Insulin Glargine (Insulin glargine-yfgn) Injection Recall Alert

Date of Notice: April 12, 2022

Brief Description of Recall Alert

Mylan Pharmaceuticals Inc., a Viatris company, is voluntarily recalling one batch of its insulin glargine (insulin glargine-yfgn) injection, 100 units/mL (U-100), which is packaged in a 10 mL vial that is inside a carton. This product is not the branded Semglee vial, but the unbranded insulin glargine-yfgn vial. This batch is being recalled 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.

For patients receiving treatment with more than one type of insulin (e.g., both short and long-acting insulin), a missing label on insulin glargine 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, no adverse events related to this recall have been received for this product.

Affected Products

Drug Name & Strength	NDC	Batch No.	Expiration Date
Insulin Glargine (insulin glargine-yfgn) Injection, 100 units/mL (U-100), 10 mL vial	49502-393-80	BF21002800	August 2023

Prescriber Information

Viatris has initiated the recall and notified its distributors and retailers by letter and is arranging for return of all recalled products. Following are actions for wholesalers, retailers, and consumers:

- Wholesaler: Immediately examine your inventory, quarantine, and discontinue distribution of the batch subject to recall. In addition, if you have further distributed the product, please identify all customers, including retail level customers, and provide a list of customers (via Microsoft excel file) to mylan5889@sedgwick.com within five (5) business days. Sedgwick (Stericycle) will notify your retail level customers that received the affected batch.
- Retailer: Immediately examine your inventory, quarantine, and discontinue distribution of this batch.
- Consumer: If you have an unlabeled product, please contact Stericycle at 1-888-912-7084 for the documentation packet to return product to Stericycle.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report Online
- Regular Mail or Fax: Download form or call 1- 800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

Member Information

Members should contact their doctor or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

Members with medical-related questions, who wish to report an adverse event or quality issues about the product being recalled, should contact Viatris Customer Relations by 1-800-796-9526 or customer.service@viatris.com, Monday through Friday from 8 a.m. – 5 p.m. EST.

RxAdvance Response

Members should continue taking insulin glargine (insulin glargine-yfgn) injection until a doctor or pharmacist provides replacement drug (if needed) or a different treatment option is given. RxAdvance is in the process of contacting members and prescribers to advise them of this recall.