

For noncritically ill hospitalized patients
with diabetes

Lantus[®] as part of a basal-prandial dosing regimen



A basal-prandial dosing option for nonintensive care inpatients with type 2 diabetes from the RABBIT 2 Study^{1,a}

<p>Calculate total daily dose based on BG and weight at the time of admission</p>	<p>Total daily dose</p> <ul style="list-style-type: none"> • For BG 140-200 mg/dL, use 0.4 Units/kg • For BG 201-400 mg/dL, use 0.5 Units/kg
<p>Divide the calculated dose into basal and prandial components</p>	<p>Dose administration</p> <ul style="list-style-type: none"> • Administer 50% of daily dose as basal insulin • Administer the other 50% as rapid-acting prandial insulin divided into 3 mealtime injections <div style="text-align: right; border: 1px solid black; padding: 5px; display: inline-block;"> <p>50 : 50 basal prandial</p> </div>
<p>Monitor BG, add supplemental rapid-acting insulin, and adjust doses as needed</p>	<p>Dose administration</p> <ul style="list-style-type: none"> • If fasting or mean BG during the day >140 mg/dL, increase basal insulin dose by 20% • If fasting and premeal BG >140 mg/dL, add supplemental rapid-acting insulin • If BG <70 mg/dL, reduce basal insulin dose by 20% • Hold prandial insulin doses in patients not eating

A basal-prandial regimen may not be appropriate for all inpatients with T2DM. Glucose levels must be monitored often to help minimize the risk of hypoglycemic events and help achieve the HCP-recommended glycemic control.^{2,3}

^a RABBIT 2, Randomized Study of Basal-Bolus Insulin Therapy in the Inpatient Management of Patients with Type 2 Diabetes.

Insulin therapy should be initiated for treatment of persistent hyperglycemia starting at a threshold ≥ 180 mg/dL. Once insulin therapy is started, a target glucose range of 140–180 mg/dL is recommended for the majority of critically ill and noncritically ill patients. More stringent goals, such as 140 mg/dL, may be appropriate for selected patients, as long as this can be achieved without significant hypoglycemia.

See study design on next page.

Lantus is a long-acting insulin analog indicated to improve glycemic control in adults and pediatric patients with type 1 diabetes mellitus and in adults with type 2 diabetes mellitus. Lantus should be administered once a day at the same time every day.

Limitations of Use: Lantus is not recommended for the treatment of diabetic ketoacidosis.

Important Safety Information for Lantus[®] (insulin glargine injection) 100 Units/mL

Contraindications

Lantus is contraindicated during episodes of hypoglycemia and in patients hypersensitive to insulin glargine or one of its excipients.

Please see additional Important Safety Information for Lantus[®] on the last page.

[Click here](#) for Full Prescribing Information for Lantus[®].

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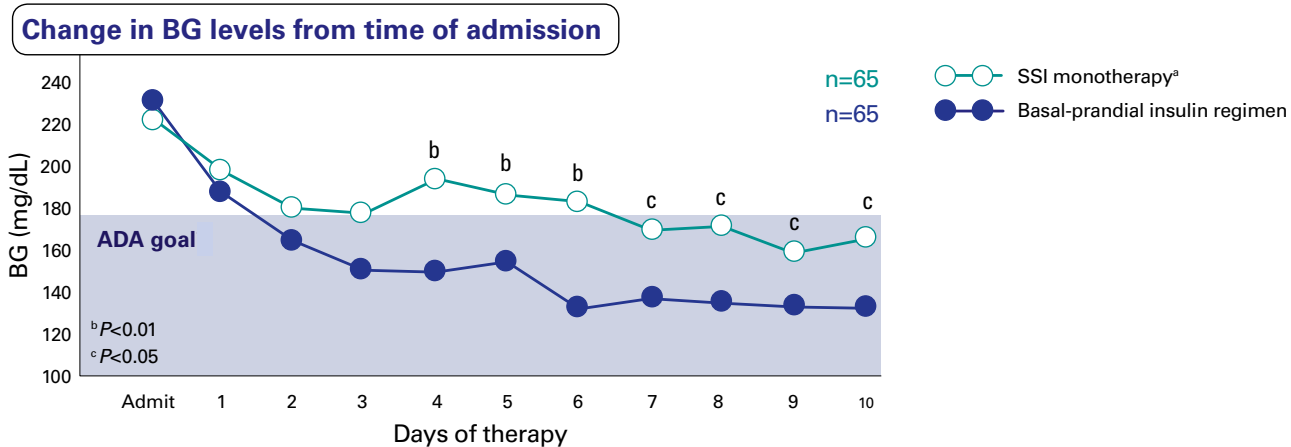
Lantus[®] as part of a basal-prandial dosing regimen



