



**November 30, 2012**

## **Manufacturer initiates nationwide voluntary, patient level recall for Nalbuphine HCL 20mg/mL**

On Nov. 21 Hospira, Inc. announced a voluntarily, patient-level recall of one lot of Nalbuphine HCl Injection, due to two confirmed customer reports of packaging defects that may compromise the product's sterility. This recall is being conducted as a precautionary measure. Hospira has not received reports of any adverse event associated with this issue for this lot.

- **Product and strengths:** Nalbuphine HCL 20mg/mL; 10 mL multi-dose vial
- **Indication:** for the relief of moderate to severe pain
- **Manufacturer:** Hospira, Inc
- **Date of recall:** November 21, 2012
- **Type of recall:** voluntary, patient-level
- **Reason for recall:** two reports of packaging defects that may compromise sterility
- **NDC of recalled product:** 0409-1467-01
- **Affected lot number:** 11-293DK; Exp May 2013
- **Legacy Medco/Accredo patients impacted:** 6
- **Return/Replacement information:** Patients are being advised to contact Stericycle at 1 866 201-9071 between the hours of 8 a.m. and 5 p.m. ET, Monday through Friday

### **Implications to Express Scripts and clients**

Express Scripts is taking the following action in response to this recall:

- Quarantining product from the impacted lot
- Evaluating non-impacted lots for continued dispensing
- Notifying customer services representatives and pharmacists about the recall
- Posting web messaging on Express-Scripts.com
- Mailing letters to affected patients informing them about the recall and instructing them on how to coordinate returns/credits through Stericycle

### **Retail impact**

- Retail patients will be managed by retail pharmacies according to their professional practices.

FOR MORE INFORMATION: Contact your Express Scripts Account Management Team.