PATIENT MEDICATION INFORMATION - LANTUS® VIAL

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

LANTUS® Vial

Insulin glargine injection (rDNA origin)

Read this carefully before you start taking **LANTUS** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **LANTUS**.

Serious Warnings and Precautions

- Hypoglycemia is the most common adverse effect of insulin, including LANTUS.
- Glucose monitoring is recommended for all patients with diabetes.
- Uncorrected hypoglycemic or hyperglycemic reactions can cause loss of consciousness, coma, or death.
- Any change of insulin should be made cautiously and only under medical supervision.
- LANTUS is not intended for intravenous or intramuscular administration.
- **LANTUS must not be mixed with any other insulin or diluted with any other solution because it might not work as intended**.
- This insulin product shall not be used if it is not water-clear and colourless or if it has formed a deposit of solid particles on the wall of the vial or cartridge.

What is LANTUS used for?

LANTUS [insulin glargine injection (rDNA origin)] is a recombinant human insulin analogue that is a long-acting blood-glucose-lowering agent administered subcutaneously (under the skin) once a day. LANTUS is indicated in the treatment of patients over 17 years of age with Type 1 or Type 2 diabetes mellitus who require basal (long-acting) insulin for the control of hyperglycemia. LANTUS is also indicated in the treatment of pediatric patients (> 6 years old) with Type 1 diabetes mellitus who require basal (long-acting) insulin for the control of hyperglycemia.

How does LANTUS work?

Insulin is a hormone produced by the pancreas, a large gland that lies near the stomach. This hormone is necessary for your body to use food, especially sugar, correctly. Diabetes occurs either when your pancreas does not make enough insulin to meet your body's needs or when your body is unable to use the insulin you normally produce properly.

When your body does not make enough insulin, you need an external source of insulin – that is why you must take insulin injections. LANTUS is similar to the insulin made by your body.

Insulin injections, such as LANTUS, play a key role in keeping your diabetes under control. In addition to proper insulin therapy, it's important to maintain a healthy lifestyle – this includes eating a balanced diet, participating in regular exercise or other physical activities, carefully monitoring your glucose levels and following your health professional's recommendations. These simple actions will compliment your insulin therapy and will ultimately help you gain greater control of your diabetes.

You have been instructed to test your blood and/or your urine regularly for glucose; it is especially important to test even more often when changing insulins or dosing schedule. If your blood tests

consistently show above- or below- normal glucose levels, or your urine tests consistently show the presence of glucose, your diabetes is not properly controlled and you must let your health professional know.

Insulin injections play an important role in keeping your diabetes under control. But the way you live – your diet, careful monitoring of your glucose levels, exercise, or planned physical activity and following your health professional's recommendations– all work with your insulin to help you control your diabetes.

Always keep an extra supply of insulin as well as a spare syringe and needle on hand. Always wear medical alert identification and carry information about your diabetes so that appropriate treatment can be given if complications occur while you are away from home.

What are the ingredients in LANTUS?

Medicinal ingredients: Insulin glargine (rDNA origin).

Non-medicinal ingredients: glycerol 85%, m-cresol, polysorbate 20, water, zinc, and hydrochloric acid and sodium hydroxide for pH adjustment.

LANTUS comes in the following dosage forms:

Solution for injection: 100 U/mL

Do not use LANTUS:

- if you are allergic to this drug or to any ingredient in the formulation or component of the container;
- if you have diabetic ketoacidosis;
- for intravenous or intramuscular injections
- if your blood sugar is too low (hypoglycemia). After treating your low blood sugar, follow your health care provider's instructions on the use of Lantus.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take LANTUS. Talk about any health conditions or problems you may have, including if you:

- You are planning to have a baby, are pregnant, or are nursing a baby;
- You are taking any medication.

If you develop 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 take LANTUS). Contact your healthcare professional if you are currently injecting into a lumpy area before you start injecting in a different area. A sudden change of site may result in hypoglycemia. Your healthcare professional may tell you to check your blood sugar more closely, and to adjust your insulin or your other antidiabetic medications dose.

Accidental mix-ups between insulin glargine and other insulins, particularly short-acting insulins, have been reported. To avoid medication errors between insulin glargine and other insulins, check your insulin labels before every injection.

Hypokalemia (low potassium) is a possible side effect with all insulins. You might be more at risk if you are using potassium lowering drugs or losing potassium through other means (e.g. diarrhea). Symptoms of hypokalemia may include: Fatigue, muscle weakness or spasms, constipation, tingling or numbness, feeling of skipped heart beats or palpitations.

If you have diabetic retinopathy (condition affecting the retina of the eye) and you have a marked change in blood glucose levels, the retinopathy may temporary get worse. Ask your doctor about this.

Other warnings you should know about:

The use of thiazolidinediones (such as rosiglitazone and pioglitazone), alone or in combination with other antidiabetic agents (including insulin), has been associated with heart failure and swelling of the lower extremities. Please contact your physician immediately if you develop symptoms of shortness of breath, fatigue, exercise intolerance, or swelling of the lower extremities while you are on these agents.

Concomitant oral antidiabetics treatment may need to be adjusted.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with LANTUS:

Other medicines, including non-prescription medicines, and dietary supplements (such as vitamins) can change the way insulin works. Your dose of insulin or other medications may need to be changed in consultation with your health professional. Please see "Proper use of this medication" section below for potential medication interactions with insulin.

How to take LANTUS:

Your doctor has recommended the type of insulin that he/she believes is best for you. DO NOT USE ANY OTHER INSULIN EXCEPT ON THE ADVICE AND DIRECTION OF YOUR DOCTOR.

LANTUS is a clear solution and looks like some short-acting insulins. Always check for the name of the insulin on your carton and the vial label when you pick it up from the pharmacy to make sure it is the same as what your doctor has recommended.

Correct Syringe

It is important to use a syringe that is marked for U-100 insulin preparations since LANTUS contains 100 units/mL. Using an incorrect syringe could lead to a mistake in dosing and cause medical problems for you, such as a blood glucose level that is too low or too high.

Syringe Use

CAREFULLY FOLLOW THE DIRECTIONS SUPPLIED BY YOUR HEALTH PROFESSIONAL ON THE CORRECT USE OF YOUR SYRINGES TO:

- **HELP AVOID CONTAMINATION AND POSSIBLE INFECTION.**
- **OBTAIN AN ACCURATE DOSE**

Do not share your syringes and needles with anyone including other family members. **You may give another person a serious infection or get a serious infection from them**. Used syringes and needles should be disposed properly.

Preparing the Dose

1. To avoid medication errors, check the vial label of the insulin before each injection.
2. Inspect the insulin. LANTUS should be a clear and colorless solution with no visible particles. Do not use it if you notice anything unusual in the appearance of the solution.
3. Make sure the insulin is at room temperature to minimize local irritation at the injection site.
4. Wash your hands.

5. It is not necessary to shake or rotate the vial before use.
6. If using a new vial, remove the protective cap, but DO NOT remove the stopper.
7. Wipe the top of the vial with an alcohol swab.
8. A new sterile syringe must be used.
9. Draw air into the syringe equal to your insulin dose. Put the needle through the rubber top of the insulin vial and inject the air into the vial.
10. Turn the vial and syringe upside down. Hold the vial and syringe firmly in one hand.
11. Make sure the tip of the needle is in the insulin and withdraw the correct dose of insulin into the syringe.
12. Before removing the needle from the vial, check your syringe for air bubbles. 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.
13. Remove the needle from the vial. Do not let the needle touch anything prior to injection.
14. An empty vial must never be reused and must be properly discarded

Injection

Cleanse the skin with alcohol where the injection is to be made. Pinch and hold the skin and insert the needle as instructed by your health professional. Slowly push the plunger of the syringe in completely. Slowly count to 10 before removing the needle from the injection site and gently apply pressure for several seconds. DO NOT RUB THE AREA. Remove the needle from the injection syringe immediately after each injection. Dispose of the needle appropriately. Do not reuse the needle. The open vial can be kept refrigerated or unrefrigerated (15 to 30 °C) for up to 28 days away from direct heat and light.

There is no relevant difference in absorption of LANTUS between abdominal, thigh, or upper arm subcutaneous injection areas. However, injection sites within an injection area (abdomen, thigh, buttock, or upper arm) must be rotated from one injection to the next as instructed by your healthcare professional. This will reduce the risk of skin shrinking or thickening or lumps at the site.

- **Do not** inject where the skin has pits, is thickened, or has lumps.
- **Do not** inject where the skin is tender, bruised, scaly or hard, or into scars or damaged skin.

Hypo- or hyperglycemia can result from injecting insulin in the wrong site or incorrectly.

