

Rezvoglar[™] (insulin glargine-aglr) – New interchangeable biosimilar approval

- On November 16, 2022, the <u>FDA approved</u> Eli Lilly's <u>Rezvoglar (insulin glargine-aglr)</u>, interchangeable biosimilar to Sanofi's Lantus[®] (insulin glargine).
 - Rezvoglar was previously FDA-approved as biosimilar to Lantus on December 17, 2021.
 - This is the second interchangeable biosimilar approval for Lantus. Viatris/Biocon Biologics' <u>Semglee[®] (insulin glargine-yfgn)</u> was approved on July 28, 2021 as the first interchangeable biosimilar to Lantus. Semglee launched on November 16, 2021.
- Rezvoglar, Semglee and Lantus share the same indication: to improve glycemic control in adult and pediatric patients with diabetes mellitus.
 - Rezvoglar, Semglee and Lantus are not recommended for treating diabetic ketoacidosis.
- 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.
- Eli Lilly's launch plans for Rezvoglar are pending. Rezvoglar will be available as a 100 mg/mL solution in a 3 mL single-use, prefilled pen (KwikPen®).



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