



Semglee® (insulin glargine-yfgn) – First new interchangeable biosimilar approval

- On July 28, 2021, the [FDA announced the approval](#) of [Viatris](#) and [Biocon Biologics' Semglee \(insulin glargine-yfgn\)](#), an interchangeable biosimilar to Sanofi's [Lantus® \(insulin glargine\)](#).
- Semglee 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 and Lantus are not recommended for treating diabetic ketoacidosis.
- Semglee is the first biosimilar product that has been granted interchangeability.
 - Semglee will receive 12-months of exclusivity from the date of commercial launch before another interchangeable biosimilar of Lantus may be approved.
 - 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.
- The approval of Semglee as biosimilar to, and interchangeable with Lantus, is based on evidence that showed the products are highly similar and that there are no clinically meaningful differences between Semglee and Lantus in terms of safety, purity and potency. It also showed that Semglee can be expected to produce the same clinical result as Lantus in any given patient and that the risks in terms of safety or diminished efficacy of switching between Semglee and Lantus is not greater than the risk of using Lantus without such switching.
 - The FDA has released additional [materials](#) for healthcare providers to enhance understanding of biosimilars and interchangeable products.
 - Refer to the [drug label](#) for additional dosing and administration recommendations.
- Per Viatris, [pricing](#) for the interchangeable biosimilar, Semglee, will be released at launch.
- Viatris plans to launch the interchangeable biosimilar Semglee before the end of the year. Semglee will be available as 100 mg/mL solution in a 10 mL multiple-dose vial and a 3 mL single-patient-use prefilled pen.
 - Semglee was launched as a new drug product in August of 2020. Over the next several months, Viatris will transition the old non-interchangeable Semglee to the newly approved interchangeable biosimilar form of Semglee, which will have different NDCs and pricing.



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