

Mylan/Viatris – Recall of insulin glargine (insulin glargine-yfgn)

- On April 12, 2022, <u>Mylan/Viatris announced</u> a consumer-level recall of one lot of <u>insulin glargine</u> (<u>insulin glargine-yfgn</u>) injection, 100 units/mL which is packaged in a 10 mL vial that is inside a carton due to the potential for the label to be missing on some vials. The product information, batch number and expiry date information are present on the carton.
- This recall does not pertain to the branded, interchangeable biosimilar, <u>Semglee[®] (insulinglargine-yfgn)</u> vial.
- The recalled lots were distributed in the U.S. between December 2021 and March 2022.

Product description	NDC #	Lot #/ Expiration date
Insulin Glargine (Insulin glargine-yfgn) Injection, 100 units/mL (U-100), 10 mL vial	49502-393-80	BF21002800 (8/2023)

- Insulin glargine-yfgn is indicated to improve glycemic control in adults and pediatric patients with type 1 diabetes mellitus and in adults with type 2 diabetes mellitus.
- For patients receiving treatment with more than one type of insulin (eg, both short and long-acting
 insulin), a missing label on insulin glargine-yfgn vials could lead to a mix-up of products/strengths,
 which may result in less optimal glycemic control (either high or low blood sugar) which could
 result in serious complications.
- To date, Mylan/Viatris has not received reports of any adverse events or identifiable safety concerns attributed to the product consumed from this lot.
- Patients who have the recalled insulin glargine-yfgn should contact their physician or health care
 provider if they have experienced any problems that may be related to using the recalled insulin
 glargine-yfgn.
- Anyone with an existing inventory of the recalled product should stop distribution and quarantine the product immediately.
- Contact Viatris Customer Relations by phone at 1-800-796-9526 or by email at customer.service@viatris.com for more information about the recall. Contact Stericycle at 1-888-912-7084 for return information.



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