NATIONAL PBM PATIENT LEVEL RECALL COMMUNICATION

PBM-2015-01 **MAY 4, 2015**

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

SPECIFIC INCIDENT(S): Hospira, Inc. is expanding the January 2015 voluntary recall (RC 15-013) of Ketorolac Tromethamine Inj., USP, to include 29 additional affected items/lots due to visible, floating particulate matter within glass flip-top vials.

GENERAL INFORMATION:

- A customer report of visible, floating particulate matter (identified as calcium-ketorolac crystals) in a glass flip-top vial prompted the original recall of Ketorolac Tromethamine Inj., USP, in January 2015, that affected multiple lots.
- If calcium-ketorolac particulates are administered by intramuscular (IM) or intravenous (IV) administration, localized inflammation, allergic reaction, granuloma formation or microembolic effects (IV only) may occur. Delay of therapy may also occur due to particulates blocking the infusion of solution.
- Hospira has not received reports of any adverse events associated with this issue for these lots to date.
- Since the original recall, an additional 29 affected item(s)/lot(s) have been identified:

Description	Lot #, Exp Date	NDC	UPC	Econo #
KETOR TR FTV 30MG 1ML HW 25	35-231-DK, 11/2015; 35-235-DK, 11/2015; 35-507-DK, 11/2015; 36-136-DK, 12/2015; 37-146-DK, 01/2016; 38-138-DK, 02/2016; 39-103-DK, 03/2016; 39-255-DK, 03/2016; 40-539-DK, 04/2016; 40-549-DK, 04/2016; 41-079-DK, 05/2016; 42-252-DK, 06/2016; 42-254-DK, 06/2016; 43-262-DK, 07/2016; 43-263-DK, 07/2016; 45-031-DK, 09/2016; 45-032-DK, 09/2016; 45-033-DK, 09/2016; 46-001-DK, 10/2016	00409379501	30409379501	1891365
KETOR FTV 30MG 1ML HW 25 NOV+	35-230-DK, 11/2015; 40-535-DK, 04/2016	00409379549	30409379549	1891456
KETOR TR FTV 60MG 2ML HW 25	38-135-DK, 02/2016; 38-136-DK, 02/2016; 44-075-DK, 08/2016; 44-356-DK, 08/2016; 44-357-DK, 08/2016; 44-358-DK, 08/2016; 46-308-DK, 10/2016	00409379601	30409379601	1892942
KETOR FTV 60MG 2ML HW 25 NOV+	38-137-DK, 02/2016	00409379649	30409379649	1893858

- This alert is an extension of the product sequestration actions in **Product Recall Office Log # 9470** (available at: http://vaww.recalls.ncps.med.va.gov/WebRecalls/Recalls.html).
- Providers should continue to report any adverse reactions with the use of any ketorolac product(s) by entering the information into CPRS' Allergies/ Adverse Reactions field and/or via local reporting mechanisms. Adverse events should

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also be reported, as appropriate, to the VA ADERS program and FDA MedWatch (1-800-FDA-1088, fax 1-800- FDA-0178, online at https://www.accessdata.fda.gov/scripts/medwatch/medwatch- online.htm, or by mail).

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, 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 05/15/2015):
  - Determine whether the affected product(s) was dispensed to any patient(s) for home administration. Affected product started shipping January 2014.
  - 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.

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SOURCE: FDA

REFERENCE(S):

1. FDA Recall – Firm Press Release: Hospira Issues a Voluntary Global Recall of Multiple Lots of Ketorolac Tromethamine Injection Due to Potential Particulate in Glass Vials. http://www.fda.gov/Safety/Recalls/ucm433857.htm . (Accessed 05/01/2015)
2. Hospira – Urgent Drug Recall. http://www.hospira.com/Images/Letter%20Event%208962%20FA501-01%20Final%20v3_81-96228_1.pdf . (Accessed 05/01/2015)
3. McKesson Important Notice: Urgent Recall. April 16, 2015. RC: 15-065.

ATTACHMENT(S): None.

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