

Teva Pharmaceuticals, USA Inc.

URGENT DRUG RECALL – WHOLESALE LEVEL - INITIATED 6/17/16

Linezolid Injection 600 mg/300mL

RECALLED BY:

Teva Pharmaceuticals USA, Inc.
Horsham, PA 19044

All Lots Within Expiry

Linezolid Injection 600 mg/300mL
NDC# 0703-9060-33 – Box of 10 Single Use Containers

Linezolid Injection 600 mg/300mL
NDC# 0703-9060-31 – Single Use Container

Dear Customer:

Teva Pharmaceuticals USA, Inc. is voluntarily recalling all lots within expiry of **Linezolid Injection 600 mg/300mL** distributed under the **Teva Pharmaceuticals label**. This recall is being carried out to the wholesale level in order to align with FDA Import Alert (IA) 66-40, which was issued because the methods and controls used in the manufacture and control of the product do not appear to conform to current good manufacturing practice (CGMP). Teva is not aware of any safety signals for this product and this product does not present a safety risk to patients.

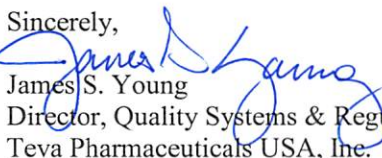
Wholesalers / Distributors - Please perform the following activities:

- Examine your inventory immediately for the specified lots of **Linezolid Injection 600 mg/300mL**.
- Our records indicate we shipped this product between January 5, 2015 and January 20, 2016.
- Immediately discontinue distribution of the specific lots being recalled.
- **Please perform a SUB-RECALL to your WHOLESALE level accounts using this Recall Notification and Stock Response Form.**
- Promptly complete the attached recall stock response and reply via fax number 817-868-5362 or mail, even if you have no product to return.

Completed Recall Stock Response forms can be mailed, emailed, or sent via FAX to Inmar Attn: Recall Coordinator, 4332 Empire Road Suite 200, Fort Worth, TX 76155. Inmar Email address: rxrecalls@inmar.com. Inmar FAX: 817-868-5362. Inmar will send a Return Goods Authorization label and shipping label. Appropriate credit for product returns, plus handling and shipping expenses, will be issued upon receipt of said product with the Return Goods Authorization form. All product returned without a Return Goods Authorization label may delay the issuance of your credit.

This recall is being made with the knowledge of the Food & Drug Administration. Your cooperation and prompt response to this notice is appreciated. If you have Customer Service related questions, please contact Teva Customer Service at 800-545-8800 (Hours of Operation: Live calls received: Monday-Friday, 8:00AM-5:00PM Eastern Time; Voicemail: 24hrs/day, 7days/week). For medical-related questions please contact Medical Information at 888-838-2872, option 3, then, option 4 (Hours of Operation: Live calls received: Monday-Friday, 8:00AM-4:30PM Eastern Time; Voicemail: 24hrs/day, 7days/week). For product quality complaint-related questions please contact Quality Assurance Services at 888-838-2872, option 3, then, option 3 (Hours of Operation: Live calls received: Monday-Friday, 9:00AM-5:00PM Eastern Time; Voicemail: 24hrs/day, 7days/week). If you need a Recall Stock Response form, contact Inmar at 800-967-5952 (Hours of Operation: Monday-Friday, 8:00AM-5:00PM Eastern Time) or acquire it from clsnetlink.com.

Sincerely,


James S. Young
Director, Quality Systems & Regulatory Compliance
Teva Pharmaceuticals USA, Inc.

Teva Pharmaceuticals, USA Inc.

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STOCK RESPONSE FORM

Please fill out completely

Date: _____

DIRECT CUSTOMERS ONLY: Does this response include **all** DC locations? ☐ YES ☐ NO

Customer/Store Name: _____ DEA #: _____

**DEA # is required; if not provided the processing of your form will be delayed*

Address: _____

City: _____ State: _____ Zip: _____

Contact Name (please print): _____ Telephone #: _____

Lot No.	Exp. Date	NDC# 0703-9060-33 Box of 10 Single Use Containers Quantity to Return (Count partials as 1)	NDC# 0703-9060-31 Single Use containers Quantity to Return (Count partials as 1)
10515	5/17		
20515	5/17		
30515	5/17		
40515	5/17		
121014	10/16		
131014	10/16		
141014	10/16		
151014	10/16		
161014	10/16		
681014	10/16		
701114	11/16		
711114	11/16		
1061114	11/16		
1071114	11/16		
1081114	11/16		
1091114	11/16		
1210615	6/17		
1220615	6/17		
1580615	6/17		
1641114	11/16		
1651114	11/16		
1661114	11/16		
1671114	11/16		
1681114	11/16		
1691114	11/16		
1720614	6/16		

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STOCK RESPONSE FORM (continued)

Lot No.	Exp. Date	NDC# 0703-9060-33 Box of 10 Single Use Containers Quantity to Return (Count partials as 1)	NDC# 0703-9060-31 Single Use containers Quantity to Return (Count partials as 1)
1970615	6/17		
1980615	6/17		
1990615	6/17		
2000615	6/17		
2031114	11/16		
2041114	11/16		
2051114	11/16		
2061114	11/16		
2071114	11/16		
2230715	7/17		
2240715	7/17		
2250614	6/16		
2260614	6/16		
2270614	6/16		
2280614	6/16		
2310614	6/16		
2400614	6/16		
2410614	6/16		
2420614	6/16		
2430614	6/16		
2440614	6/16		
2450715	7/17		
2460715	7/17		
2470715	7/17		
2480715	7/17		
2490715	7/17		
2500715	7/17		
2510715	7/17		
2731114	11/16		
2741114	11/16		
2751114	11/16		
2761114	11/16		
2820614	6/16		
2830614	6/16		

