# Teva Pharmaceuticals USA, Inc.

## URGENT DRUG RECALL – RETAIL LEVEL - INITIATED 10/6/2014

## Hydromorphone Hydrochloride Injection, USP (CII), 10mg/mL

**RECALLED BY:**
**Hospira, Inc.**
**Lake Forest, IL 60045**

**MANUFACTURED FOR:**
**Teva Parenteral Medicines, Inc.**
**Irvine, CA 92618**

| Lot # | Exp. Date | Size | NDC |
|---|---|---|---|
| 260753F | 2/1/2015 | 1 mL in 2 mL Vial | 0703-0110-03 (carton of 10 vials)/ 0703-0110-01(single dose vial) |
| 261403F | 2/1/2015 | 1 mL in 2 mL Vial | 0703-0110-03 (carton of 10 vials)/ 0703-0110-01(single dose vial) |
| 290153F | 5/1/2015 | 1 mL in 2 mL Vial | 0703-0110-03 (carton of 10 vials)/ 0703-0110-01(single dose vial) |

Dear Customer:

Hospira, Inc. has notified Teva Pharmaceuticals USA, Inc. of their intent to recall the above mentioned lots of **Hydromorphone Hydrochloride Injection, USP (CII), 10mg/mL** distributed under the **Teva label.** This sub-recall is being carried out to the **RETAIL LEVEL** due to confirmed customer complaints where either the glass vial was empty or displayed a crack in the heel of the vial.

Hospira reports that risk factors associated with a defective vial include the potential for a loss of sterility, contamination of the vial contents, delay in therapy/administration and/or leakage of contents. The loss of sterility is a primary concern when a container has a leak, since an open pathway exists for contamination of fluid. If contaminated solution is used on a patient, this may cause bacteremia, sepsis, septic shock, and endocarditis, and death may result. Signs and symptoms could include redness, pain, swelling at the site, fever, shortness of breath, tachycardia, nausea, and vomiting. Septicemia could lead to shock and multisystem organ failure, requiring critical medical intervention.

Wholesalers / Distributors - Please perform the following activities:

- Examine your inventory immediately for the specified lots of **Hydromorphone Hydrochloride Injection, USP (CII), 10mg/mL.**
- Our records indicate we shipped this product between April 9, 2013 and December 5, 2013.
- Immediately discontinue distribution of the specific lots being recalled.
- **Please perform a SUB-RECALL to the retail/medical facility level 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: recallnotice@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 recalled product returned without a Return Goods Authorization label may delay the issuance of your credit.

This sub-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. For medical-related questions please contact Medical Information at 888-838-2872. If you need a Recall Stock Response form, contact Inmar at 800-967-5952 or acquire it from clsnetlink.com.

Sincerely,

Don H. Gee
Sr. Manager, Quality & Compliance
Teva Pharmaceuticals USA, Inc.

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## URGENT DRUG RECALL – RETAIL LEVEL - INITIATED 10/6/2014

## Hydromorphone Hydrochloride Injection, USP (CII), 10mg/mL

## 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 | Size | NDC# 0703-0110-03 Carton of 10 vials Quantity to Return | NDC# 0703-0110-01 Single dose vial Quantity to Return |
|---|---|---|---|---|
| 260753F | 2/1/2015 | 1 mL in 2 mL Vial | | |
| 261403F | 2/1/2015 | 1 mL in 2 mL Vial | | |
| 290153F | 5/1/2015 | 1 mL in 2 mL Vial | | |

**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. Please **do not resubmit** response form.
Customer service related questions - contact Teva Customer Service at 800-545-8800
Medical-related questions - contact Medical Information at 888-838-2872.

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

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