Teva Pharmaceuticals USA, Inc.

URGENT DRUG RECALL – RETAIL LEVEL - INITIATED 08/06/2018

Paliperidone Extended-Release Tablets 3 mg and 9 mg

RECALLED BY:
Teva Pharmaceuticals USA, Inc.
North Wales, PA 19454

Lot #	Exp. Date	Strength	Bottle Size	NDC
1220221A	03/2019	3mg	30 count	0591-3693-30
1220222A	03/2019	3mg	90 count	0591-3693-19
1269627A	09/2019	3mg	30 count	0591-3693-30
1270501A	09/2019	3mg	90 count	0591-3693-19
1274295A	10/2019	3mg	30 count	0591-3693-30
1274296A	10/2019	3mg	90 count	0591-3693-19
1288766A	01/2020	3mg	90 count	0591-3693-19
1291192A	01/2020	9mg	30 count	0591-3695-30
1291193A	01/2020	9mg	90 count	0591-3695-19

Dear Valued Customer:

Teva Pharmaceuticals USA, Inc. is voluntarily recalling to the **RETAIL LEVEL** the above lots of **Paliperidone Extended-Release Tablets 3 mg and 9 mg** distributed under the **Actavis label.** This recall is being carried out because there is a potential for some tablets to be missing the laser drilling which might affect drug release. It is unlikely undrilled product will cause adverse health consequences.

Wholesalers / Distributors / Retailers - Please perform the following activities:

- Immediately examine your inventory for the specified lots of **Paliperidone Extended-Release Tablets 3 mg and 9 mg.**
- Our records indicate we shipped this product from 07/05/2017 through 7/05/2018.
- Immediately discontinue distribution of the specific lots being recalled.
- **Wholesalers/Distributors/Retailers, if you have further distributed the specific lot, please perform a SUB-RECALL to your RETAIL accounts using this Recall Notification and Stock Response Form.**
- Even if you have **no** product to return, promptly complete the attached recall stock response form (SRF) and return by mail, email, or FAX to Inmar, Attn: Recall Coordinator,
  Inmar, 635 Vine Street, Winston Salem, NC 27101.
  Email address: **rxrecalls@inmar.com.**
  FAX: 817-868-5362.

Inmar will send a Return Goods Authorization label and shipping label, if requested on your SRF. 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 recalled product returned without a Return Goods Authorization label may delay the issuance of a credit. 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: 800-967-5952. (Hours of Operation: 9 am to 5 pm Eastern Time) Recall Stock Response forms Contact Inmar at: 800-967-5952 or acquire it from clsnetlink.com.
Customer Service-related Questions: Contact Teva Customer Service: 800-545-8800 (Hours of Operation: Live calls received: Monday-Friday, 8:30AM-5:00PM Eastern Time; Voicemail: 24 hrs./day, 7 days/week).
Medical-related Questions or to report an Adverse Event: Contact Medical Information at: 888-838-2872, option 3, then, option 4 Live calls received: Monday-Friday, 9:00AM-5:00PM Eastern Time; Voicemail: 24 hrs./day, 7 days/week
Product Quality Complaint-related Questions: Contact Quality Assurance Services: 888-838-2872, option 3, then, option 3 (Hours of Operation: Live calls received: Monday-Friday, 9:00AM-5:00PM 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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Paliperidone Extended-Release Tablets 3 mg and 9 mg

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 #	Exp. Date	Strength	Bottle Size	NDC	Quantity to Return (count partial as 1)
1220221A	3/2019	3mg	30 count	0591-3693-30	
1220222A	3/2019	3mg	90 count	0591-3693-19	
1269627A	9/2019	3mg	30 count	0591-3693-30	
1270501A	9/2019	3mg	90 count	0591-3693-19	
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1274296A	10/2019	3mg	90 count	0591-3693-19	
1288766A	1/2020	3mg	90 count	0591-3693-19	
1291192A	1/2020	9mg	30 count	0591-3695-30	
1291193A	1/2020	9mg	30 count	0591-3695-19	

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: _____

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Please FAX this form to: 817-868-5362 or E-mail at: rxrecalls@inmar.com or mail to: Inmar, Attn: Recall Coordinator, Inmar, 635 Vine Street, Winston Salem, NC 27101.

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