Hypoglycemia can result from injection directly into a blood vessel and if not recognized or treated may be followed by hyperglycemia since there was no LANTUS deposition for long-term absorption.

Usual dose:

The dosage of LANTUS should be individualized and determined based on your health professional's advice in accordance with your needs. You may take LANTUS at any time during the day, but you must take it at the same time every day.

Many factors may affect your usual LANTUS dose, which may include changes in your diet, activity, or work schedule. Follow your health professional's instructions carefully. Consult your health professional if you notice your insulin requirements changing markedly. Other factors that may affect your dose of insulin or your need to do additional blood/urine testing are**:**

Illness

Illness, especially with nausea and vomiting, diarrhea and/or fever, may change how much insulin you need. Even if you are not eating, you will still require insulin. You and your health professional should establish a sick day plan for you to use in case of illness. When you are sick, test your blood/urine frequently and call your health professional as instructed.

Pregnancy

If you are planning to have a baby, are pregnant, or are nursing a baby, consult your health professional. Good control of diabetes is especially important for you and your unborn baby. Pregnancy may make managing your diabetes more difficult.

Medication

Always discuss any medications you are taking, prescription or "over-the-counter", with your health professional. To prevent drug interactions, volunteer the names of everything you are taking even before they ask if there have been any changes. Insulin requirements may be increased in the presence of drugs with hyperglycemic activity, such as contraceptives (for example, birth control pills, injections and patches), and hormone replacement therapies, corticosteroids, thyroid replacement therapy, and sympathomimetic agents such as decongestants and diet pills. Insulin requirements may be reduced in the presence of drugs with hypoglycemic activity, such as oral antidiabetic agents, salicylates (for example, aspirin), sulfa antibiotics, blood pressure medications including ACE inhibitors, and certain psychiatric medications including MAO inhibitors or antidepressants and anti-anxiety medications.

Substances such as beta-blockers (medicines used for conditions including blood pressure, heart arrhythmias, palpitations and headache) and alcohol may enhance or weaken the blood-glucose-lowering effect of insulins, and signs of hypoglycemia may be reduced or absent, as well.

Exercise

If your exercise routine changes, discuss with your health professional the possible need to adjust your insulin regimen. Exercise may lower your body's need for insulin during, and for some time after, the activity. As for all insulins, the rate of absorption, and consequently the onset and duration of action, may be affected by exercise and other variables.

Travel

Consult your health professional concerning possible adjustments in your insulin schedule if you will be traveling across time zones. You may want to take along extra insulin and supplies whenever you travel.

Overdose:

If you have **injected too much LANTUS**, your blood sugar level may become too low (hypoglycemia). Check your blood sugar frequently. In general, to prevent hypoglycemia you must eat more food and monitor your blood sugar. For information on the treatment of hypoglycemia, see "Common problems of diabetes" below.

Hypoglycemia may occur as a result of an excess of insulin relative to food intake, energy expenditure or both.

If you think you have taken too much LANTUS, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If you have missed a dose of LANTUS or if you have not injected enough insulin, your blood sugar level may become too high (hyperglycemia). Check your blood sugar frequently. For information on the treatment of hyperglycemia, see "Common problems of diabetes" below.

Do not take a double dose to make up for a forgotten dose.

What are possible side effects from using LANTUS?

These are not all the possible side effects you may feel when taking LANTUS. If you experience any side effects not listed here, contact your healthcare professional.

Common Problems of diabetes

Hypoglycemia (Insulin Reaction)

Hypoglycemia (too little glucose in the blood) is one of the most frequent adverse events experienced by insulin users. It can be brought on by situations such as:

- intercurrent conditions (illness, stress, or emotional disturbances),
- accidental injection of an increased insulin dose,
- malfunction and/or misuse of medical devices,
- too-low food intake, or skipped meals,
- an increase in exercise,
- a new insulin type or schedule,
- some new medications, including prescriptions, over-the counter medication, herbs, vitamins and street drugs.
    - Symptoms of mild to moderate hypoglycemia may occur suddenly and can include:
    - abnormal behavior (anxiety, irritability, restlessness, trouble concentrating, personality changes, mood changes, confusion or nervousness),
    - fatigue,
    - tingling in your hands, feet, lips, or tongue,
    - tremor (shaking),
    - unsteady gait (walking),
    - dizziness, light-headedness, or drowsiness,
    - headache,
    - blurred vision,
    - slurred speech,
    - palpitations (rapid heartbeat),
    - cold sweat,
    - pale skin,
    - nightmares or trouble sleeping,
    - nausea,
    - hunger.

Mild to moderate hypoglycemia may be treated by consuming foods or drinks that contain sugar. Patients should always carry a quick source of sugar, such as candy, juice or glucose tablets, prominently labelled for rescuers. Contact your health professional about appropriate proportions of carbohydrates.

Signs of severe hypoglycemia can include:

- disorientation,
- convulsions,
- loss of consciousness,
- seizures.

Severe hypoglycemia may require the assistance of another person. Patients who are unable to take sugar orally or who are unconscious may require an injection of glucagon or should be treated with

intravenous administration of glucose by medical personnel. Without immediate medical help, serious reactions or even death could occur.

The early warning symptoms of hypoglycemia may be changed, be less pronounced, or be absent, as for example, in patients whose sugar levels are markedly improved, in elderly patients, in patients with diabetic nerve disease, in patients with a long history of diabetes, or in patients receiving treatment with certain other drugs. Such situations may result in severe hypoglycemia (and possibly, loss of consciousness) before a patient has symptoms.

Some people may not recognize when their blood sugar drops too low. Often the first sign of this is confusion of loss or consciousness. Educational and behavioural programs, including blood glucose awareness training, may help improve your ability to detect hypoglycemia and reduce the frequency of severe hypoglycemia.

Without recognition of early warning symptoms, you may not be able to take steps to avoid more serious hypoglycemia. Be alert for all of the various types of symptoms that may indicate hypoglycemia. Patients who experience hypoglycemia without early warning symptoms should monitor their blood glucose frequently, especially prior to activities such as driving a car or using mechanical equipment. If the blood glucose is below your normal fasting glucose, you should consider eating or drinking sugar-containing foods to treat your hypoglycemia.

Other people may develop hypoglycemia during the night – this is called nocturnal hypoglycemia. It is fairly common and lasts over 4 hours. Because the person is usually asleep when it occurs, nocturnal hypoglycemia can go undetected, resulting in increased risk of severe hypoglycemia compared to the daytime. To help reduce your risk of asymptomatic nocturnal hypoglycemia, your doctor may ask you to periodically monitor your overnight blood glucose levels.

If you have frequent episodes of hypoglycemia, experience difficulty in recognizing the symptoms, or if your diabetes is getting worse, you should consult your health professional to discuss possible changes in therapy, meal plans, and/or exercise programs to help you avoid hypoglycemia.

Hyperglycemia

Hyperglycemia (too much glucose in the blood) may develop if your body has too little insulin.

Hyperglycemia can be brought about by:

- intercurrent conditions (illness, stress, or emotional disturbances),
- not taking your insulin or taking less than recommended by your health professional,
- malfunction and/or misuse of medical devices,
- eating significantly more than your meal plan suggests,
- a new insulin type or schedule,
- some new medications, including prescriptions, over-the counter medication, herbs, vitamins and street drugs.

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),
- blurred vision,
- flushed dry skin,
- acetone odour of breath.

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

Diabetic ketoacidosis (DKA)

The first symptoms of diabetic ketoacidosis usually come on over a period of hours or days. With ketoacidosis, urine tests show large amounts of glucose and acetone

Symptoms of diabetic ketoacidosis include:

First symptoms:

- drowsiness,
- flushed face,
- thirst,
- loss of appetite,
- fruity smelling breath,
- rapid, deep breathing,
- abdominal (stomach area) pain.

Severe symptoms:

- heavy breathing,
- rapid pulse.

Prolonged hyperglycemia or diabetic ketoacidosis can lead to:

- nausea,
- vomiting,
- dehydration,
- loss of consciousness,
- death.

Severe or continuing hyperglycemia or DKA requires prompt evaluation and treatment by your health professional. LANTUS should not be used to treat DKA, and the persons treating you should be advised you are taking a long-acting insulin and about your regimen.

Allergic reactions

In rare cases, a patient may be allergic to an insulin product. Severe insulin allergies may be life-threatening. If you think you are having an allergic reaction, seek medical help immediately.

Signs of insulin allergy include:

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

Possible reactions on the skin at the injection site

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

- a little depression in the skin (lipoatrophy),
- skin thickening (lipohypertrophy),
- skin lumps (localized cutaneous amyloidosis),
- redness, swelling, or itching at injection site.

