Hospira — Recall of Ketorolac Tromethamine Injection

- On April 13, 2015, Hospira announced the voluntary recall of multiple lots of ketorolac tromethamine injection due to visible, floating particulate matter within certain glass fliptop vials. This recall was initially announced in January 22, 2015 and has been escalated to the user level.
- The recalled lots are listed below.

Product Description	NDC	Lot # * (Expiration Date)
Ketorolac tromethamine injection, USP, 30 mg (30 mg/mL), 1 mL fill, single-dose vial	0409-3795-01	25-047-DK (1/1/2015); 25-048-DK (1/1/2015); 26-151-DK (2/1/2015); 28-059-DK (4/1/2015); 28-071-DK (4/1/2015); 28-072-DK (4/1/2015); 28-479-DK (4/1/2015); 28-480-DK (4/1/2015); 29-556-DK (5/1/2015); 29-557-DK (5/1/2015); 35-232-DK (11/1/2015); 35-233-DK (11/1/2015); 35-234-DK (11/1/2015); 35-501-DK (11/1/2015); 36-341-DK (12/1/2015); 36-342-DK (12/1/2015); 36-343-DK (12/1/2015); 36-353-DK (12/1/2015); 36-429-DK (12/1/2015); 36-430-DK (12/1/2015); 37-141-DK (1/1/2016); 37-142-DK (1/1/2016); 37-144-DK (1/1/2016); 37-145-DK (1/1/2016); 37-353-DK (1/1/2016); 38-141-DK (2/1/2016); 38-143-DK (2/1/2016); 39-014-DK (3/1/2016); 39-104-DK (3/1/2016); 40-301-DK (4/1/2016); 40-536-DK (4/1/2016); 40-537-DK (4/1/2016); 40-544-DK (4/1/2016); 40-548-DK (4/1/2016); 41-078-DK (5/1/2016); 42-207-DK (6/1/2016); 42-253-DK (6/1/2016); 45-358-DK (9/1/2016); 45-359-DK (9/1/2016); 46-043-DK (10/1/2016); 46-044-DK (10/1/2016); 46-047-DK (10/1/2016); 35-231-DK (11/1/2015); 35-235-DK (11/1/2015); 35-507-DK (11/1/2015); 36-136-DK (12/1/2015); 37-146-DK (1/1/2016); 38-138-DK (2/1/2016); 39-103-DK (3/1/2016); 39-255-DK (3/1/2016); 40-539-DK (4/1/2016); 40-549-DK (4/1/2016); 41-079-DK (5/1/2016); 42-252-DK (6/1/2016); 42-254-DK (6/1/2016); 43-262-DK (7/1/2016); 43-263-DK (7/1/2016); 45-031-DK (9/1/2016); 45-032-DK (9/1/2016); 45-033-DK (9/1/2016); 46-001-DK (10/1/2016)
Ketorolac tromethamine injection, USP, 30 mg (30 mg/mL), 1 mL fill, single-dose vial, NOVAPLUS®	0409-3795-49	27-101-DK (3/1/2015); 35-229-DK (11/1/2015); 36-217-DK (12/1/2015); 36-218-DK (12/1/2015); 40-534-DK (4/1/2016); 35-230-DK (11/1/2015); 40-535-DK (4/1/2016)
Ketorolac tromethamine injection, USP, 60 mg (30 mg/mL), 2 mL fill, single-dose vial	0409-3796-01	26-098-DK (2/1/2015); 29-239-DK (5/1/2015); 29-240-DK (5/1/2015); 34-540-DK (10/1/2015); 37-037-DK (1/1/2016); 37-038-DK (1/1/2016); 37-147-DK (1/1/2016); 37-148-DK (1/1/2016); 37-228-DK (1/1/2016); 37-282-DK (1/1/2016); 41-282-DK (5/1/2016); 41-284-DK (5/1/2016); 44-076-DK (8/1/2016); 45-240-DK (9/1/2016); 46-306-DK (10/1/2016); 38-135-DK (2/1/2016);

Continued . . .

		38-136-DK (2/1/2016); 44-075-DK (8/1/2016); 44-356-DK (8/1/2016); 44-357-DK (8/1/2016); 44-358-DK (8/1/2016); 46-308-DK (10/1/2016)
Ketorolac tromethamine injection, USP, 60 mg (30 mg/mL), 2 mL fill, single-dose vial, NOVAPLUS®	0409-3796-49	26-097-DK (2/1/2015); 38-137-DK (2/1/2016)

*The lot number may be followed by 01 to 99

- Ketorolac tromethamine injection is a prescription product administered intravenously or intramuscularly for moderately severe acute pain.
- The affected lots included in this recall started shipping in February 2013. Additional lots were distributed by Hospira to direct accounts between January 2014 and March 2015.
- The floating particulate matter was identified as calcium-ketorolac crystals.
  - Risk factors associated with particulate matter include the potential for particles to be injected and/or therapy may be delayed.
  - If particulate matter is not observed prior to administration, intramuscular (IM) or intravenous (IV) administration theoretically could result in localized inflammation, allergic reaction, granuloma formation, or microembolic effects (IV only). However, there is no evidence indicating that IM or IV injection of inert particles results in harm to patients when only a small amount over a limited period of time is administered as is the case with ketorolac.
- To date, Hospira has not received reports of any adverse events associated with this issue for the recalled lot.
  - Hospira has initiated an investigation to determine the root cause and corrective and preventive actions.
  - Anyone with an existing inventory of the recalled lot should quarantine the product immediately, discontinue distribution, and return the recalled lots of product.
- Any questions about returning unused product should be directed to Stericycle at **1-877-857-4139.**
- Individuals with medical inquiries about the recalled products may contact Hospira Medical Communications at **1-800-615-0187** or medcom@hospira.com.