Teva Pharmaceuticals USA, Inc.

URGENT DRUG RECALL
Octreotide Acetate Injectable Suspension 30 mg/vial
April 24, 2026

Octreotide Acetate Injection 30 mg/vial						
NDC Kit Carton	Diluent Label	Vial Label	Tray Label	Lot #	Exp. Date	Size
0480-9262-08	0480-9263-21	0480-9260-01	0480-9262-08	4501102	03/2027	1 kit

Dear Valued Customer:

Teva Pharmaceuticals USA, Inc. (Teva USA) is initiating a voluntary nationwide recall of *the above one (1) lot* of **Octreotide Acetate Injectable Suspension, 30 mg/day** to the **RETAIL LEVEL.** The product in this recall is distributed under the Teva Pharmaceuticals Inc. label. The reason for the recall is due to quality system deficiencies identified during a routine U.S Food and Drug Administration (FDA) inspection of the Pharmathen International SA Sapes facility which manufactures Octreotide for Teva. Observations by FDA included deficiencies implicating microbiological contamination, contamination with foreign matter or particles, potential out of specification due to poor laboratory controls, and data integrity.

Teva's health hazard assessment concluded that the likelihood of harm is remote/unlikely and the overall risk of harm in the patient population is considered to be medium.

This recall is being made with the knowledge of the U.S. Food and Drug Administration.

Please take the following actions upon receipt of this letter:

- Immediately examine your inventory for the one (1) lot Octreotide Acetate Injectable Suspension 30 mg/vial listed above.
- Immediately discontinue distribution of and quarantine the one (1) lot Octreotide Acetate Injectable Suspension 30 mg/vial listed above.
- TEVA's records indicate that the recalled lots were commercially distributed/shipped to its direct customers from 12/15/2025 through 02/02/2026.
- **If you have further distributed the one (1) lot of Octreotide Acetate Injectable Suspension 30 mg/vial listed above, please perform a SUB-RECALL to your sub-accounts using this Recall Notification and Business Reply Form (BRF) as a basis for your recall notification.**

Promptly complete the attached Recall BRF, even if you have no product to return, and return the completed Recall BRF in its entirety to Inmar, Attention: Recall Coordinator, by any one of these means:

MAIL: Inmar, One West Fourth Street, Suite 500, Winston Salem, NC 27101
EMAIL: **rxrecalls@inmar.com**.
FAX: 817-868-5362

Please note: the Recall BRF must be filled out. If the Recall BRF form is not filled out correctly and, in its entirety, no credit will be issued.

After receipt of your Recall BRF, Inmar will send labels for your Return Goods Authorization (RGA) and shipping of your product return. Products returned that are not the subject of the recall will not be credited and will be destroyed.

CONTACT INFORMATION AND CREDIT
Product Returns: Contact Inmar at 877-213-3870 (Hours of Operation: M – F, 9.00 am to 5.00 pm Eastern Time) for Recall Stock Response forms or acquire from: clsnetlink.com
Medical-related Questions or to report an Adverse Event: Contact Teva Medical Information at: 888-838-2872, option 3, then option 4 Live calls received: M - F, 9:00 AM - 5:00 PM Eastern Time; Voicemail: 24 hrs./day, 7 days/week or by email at druginfo@tevapharm.com
Product Quality Complaint-related Questions: Contact Teva Quality Assurance Services: 888-838-2872, option 4 Live calls received: M - F, 9:00 AM - 5:00 PM Eastern Time; Voicemail: 24 hrs./day, 7 days/week or by email at QAS.QAS@tevapharm.com
Customer Service-related Questions: Contact Teva Customer Service: 888-838-2872, option 3, then option 2 Live calls received: M - F, 8:30 AM - 5:00 PM Eastern Time; Voicemail: 24 hrs./day, 7 days/week

FDA contact information for reporting adverse events/quality complaints:
Online at www.fda.gov/medwatch/report.htm or call FDA at 1-800-FDA-1088

Sincerely,

Regulatory Compliance, Teva Pharmaceuticals USA, Inc.

Teva Pharmaceuticals USA, Inc.

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30 mg/vial
April 24, 2026

RECALL BUSINESS REPLY FORM

Date Form Completed _____

This form must be filled out completely. If this form is not filled out correctly and, in its entirety, no credit will be issued. Promptly return your completed Business Reply Form (BRF) by any one of these means to Inmar, Attn: Recall Coordinator

MAIL: Inmar, 1 W 4th St., Winston Salem, NC 27101 EMAIL: rxrecalls@inmar.com FAX: 817-868-5362

Section 1 – Customer Information

This Stock Response is for (Check One):

☐ **Teva Direct Account** ☐ **Non-Direct Customer**

Customer/Store Name:	Address (Street/City/State/Zip):
*DEA #: ***DEA # is required in order to process your form.***	*Debit Memo #: ***Debit Memo # is required in order to process your form.***
Contact Name (please print):	Telephone #:

Please mark your answer - I have checked my stock and:

☐ I ***do*** have stock of the recalled item(s) **(complete section 2)** **OR** ☐ I **do not** have stock of the recalled item(s).

