Teva Pharmaceuticals USA

URGENT DRUG RECALL – Hospital/Institution LEVEL - INITIATED 08/01/17

Hydromorphone Hydrochloride Injection, USP, CII, High Potency Formulation

RECALLED BY:
Teva Pharmaceuticals USA, Inc.
Horsham, PA 19044

Lot #	Exp. Date	Strength	Size	NDC
560053F	01AUG2017	500 mg/50 mL (10 mg/mL)	50 mL Single-Dose Vial	0703-0018-01
560103F	01AUG2017	50 mg/5 mL (10 mg/mL)	Ten 5 mL Single-Dose vials/carton	0703-0113-03
560103F	01AUG2017	50 mg/5 mL (10 mg/mL)	5 mL Single-Dose Vial	0703-0113-01

Dear Valued Customer:

Hospira, Inc. has notified Teva Pharmaceuticals USA, Inc. of their intent to recall the above mentioned lots of **Hydromorphone Hydrochloride Injection, USP (CII), 10 mg/mL** distributed under the **Teva Pharmaceuticals USA, Inc. label.** This sub-recall is being carried out to the **HOSPITAL/INSTITUTION LEVEL** due to visible particulates composed of silicone found within internal reserve samples.
Adverse events including infusion-site /vein phlebitis, local tissue or vein irritation, embolic events and granuloma formation could occur. The risk is reduced due to the likelihood of visible detection, as the label contains a clear statement directing the healthcare professional to visually inspect the product for particulate matter and discoloration prior to administration.

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

- Examine your inventory immediately for the specified lots of **Hydromorphone Hydrochloride Injection, USP (CII), 10 mg/mL**
- Our records indicate we shipped this product between December 07, 2015 and January 27, 2016.
- Immediately discontinue distribution of the specific lots being recalled.
- **Wholesalers/Distributors/Retailers, if you have further distributed the specific lots, please perform a SUB-RECALL to your HOSPITAL/INSTITUTION LEVEL 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 your 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: 8 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 Live calls received: Monday-Friday, 8:30 AM-5:00 PM 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 or druginfo@tevapharm.com Live calls received: Monday-Friday, 9:00 AM-5:00 PM 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 Live calls received: Monday-Friday, 9:00 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

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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 #	Exp. Date	Strength	Size	NDC	Quantity to Return (count partial as 1)
560053F	01AUG2017	500 mg/50 mL (10 mg/mL)	50 mL Single-Dose Vial	0703-0018-01	
560103F	01AUG2017	50 mg/5 mL (10 mg/mL)	Ten 5 mL Single-Dose vials/carton	0703-0113-03	
560103F	01AUG2017	50 mg/5 mL (10 mg/mL)	5 mL Single-Dose Vial	0703-0113-01	

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 #: _____

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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

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