You can reduce the chance of getting an injection site reaction if you change the injection site each time. If you have local injection site reactions, contact your health professional as a sudden change of site may result in hypoglycemia.

In some instances, these reactions may be related to factors other than insulin, such as irritants in the skin cleansing agent or poor injection technique.

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects
You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Unopened Vial:

Unopened LANTUS vials should be stored in a refrigerator, between 2°C and 8°C. Keep LANTUS away from direct heat and light. LANTUS should not be stored in the freezer and should not be allowed to freeze. If LANTUS freezes or overheats, discard it.

Opened (In Use) Vial:

The opened vial can be kept refrigerated or unrefrigerated (15 to 30°C) for up to 28 days away from direct heat and light, as long as the temperature is not greater than 30°C. Opened LANTUS vials, whether or not refrigerated, must be discarded after 28 days even if they contain insulin.

Opened LANTUS vials should not be stored in the freezer and should not be allowed to freeze. If a vial freezes or overheats, discard it.

Do not use a vial of LANTUS after the expiration date stamped on the label or if it is cloudy or if you see particles.

Keep out of reach and sight of children.

If you want more information about LANTUS:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html; the manufacturer's website www.sanofi.ca, or by calling 1-888-8LANTUS (1-888-852-6887).

This document is available in large print format by contacting the sponsor, sanofi-aventis Canada Inc., at: 1-888-8LANTUS (1-888-852-6887).

The size of the large print can be further enlarged if needed.

This leaflet was prepared by sanofi-aventis Canada Inc.

Last revised: December 01, 2021

PATIENT MEDICATION INFORMATION - LANTUS® CARTRIDGE

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

LANTUS® Cartridge

Insulin glargine injection (rDNA origin)

Cartridges are for use ONLY with AllStar® PRO and JuniorSTAR® pens.

Read this carefully before you start taking **LANTUS** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **LANTUS**.

Serious Warnings and Precautions

- Hypoglycemia is the most common adverse effect of insulin, including LANTUS.
- Glucose monitoring is recommended for all patients with diabetes.
- Uncorrected hypoglycemic or hyperglycemic reactions can cause loss of consciousness, coma, or death.
- Any change of insulin should be made cautiously and only under medical supervision.
- LANTUS is not intended for intravenous or intramuscular administration.
- **LANTUS must not be mixed with any other insulin or diluted with any other solution because it might not work as intended.**
- This insulin product shall not be used if it is not water-clear and colourless or if it has formed a deposit of solid particles on the wall of the vial or cartridge.

What is LANTUS used for?

LANTUS [insulin glargine injection (rDNA origin)] is a recombinant human insulin analogue that is a long-acting blood-glucose-lowering agent administered subcutaneously (under the skin) once a day. LANTUS is indicated in the treatment of patients over 17 years of age with Type 1 or Type 2 diabetes mellitus who require basal (long-acting) insulin for the control of hyperglycemia. LANTUS is also indicated in the treatment of pediatric patients (> 6 years old) with Type 1 diabetes mellitus who require basal (long-acting) insulin for the control of hyperglycemia.

How does LANTUS work?

Insulin is a hormone produced by the pancreas, a large gland that lies near the stomach. This hormone is necessary for your body to use food, especially sugar, correctly. Diabetes occurs either when your pancreas does not make enough insulin to meet your body's needs or when your body is unable to use the insulin you normally produce properly.

When your body does not make enough insulin, you need an external source of insulin – that is why you must take insulin injections. LANTUS is similar to the insulin made by your body.

Insulin injections, such as LANTUS, play a key role in keeping your diabetes under control. In addition to proper insulin therapy, it's important to maintain a healthy lifestyle – this includes eating a balanced diet, participating in regular exercise or other physical activities, carefully monitoring your glucose levels and following your health professional's recommendations. These simple actions will compliment your insulin therapy and will ultimately help you gain greater control of your diabetes.

You have been instructed to test your blood and/or your urine regularly for glucose; it is especially important to test even more often when changing insulins or dosing schedule. If your blood tests consistently show above- or below- normal glucose levels, or your urine tests consistently show the presence of glucose, your diabetes is not properly controlled and you must let your health professional know.

Insulin injections play an important role in keeping your diabetes under control. But the way you live – your diet, careful monitoring of your glucose levels, exercise, or planned physical activity and following your health professional's recommendations– all work with your insulin to help you control your diabetes.

Always keep an extra supply of insulin and needle on hand. Always wear medical alert identification and carry information about your diabetes so that appropriate treatment can be given if complications occur while you are away from home.

What are the ingredients in LANTUS?

Medicinal ingredients: insulin glargine (rDNA origin)

Non-medicinal ingredients: glycerol 85%, m-cresol, polysorbate 20, water, zinc, and hydrochloric acid and sodium hydroxide for pH adjustment.

LANTUS comes in the following dosage forms:

Solution for injection 100 U/mL

Do not use LANTUS:

- if you are allergic to this drug or to any ingredient in the formulation or component of the container;
- if you have diabetic ketoacidosis;
- for intravenous or intramuscular injections.
- if your blood sugar is too low (hypoglycemia). After treating your low blood sugar, follow your health care provider's instructions on the use of Lantus.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take LANTUS. Talk about any health conditions or problems you may have, including if you:

- You are planning to have a baby, are pregnant, or are nursing a baby;
- You are taking any medication.

If you develop 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 take LANTUS). Contact your healthcare professional if you are currently injecting into a lumpy area before you start injecting in a different area. A sudden change of site may result in hypoglycemia. Your healthcare professional may tell you to check your blood sugar more closely, and to adjust your insulin or your other antidiabetic medications dose.

Accidental mix-ups between insulin glargine and other insulins, particularly short-acting insulins, have been reported. To avoid medication errors between insulin glargine and other insulins, check your insulin labels before every injection.

Hypokalemia (low potassium) is a possible side effect with all insulins. You might be more at risk if you are using potassium lowering drugs or losing potassium through other means (e.g. diarrhea). Symptoms

of hypokalemia may include: Fatigue, muscle weakness or spasms, constipation, tingling or numbness, feeling of skipped heart beats or palpitations.

If you have diabetic retinopathy (condition affecting the retina of the eye) and you have a marked change in blood glucose levels, the retinopathy may temporary get worse. Ask your doctor about this.

Other warnings you should know about:

The use of thiazolidinediones (such as rosiglitazone and pioglitazone), alone or in combination with other antidiabetic agents (including insulin), has been associated with heart failure and swelling of the lower extremities. Please contact your physician immediately if you develop symptoms of shortness of breath, fatigue, exercise intolerance, or swelling of the lower extremities while you are on these agents.

Concomitant oral antidiabetics treatment may need to be adjusted.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with LANTUS:

Other medicines, including non-prescription medicines, and dietary supplements (such as vitamins) can change the way insulin works. Your dose of insulin or other medications may need to be changed in consultation with your health professional. Please see "Proper use of this medication" section below for potential medication interactions with insulin.

How to take LANTUS:

Your doctor has recommended the type of insulin that he/she believes is best for you. DO NOT USE ANY OTHER INSULIN EXCEPT ON THE ADVICE AND DIRECTION OF YOUR DOCTOR.

LANTUS is a clear solution and looks like some short-acting insulins. Always check for the name of the insulin on your carton and your cartridge label when you pick it up from the pharmacy to make sure it is the same as what your doctor has recommended.

It is important to use the LANTUS cartridge only with AllStar PRO and JuniorSTAR pens.

Using the cartridge in any other injection pen not suitable for the LANTUS cartridge could lead to a mistake in dosing and cause medical problems for you, such as a blood glucose level that is too low or too high.

JuniorSTAR delivers LANTUS in 0.5 unit dose increments. AllStar PRO delivers LANTUS in 1 unit dose increments.

Although rare, technical problems with the cartridge can occur which may prevent correct dosing. They include: broken, cracked or damaged cartridges, air bubbles or foam, and blocked needles. If technical problems occur or are suspected, contact the call center, your physician, pharmacist or nurse.

CAREFULLY FOLLOW THE DIRECTIONS SUPPLIED BY YOUR HEALTH PROFESSIONAL ON THE CORRECT USE OF YOUR AllStar PRO and JuniorSTAR, TO:

- **HELP AVOID CONTAMINATION AND POSSIBLE INFECTION**
- **OBTAIN AN ACCURATE DOSE.**

Do not reuse needles. INJECTION PENS, CARTRIDGES, NEEDLES, AND SYRINGES MUST NOT BE SHARED. **Do not** share an injection pen or LANTUS cartridge with anyone, **including family members**, even if the

needle on the injection pen is changed. **You may give another person a serious infection, or get a serious infection from them.**

Preparing the LANTUS Cartridge for Insertion into the injection pen

1. To avoid medication errors, check the cartridge label of the insulin before each insertion.
2. Inspect the insulin cartridge. LANTUS should be a clear and colorless solution with no visible particles. Do not use it if you notice anything unusual in the appearance of the solution.
3. Make sure the insulin is at room temperature to minimize local irritation at the injection site.
4. Wash your hands.
5. Carefully follow the injection pen directions for loading the cartridge into the injection pen.