In noncritically ill hospitalized patients with type 2 diabetes¹

Consider a basal-prandial approach instead of SSI

In the RABBIT 2 study, a basal-prandial regimen significantly reduced BG vs SSI monotherapy.



^a Regular human insulin q6h without basal coverage.

A multicenter, prospective, open-label, randomized study (N=130) compared the efficacy of Lantus[®] + Apidra[®] with standard SSI monotherapy in insulin-naïve nonsurgical patients with type 2 diabetes aged 18 to 80 years (mean age was 56 years in both treatment groups). Glargine was dosed once daily and glulisine before meals at a starting dose of 0.4 Units/kg/day for BG 140-200 mg/dL or 0.5 Units/kg/day for BG 201-400 mg/dL. SSI was given 4 times per day for BG >140 mg/dL.¹

The mean daily dose of insulin glargine was 22 ±2 Units and the daily dose of insulin glulisine was 20 ±1 Units. The mean daily dose of regular insulin (SSI) was 12.5 ±2 Units/day, with approximately one-half of patients receiving <10 Units/day.¹

Important Safety Information for Lantus[®] (insulin glargine injection) 100 Units/mL

Warnings and Precautions

Insulin pens, needles, or syringes must never be shared between patients. Do NOT reuse needles.

Monitor blood glucose in all patients treated with insulin. Modify insulin regimen only under medical supervision. Changes in insulin regimen including, strength, manufacturer, type, injection site or method of administration may result in the need for a change in insulin dose or an adjustment in concomitant oral antidiabetic treatment.

Please see additional Important Safety Information for Lantus[®] on the last page.

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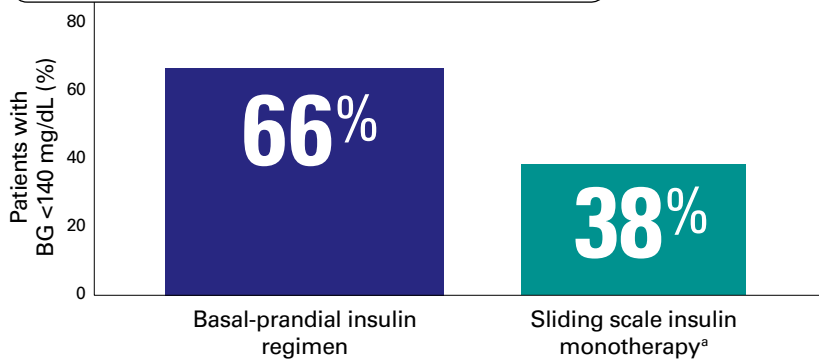
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In the RABBIT 2 study, more patients had a BG < 140 mg/dL with a basal-prandial insulin regimen¹

The percentages of patients that reached goal



- Primary endpoint: Difference in glycemic control as measured by mean daily BG

Rates of adverse events

	Basal-prandial group (n=65)	SSI group (n=65)
Number (%) of patients with BG remaining at ≥ 240 mg/dL despite increasing doses	0	9 (14)
Patients with hypoglycemia ^a	2 (3.1)	2 (3.1)
Patients with severe hypoglycemia ^b	0 (0)	0 (0)

- No episodes of hypoglycemia were associated with adverse outcomes in either group
- Of 1005 BG readings in the basal-prandial group, 4 (0.4%) indicated hypoglycemia, and of 1021 BG readings in the SSI group, 2 (0.2%) indicated hypoglycemia^d

^a Hypoglycemia defined as BG < 60 mg/dL.