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STOCK RESPONSE FORM (continued)

Lot No.	Exp. Date	NDC# 0703-9060-33 Box of 10 Single Use Containers Quantity to Return (Count partials as 1)	NDC# 0703-9060-31 Single Use containers Quantity to Return (Count partials as 1)
2840614	6/16		
2850614	6/16		
2860614	6/16		
2941214	12/16		
3280614	6/16		
3290614	6/16		
3300614	6/16		
3420715	7/17		
3430715	7/17		
3440715	7/17		
3450715	7/17		
3770714	7/16		
3780714	7/16		
3800714	7/16		
3810714	7/16		
3930815	8/17		
3940815	8/17		
3950815	8/17		
4070614	6/16		
4320815	8/17		
4500115	1/17		
4510115	1/17		
4520115	1/17		
4530115	1/17		
4540115	1/17		
4690915	9/17		
4700915	9/17		
4710915	9/17		
4790714	7/16		
4800714	7/16		
4810714	7/16		
4820714	7/16		
4830714	7/16		
4890915	9/17		

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STOCK RESPONSE FORM (continued)

Lot No.	Exp. Date	NDC# 0703-9060-33 Box of 10 Single Use Containers Quantity to Return (Count partials as 1)	NDC# 0703-9060-31 Single Use containers Quantity to Return (Count partials as 1)
4900915	9/17		
4910915	9/17		
4920915	9/17		
5060115	1/17		
5070115	1/17		
5080115	1/17		
5160215	2/17		
5170215	2/17		
5170714	7/16		
5180215	2/17		
5180714	7/16		
5180915	9/17		
5190215	2/17		
5190714	7/16		
5190915	9/17		
5200215	2/17		
5200714	7/16		
5200915	9/17		
5210714	7/16		
5270714	7/16		
5280714	7/16		
5300814	8/16		
5310814	8/16		
5560215	2/17		
5880814	8/16		
5940215	2/17		
5950215	2/17		
5960215	2/17		
6230215	2/17		
6240215	2/17		
6250215	2/17		
6270315	3/17		
6290814	8/16		
6300814	8/16		

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Lot No.	Exp. Date	NDC# 0703-9060-33 Box of 10 Single Use Containers Quantity to Return (Count partials as 1)	NDC# 0703-9060-31 Single Use containers Quantity to Return (Count partials as 1)
6530914	9/16		
6730914	9/16		
6740914	9/16		
6750914	9/16		
6760914	9/16		
6770315	3/17		
7110914	9/16		
7120914	9/16		
7130914	9/16		
7140914	9/16		
7150914	9/16		
7290315	3/17		
7300315	3/17		
7540914	9/16		
7550914	9/16		
7560914	9/16		
7680315	3/17		
7690315	3/17		
7700315	3/17		
7710315	3/17		
7880415	4/17		
7890415	4/17		
7900415	4/17		
7910415	4/17		
8140415	4/17		
8150415	4/17		
8160415	4/17		
8170415	4/17		
8620415	4/17		
8630415	4/17		
8640415	4/17		
8650415	4/17		
8681014	10/16		
8691014	10/16		

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STOCK RESPONSE FORM (continued)

Lot No.	Exp. Date	NDC# 0703-9060-33 Box of 10 Single Use Containers Quantity to Return (Count partials as 1)	NDC# 0703-9060-31 Single Use containers Quantity to Return (Count partials as 1)
8701014	10/16		
8981014	10/16		
8990415	4/17		
9000415	4/17		
9010415	4/17		
9020415	4/17		
9330515	5/17		
9641014	10/16		
9651014	10/16		
9661014	10/16		
9671014	10/16		
9980515	5/17		
9990515	5/17		

I have checked my stock and:

_____ I **do not** have stock of the recalled item(s) **OR** _____ I **do** have stock of the recalled item(s) listed above.

Please send me _____ shipping box labels

NON DIRECT CUSTOMERS ONLY: Please complete the following:

Purchased From (Wholesaler name): _____ DEA #: _____

City: _____ State: _____

Inquiries regarding this Recall are to be directed to the following:

Recall Stock Response forms - If your return kit is not received between 7-10 business days contact Inmar at 800-967-5952, Option 1 then Option 3 (Hours of Operation: Monday-Friday, 8:00AM-5:00PM Eastern Time)

Please **do not resubmit** response form.

Customer service related questions - contact Teva Customer Service at 800-545-8800

(Hours of Operation: Live calls received: Monday-Friday, 8:00AM-5:00PM Eastern Time; Voicemail: 24hrs/day, 7days/week)

Medical-related questions - contact Medical Information 888-838-2872, option 3, then, option 4

(Hours of Operation: Live calls received: Monday-Friday, 8:00AM-4:30PM Eastern Time; Voicemail: 24hrs/day, 7days/week)

Product quality complaint-related questions please contact Quality Assurance Services at 888-838-2872, option 3, then, option 3

(Hours of Operation: Live calls received: Monday-Friday, 9:00AM-5:00PM Eastern Time; Voicemail: 24hrs/day, 7days/week)

Please fax this form to: 817-868-5362 or E-mail at: rxrecalls@inmar.com

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Inmar/MedTurn Use Only:

Scan	Labels	Store	Kit	D.B
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