Injecting Each Dose:

1. Wash your hands.
2. Inspect the insulin. LANTUS should be a clear and colorless solution with no visible particles. Do not use it if you notice anything unusual in the appearance of solution.
3. It is not necessary to shake or rotate the cartridge inserted into the injection pen before use.
4. Remove the protective cap.
5. Follow the injection pen directions for attaching and changing the needle.
6. Check the cartridge inserted into the injection pen for air bubbles. If bubbles are present, remove them as instructed in the injection pen directions.
7. **Follow the injection pen directions for performing the Safety Test or Priming.**
8. Set the injection pen to the correct LANTUS dose as instructed in the injection pen directions.
9. There is no relevant difference in absorption of LANTUS between abdominal, thigh, or upper arm subcutaneous injection areas. However, injection sites within an injection area (abdomen, thigh, buttock, or upper arm) must be rotated from one injection to the next as instructed by your healthcare professional. This will reduce the risk of skin shrinking or thickening or lumps at the site.
    - **Do not** inject where the skin has pits, is thickened, or has lumps.
    - **Do not** inject where the skin is tender, bruised, scaly or hard, or into scars or damaged skin.
10. Cleanse the skin with alcohol where the injection is to be made.
11. Pinch and hold the skin and insert the needle attached to the injection pen as instructed by your doctor or diabetes educator.
12. To inject LANTUS, follow the directions for the injection pen.
13. Slowly count to 10 before removing the needle from the injection site and gently apply pressure for several seconds. DO NOT RUB THE AREA.
14. Remove the needle from the injection pen immediately after each injection as instructed in the directions for the injection pen. Dispose of the needle appropriately. Do not reuse the needle.

Hypo- or hyperglycemia can result from injecting insulin in the wrong site or incorrectly.

Hypoglycemia can result from injection directly into a blood vessel and if not recognized or treated may be followed by hyperglycemia since there was no LANTUS deposition for long-term absorption.

Usual dose:

The dosage of LANTUS should be individualized and determined based on your health professional's advice in accordance with your needs. You may take LANTUS at any time during the day, but you must take it at the same time every day.

Many factors may affect your usual LANTUS dose, which may include changes in your diet, activity, or work schedule. Follow your health professional's instructions carefully. Consult your health professional if you notice your insulin requirements changing markedly. Other factors that may affect your dose of insulin or your need to do additional blood/urine testing are:

Illness

Illness, especially with nausea and vomiting, diarrhea and/or fever, may cause your insulin requirements to change. Even if you are not eating, you will still require insulin. You and your doctor should establish a sick day plan for you to use in case of illness. When you are sick, test your blood/urine frequently and call your doctor as instructed.

Pregnancy

If you are planning to have a baby, are pregnant, or are nursing a baby, consult your doctor. Good control of diabetes is especially important for you and your unborn baby. Pregnancy may make managing your diabetes more difficult.

Medication

Always discuss any medications you are taking, prescription or "over-the-counter", with your health professional. To prevent drug interactions, volunteer the names of everything you are taking even before they ask if there have been any changes. Insulin requirements may be increased in the presence of drugs with hyperglycemic activity, such as contraceptives (for example, birth control pills, injections and patches), and hormone replacement therapies, corticosteroids, thyroid replacement therapy, and sympathomimetic agents such as decongestants and diet pills. Insulin requirements may be reduced in the presence of drugs with hypoglycemic activity, such as oral antidiabetic agents, salicylates (for example, aspirin), sulfa antibiotics, blood pressure medications including ACE inhibitors, and certain psychiatric medications including MAO inhibitors or antidepressants and anti-anxiety medications.

Substances such as beta-blockers (medicines used for conditions including blood pressure, heart arrhythmias, palpitations and headache) and alcohol may enhance or weaken the blood-glucose-lowering effect of insulins, and signs of hypoglycemia may be reduced or absent, as well.

Exercise

If your exercise routine changes, discuss with your health professional the possible need to adjust your insulin regimen. Exercise may lower your body's need for insulin during, and for some time after, the activity. As for all insulins, the rate of absorption, and consequently the onset and duration of action, may be affected by exercise and other variables.

Travel

Consult your health professional concerning possible adjustments in your insulin schedule if you will be traveling across time zones. You may want to take along extra insulin and supplies whenever you travel.

Overdose:

If you have **injected too much LANTUS,** your blood sugar level may become too low (hypoglycemia). Check your blood sugar frequently. In general, to prevent hypoglycemia you must eat more food and monitor your blood sugar. For information on the treatment of hypoglycemia, see "Common problems of diabetes" below.

Hypoglycemia may occur as a result of an excess of insulin relative to food intake, energy expenditure or both.

If you think you have taken too much LANTUS, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If you have **missed a dose of LANTUS** or if you **have not injected enough insulin,** your blood sugar level may become too high (hyperglycemia). Check your blood sugar frequently. For information on the treatment of hyperglycemia, see "Common problems of diabetes" below.

Do not take a double dose to make up for a forgotten dose.

What are possible side effects from using LANTUS?

These are not all the possible side effects you may feel when taking LANTUS. If you experience any side effects not listed here, contact your healthcare professional.

Common problems of diabetes

Hypoglycemia (Insulin Reaction)

Hypoglycemia (too little glucose in the blood) is one of the most frequent adverse events experienced by insulin users. It can be brought on by situations such as:

- intercurrent conditions (illness, stress, or emotional disturbances),
- accidental injection of an increased insulin dose,
- malfunction and/or misuse of medical devices,
- too-low food intake, or skipped meals,
- an increase in exercise,
- a new insulin type or schedule,
- some new medications, including prescriptions, over-the counter medication, herbs, vitamins and street drugs.

Symptoms of mild to moderate hypoglycemia may occur suddenly and can include:

- abnormal behavior (anxiety, irritability, restlessness, trouble concentrating, personality changes, mood changes, confusion or nervousness),
- fatigue,
- tingling in your hands, feet, lips, or tongue,
- tremor (shaking),
- unsteady gait (walking),
- dizziness, light-headedness, or drowsiness,
- headache,
- blurred vision,
- slurred speech,
- palpitations (rapid heartbeat),
- cold sweat,
- pale skin,
- nightmares or trouble sleeping,
- nausea,
- hunger.

Mild to moderate hypoglycemia may be treated by consuming foods or drinks that contain sugar. Patients should always carry a quick source of sugar, such as candy, juice or glucose tablets,

prominently labelled for rescuers. Contact your health professional about appropriate proportions of carbohydrates.

Signs of severe hypoglycemia can include:

- disorientation,
- convulsions,
- loss of consciousness,
- seizures.

Severe hypoglycemia may require the assistance of another person. Patients who are unable to take sugar orally or who are unconscious may require an injection of glucagon or should be treated with intravenous administration of glucose by medical personnel. Without immediate medical help, serious reactions or even death could occur.

The early warning symptoms of hypoglycemia may be changed, be less pronounced, or be absent, as for example, in patients whose sugar levels are markedly improved, in elderly patients, in patients with diabetic nerve disease, in patients with a long history of diabetes, or in patients receiving treatment with certain other drugs. Such situations may result in severe hypoglycemia (and possibly, loss of consciousness) before a patient has symptoms.

Some people may not recognize when their blood sugar drops too low. Often the first sign of this is confusion or loss of consciousness. Educational and behavioural programs, including blood glucose awareness training, may help improve your ability to detect hypoglycemia and reduce the frequency of severe hypoglycemia.

Without recognition of early warning symptoms, you may not be able to take steps to avoid more serious hypoglycemia. Be alert for all of the various types of symptoms that may indicate hypoglycemia. Patients who experience hypoglycemia without early warning symptoms should monitor their blood glucose frequently, especially prior to activities such as driving a car or using mechanical equipment. If the blood glucose is below your normal fasting glucose, you should consider eating or drinking sugar-containing foods to treat your hypoglycemia.

Other people may develop hypoglycemia during the night – this is called nocturnal hypoglycemia. It is fairly common and lasts over 4 hours. Because the person is usually asleep when it occurs, nocturnal hypoglycemia can go undetected, resulting in increased risk of severe hypoglycemia compared to the daytime. To help reduce your risk of asymptomatic nocturnal hypoglycemia, your doctor may ask you to periodically monitor your overnight blood glucose levels.

