



Teva Pharmaceuticals USA, Inc.

**URGENT DRUG RECALL**  
**Octreotide Acetate Injectable Suspension**  
**10, 20, 30 mg/vial**  
**March 17, 2025**

<i>Octreotide Acetate Injection 10 mg/vial</i>						
NDC Kit Carton	Diluent Label	Vial Label	Tray Label	Lot #	Exp. Date	Size
0480-9257-08	0480-9263-21	0480-9256-01	0480-9257-08	4401619	09/2026	1 kit
0480-9257-08	0480-9263-21	0480-9256-01	0480-9257-08	4501005	03/2027	1 kit

<i>Octreotide Acetate Injection 20 mg/vial</i>						
NDC Kit Carton	Diluent Label	Vial Label	Tray Label	Lot #	Exp. Date	Size
0480-9259-08	0480-9263-21	0480-9258-01	0480-9259-08	4401491	9/2026	1 kit
0480-9259-08	0480-9263-21	0480-9258-01	0480-9259-08	4401600	9/2026	1 kit
0480-9259-08	0480-9263-21	0480-9258-01	0480-9259-08	4401603	9/2026	1 kit
0480-9259-08	0480-9263-21	0480-9258-01	0480-9259-08	4401629	9/2026	1 kit
0480-9259-08	0480-9263-21	0480-9258-01	0480-9259-08	4500594	3/2027	1 kit
0480-9259-08	0480-9263-21	0480-9258-01	0480-9259-08	4500786	3/2027	1 kit
0480-9259-08	0480-9263-21	0480-9258-01	0480-9259-08	4500920	3/2027	1 kit
0480-9259-08	0480-9263-21	0480-9258-01	0480-9259-08	4501007	3/2027	1 kit
0480-9259-08	0480-9263-21	0480-9258-01	0480-9259-08	4501462	3/2027	1 kit

<i>Octreotide Acetate Injection 30 mg/vial</i>						
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	4400401	6/2026	1 kit
0480-9262-08	0480-9263-21	0480-9260-01	0480-9262-08	4401393	9/2026	1 kit
0480-9262-08	0480-9263-21	0480-9260-01	0480-9262-08	4401494	9/2026	1 kit
0480-9262-08	0480-9263-21	0480-9260-01	0480-9262-08	4401604	9/2026	1 kit
0480-9262-08	0480-9263-21	0480-9260-01	0480-9262-08	4500564	3/2027	1 kit
0480-9262-08	0480-9263-21	0480-9260-01	0480-9262-08	4500601	3/2027	1 kit
0480-9262-08	0480-9263-21	0480-9260-01	0480-9262-08	4500707	3/2027	1 kit
0480-9262-08	0480-9263-21	0480-9260-01	0480-9262-08	4500796	3/2027	1 kit
0480-9262-08	0480-9263-21	0480-9260-01	0480-9262-08	4500859	3/2027	1 kit
0480-9262-08	0480-9263-21	0480-9260-01	0480-9262-08	4500918	3/2027	1 kit
0480-9262-08	0480-9263-21	0480-9260-01	0480-9262-08	4500919	3/2027	1 kit
0480-9262-08	0480-9263-21	0480-9260-01	0480-9262-08	4501006	3/2027	1 kit

Dear Valued Customer:

Teva Pharmaceuticals USA, Inc. (Teva USA) is initiating a voluntary nationwide recall of *the above twenty-three (23) lots* of **Octreotide Acetate Injectable Suspension, 10, 20 and 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 Food and Drug Administration.



Teva Pharmaceuticals USA, Inc.

**URGENT DRUG RECALL**  
**Octreotide Acetate Injectable Suspension**  
**10, 20, 30 mg/vial**  
**March 17, 2025**

**Please take the following actions upon receipt of this letter:**

- Immediately examine your inventory for the twenty-three (23) lots Octreotide Acetate Injectable Suspension 10, 20 and 30 mg/vial listed above.
- Immediately discontinue distribution of and quarantine the twenty-three (23) lots Octreotide Acetate Injectable Suspension 10, 20 and 30 mg/vial listed above.
- TEVA's records indicate that the recalled lots were commercially distributed/shipped to its direct customers from 10/01/2024 through 03/06/2026.
- **If you have further distributed the twenty-three (23) lots of Octreotide Acetate Injectable Suspension 10, 20 and 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](mailto: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.

