**Severe or continuing hyperglycemia or DKA needs evaluation and treatment right away by your healthcare provider.**

**Do not use LANTUS to treat diabetic ketoacidosis.**

Other possible side effects of LANTUS include:

**Serious allergic reactions:**

Some times severe, life-threatening allergic reactions can happen with insulin. If you think you are having a severe allergic reaction, get medical help right away. Signs of insulin allergy include:

- rash all over your body
- shortness of breath
- wheezing (trouble breathing)
- fast pulse
- sweating
- low blood pressure.

**Reactions at the injection site:**

Injecting insulin can cause the following reactions on the skin at the injection site:

- little depression in the skin (lipoatrophy)
- skin thickening (lipohypertrophy)
- red, swelling, itchy skin (injection site reaction).

You can reduce the chance of getting an injection site reaction if you change (rotate) the injection site each time. An injection site reaction should clear up in a few days or a few weeks. If injection site reactions do not go away or keep happening call your healthcare provider.

Tell your healthcare provider if you have any side effects that bother you.

These are not all the side effects of LANTUS. Ask your healthcare provider or pharmacist for more information.

**How should I store LANTUS?**

- **Unopened SoloStar®:**  
Store new unopened SoloStar® disposable insulin pen in a refrigerator (not the freezer) between 36°F to 46°F (2°C to 8°C). Do not freeze LANTUS. Keep LANTUS out of direct heat and light. If a disposable insulin pen has been frozen or overheated, throw it away.
- **Open (In-Use) SoloStar®:**  
Once SoloStar® is opened (in-use), SoloStar® should **NOT** be refrigerated but should be kept at room temperature (below 86°F [30°C]) away from direct heat and light. The opened (in-use) SoloStar® kept at room temperature must be discarded after 28 days.

These storage conditions are summarized in the following table:

	<b>Not in-use (unopened)</b>  <b>Refrigerated</b>	<b>Not in-use (unopened)</b>  <b>Room Temperature</b>	<b>In-use (opened)</b>  <b>Room Temperature (Do not refrigerate)</b>
3 mL SoloStar® disposable insulin device	Until expiration date	28 days	28 days

- Do not use SoloStar® with LANTUS after the expiration date stamped on the label.
- Do not use LANTUS if it is cloudy, colored, or if you see particles.

**General Information about LANTUS**

- Use LANTUS only to treat your diabetes. **Do not** give or share LANTUS with another person, even if they have diabetes also. It may harm them.
- This leaflet summarizes the most important information about LANTUS. If you would like more information, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about LANTUS that is written for healthcare professionals. For more information about LANTUS call 1-800-633-1610 or go to website [www.lantus.com](http://www.lantus.com).



## **ADDITIONAL INFORMATION**

**DIABETES FORECAST** is a national magazine designed especially for patients with diabetes and their families and is available by subscription from the American Diabetes Association (ADA), P.O. Box 363, Mt. Morris, IL 61054-0363, 1-800-DIABETES (1-800-342-2383). You may also visit the ADA website at [www.diabetes.org](http://www.diabetes.org).

Another publication, **COUNTDOWN**, is available from the Juvenile Diabetes Research Foundation International (JDRF), 120 Wall Street, 19th Floor, New York, New York 10005, 1-800-JDF-CURE (1-800-533-2873). You may also visit the JDRF website at [www.jdf.org](http://www.jdf.org).

To get more information about diabetes, check with your healthcare professional or diabetes educator or visit [www.DiabetesWatch.com](http://www.DiabetesWatch.com).

Additional information about LANTUS can be obtained by calling 1-800-633-1610 or by visiting [www.lantus.com](http://www.lantus.com).

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# LANTUS<sup>®</sup> SOLOSTAR<sup>®</sup>

(insulin glargine [rDNA origin] injection)

## Instruction Leaflet

Your healthcare professional has decided that SoloStar<sup>®</sup> is right for you. Talk with your healthcare professional about proper injection technique before using SoloStar<sup>®</sup>.

