COMMUNICATION

COM-2022-040

08
JULY
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:

07/06/2022

Drug Information:

National Drug Code

49502-0394-75

Product Description

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

Batch Number

BF21002895

Expiration Date

August 2023

Company:

Mylan Pharmaceuticals Inc., a Viatris Company

QUESTIONS

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

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

Insulin Glargine (insulin glargine-yfgn)

It is for this reason that we are notifying you that on 07.06.2022 the US Food and Drug Administration published a drug recall for the following product(s): Insulin Glargine (insulin glargine-yfgn) injection 100 units/mL (U-100), 3mL prefilled pens.

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 they should not discontinue using the medication without contacting their healthcare provider. Patients experiencing any problem while taking or using this product must contact their physician.

Reason for Recall:

Mylan Pharmaceuticals Inc., a Viatris company, is voluntarily recalling one batch of Insulin Glargine (insulin glargine-yfgn) injection, 100 units/mL, 3 mL prefilled pens which are packaged in cartons of five pens to the consumer level. The batch is being recalled due to the potential for the label to be missing on some pens. This recall is only for the unbranded interchangeable biosimilar Insulin Glargine-yfgn pens and does not impact the branded interchangeable biosimilar Semglee™.

A missing label on the Insulin Glargine pens could lead to a mix-up of products/strengths, which may result in less optimal glycemic control and higher risk of 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/.

pharmpix
POWERED BY ONEARK

urac
ACCREDITED
Pharmacy Benefit Management
Expires 12/01/2022

REFERENCES:
1. U.S. Food and Drug Administration. (2022). Viona Mylan Pharmaceuticals Inc., a Viatric 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. https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/mylan-pharmaceuticals-inc-viatris-company-issues-voluntary-nationwide-recall-one-batch-insulin
2. MedWatch: The FDA Safety Information and Adverse Event Reporting Program. https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda

2 Street 1, Suite 500
Guaynabo, PR 00968
Tel. 787.522.5252
Fax 866.912.2830
www.pharmpix.com
FRM-CL-000126-000

CLINICAL PEARLS
BY PHARMPIX