<b>CONTACT INFORMATION AND CREDIT</b>
<p><b>Product Returns:</b> Contact Inmar at 877-268-2948 (Hours of Operation: M – F, 9.00 am to 5.00 pm Eastern Time) for Recall Stock Response forms or acquire from: <a href="http://clsnetlink.com">clsnetlink.com</a></p>
<p><b>Medical-related Questions or to report an Adverse Event:</b> 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 <a href="mailto:druginfo@tevapharm.com">druginfo@tevapharm.com</a></p>
<p><b>Product Quality Complaint-related Questions:</b> 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 <a href="mailto:QAS.QAS@tevapharm.com">QAS.QAS@tevapharm.com</a></p>
<p><b>Customer Service-related Questions:</b> 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</p>
<p><b>FDA contact information for reporting adverse events/quality complaints:</b> Online at <a href="http://www.fda.gov/medwatch/report.htm">www.fda.gov/medwatch/report.htm</a> or call FDA at 1-800-FDA-1088</p>

Sincerely,

Regulatory Compliance, Teva Pharmaceuticals USA, Inc.



Teva Pharmaceuticals USA, Inc.

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**Octreotide Acetate Injectable Suspension**  
**10, 20, 30 mg/vial**  
**March 17, 2025**

**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](mailto: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 Partial as 1)
0480-9257-08	0480-9263-21	0480-9256-01	0480-9257-08	4401619	09/2026	1 kit	
0480-9257-08	0480-9263-21	0480-9256-01	0480-9257-08	4501005	03/2027	1 kit	
0480-9259-08	0480-9263-21	0480-9258-01	0480-9259-08	4401491	9/2026	1 kit	
0480-9259-08	0480-9263-21	0480-9258-01	0480-9259-08	4401600	9/2026	1 kit	
0480-9259-08	0480-9263-21	0480-9258-01	0480-9259-08	4401603	9/2026	1 kit	
0480-9259-08	0480-9263-21	0480-9258-01	0480-9259-08	4401629	9/2026	1 kit	
0480-9259-08	0480-9263-21	0480-9258-01	0480-9259-08	4500594	3/2027	1 kit	
0480-9259-08	0480-9263-21	0480-9258-01	0480-9259-08	4500786	3/2027	1 kit	
0480-9259-08	0480-9263-21	0480-9258-01	0480-9259-08	4500920	3/2027	1 kit	
0480-9259-08	0480-9263-21	0480-9258-01	0480-9259-08	4501007	3/2027	1 kit	
0480-9259-08	0480-9263-21	0480-9258-01	0480-9259-08	4501462	3/2027	1 kit	
0480-9262-08	0480-9263-21	0480-9260-01	0480-9262-08	4400401	6/2026	1 kit	
0480-9262-08	0480-9263-21	0480-9260-01	0480-9262-08	4401393	9/2026	1 kit	
0480-9262-08	0480-9263-21	0480-9260-01	0480-9262-08	4401494	9/2026	1 kit	