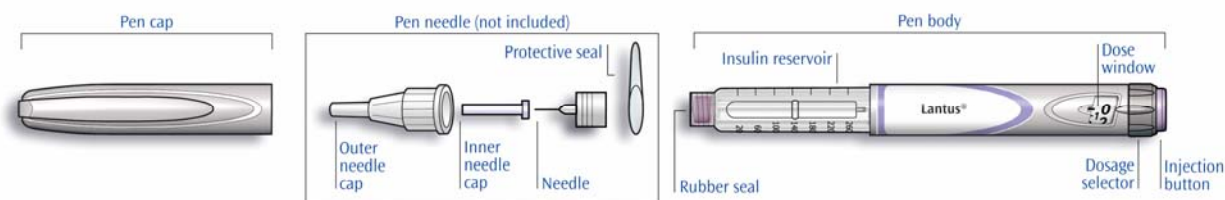
Read these instructions carefully before using your SoloStar<sup>®</sup>. If you are not able to follow all the instructions completely on your own, use SoloStar<sup>®</sup> only if you have help from a person who is able to follow the instructions.

**Follow these instructions completely each time you use SoloStar<sup>®</sup> to ensure that you get an accurate dose. If you do not follow these instructions you may get too much or too little insulin, which may affect your blood glucose.**

SoloStar<sup>®</sup> is a disposable pen for the injection of insulin. Each SoloStar<sup>®</sup> contains in total 300 units of insulin. You can set doses from 1 to 80 units in steps of 1 unit.

Keep this leaflet for future reference.

If you have any questions about SoloStar<sup>®</sup> or about diabetes, ask your healthcare professional, go to [www.lantus.com](http://www.lantus.com) or call sanofi aventis at 1-800-633-1610.



## **Important information for use of SoloStar<sup>®</sup>:**

- Always attach a new needle before each use.  
BD Ultra-Fine needles are compatible with SoloStar<sup>®</sup>. These are sold separately and are manufactured by BD. Contact your healthcare professional for further information.
- Always perform the safety test before each injection.
- This pen is only for your use. Do not share it with anyone else.
- If your injection is given by another person, special caution must be taken by this person to avoid accidental needle injury and transmission of infection.
- Never use SoloStar<sup>®</sup> if it is damaged or if you are not sure that it is working properly.
- Always have a spare SoloStar<sup>®</sup> in case your SoloStar<sup>®</sup> is lost or damaged.

## **Storage Instructions**

Please check the leaflet for the insulin for complete instructions on how to store SoloStar<sup>®</sup>.

If your SoloStar<sup>®</sup> is in cool storage, take it out 1 to 2 hours before you inject to allow it to warm up. Cold insulin is more painful to inject.

Keep SoloStar<sup>®</sup> out of the reach and sight of children.

Keep your SoloStar<sup>®</sup> in cool storage (36°F - 46°F [2°C – 8°C]) until first use. Do not allow it to freeze. Do not put it next to the freezer compartment of your refrigerator, or next to a freezer pack.

Once you take your SoloStar<sup>®</sup> out of cool storage, for use or as a spare, you can use it for up to 28 days. During this time it can be safely kept at room temperature up to 86°F (30°C). Do not use it after this time. SoloStar<sup>®</sup> in use must not be stored in a refrigerator.

Do not use SoloStar<sup>®</sup> after the expiration date printed on the label of the pen or on the carton.

Protect SoloStar<sup>®</sup> from light.

Discard your used SoloStar<sup>®</sup> as required by your local authorities.

## **Maintenance**

Protect your SoloStar<sup>®</sup> from dust and dirt.

You can clean the outside of your SoloStar<sup>®</sup> by wiping it with a damp cloth.

Do not soak, wash or lubricate the pen as this may damage it.

Your SoloStar<sup>®</sup> is designed to work accurately and safely. It should be handled with care. Avoid situations where SoloStar<sup>®</sup> might be damaged. If you are concerned that your SoloStar<sup>®</sup> may be damaged, use a new one.

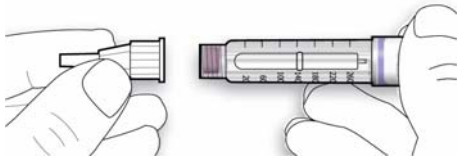
## **Step 1. Check the insulin**

- A. Check the label on your SoloStar<sup>®</sup> to make sure you have the correct insulin.. The Lantus<sup>®</sup> SoloStar<sup>®</sup> is grey with a purple injection button.
- B. Take off the pen cap.
- C. Check the appearance of your insulin. Lantus<sup>®</sup> is a clear insulin. Do not use this SoloStar<sup>®</sup> if the insulin is cloudy, colored or has particles.

