COMMUNICATION

COM-2022-022

18 APRIL 2022

URGENT PLEASE REVIEW

Recall Notification

PharmPix Clinical Department

PharmPix is committed to the health and wellness of our members.

The clinical team wants to communicate you with the latest up-to-date drug recall information.

U.S. Food & Drug Administration Publication Date:

04/12/2022

Drug Information:

National Drug Code

49502-0393-80

Product Description

Insulin Glargine (insulin glargine-yfgn) injection, 100 units/mL (U-100)

Batch Number

BF21002800

Expiration Date

August 2023

QUESTIONS

Call Viatris Customer Relations at 1.800.796.9526 Monday – Friday from 8:00 a.m. to 5:00 p.m. ET.

Email Viatris Customer Relations at customer.service@viatris.com.

Insulin Glargine

It is for this reason that we are notifying you that on 04/12/2022 the US Food and Drug Administration published a drug recall for the following product(s): Insulin Glargine (insulin glargine-yfgn) injection.

Pharmacy Required Action:

Identify if the product is in inventory and immediately stop using and dispensing it. The product should be returned to the place of purchase or as directed in the recall notification.

Advise patients that if they have an unlabeled product, they should contact Stericycle at 1-888-912-7084 for the documentation packet to return product to Stericycle.

Reason for Recall:

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 10mL vial that is inside a carton. The batch is being recalled due to the potential for the label to be missing on some vials. This batch was manufactured by Biocon Sdn. Bhd. and was distributed by Mylan Specialty L.P. in the US between December 9, 2021, and March 4, 2022. Of note, this recall does not pertain to the branded interchangeable biosimilar, Semglee™ (insulin glargine-yfgn) injection but to the unbranded interchangeable biosimilar Insulin Glargine-yfgn vial.

For patients receiving treatment with more than one type of 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 which could result in serious complications. To date, no adverse events related to this recall have been received for this product.

Remember you can report adverse events related to this or any other drug product at MedWatch: The FDA Safety Information and Adverse Event Reporting Program by any of the following ways:

Complete and submit the MedWatch Online Voluntary Reporting Form online.

Download FDA Form 3500 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.

Additional information can be found at: MedWatch: The FDA Safety Information and Adverse Event Reporting Program.

If you have any questions or wish to have more information regarding this document, you can call us at 787-522-5252- Clinical Department. Our pharmacists will help you.

In addition, know that you can access our recent communications at our providers' portal: https://www.pharmpix.com/providers/.

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Pharmacy Benefit Management
Expires 12/01/2022

REFERENCES:
1. U.S. Food and Drug Administration. (2022). Mylan Pharmaceuticals Inc., a Viatris Company, Conducting Voluntary Nationwide Recall of One Batch of Insulin Glargine Injection, 100 units/mL (U-100), Due to the Potential for a Missing Label in the Batch. https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/mylan-pharmaceuticals-inc-viatris-company-conducting-voluntary-nationwide-recall-one-batch-insulin
2. MedWatch: The FDA Safety Information and Adverse Event Reporting Program- Available at: https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda

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