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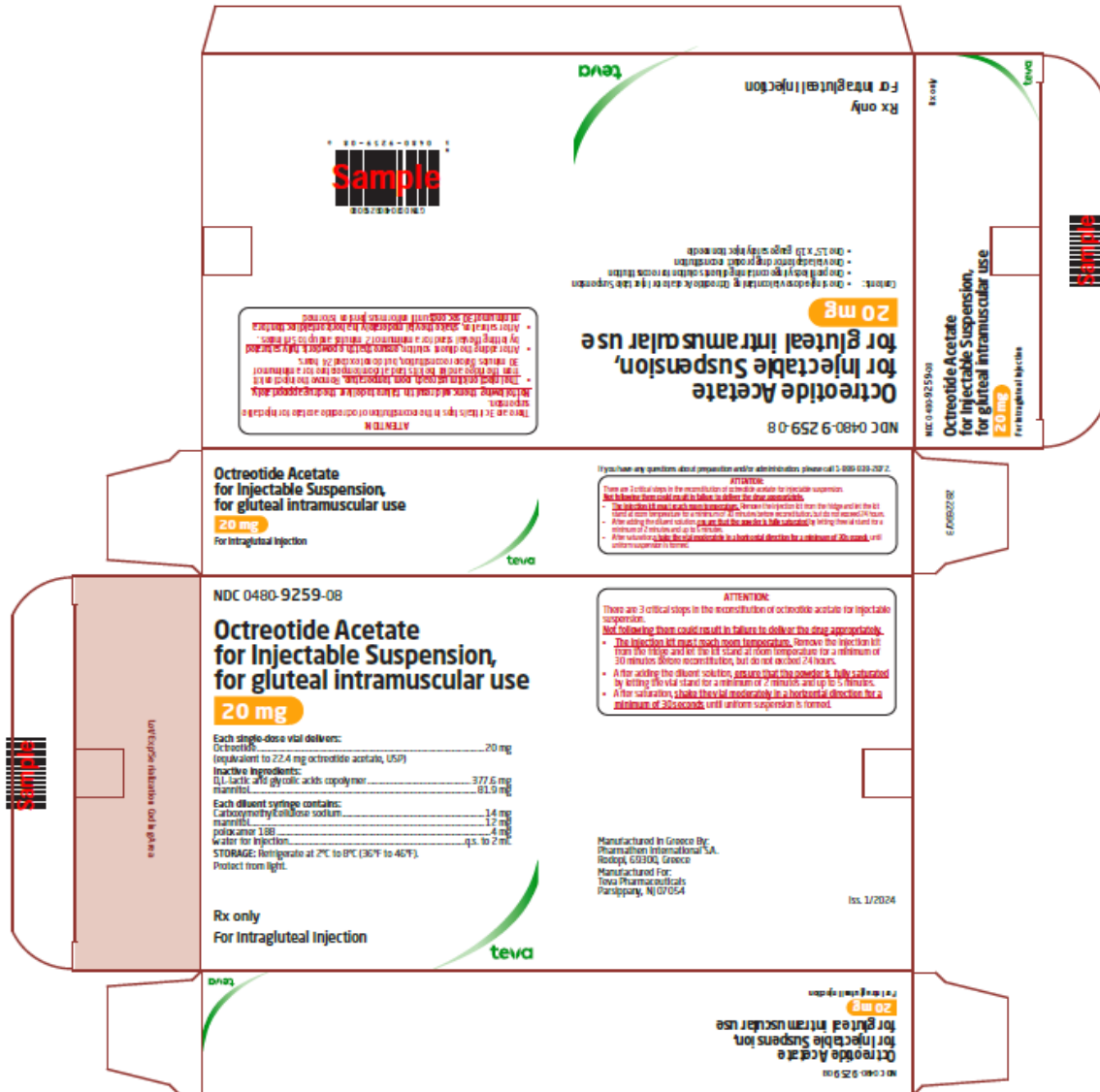
<b>NDC Kit Carton</b>	<b>Diluent Label</b>	<b>Vial Label</b>	<b>Tray Label</b>	<b>Lot #</b>	<b>Expiry</b>	<b>Size</b>	<b># of Cartons to Return (Count Partial as 1)</b>
0480-9262-08	0480-9263-21	0480-9260-01	0480-9262-08	4401604	9/2026	1 kit	
0480-9262-08	0480-9263-21	0480-9260-01	0480-9262-08	4500564	3/2027	1 kit	
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0480-9262-08	0480-9263-21	0480-9260-01	0480-9262-08	4501006	3/2027	1 kit	





