COMMUNICATION

COM-2022-059

01
NOVEMBER
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 the latest up-to-date drug recall information.

U.S. Food & Drug Administration Publication Date:

10/25/2022

Drug Information:

National Drug Code

67457-246-00 (Syringe)

67457-246-01 (Carton)

Product Description

OCTREOTIDE ACETATE INJECTION 500MCG/ML

Lot Number

AJ21002

Expiration Date

MARCH 2024

Company:

MYLAN INSTITUTIONAL LLC, A VIATRIS COMPANY

CONTACT INFORMATION
RETURN OF RECALLED DRUG

Sedgwick

Event #8281

2670 Executive Drive, Suite A

Indianapolis, IN 46241

QUESTIONS

Call SEDGWICK at 888.266.7974.

Octreotide Acetate Injection

It is for this reason that we are notifying you that on 10.25.2022 the US Food and Drug Administration published a drug recall for the following product(s): Octreotide acetate injection 500mcg/mL.

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 Institutional LLC, a Viatris Company, is voluntarily recalling lot AJ21002 of octreotide acetate injection 500mcg/mL packaged in a carton of ten 1mL syringes. The recall is at the user level (hospitals/pharmacies) due to a product complaint of the presence of glass particles in a syringe.

Intravenous administration of a solution containing glass particles may cause serious adverse events including, but not limited to, local irritation, swelling, vasculitis/phlebitis, antigenic or allergic reactions, and microvascular obstruction. The probability of exposure is low. To date, no reports of adverse reactions associated with this lot have been received.

The lot was manufactured by Italfarmaco SpA, Italy and was distributed by Mylan Institutional LLC in the United States between 1/11/2022 and 6/21/2022. The company has initiated the recall of the lot and has notified its distributors by letter/phone and has arranged for return of all recalled products.

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 Drug Recall Communication Number COM-2022-059 November 2022

pharmpix
POWERED BY ONEARK

urac
ACCREDITED
Pharmacy Benefit Management
Expires 12/01/2022

REFERENCES:

1. U.S. Food and Drug Administration. (2022). Mylan Institutional LLC, a Viatris Company, Issues a Voluntary Recall of One Lot of Octreotide Acetate Injection, 500 mcg/mL, Due to Glass Particulates in a Syringe. https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/mylan-institutional-llc-viatris-company-issues-voluntary-recall-one-lot-octreotide-acetate-injection
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