Semglee® (insulin glargine injection) Recall Alert

Date of Notice: January 19, 2022

Brief Description of Recall Alert

Mylan Pharmaceuticals Inc. is voluntarily recalling one (1) batch of its non-interchangeable Semglee® (insulin glargine injection), 100 units/ml (U-100), 3mL prefilled pens, which are packaged in a labeled carton of five (5) pens.* The product is being recalled due to the potential for the label to be missing on some prefilled pens within a labeled carton for this batch. This batch was manufactured by Biocon SDN Bhd. and distributed by Mylan Specialty L.P. in the U.S. between May 11, 2021 and November 11, 2021.

A missing label on Semglee® (insulin glargine) prefilled pens, for patients receiving treatment with more than one type of insulin (e.g., both short and long-acting insulin), could lead to a mix-up of products/ strengths, resulting in the administration of the wrong insulin. Administration of the wrong insulin could result in less optimal glycemic control (either high or low blood sugar) which could result in serious complications.

**This recall does not pertain to the recently launched interchangeable biosimilars, Semglee® (insulin glargine-yfgn) injection, a branded product, or Insulin Glargine (insulin glargine-yfgn) injection, an unbranded product.*

Affected Products

Drug Name & Strength	NDC	Batch #	Expiration Date
Semglee® (insulin glargine injection), 100 units/mL (U-100), 3mL prefilled pen	49502-196-75	BF20003118	August 2022

Prescriber Information

The company has initiated this 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 prescribers:

- Wholesalers: Immediately examine your inventory, quarantine, and discontinue distribution of this lot. In addition, if you have further distributed the product, please identify your retail level customers and provide a list of customers via Microsoft excel file to mylan6069@sedgwick.com within ten (10) business days. Stericycle will notify your retail level customers that received the affected batch.
- Retailers: Immediately examine your inventory, quarantine, and discontinue distribution of this batch.
- Prescribers: If your patient has an unlabeled product, please contact Stericycle at 1-888-843-0255 for the documentation packet to return product to Stericycle.

To date, the company has not received any reports of adverse events related to this recall. 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 800-796-9526 or customer.service@viatris.com , Monday - Friday from 8 am – 5 pm EST.

RxAdvance Response

Members should continue taking Semglee® (insulin glargine 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.