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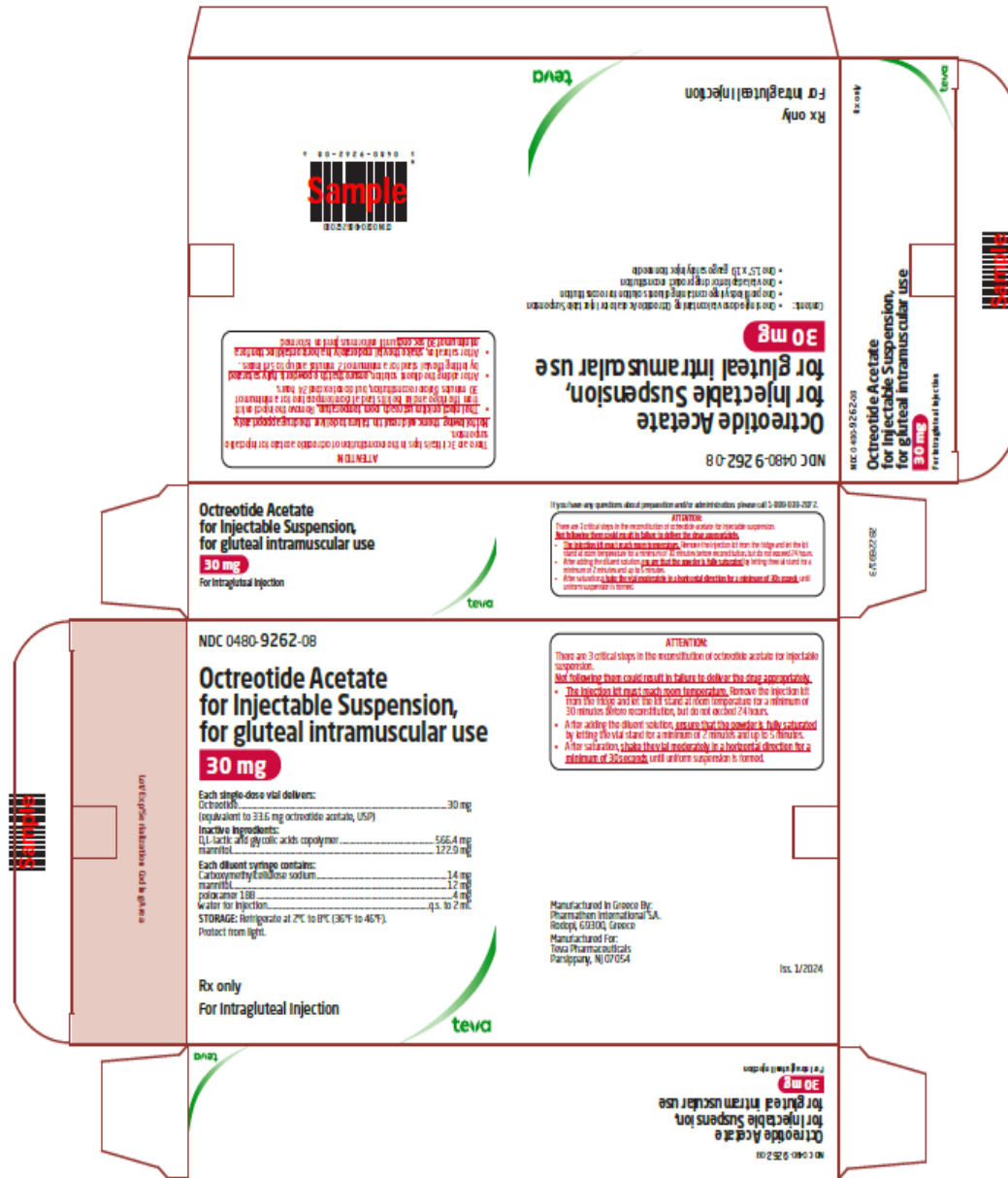
# URGENT DRUG RECALL Octreotide Acetate Injectable Suspension 10, 20, 30 mg/vial March 17, 2025





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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