Important Drug Recall Notice

TO ALL PARTICIPATING PHARMACIES

Circular Letter MC22-084-CG
October 27, 2022

FDA announced that, Mylan Institutional LLC, a Viatris company, is voluntarily recalling lot AJ21002, exp 3/2024, of Octreotide Acetate Injection, 500 mcg/mL, packaged in a carton of ten 1mL syringes. This lot is being recalled at the user (hospital/pharmacy) level due to a product complaint of the presence of glass particles in a syringe.

RECOMMENDATIONS

1. **Wholesalers:** 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 mylan8281@sedgwick.com within 5 business days. Sedgwick will notify your retail level customers that received the affected batches.

2. **Retailers/Users (Hospitals/Pharmacies):** Immediately examine your inventory, quarantine and discontinue distribution of this lot.

3. **Wholesalers and retailers (hospitals/pharmacies)** please proceed to items listed below:

   - Immediately examine your inventory, quarantine, and discontinue distribution of this lot.
   - Carry out a physical count and record this data on the Business Reply Card and Packing Slip which are included.
   - Mail the postage paid Business Reply Card to the address provided.
   - Return the recalled product with the Packing Slip using the prepaid UPS Return Service shipping labels to:
     - Sedgwick Event # 8281 2670 Executive Drive, Suite A Indianapolis, IN 46241 (888) 266-7974

4. 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
1267 Professional Pkwy, Gainesville, GA 30507
T. (787) 286-6032
Call Box 4908, Caguas, P.R. 00726
MC-Rx.com

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

Summary:

Company Announcement Date:	October 25, 2022
FDA Publish Date:	October 25, 2022
Product Type:	Drugs
Reason for Announcement:	Due to glass particulates
Company Name:	Mylan Institutional LLC, a Viatris company
Brand Name:	Mylan Institutional LLC
Product Description:	Octreotide Acetate Injection, 500 mcg/mL

Company Announcement

FOR IMMEDIATE RELEASE – PITTSBURGH, October 25, 2022- Mylan Institutional LLC, a Viatris company, is voluntarily recalling lot AJ21002, exp 3/2024, of Octreotide Acetate Injection, 500 mcg/mL, packaged in a carton of ten 1mL syringes. This lot is being recalled at the user (hospital/pharmacy) level due to a product complaint of the presence of glass particles in a syringe. This lot was manufactured by Italfarmaco SpA, Italy and was distributed by Mylan Institutional LLC in the US between January 11 and June 21, 2022. The recalled lot is as follows:

NDC #	Name and Strength	Size	Lot#	Expiry
67457-246-00 (Syringe) 67457-246-01 (Carton)	Octreotide Acetate Injection 500 mcg/mL	10 X 1 mL Single dose unit-of-use Syringe	AJ21002	March 2024

Risk Statement: Intravenous administration of a solution containing particulate matter, such as a glass, could lead to events including, but not limited to, local irritation or swelling, vasculitis/phlebitis, antigenic or allergic reactions, and microvascular obstruction, including pulmonary embolism. Although the intravenous administration of a solution containing particulate matter may pose potential risk of serious adverse events, the probability of exposure from this incident and subsequent risk is low. To date, no reports of adverse reactions associated with this lot have been received.

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Octreotide Acetate Injection is indicated to reduce blood levels of growth hormone (GH) and insulin growth factor-1 (IGF-1; somatomedin C) in acromegaly patients who have had inadequate response to or cannot be treated with surgical resection, pituitary irradiation, and bromocriptine mesylate at maximally tolerated doses. It is also indicated for the symptomatic treatment of patients with metastatic carcinoid tumors where it suppresses or inhibits the severe diarrhea and flushing episodes associated with the disease and for the treatment of the profuse watery diarrhea associated with vasoactive intestinal peptide (VIP)-secreting tumors.

Action: The Company has initiated the recall of lot AJ21002 and notified its distributors by letter/phone and is arranging for return of all recalled products. Following are actions for wholesalers and retailers/users (hospitals/pharmacies):

- **Wholesalers:** 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 mylan8281@sedgwick.com within 5 business days. Sedgwick will notify your retail level customers that received the affected batches.

- **Retailers/Users (Hospitals/Pharmacies):** Immediately examine your inventory, quarantine and discontinue distribution of this lot.

Wholesalers and retailers (hospitals/pharmacies) please proceed to items listed below:

- Immediately examine your inventory, quarantine, and discontinue distribution of this lot.
- Carry out a physical count and record this data on the Business Reply Card and Packing Slip which are included.
- Mail the postage paid Business Reply Card to the address provided.
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FDA U.S. FOOD & DRUG ADMINISTRATION

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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