



ADDENDUM

PBM-2015-03

JULY 2, 2015

NATIONAL PBM PATIENT LEVEL RECALL COMMUNICATION

ITEM: Ketorolac Tromethamine Inj., USP, Updated Recall for Floating Particulates in Glass Flip-top Vials

SPECIFIC INCIDENT(S): Hospira, Inc. is expanding its previous voluntary recalls from January 2015 and May 2015 of Ketorolac Tromethamine Inj., USP, to include 63 additional affected items/lots due to visible, floating particulate matter within glass flip-top vials.

GENERAL INFORMATION:

- Visible, floating particulate matter has been identified as calcium-ketorolac crystals.
- Multiple product lists and potentially affected lots included in this recall were distributed by Hospira to direct accounts from August 2013 through May 2015.
- If calcium-ketorolac particulates are administered by intramuscular (IM) or intravenous (IV) administration, localized inflammation, allergic reaction, granuloma formation or microembolic effects may occur. Hospira has deemed the probability of harm to be negligible. Delay in pain management may occur as a result of the defective vial not being detected until the point of care, thus prompting the need to obtain another vial. This should be of limited duration and low clinical significance.
- Hospira has not received reports of any adverse events associated with this issue for these lots to date.
- Since the original recall, an additional 63 affected item(s)/lot(s) have been identified:

Description	Lot #*, Exp Date	NDC	UPC	Econo #
0409	31-077-DK, 07/2015; 31-078-DK, 07/2015; 31-338-DK, 07/2015; 31-339-DK, 07/2015; 31-340-DK, 07/2015; 32-068-DK, 08/2015; 32-069-DK, 08/2015; 33-270-DK, 09/2015; 34-084-DK, 10/2015; 34-085-DK, 10/2015; 34-161-DK, 10/2015; 34-162-DK, 10/2015; 34-298-DK, 10/2015; 34-299-DK, 10/2015; 34-300-DK, 10/2015; 35-011-DK, 11/2015; 35-081-DK, 11/2015; 35-082-DK, 11/2015; 35-116-DK, 11/2015; 38-139-DK, 02/2016; 38-140-DK, 02/2016; 38-144-DK, 02/2016; 39-256-DK, 03/2016; 39-257-DK, 03/2016; 42-210-DK, 06/2016; 42-227-DK, 06/2016; 43-017-DK, 07/2016; 43-116-DK, 07/2016; 43-117-DK, 07/2016; 43-292-DK, 07/2016; 43-293-DK, 07/2016; 45-034-DK, 09/2016; 45-035-DK, 09/2016; 45-118-DK, 09/2016; 45-120-DK, 09/2016; 46-310-DK, 10/2016; 46-311-DK, 10/2016	0409-3795-01	30409379501	1891365
Ketorolac Tromethamine Inj., USP, 30 mg (30 mg/mL), 1 mL Fill, Single-dose, NOVAPLUS®	32-106-DK, 08/2015; 32-220-DK, 08/2015; 32-221-DK, 08/2015; 33-235-DK, 09/2015; 33-236-DK, 09/2015; 34-163-DK, 10/2015; 34-164-DK, 10/2015; 39-263-DK, 03/2016; 39-264-DK, 03/2016	0409-3795-49	30409379549	1891456

Description	Lot #*, Exp Date	NDC	UPC	Econo #
Ketorolac Tromethamine Inj., USP, 60 mg (30 mg/mL), 2 mL Fill, Single-dose	31-075-DK, 07/2015, 31-076-DK, 07/2015; 32-345-DK, 08/2015; 32-368-DK, 08/2015; 33-152-DK, 09/2015; 34-538-DK, 10/2015; 37-227-DK, 01/2016; 41-525-DK, 05/2016; 42-255-DK, 06/2016; 46-042-DK, 10/2016; 46-045-DK, 10/2016; 46-048-DK, 10/2016; 46-304-DK, 10/2016; 46-305-DK, 10/2016; 46-432-DK, 10/2016; 46-433-DK, 10/2016	0409-3796-01	30409379601	1892942
Ketorolac Tromethamine Inj., USP, 60 mg (30 mg/mL), 2 mL Fill, Single-dose, NOVAPLUS®	31-074-DK, 07/2015	0409-3796-49	30409379649	1893858

*Note: the lot number may be followed by additional numbers from 01 to 99

- This alert is an extension of the product sequestration actions in **Product Recall Office Log # 9773** (available at: <http://vaww.recalls.ncps.med.va.gov/WebRecalls/Recalls.html>).
- Providers should report any adverse outcomes relating to the presence of this particulate matter via local reporting mechanisms. Adverse events should also be reported, as appropriate, to the VA ADERS program and FDA MedWatch.

ACTIONS:

PROVIDER NOTIFICATION:

- **Facility Director** (or physician designee): Forward this document to the Facility Chief of Staff (COS).
- **Facility COS** (and Chief Nurse Executives): Forward this document to all appropriate providers who prescribe this agent (e.g., **primary care providers, pain specialists, ED providers, and pharmacy staff, including contract providers**, etc.). In addition, forward to the Associate Chief of Staff (ACOS) for Research and Development (R&D). Forward to other VA employees as deemed appropriate.
- **ACOS for R&D**: Forward this document to Principal Investigators (PIs) who have authority to practice at the facility and to your respective Institutional Review Board (IRB).

PATIENT NOTIFICATION:

- **Chief of Pharmacy**: Within 10 business days of issue (due 07/17/2015):
 - Determine whether the affected product(s) was dispensed to any patient(s) for home administration. Affected product started shipping August 2013.
 - If an affected lot(s) was dispensed to a patient(s) for home administration, then:
 - Identify the patient(s).
 - Contact the patient(s) who may have received the affected product(s) for home administration by letter (or other means).
 - A sample letter can be found at: <https://vaww.cmopnational.va.gov/cmop/PBM/Other%20Documents%20and%20Resources/ASA%20Recall%20Patient%20Letter%20Template.doc>.
- This template can be altered according to site-specific needs.

- Provide patient(s) in possession of the recalled product with instructions on the following:
 - How to return the product being recalled to the pharmacy.
 - How to obtain a new supply of product.
 - Patients should not continue to take the product until they obtain replacement product.
 - When the correct product is received, patients should begin using the new product and return the recalled supply as instructed.
- Communicate to PBM/VAMedSAFE that all patient notification actions have been completed via the VHA Alerts and Recalls Website:
<http://vaww.recalls.ncps.med.va.gov/WebRecalls/Recalls.html>.

SOURCE: FDA

REFERENCE(S): 1. National PBM Communication: Ketorolac Recall Due to Particles in Glass Vial. May 4, 2015
http://www.pbm.va.gov/PBM/vacenterformedicationsafety/nationalpbmcommunication/Ketorolac_Recall_Due_to_Particles_in_Glass_Vial_National_PBM_Patient_Lev.pdf

ATTACHMENT(S): None.

CONTACTS: Pharmacy Benefits Management Services (PBM) at (708)786-7862.