

Lantus® (insulin glargine injection) 100 Units/mL Fact Sheet

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What is Lantus (insulin glargine injection) 100 Units/mL?

Prescription Lantus is a long-acting insulin used to treat adults with type 2 diabetes and adults and pediatric patients (children 6 years and older) with type 1 diabetes for the control of high blood sugar.

Do not use Lantus to treat diabetic ketoacidosis.

Key Features of Lantus

- Lantus has been shown to lower A1C numbers as part of an overall diabetes treatment regimen, which includes diet, exercise, oral diabetes medications, and/or mealtime insulin.
- Lantus can be administered using the disposable prefilled Lantus SoloSTAR insulin pen or with a vial and syringe.
 Lantus SoloSTAR allows patients to set doses from 1 to 80 units, in one unit steps, dialed up and down, in one injection. Do not share needles, insulin pens or syringes with others. Do not reuse needles.
- Lantus works to help manage blood sugar control. The dosage of Lantus should be individualized and determined based on the physician's advice in accordance with the needs of the patient.
- Exercise or activity level may change the way the body uses insulin. Patients should check with their treating
 healthcare provider before making any changes to an exercise program since their dose may need to be changed.

Lantus received approval from the U.S. Food and Drug Administration (FDA) on April 21, 2000, and was granted marketing authorization by the European Commission on June 14, 2000.

Lantus SoloSTAR was approved by the U.S. Food and Drug Administration (FDA) on April 25, 2007.

Important Safety Information For Lantus (insulin glargine injection) 100 Units/mL

Do not take Lantus during episodes of low blood sugar or if you are allergic to insulin or any of the inactive ingredients in Lantus.

Do not share needles, insulin pens, or syringes with others. Do NOT reuse needles.

Before starting Lantus®, tell your doctor about all your medical conditions, including if you have liver or kidney problems, if you are pregnant or planning to become pregnant or if you are breast-feeding or planning to breast-feed.

Heart failure can occur if you are taking insulin together with certain medicines called TZDs (thiazolidinediones), even if you have never had heart failure or other heart problems. If you already have heart failure, it may get worse while you take TZDs with Lantus®. Your treatment with TZDs and Lantus® may need to be changed or stopped by your doctor if you have new or worsening heart failure. Tell your doctor if you have any new or worsening symptoms of heart failure, including:

- Shortness of breath
- Swelling of your ankles or feet

Sudden weight gain

Tell your doctor about all the medications you take, including OTC medicines, vitamins, and supplements, including herbal supplements.

Please see additional Important Safety Information for Lantus® on the following page and accompanying full prescribing information.

Please see full Prescribing Information for Lantus[®] on Lantus.com or click here http://products.sanofi.us/lantus/lantus.html.

IMPORTANT SAFETY INFORMATION FOR LANTUS® (insulin glargine injection) 100 Units/mL (continued)

Lantus should be taken once a day at the same time every day. Test your blood sugar levels while using insulin, such as Lantus. Do not make any changes to your dose or type of insulin without talking to your healthcare provider. Any change of insulin should be made cautiously and only under medical supervision.

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. Lantus must only be used if the solution is clear and colorless with no particles visible. Always make sure you have the correct insulin before each injection.

While using Lantus®, do not drive or operate heavy machinery until you know how Lantus® affects you. You should not drink alcohol or use other medicines that contain alcohol.

The most common side effect of insulin, including Lantus, is low blood sugar (hypoglycemia), which may be serious and life threatening. It may cause harm to your heart or brain. Symptoms of serious low blood sugar may include shaking, sweating, fast heartbeat, and blurred vision.

Lantus may cause serious side effects that can lead to death, such as severe allergic reactions. Get medical help right away if you have:

- A rash over your whole body
- Trouble breathing
- A fast heartbeat
- Sweating

- Swelling of your face, tongue, or throat
- Shortness of breath
- Extreme drowsiness, dizziness, or confusion

Other possible side effects may include swelling, weight gain, low potassium levels, injection site reactions, including changes in fat tissue at the injection site, and allergic reactions.

Lantus SoloSTAR is a disposable prefilled insulin pen. Please talk to your healthcare provider about proper injection technique and follow instructions in the Instruction Leaflet that accompanies the pen.

Please see full Prescribing Information for Lantus® on Lantus.com or click here http://products.sanofi.us/lantus/lantus.html.

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