^b Severe hypoglycemia defined as BG < 40 mg/dL.

^d Data were not available to determine significance.

One death was reported in the basal-prandial treatment group. The patient was admitted with shortness of breath and later developed respiratory failure secondary to a pulmonary embolism.

Important Safety Information for Lantus® (insulin glargine injection) 100 Units/mL Warnings and Precautions (cont'd)

Repeated insulin injections into areas of lipodystrophy or localized cutaneous amyloidosis may result in hyperglycemia; sudden change in the injection site (to unaffected area) has been reported to result in hypoglycemia. Advise patients to rotate injection site to unaffected areas and closely monitor for hypoglycemia.

Do not dilute or mix Lantus with any other insulin or solution. If mixed or diluted, the solution may become cloudy, and the onset of action/time to peak effect may be altered in an unpredictable manner. Do not administer Lantus via an insulin pump or intravenously because severe hypoglycemia can occur.

Hypoglycemia is the most common adverse reaction of insulin therapy, including Lantus, and may be life-threatening.

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

Contraindications

Lantus is contraindicated during episodes of hypoglycemia and in patients hypersensitive to insulin glargine or one of its excipients.

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Insulin pens, needles, or syringes must never be shared between patients. Do NOT reuse needles.

Monitor blood glucose in all patients treated with insulin. Modify insulin regimen only under medical supervision. Changes in insulin regimen including, strength, manufacturer, type, injection site or method of administration may result in the need for a change in insulin dose or an adjustment in concomitant oral antidiabetic treatment.

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Hypoglycemia is the most common adverse reaction of insulin therapy, including Lantus, and may be life-threatening.

Medication errors, such as accidental mix-ups between basal insulin products and other insulins, particularly rapid-acting insulins, have been reported. Patients should be instructed to always verify the insulin label before each injection.

Severe life-threatening, generalized allergy, including anaphylaxis, can occur. Discontinue Lantus, treat and monitor until symptoms resolve.

A reduction in the Lantus dose may be required in patients with renal or hepatic impairment.

As with all insulins, Lantus use can lead to life-threatening hypokalemia. Untreated hypokalemia may cause respiratory paralysis, ventricular arrhythmia, and death. Closely monitor potassium levels in patients at risk of hypokalemia and treat if indicated.

Fluid retention, which may lead to or exacerbate heart failure, can occur with concomitant use of thiazolidinediones (TZDs) with insulin. These patients should be observed for signs and symptoms of heart failure. If heart failure occurs, dosage reduction or discontinuation of TZD must be considered.

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Drug Interactions

Certain drugs may affect glucose metabolism, requiring insulin dose adjustment and close monitoring of blood glucose. The signs of hypoglycemia may be reduced in patients taking anti-adrenergic drugs (e.g., beta-blockers, clonidine, guanethidine, and reserpine).

Adverse Reactions

Adverse reactions commonly associated with Lantus include hypoglycemia, allergic reactions, injection site reactions, lipodystrophy, pruritus, rash, edema and weight gain.

Important Safety Information for Lantus[®] SoloSTAR[®]

Lantus SoloSTAR is a disposable single-patient-use prefilled insulin pen. To help ensure an accurate dose each time, patients should follow all steps in the Instruction Leaflet accompanying the pen: otherwise they may not get the correct amount of insulin, which may affect their blood glucose.

[Click here](#) for Full Prescribing Information for Lantus[®].

References: 1. Umpierrez GE, Smiley D, Zisman A, et al. *Diabetes Care*. 2007;30(9):2181-2186. 2. AACE/ACE. Diabetes Guidelines. *Endocr Pract*. 2015;21(Suppl 1):1-87. 3. Lantus[®] Prescribing Information.