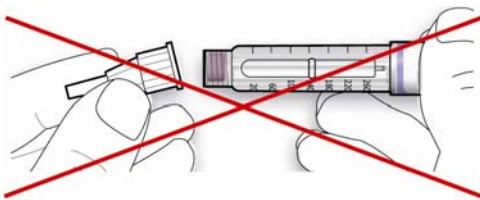
## Step 2. Attach the needle

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

- A. Wipe the Rubber Seal with alcohol.
- B. Remove the protective seal from a new needle.
- C. Line up the needle with the pen, and keep it straight as you attach it (screw or push on, depending on the needle type).



- If the needle is not kept straight while you attach it, it can damage the rubber seal and cause leakage, or break the needle.

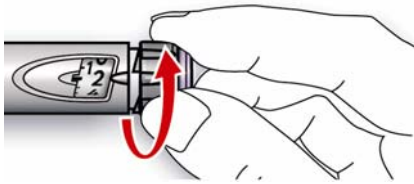


## Step 3. Perform a Safety test

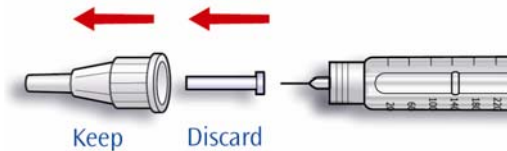
**Always perform the safety test before each injection.**

Performing the safety test ensures that you get an accurate dose by:

- ensuring that pen and needle work properly
  - removing air bubbles
- A. Select a dose of 2 units by turning the dosage selector.



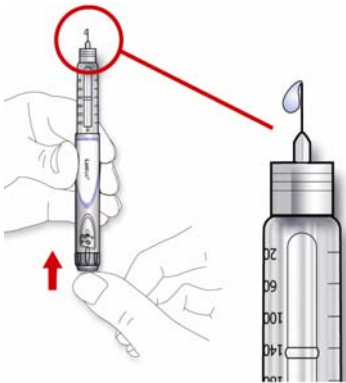
**B.** Take off the outer needle cap and keep it to remove the used needle after injection. Take off the inner needle cap and discard it.



**C.** Hold the pen with the needle pointing upwards.

**D.** Tap the insulin reservoir so that any air bubbles rise up towards the needle.

**E.** Press the injection button all the way in. Check if insulin comes out of the needle tip.



You may have to perform the safety test several times before insulin is seen.

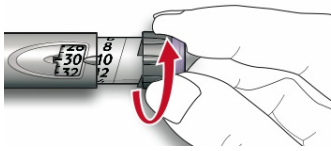
- If no insulin comes out, check for air bubbles and repeat the safety test two more times to remove them.
- If still no insulin comes out, the needle may be blocked. Change the needle and try again.
- If no insulin comes out after changing the needle, your SoloStar<sup>®</sup> may be damaged. Do not use this SoloStar<sup>®</sup>.

#### **Step 4. Select the dose**

You can set the dose in steps of 1 unit, from a minimum of 1 unit to a maximum of 80 units. If you need a dose greater than 80 units, you should give it as two or more injections.

**A.** Check that the dose window shows “0” following the safety test.

B. Select your required dose (in the example below, the selected dose is 30 units). If you turn past your dose, you can turn back down.

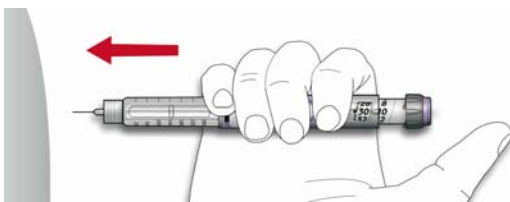


- Do not push the injection button while turning, as insulin will come out.
- You cannot turn the dosage selector past the number of units left in the pen. Do not force the dosage selector to turn. In this case, either you can inject what is remaining in the pen and complete your dose with a new SoloStar<sup>®</sup> or use a new SoloStar<sup>®</sup> for your full dose.

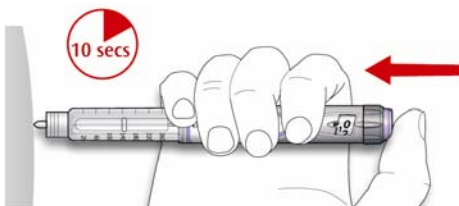
### Step 5. Inject the dose

A. Use the injection method as instructed by your healthcare professional.

B. Insert the needle into the skin.



C. Deliver the dose by pressing the injection button in all the way. The number in the dose window will return to “0” as you inject.