If you have frequent episodes of hypoglycemia, experience difficulty in recognizing the symptoms, or if your diabetes is getting worse, you should consult your health professional to discuss possible changes in therapy, meal plans, and/or exercise programs to help you avoid hypoglycemia.

Hyperglycemia

Hyperglycemia (too much glucose in the blood) may develop if your body has too little insulin.

Hyperglycemia can be brought about by:

- intercurrent conditions (illness, stress, or emotional disturbances),
- not taking your insulin or taking less than recommended by your health professional,
- malfunction and/or misuse of medical devices,
- eating significantly more than your meal plan suggests,
- a new insulin type or schedule,
- some new medications, including prescriptions, over-the counter medication, herbs, vitamins and street drugs,

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),
- blurred vision,
- flushed dry skin,
- acetone odour of breath.

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

Diabetic ketoacidosis (DKA)

The first symptoms of diabetic ketoacidosis usually come on over a period of hours or days. With ketoacidosis, urine tests show large amounts of glucose and acetone.

Symptoms of diabetic ketoacidosis include:

First symptoms:

- drowsiness,
- flushed face,
- thirst,
- loss of appetite,
- fruity smelling breath,
- rapid, deep breathing,
- abdominal (stomach area) pain.

Severe symptoms:

- heavy breathing,
- rapid pulse.

Prolonged hyperglycemia or diabetic ketoacidosis can lead to:

- nausea,
- vomiting,
- dehydration,
- loss of consciousness,
- death.

Severe or continuing hyperglycemia or DKA requires prompt evaluation and treatment by your health professional. LANTUS should not be used to treat DKA, and the persons treating you should be advised you are taking a long-acting insulin and about your regimen.

Allergic reactions

In rare cases, a patient may be allergic to an insulin product. Severe insulin allergies may be life-threatening. If you think you are having an allergic reaction, seek medical help immediately.

Signs of insulin allergy include:

- a rash all over your body,
- shortness of breath,
- wheezing (trouble breathing),

- a fast pulse,
- sweating,
- low blood pressure.

Possible reactions on the skin at the injection site

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

- a little depression in the skin (lipoatrophy),
- skin thickening (lipohypertrophy),
- skin lumps (localized cutaneous amyloidosis),
- redness, swelling, or itching at injection site.

You can reduce the chance of getting an injection site reaction if you change the injection site each time. If you have local injection site reactions, contact your health professional as a sudden change of site may result in hypoglycemia.

In some instances, these reactions may be related to factors other than insulin, such as irritants in the skin cleansing agent or poor injection technique.

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects
You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Unopened Cartridge:

Unopened LANTUS cartridges should be stored in a refrigerator, between 2°C and 8°C. Keep LANTUS away from direct heat and light. LANTUS should not be stored in the freezer and should not be allowed to freeze. If LANTUS freezes or overheats, discard it.

Opened (In Use) Cartridge:

The opened cartridge in use must be kept unrefrigerated (15 to 30°C) for up to 28 days away from direct heat and light, as long as the temperature is not greater than 30°C. If the cartridge overheats or if there is any remaining insulin after 28 days, discard it. The opened cartridge in use must never be removed from and reinserted into the injection pen.

Do not use a cartridge of LANTUS after the expiration date stamped on the label or if it is cloudy or if you see particles.

Keep out of reach and sight of children.

If you want more information about LANTUS:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html; the manufacturer's website www.sanofi.ca, or by calling 1-888-8LANTUS (1-888-852-6887).

This document is available in large print format by contacting the sponsor, sanofi-aventis Canada Inc., at: 1-888-8LANTUS (1-888-852-6887).The size of the large print can be further enlarged if needed.

This leaflet was prepared by sanofi-aventis Canada Inc.

Last Revised: December 01, 2021

PATIENT MEDICATION INFORMATION - LANTUS® SOLOSTAR®

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

LANTUS® SoloSTAR® (Pre-filled disposable pen)

Insulin glargine injection (rDNA origin)

Read this carefully before you start taking LANTUS and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about LANTUS.

Serious Warnings and Precautions

- Hypoglycemia is the most common adverse effect of insulin, including LANTUS.
- Glucose monitoring is recommended for all patients with diabetes.
- Uncorrected hypoglycemic or hyperglycemic reactions can cause loss of consciousness, coma, or death.
- Any change of insulin should be made cautiously and only under medical supervision.
- LANTUS is not intended for intravenous or intramuscular administration.
- **LANTUS must not be mixed with any other insulin or diluted with any other solution because it might not work as intended**.
- This insulin product shall not be used if it is not water-clear and colourless or if it has formed a deposit of solid particles on the wall of the vial or cartridge.

What is LANTUS used for?

LANTUS [insulin glargine injection (rDNA origin)] is a recombinant human insulin analogue that is a long-acting blood-glucose-lowering agent administered subcutaneously (under the skin) once a day. LANTUS is indicated in the treatment of patients over 17 years of age with Type 1 or Type 2 diabetes mellitus who require basal (long-acting) insulin for the control of hyperglycemia. LANTUS is also indicated in the treatment of pediatric patients (> 6 years old) with Type 1 diabetes mellitus who require basal (long-acting) insulin for the control of hyperglycemia.

How does LANTUS work?

Insulin is a hormone produced by the pancreas, a large gland that lies near the stomach. This hormone is necessary for your body to use food, especially sugar, correctly. Diabetes occurs either when your pancreas does not make enough insulin to meet your body's needs or when your body is unable to use the insulin you normally produce properly.

When your body does not make enough insulin, you need an external source of insulin – that is why you must take insulin injections. LANTUS is similar to the insulin made by your body.

Insulin injections, such as LANTUS, play a key role in keeping your diabetes under control. In addition to proper insulin therapy, it's important to maintain a healthy lifestyle – this includes eating a balanced diet, participating in regular exercise or other physical activities, carefully monitoring your glucose levels and following your health professional's recommendations. These simple actions will compliment your insulin therapy and will ultimately help you gain greater control of your diabetes.

You have been instructed to test your blood and/or your urine regularly for glucose; it is especially important to test even more often when changing insulins or dosing schedule. If your blood tests consistently show above- or below- normal glucose levels, or your urine tests consistently show the

presence of glucose, your diabetes is not properly controlled and you must let your health professional know.

Insulin injections play an important role in keeping your diabetes under control. But the way you live – your diet, careful monitoring of your glucose levels, exercise, or planned physical activity and following your health professional's recommendations– all work with your insulin to help you control your diabetes.

Always keep an extra supply of insulin and needle on hand. Always wear medical alert identification and carry information about your diabetes so that appropriate treatment can be given if complications occur while you are away from home.

What are the ingredients in LANTUS?

Medicinal ingredient: insulin glargine (rDNA origin)

Non-medicinal ingredients: glycerol 85%, m-cresol, polysorbate 20, water, zinc, and hydrochloric acid and sodium hydroxide for pH adjustment.

LANTUS comes in the following dosage forms:

Solution for injection: 100 U/mL

Do not use LANTUS:

- if you are allergic to this drug or to any ingredient in the formulation or component of the container,
- if you have diabetic ketoacidosis;
- for intravenous or intramuscular injections.
- if your blood sugar is too low (hypoglycemia). After treating your low blood sugar, follow your health care provider's instructions on the use of Lantus.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take LANTUS. Talk about any health conditions or problems you may have, including if you:

- You are planning to have a baby, are pregnant, or are nursing a baby;
- You are taking any medication.

If you develop 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 take LANTUS). Contact your healthcare professional if you are currently injecting into a lumpy area before you start injecting in a different area. A sudden change of site may result in hypoglycemia. Your healthcare professional may tell you to check your blood sugar more closely, and to adjust your insulin or your other antidiabetic medications dose.

Accidental mix-ups between insulin glargine and other insulins, particularly short-acting insulins, have been reported. To avoid medication errors between insulin glargine and other insulins, check your insulin labels before every injection.

Hypokalemia (low potassium) is a possible side effect with all insulins. You might be more at risk if you are using potassium lowering drugs or losing potassium through other means (e.g. diarrhea). Symptoms of hypokalemia may include: Fatigue, muscle weakness or spasms, constipation, tingling or numbness, feeling of skipped heart beats or palpitations.

If you have diabetic retinopathy (condition affecting the retina of the eye) and you have a marked change in blood glucose levels, the retinopathy may temporary get worse. Ask your doctor about this.

Other warnings you should know about:

The use of thiazolidinediones (such as rosiglitazone and pioglitazone), alone or in combination with other antidiabetic agents (including insulin), has been associated with heart failure and swelling of the lower extremities. Please contact your physician immediately if you develop symptoms of shortness of breath, fatigue, exercise intolerance, or swelling of the lower extremities while you are on these agents.