Teva Direct Accounts

Does your response include **all** your DC locations? ☐ YES ☐ NO

Did you communicate the recalls to your direct accounts ☐ YES ☐ NO

Non-Direct Customer

The product(s) in this recall were purchased from: _____

Name of Your Wholesaler/Distributor and Location

Section 2 – Quantity of Product to Return

Enter the information of the recalled product(s) to be returned in the table below. If additional space is needed, please make copies of this form.

NDC Kit Carton	Diluent Label	Vial Label	Tray Label	Lot #	Expiry	Size	# of Cartons to Return *(Count Partials as 1)*
0480-9262-08	0480-9263-21	0480-9260-01	0480-9262-08	4501102	3/2027	1 kit	

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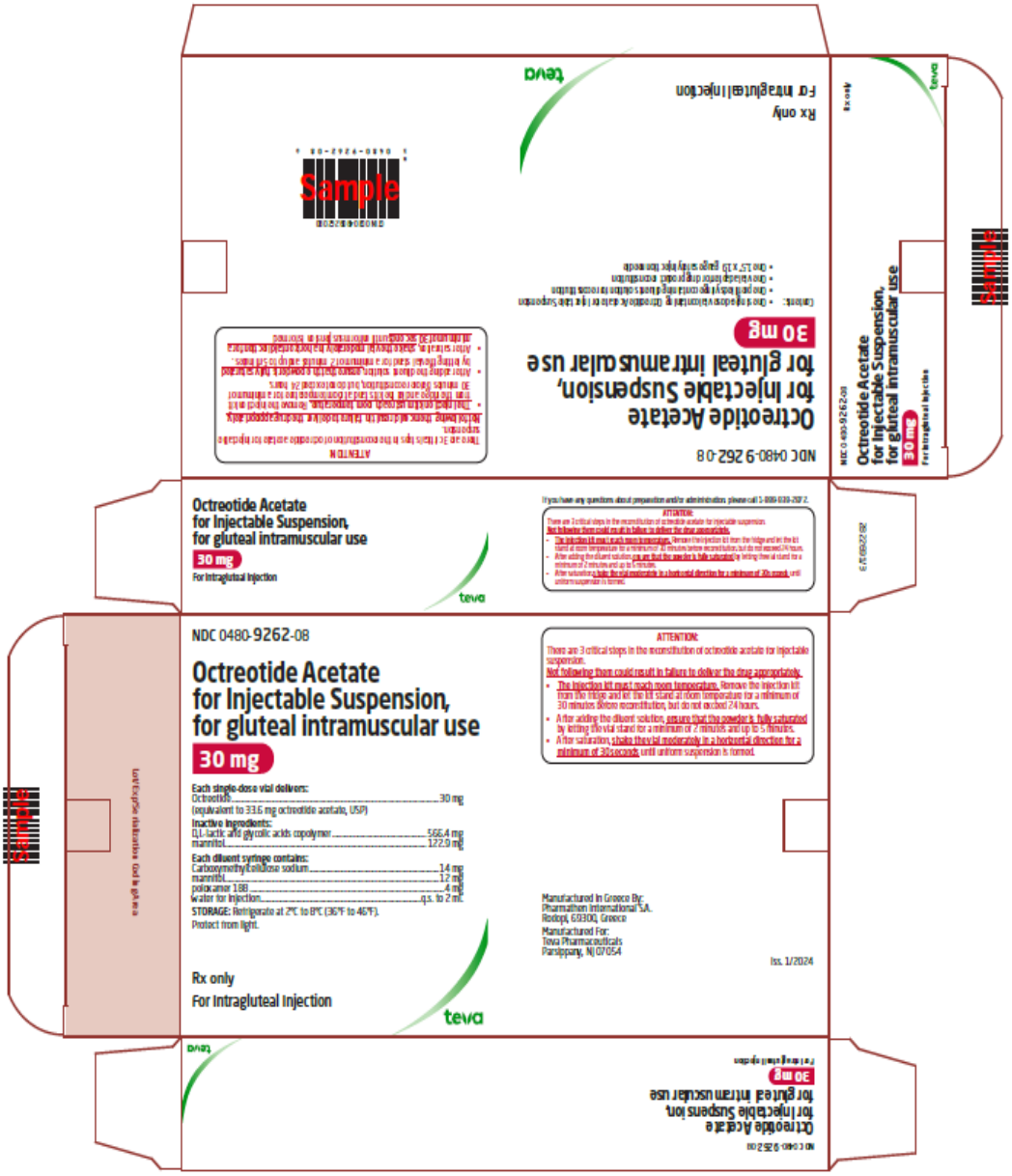
Image Shown Has Not Been Reproduced to Scale of Actual Label



Please indicate the number of shipping labels that you need to return the recalled product(s): _____

Inmar/MedTurn Use Only:				
Scan	Labels	Store	Kit	D.B