D. Keep the injection button pressed all the way in.

**Slowly count to 10 before you withdraw the needle from the skin.** This ensures that the full dose will be delivered.

### Step 6. Remove and discard the needle

Always remove the needle after each injection and store SoloStar without a needle attached. This helps prevent:

- Contamination and/or infection
- Entry of air into the insulin reservoir and leakage of insulin, which can cause inaccurate dosing.

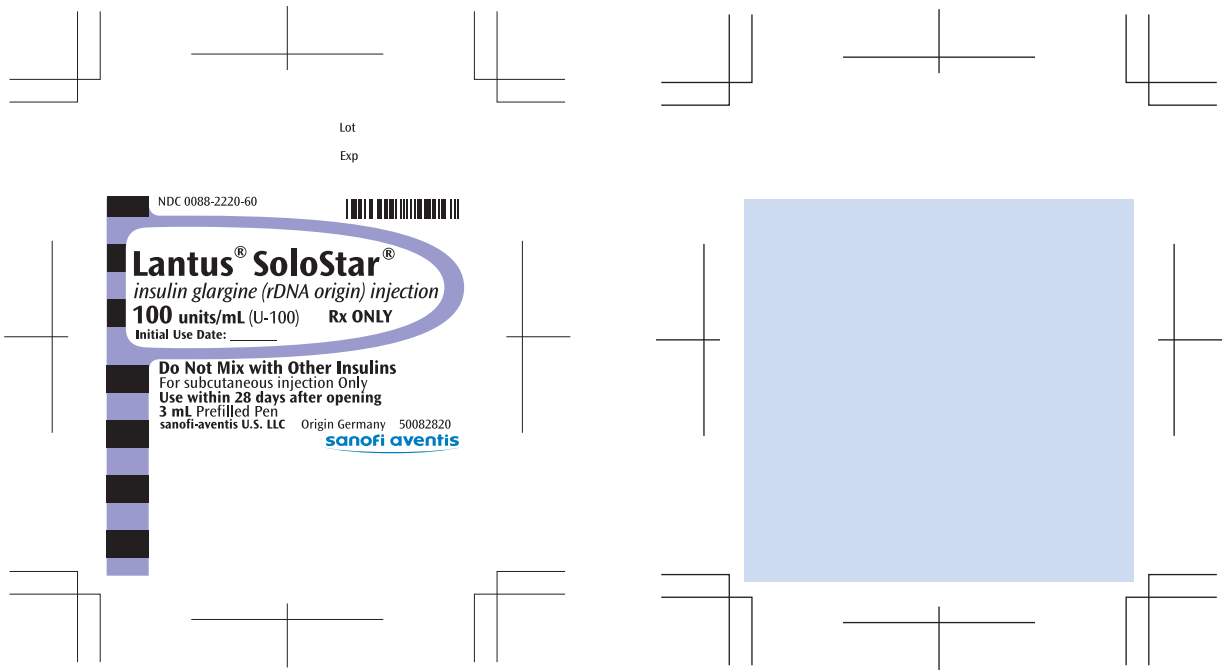
- A. Put the outer needle cap back on the needle, and use it to unscrew the needle from the pen. To reduce the risk of accidental needle injury, never replace the inner needle cap.
- If your injection is given by another person, special caution must be taken by this person when removing and disposing the needle. Follow recommended safety measures for removal and disposal of needles (e.g. a one handed capping technique) in order to reduce the risk of accidental needle injury and transmission of infectious diseases.
- B. Dispose of the needle safely. Used needles should be placed in sharps containers (such as red biohazard containers), hard plastic containers (such as detergent bottles), or metal containers (such as an empty coffee can). Such containers should be sealed and disposed of properly. If you are giving an injection to a third person, you should remove the needle in an approved manner to avoid needle-stick injuries.
- C. Always put the pen cap back on the pen, then store the pen until your next injection.

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Lot  
Exp

NDC 0088-2220-60



**Lantus<sup>®</sup> SoloStar<sup>®</sup>**  
*insulin glargine (rDNA origin) injection*  
**100 units/mL (U-100) Rx ONLY**  
Initial Use Date: \_\_\_\_\_

**Do Not Mix with Other Insulins**  
For subcutaneous injection Only  
**Use within 28 days after opening**  
3 mL Prefilled Pen  
sanofi-aventis U.S. LLC    Origin Germany    50082820  
**sanofi aventis**