Concomitant oral antidiabetics treatment may need to be adjusted.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with LANTUS:

Other medicines, including non-prescription medicines, and dietary supplements (such as vitamins) can change the way insulin works. Your dose of insulin or other medications may need to be changed in consultation with your health professional. Please see "Proper use of this medication" section below for potential medication interactions with insulin.

How to take LANTUS:

Your doctor has recommended the type of insulin that he/she believes is best for you. DO NOT USE ANY OTHER INSULIN EXCEPT ON THE ADVICE AND DIRECTION OF YOUR DOCTOR.

LANTUS is a clear solution and looks like some short-acting insulins. Always check for the name of the insulin on your carton and your SoloSTAR label when you pick it up from the pharmacy to make sure it is the same as what your doctor has recommended.

CAREFULLY FOLLOW THE DIRECTIONS SUPPLIED BY YOUR HEALTH PROFESSIONAL ON THE CORRECT USE OF YOUR SOLOSTAR TO:

- **HELP AVOID CONTAMINATION AND POSSIBLE INFECTION**
- **AND TO OBTAIN AN ACCURATE DOSE.**

Do not reuse needles. INJECTION PENS, CARTRIDGES, NEEDLES, AND SYRINGES MUST NOT BE SHARED. **You may give another person a serious infection, or get a serious infection from them**. This injection pen is for single patient use. Do not share it with anyone including other family members, even if the needle on the injection pen is changed. Do not use on multiple patients.

Preparing the Dose

1. To avoid medication errors, check the label of the insulin of the SoloSTAR pen to make sure you have the correct insulin.
2. Inspect the insulin. LANTUS should be a clear and colorless solution with no visible particles. Do not use it if you notice anything unusual in the appearance of the solution.
3. Make sure the insulin is at room temperature to minimize local irritation at the injection site.
4. Wash your hands.
5. It is not necessary to shake or rotate the SoloSTAR before use.
6. Remove the protective cap.
7. Follow the SoloSTAR directions for attaching and changing the needle.
8. Check the SoloSTAR for air bubbles. If bubbles are present, remove them as instructed in the SoloSTAR directions.

9. **Follow the SoloSTAR directions for performing the Safety Test.**
10. Set the SoloSTAR to the correct LANTUS dose as instructed in the SoloSTAR directions.
11. There is no relevant difference in absorption of LANTUS between abdominal, thigh, or upper arm subcutaneous injection areas. However, injection sites within an injection area (abdomen, thigh, buttock, or upper arm) must be rotated from one injection to the next as instructed by your healthcare professional. This will reduce the risk of skin shrinking or thickening or lumps at the site.
    - **Do not** inject where the skin has pits, is thickened, or has lumps.
    - **Do not** inject where the skin is tender, bruised, scaly or hard, or into scars or damaged skin.
12. Cleanse the skin with alcohol where the injection is to be made.
13. Pinch and hold the skin and insert the needle attached to the SoloSTAR as instructed by your doctor or diabetes educator.
14. To inject LANTUS, follow the directions for the SoloSTAR.
15. Slowly count to 10 before removing the needle from the injection site and gently apply pressure for several seconds. DO NOT RUB THE AREA.
16. Remove the needle from the SoloSTAR immediately after each injection as instructed in the directions for the SoloSTAR. Dispose of the needle appropriately. Do not reuse the needle.

Hypo- or hyperglycemia can result from injecting insulin in the wrong site or incorrectly. Hypoglycemia can result from injection directly into a blood vessel and if not recognized or treated may be followed by hyperglycemia since there was no deposition for long-term absorption.

Usual dose:

The dosage of LANTUS should be individualized and determined based on your health professional's advice in accordance with your needs. You may take LANTUS at any time during the day, but you must take it at the same time every day.

Many factors may affect your usual LANTUS dose, which may include changes in your diet, activity, or work schedule. Follow your health professional's instructions carefully. Consult your health professional if you notice your insulin requirements changing markedly. Other factors that may affect your dose of insulin or your need to do additional blood/urine testing are**:**

Illness

Illness, especially with nausea and vomiting, diarrhea and/or fever, may cause your insulin requirements to change. Even if you are not eating, you will still require insulin. You and your doctor should establish a sick day plan for you to use in case of illness. When you are sick, test your blood/urine frequently and call your doctor as instructed.

Pregnancy

If you are planning to have a baby, are pregnant, or are nursing a baby, consult your doctor. Good control of diabetes is especially important for you and your unborn baby. Pregnancy may make managing your diabetes more difficult.

Medication

Always discuss any medications you are taking, prescription or "over-the-counter", with your health professional. To prevent drug interactions, volunteer the names of everything you are taking even before they ask if there have been any changes. Insulin requirements may be increased in the presence of drugs with hyperglycemic activity, such as contraceptives (for example, birth control pills, injections

and patches) and hormone replacement therapies, corticosteroids, thyroid replacement therapy, and sympathomimetic agents such as decongestants and diet pills. Insulin requirements may be reduced in the presence of drugs with hypoglycemic activity, such as oral antidiabetic agents, salicylates (for example, aspirin), sulfa antibiotics, blood pressure medications including ACE inhibitors, and certain psychiatric medications including MAO inhibitors or antidepressants and anti-anxiety medications.

Substances such as beta-blockers (medicines used for conditions including blood pressure, heart arrhythmias, palpitations and headache) and alcohol may enhance or weaken the blood-glucose-lowering effect of insulins, and signs of hypoglycemia may be reduced or absent, as well.

Exercise

If your exercise routine changes, discuss with your health professional the possible need to adjust your insulin regimen. Exercise may lower your body's need for insulin during, and for some time after, the activity. As for all insulins, the rate of absorption, and consequently the onset and duration of action, may be affected by exercise and other variables.

Travel

Consult your health professional concerning possible adjustments in your insulin schedule if you will be traveling across time zones. You may want to take along extra insulin and supplies whenever you travel.

Overdose:

If you have **injected too much LANTUS**, your blood sugar level may become too low (hypoglycemia). Check your blood sugar frequently. In general, to prevent hypoglycemia you must eat more food and monitor your blood sugar. For information on the treatment of hypoglycemia, see “Common Problems of diabetes” below.

Hypoglycemia may occur as a result of an excess of insulin relative to food intake, energy expenditure or both.

If you think you have taken too much LANTUS, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:
If you have missed a dose of LANTUS or if you have not injected enough insulin, your blood sugar level may become too high (hyperglycemia). Check your blood sugar frequently. For information on the treatment of hyperglycemia, see “Common Problems of diabetes” below.

Do not take a double dose to make up for a forgotten dose.

What are possible side effects from using LANTUS?

These are not all the possible side effects you may feel when taking LANTUS. If you experience any side effects not listed here, contact your healthcare professional**.**

Common problems of diabetes

Hypoglycemia (Insulin Reaction)

Hypoglycemia (too little glucose in the blood) is one of the most frequent adverse events experienced by insulin users. It can be brought on by situations such as:

- intercurrent conditions (illness, stress, or emotional disturbances),
- accidental injection of an increased insulin dose,

- malfunction and/or misuse of medical devices,
- too-low food intake, or skipped meals,
- an increase in exercise,
- a new insulin type or schedule,
- some new medications, including prescriptions, over-the counter medication, herbs, vitamins and street drugs.

Symptoms of mild to moderate hypoglycemia may occur suddenly and can include:

- abnormal behavior (anxiety, irritability, restlessness, trouble concentrating, personality changes, mood changes, confusion or nervousness),
- fatigue,
- tingling in your hands, feet, lips, or tongue,
- tremor (shaking),
- unsteady gait (walking),
- dizziness, light-headedness, or drowsiness,
- headache,
- blurred vision,
- slurred speech,
- palpitations (rapid heartbeat),
- cold sweat,
- pale skin,
- nightmares or trouble sleeping,
- nausea,
- hunger.

Mild to moderate hypoglycemia may be treated by consuming foods or drinks that contain sugar. Patients should always carry a quick source of sugar, such as candy, juice or glucose tablets, prominently labelled for rescuers. Contact your health professional about appropriate proportions of carbohydrates.

Signs of severe hypoglycemia can include:

- disorientation,
- convulsions,
- loss of consciousness,
- seizures.

Severe hypoglycemia may require the assistance of another person. Patients who are unable to take sugar orally or who are unconscious may require an injection of glucagon or should be treated with intravenous administration of glucose by medical personnel. Without immediate medical help, serious reactions or even death could occur.

The early warning symptoms of hypoglycemia may be changed, be less pronounced, or be absent, as for example, in patients whose sugar levels are markedly improved, in elderly patients, in patients with diabetic nerve disease, in patients with a long history of diabetes, or in patients receiving treatment with certain other drugs. Such situations may result in severe hypoglycemia (and possibly, loss of consciousness) before a patient has symptoms.

