Important Drug Recall Notice

TO ALL PARTICIPATING PHARMACIES

Circular Letter MC22-064-CG
July 7, 2022

The FDA announced that, Mylan Pharmaceuticals Inc., a Viatris company, is voluntarily recalling one batch of Insulin Glargine (Insulin glargine-yfgn) Injection, 100 units/mL (U-100), 3 mL prefilled pens which are packaged in cartons of five pens to the consumer level. This product is not the branded Semglee® pen but the unbranded Insulin Glargine-yfgn pens. This batch is being recalled due to the potential for the label to be missing on some pens.

RECOMMENDATIONS

1. Retailers: Immediately examine your inventory, quarantine and discontinue distribution of this batch. In addition, if you have further distributed the subject batch, please identify the consumer and notify them of this product recall and to immediately return any unlabeled product per the instructions below.

2. Consumers: If you have an unlabeled pen, please contact Sedgwick at 1-877-643-8438 for the documentation packet to return the product.

3. Consumers with questions regarding this recall can contact Viatris Customer Relations by phone at 1-800-796-9526 or by email at 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.

4. Review your inventory to identify existence of recalled products.

5. 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

T. (800) 377-1037
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Call Box 4908, Caguas, P.R. 00726
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Mylan Pharmaceuticals Inc., a Viatris Company, Issues Voluntary Nationwide Recall of One Batch of Insulin Glargine (Insulin glargine-yfgn) Injection Pens, 100 units/mL (U-100), Due to the Potential of Missing Labels on Some Pens

Summary:

Company Announcement Date:	July 05, 2022
FDA Publish Date:	July 06, 2022
Product Type:	Drugs
Reason for Announcement:	Potential for the label to be missing on some pens.
Company Name:	Mylan Pharmaceuticals Inc.
Brand Name:	Mylan Pharmaceuticals Inc.
Product Description:	Insulin Glargine (Insulin glargine-yfgn) Injection Pens

Company Announcement

FOR IMMEDIATE RELEASE - PITTSBURGH – July 5, 2022 – Mylan Pharmaceuticals Inc., a Viatris company, is voluntarily recalling one batch of Insulin Glargine (Insulin glargine-yfgn) Injection, 100 units/mL (U-100), 3 mL prefilled pens which are packaged in cartons of five pens to the consumer level. This product is not the branded Semglee® pen but the unbranded Insulin Glargine-yfgn pens. This batch is being recalled due to the potential for the label to be missing on some pens.

Risk Statement: 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 pens 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.

This recall pertains **only** to the unbranded interchangeable biosimilar Insulin Glargine-yfgn pens and does not impact the branded interchangeable biosimilar Semglee® (insulin glargine-yfgn) injection pens.

This 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. The product is packaged in a 3 mL prefilled pen which is then packaged in cartons of five pens. The product information, batch number and expiry date information are present on the carton.

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This batch was manufactured by Biocon Sdn. Bhd. and was distributed by Mylan Specialty L.P. in the US between April 4, 2022 and May 5, 2022. The recalled batch information is as follows:

NDC #	Name and Strength	Size	Batch #	Expiry
49502-394-75	Insulin Glargine (Insulin glargine-yfgn) Injection, 100 units/mL (U-100)	3 mL Prefilled Pen	BF21002895	Aug 2023

The company has initiated the recall of batch BF21002895 by notifying its distributors and retailers by letter and arranging for return of all recalled products. Following are actions for wholesalers, retailers and consumers:

- **Wholesalers:** 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 via Microsoft Excel file to mylan8775@sedgwick.com within five (5) business days. Sedgwick will notify your retail level customers that received the affected batch.

- **Retailers:** Immediately examine your inventory, quarantine and discontinue distribution of this batch. In addition, if you have further distributed the subject batch, please identify the consumer and notify them of this product recall and to immediately return any unlabeled product per the instructions below.

- **Consumers:** If you have an unlabeled pen, please contact Sedgwick at 1-877-643-8438 for the documentation packet to return the product.

Consumers with questions regarding this recall can contact Viatris Customer Relations by phone at 1-800-796-9526 or by email at 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:** www.fda.gov/medwatch/report.htm

- **Regular Mail or Fax:** Download form www.fda.gov/MedWatch/getforms.htm 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

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