



## Semglee® (insulin glargine-yfgn) – First interchangeable biosimilar launch

- On November 16, 2021, [Viatris launched Semglee \(insulin glargine-yfgn\)](#) and [insulin glargine-yfgn](#), the first interchangeable biosimilars to Sanofi's [Lantus® \(insulin glargine\)](#).
  - Semglee is the branded interchangeable biosimilar and was approved on [July 28, 2021](#).
  - Insulin glargine-yfgn is the unbranded interchangeable biosimilar.
- Semglee, insulin glargine-yfgn, and Lantus share the same indication: to improve glycemic control in adults and pediatric patients with type 1 diabetes mellitus and in adults with type 2 diabetes mellitus.
- Semglee is the first biosimilar product that has been granted the interchangeability designation by the FDA.
  - An interchangeable biosimilar product may be substituted for the reference product by the pharmacist without the intervention of the prescriber.
  - The substitution can occur at the pharmacy, a practice commonly called “pharmacy-level substitution”— much like how generic drugs are substituted for brand name drugs, subject to state pharmacy laws, which vary by state.
  - Semglee will receive 12-months of exclusivity from the date of commercial launch before another interchangeable biosimilar of Lantus may be approved.
- Semglee and insulin glargine-yfgn are available as 100 mg/mL solution in 10 mL multiple-dose vials and 3 mL single-patient-use prefilled pens.
  - The currently marketed non-interchangeable Semglee (insulin glargine) is anticipated to be phased out by the end of the 2021 calendar year.



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