Some people may not recognize when their blood sugar drops too low. Often the first sign of this is confusion or loss of consciousness. Educational and behavioural programs, including blood glucose

awareness training, may help improve your ability to detect hypoglycemia and reduce the frequency of severe hypoglycemia.

Without recognition of early warning symptoms, you may not be able to take steps to avoid more serious hypoglycemia. Be alert for all of the various types of symptoms that may indicate hypoglycemia. Patients who experience hypoglycemia without early warning symptoms should monitor their blood glucose frequently, especially prior to activities such as driving a car or using mechanical equipment. If the blood glucose is below your normal fasting glucose, you should consider eating or drinking sugar-containing foods to treat your hypoglycemia.

Other people may develop hypoglycemia during the night – this is called nocturnal hypoglycemia. It is fairly common and lasts over 4 hours. Because the person is usually asleep when it occurs, nocturnal hypoglycemia can go undetected, resulting in increased risk of severe hypoglycemia compared to the daytime. To help reduce your risk of asymptomatic nocturnal hypoglycemia, your doctor may ask you to periodically monitor your overnight blood glucose levels.

If you have frequent episodes of hypoglycemia, experience difficulty in recognizing the symptoms, or if your diabetes is getting worse, you should consult your health professional to discuss possible changes in therapy, meal plans, and/or exercise programs to help you avoid hypoglycemia.

Hyperglycemia

Hyperglycemia (too much glucose in the blood) may develop if your body has too little insulin.

Hyperglycemia can be brought about by:

- intercurrent conditions (illness, stress, or emotional disturbances),
- not taking your insulin or taking less than recommended by your health professional,
- malfunction and/or misuse of medical devices,
- eating significantly more than your meal plan suggests,
- a new insulin type or schedule,
- some new medications, including prescriptions, over-the counter medication, herbs, vitamins and street drugs,

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),
- blurred vision,
- flushed dry skin,
- acetone odour of breath.

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

Diabetic ketoacidosis (DKA)

The first symptoms of diabetic ketoacidosis usually come on over a period of hours or days. With ketoacidosis, urine tests show large amounts of glucose and acetone.

Symptoms of diabetic ketoacidosis include:

First symptoms:

- drowsiness,
- flushed face,
- thirst,
- loss of appetite,
- fruity smelling breath,
- rapid, deep breathing,
- abdominal (stomach area) pain.

Severe symptoms:

- heavy breathing,
- rapid pulse.

Prolonged hyperglycemia or diabetic ketoacidosis can lead to:

- nausea,
- vomiting,
- dehydration,
- loss of consciousness,
- death.

Severe or continuing hyperglycemia or DKA requires prompt evaluation and treatment by your health professional. LANTUS should not be used to treat DKA, and the persons treating you should be advised you are taking a long-acting insulin and about your regimen.

Allergic reactions

In rare cases, a patient may be allergic to an insulin product. Severe insulin allergies may be life-threatening. If you think you are having an allergic reaction, seek medical help immediately.

Signs of insulin allergy include:

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

Possible reactions on the skin at the injection site

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

- a little depression in the skin (lipoatrophy),
- skin thickening (lipohypertrophy),
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You can reduce the chance of getting an injection site reaction if you change the injection site each time. If you have local injection site reactions, contact your health professional as a sudden change of site may result in hypoglycemia.

In some instances, these reactions may be related to factors other than insulin, such as irritants in the skin cleansing agent or poor injection technique.

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects
You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Unopened SoloSTAR:

Unopened LANTUS SoloSTAR should be stored in a refrigerator, between 2°C and 8°C. Keep LANTUS away from direct heat and light. LANTUS SoloSTAR should not be stored in the freezer and should not be allowed to freeze. If LANTUS SoloSTAR freezes or overheats, discard it.

Opened (In Use) SoloSTAR:

Opened LANTUS SoloSTAR in use must be kept unrefrigerated (15 to 30°C) for up to 28 days away from direct heat and light, as long as the temperature is not greater than 30°C. If the LANTUS SoloSTAR overheats or if there is any remaining insulin after 28 days, discard it.

Opened LANTUS SoloSTAR should not be stored in the freezer and should not be allowed to freeze. If LANTUS SoloSTAR freezes, discard it.

Do not use a LANTUS SoloSTAR after the expiration date stamped on the label or if it is cloudy or if you see particles.

Keep out of reach and sight of children.

If you want more information about LANTUS:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html; the manufacturer's website www.sanofi.ca, or by calling 1-888-8LANTUS (1-888-852-6887).

This document is available in large print format by contacting the sponsor, sanofi-aventis Canada Inc., at: 1-888-8LANTUS (1-888-852-6887). The size of the large print can be further enlarged if needed.

This leaflet was prepared by sanofi-aventis Canada Inc.

Last revised: December 01, 2021

INSTRUCTIONS FOR USE: LANTUS® SOLOSTAR ®

SoloSTAR® is a prefilled pen for the injection of insulin. Your health professional has decided that SoloSTAR is appropriate for you, based on your ability to handle SoloSTAR. Talk with your health professional about proper injection technique before using SoloSTAR.

Read these instructions carefully before using your SoloSTAR. If you are not able to use SoloSTAR or to follow all the instructions completely on your own, you must use SoloSTAR only if you have help from a person who is able to follow the instructions completely.

Each SoloSTAR contains in total 300 units of insulin. You can set doses from 1 to 80 units in steps of 1 unit. Each pen contains multiple doses.

Keep this leaflet for future reference.

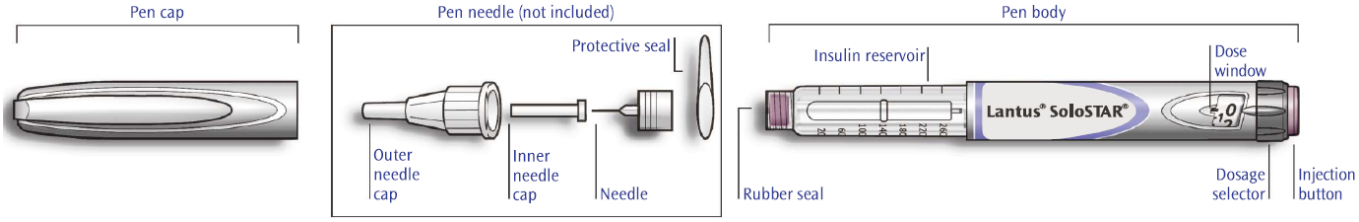
If you have any questions about SoloSTAR or about diabetes, ask your health professional or call sanofi-aventis at **1-888-8LANTUS (1-888-852-6887).**

IMPORTANT INFORMATION FOR USE OF SoloSTAR

- To avoid transmission of disease do not share injection pens, cartridges, needles or syringes. This injection pen is for single patient use. Do not share it with anyone including other family members, even if the needle on the injection pen is changed. Do not use on multiple patients.
- Always attach a new needle before each use. Needles are available in different lengths and gauges. Only use needles that have been approved for use with SoloSTAR. Contact your health professional for further information.
- Do not select a dose and/or press the injection button without a needle attached.
- Always perform the safety test before each injection (see Step 3).
- 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 if it is damaged or if you are not sure that it is working properly.
- Always have a spare SoloSTAR in case your SoloSTAR is lost or damaged.

<u>Check the pen:</u>

Hold the pen as shown in this leaflet. To ensure that you read the dose correctly, hold the pen horizontally, with the needle on the left and the dosage selector to the right as shown in the illustrations below.



Step 1: Check the insulin

A. Check the label on your SoloSTAR to make sure you have the correct insulin. The Lantus SoloSTAR is grey with a lilac injection button. Check the expiry date printed on the label of your pen. Do NOT use your LANTUS SoloSTAR after the expiration date.

B. Take off the pen cap.

C. Check the appearance of your insulin. Lantus is a clear insulin. Do not use this SoloSTAR 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.

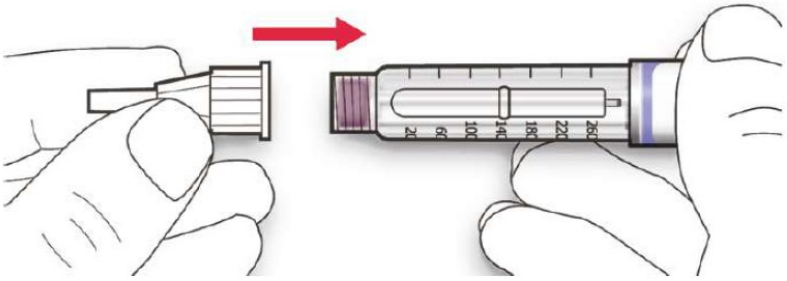
Before use of needle, carefully read "Instructions for Use" accompanying the needles.

