

The Medical Letter[®]

on Drugs and Therapeutics

Volume 63

January 25, 2021

ISSUE No.
1616

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Volume 63 (Issue 1616)

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IN BRIEF

Semglee — A New Insulin Glargine for Diabetes

The FDA has approved *Semglee* (Mylan), an insulin glargine product similar to *Lantus*, for treatment of type 1 diabetes in children and adults and type 2 diabetes in adults. *Semglee* is the second “follow-on” insulin glargine product to become available in the US; *Basaglar*, which is also similar to *Lantus*, was the first.¹ *Lantus* is a recombinant analog of human insulin that forms microprecipitates in subcutaneous tissue, prolonging its duration of action to a mean of about 24 hours with no pronounced peak effect.²

Pronunciation Key

Semglee: seh-m glee'

REGULATORY STATUS — Even though *Basaglar* and *Semglee* are highly similar to *Lantus* in composition, strength, and biological properties, and they appear to produce similar clinical results, the three products are not considered interchangeable; pharmacists generally cannot substitute one product for the other without permission from the prescriber. For a biosimilar to be approved as an interchangeable product, the manufacturer must conduct clinical trials to prove that the results will be the same if the patient switches back and forth between the reference product and the biosimilar. In one trial, switching between *Semglee* and *Lantus* resulted in similar efficacy, but to date *Semglee* has not received interchangeability status from the FDA.³

CLINICAL STUDIES — FDA approval of *Semglee* was based on the results of one open-label trial in 558 patients with **type 1 diabetes** (INSTRIDE 1) and one in 560 patients with **type 2 diabetes** (INSTRIDE 2). Patients were randomized to receive once-daily treatment with *Semglee* or *Lantus* in addition to mealtime insulin lispro. In both trials, the mean decrease in A1C levels from baseline to 24 weeks, the primary endpoint, was similar with *Semglee* and *Lantus*.^{4,5}

Table 1. Insulin Glargine Products¹

Drug	Concentration	Some Formulations	Cost ²
<i>Lantus</i> (Sanofi)	100 units/mL	10 mL vials	\$283.60
		3 mL <i>SoloStar</i> ³	85.10
<i>Basaglar</i> ⁴ (Lilly)	100 units/mL	3 mL <i>KwikPen</i> ³	65.30
<i>Semglee</i> ⁴ (Mylan)	100 units/mL	10 mL vials	98.70
		3 mL prefilled pens ⁵	29.60

1. Insulin glargine is also available in a 300 unit/mL formulation (*Toujeo*).
2. Approximate WAC for one 10-mL vial or one disposable pen. WAC = wholesaler acquisition cost or manufacturer's published price to wholesalers; WAC represents a published catalogue or list price and may not represent an actual transactional price. Source: Analysource@Monthly. January 5, 2021. Reprinted with permission by First Databank, Inc. All rights reserved. ©2021. www.fdbhealth.com/policies/drug-pricing-policy.
3. Prefilled, disposable pens. Available in boxes containing 5 pens each.
4. “Follow-on” product highly similar to *Lantus*; *Basaglar* and *Semglee* are not interchangeable with *Lantus*.
5. Available in boxes containing 1, 3, or 5 pens each.

ADVERSE EFFECTS — All insulins can cause hypoglycemia and weight gain. Adverse effects of *Semglee* are similar to those observed with other insulin glargine products.

PREGNANCY AND LACTATION — Poorly controlled diabetes increases the risk of pre-eclampsia, spontaneous abortion, and preterm delivery.⁶ Administration of insulin glargine to pregnant animals has not been associated with fetal adverse developmental outcomes.

Insulin is a normal component of human breast milk and adequate glycemic control is needed for milk production. Women taking exogenous insulin, which passes into breast milk, can breastfeed.

DOSAGE AND ADMINISTRATION — *Semglee* should be injected subcutaneously once daily at the same time each day. Patients receiving *Lantus* or *Basaglar* can switch to *Semglee* at the same daily dosage.

CONCLUSION — *Semglee*, a “follow-on” version of the long-acting insulin analog insulin glargine, offers a lower-cost alternative to *Lantus*. Although similar in efficacy and safety to *Lantus*, to date it has not been approved by the FDA as an interchangeable product and cannot be substituted for *Lantus* without permission from the prescriber. ■

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