MC-Rx
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Important Drug Recall Notice

TO ALL PARTICIPATING PHARMACIES

Circular Letter MC22-013-CG
January 20, 2022

FDA announced that, Mylan Pharmaceuticals Inc., a Viatris company, is voluntarily recalling one batch of its non-interchangeable Semglee® (insulin glargine injection), 100 units/ml (U-100), 3mL prefilled pens, which are packaged in a labelled 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 labelled carton for this particular batch. **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.**

RECOMMENDATIONS

1. **Wholesaler:** 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 10 business days. Stericycle will notify your retail level customers that received the affected batch.
2. **Retailer:** Immediately examine your inventory, quarantine, and discontinue distribution of this batch.
3. **Consumer:** If you have an unlabeled product, please contact Stericycle at 1-888-843-0255 for the documentation packet to return product to Stericycle.
4. Consumers with questions regarding this recall can contact Viatris Customer Relations by 800-796-9526 or customer.service@viatris.com, Monday through Friday from 8 a.m. – 5 p.m. EST. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.
5. Review your inventory to identify existence of recalled products.
6. Expect patients to visit your pharmacy to deliver recalled products and prepare your pharmacy staff on how to handle the situation.

MC-Rx Pharmacy Services Department

Mylan Pharmaceuticals Inc., a Viatris Company, Conducting Voluntary Recall of One Batch of Semglee® (insulin glargine injection), 100 units/mL (U-100), 3 mL Prefilled Pens, Due to the Potential for a Missing Label in the Batch

Summary

Company Announcement Date:	January 18, 2022
FDA Publish Date:	January 19, 2022
Product Type:	Drugs
Reason for Announcement:	Missing Label
Company Name:	Mylan Pharmaceutical Inc.
Brand Name:	Semglee
Product Description:	Insulin glargine injection), 100 units/ml (U-100), 3mL prefilled pens

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Company Announcement

PITTSBURGH – Jan. 18, 2022 – Mylan Pharmaceuticals Inc., a Viatris company, is voluntarily recalling one batch of its non-interchangeable Semglee® (insulin glargine injection), 100 units/ml (U-100), 3mL prefilled pens, which are packaged in a labelled 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 labelled carton for this particular 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. The recalled lot is as follows:

NDC #	Name and Strength	Size	Batch#	Expiry
49502-196-75	Semglee® (insulin glargine injection), 100 units/mL (U-100)	3mL Prefilled Pen	BF20003118	August 2022

Risk Statement: 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 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. To date, the company has not received any reports of adverse events related to this recall.

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.

The product is a long-acting human insulin analog indicated to improve glycemic control in adults and pediatric patients with type 1 diabetes mellitus and in adults with type 2 diabetes mellitus and is packaged in prefilled pens in cartons of five (5) pens. The recalled product can be identified by prefilled pens missing a white label with the product name and dosage information affixed around the pen.

The company has initiated the recall of batch BF20003118 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 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 10 business days. 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 1-888-843-0255 for the documentation packet to return product to Stericycle.

Consumers with questions regarding this recall can contact Viatris Customer Relations by 800-796-9526 or customer.service@viatris.com, Monday through Friday from 8 a.m. – 5 p.m. EST. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

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