Please note: The needles shown are for illustrative purposes only.

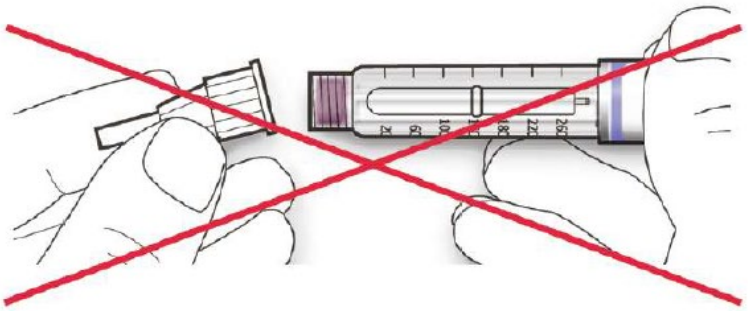
A. Wipe the rubber seal with alcohol.

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.

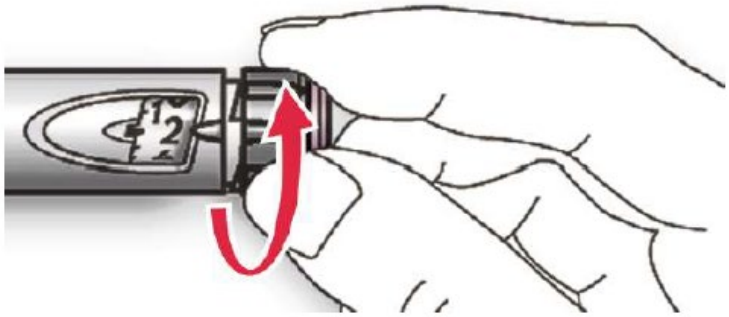


Step 3: Perform a safety test

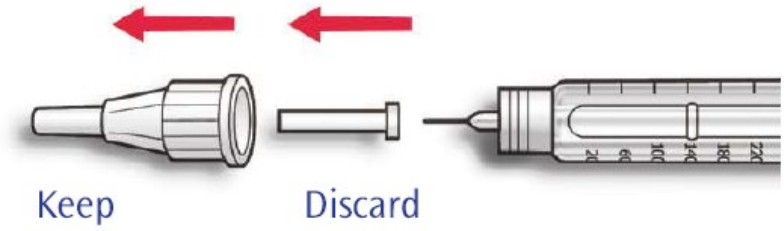
Always perform the safety test before each injection. This ensures that you get an accurate dose by:

- ensuring that pen and needle work properly
- removing air bubbles

A. Select a dose of 2 units by turning the dosage selector clockwise.



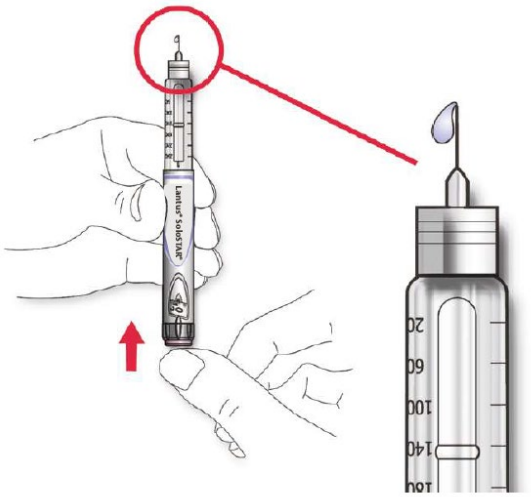
B. Take off the outer needle cap and keep it to remove the used needle after injection. Take off the inner needle cap and discard it.



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 may be damaged. Do not use this SoloSTAR.

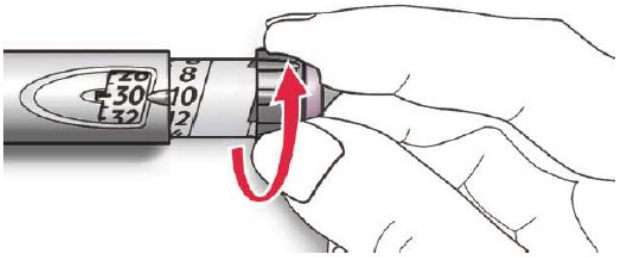
You must perform safety tests before you use the pen until you see insulin coming out of the needle tip. If you see insulin coming out of the needle tip, the pen is ready to use. If you do not see insulin coming out before taking your dose, you could get an underdose or no insulin at all. This could cause high blood sugar.

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 turning the dosage selector clockwise (in the example below, the selected dose is 30 units). If you turn past your dose, you can turn back down. (counter-clockwise).



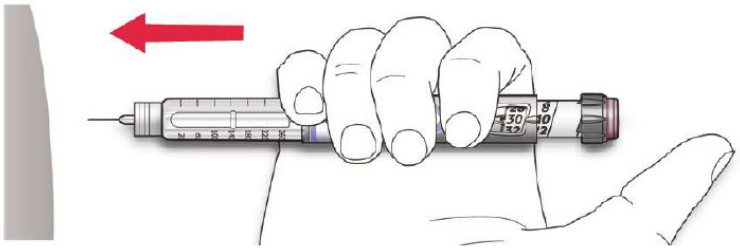
- Do not push the injection button while turning, as insulin will come out.
- You cannot turn the dosage selector past the number of units left in the pen. Do not force the dosage selector to turn. In this case, either you can inject what is remaining in the pen and complete your dose with a new SoloSTAR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

Step 5: Inject the dose

A. Clean the area of skin to be injected (e.g. with rubbing alcohol).

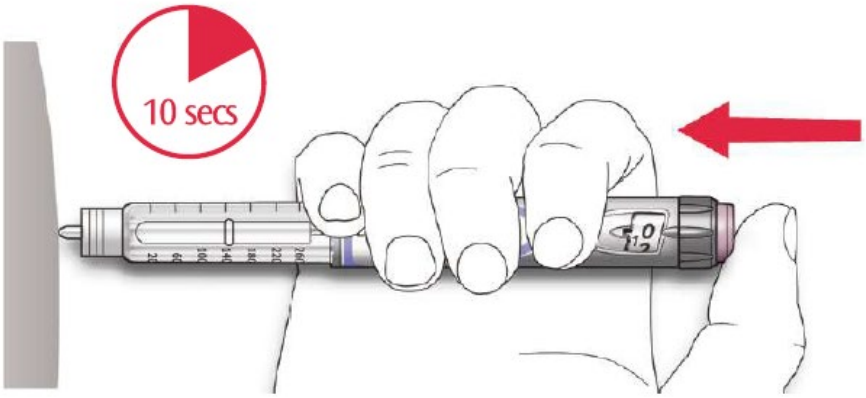
B. Use the injection method as instructed by your health professional.

C. Insert the needle into the skin.



D. Deliver the dose by pressing the injection button in all the way. The number in the dose window will progressively return to "0" as you inject.

E. 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.



The pen plunger moves with each dose. The plunger will reach the end of the cartridge when the total of 300 units of insulin has been used.

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.

- Grip the widest part of the outer needle cap. Keep the needle straight and guide it into the outer needle cap back and push firmly on. The needle can puncture the cap if it is recapped at an angle
- Grip and squeeze the widest part of the outer need cap. Turn your pen several times with your other hand to remove the needle. Try again if the needle does not come off the first time.

- 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 (e.g. contact your health professional) in order to reduce the risk of accidental needle injury and transmisison of infectious diseases.

B. Dispose of the needle safetly. Used needles should be placed in sharps containers (such as 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.

C. Always put the pen cap back on the pen, then store the pen until your next injection.

STORAGE INSTRUCTIONS

Keep SoloSTAR out of the reach and sight of children.

Keep your SoloSTAR in cool storage (2°C to 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.

If your SoloSTAR 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.

Once you take your SoloSTAR out of cool storage, for use or as a spare, you can use it for up to 28 days. During this time it should be kept at room temperature (15 to 30°C) and must not be stored in the refrigerator. If there is any remaining insulin after 28 days, discard it.

Do not use SoloSTAR after the expiration date printed on the label of the pen or if it is cloudy, colored or if you see particles.

Protect SoloSTAR from light.

Discard your used SoloSTAR as required by your local authorities.

MAINTENANCE

Protect your SoloSTAR from dust and dirt.

You can clean the outside of your SoloSTAR by wiping it with a damp cloth.

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

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

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

Importer/Distributor:
sanofi-aventis Canada Inc., Laval, Quebec, Canada H7V 0A3
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Call toll free **1-888-8LANTUS (1-888-852-6887)**