NATIONAL PBM COMMUNICATION · March 23, 2011

Dexamethasone Sodium Phosphate Injection, USP, 4mg/mL: Voluntary Recall Due to Particulate Formation [NDC# 0517-4901-25 (1mL Single Dose Vial), NDC# 0517-4905-25 (5mL Multiple Dose Vial), NDC# 0517-4930-25 (30mL Multiple Dose Vial)]

- Luitpold Pharmaceuticals, Inc., is voluntarily recalling select Dexamethasone Sodium Phosphate Injection, USP, 4mg/mL products due to presence of particles in, or potential for particulate formation within, the injection solution prior to product expiration date.
- Potential adverse effects include:
  - Interruption in blood flow within the small vessels of the lung (associated with intravenous administration);
  - Inflammation, pain, swelling, redness, and granulation formation (associated with intravenous or intramuscular administration).
- This product is typically administered to a patient in clinic by a provider, but prescription and CMOP data show dispensing activity to the patient level on an outpatient basis.

ACTIONS FOR PHARMACY SERVICE

- THESE ACTIONS ARE SEPARATE FROM BUT RELATED TO NCPS PRO RECALL LOG #1035 WHICH CONTAINS ADDITIONAL LOT NUMBERS OF PRODUCT TO BE SEQUESTERED. PATIENT CONTACT AND NOTIFICATION IS REQUIRED AS PER INSTRUCTIONS BELOW.
- All unexpired lots of Dexamethasone Sodium Phosphate Injection, USP, 4mg/mL with the following NDC numbers are affected (See Attachment [Page 2 of 2] for detailed lot information):
  - NDC# 0517-4901-25 (1mL Single Dose Vial)
  - NDC# 0517-4905-25 (5mL Multiple Dose Vial)
  - NDC# 0517-4930-25 (30mL Multiple Dose Vial)
- No other lots of this product are affected by this recall.
- Sequester and return all remaining product at the facility/CMOP level with the affected lot number(s) per the manufacturer’s instructions. Please inform your Facility Recall Coordinator when completed.
- Determine whether the affected lot number(s) (refer to lot number(s) provided in attachment) was dispensed to any patient(s). CMOP data (if available) will be provided by a CMOP representative to Pharmacy Chiefs.
- In all or almost all cases, this medication should have been picked up by the patient, or sent out, for administration in clinic. If an affected lot was dispensed to a/multiple patient(s), then:
  - Identify the patient(s).
  - Contact patient(s) who may have received the affected product for home administration by any appropriate method.
    - A sample letter can be found at:
      This template can be altered according to site-specific needs.
  - Provide patient(s) with instructions on the following:
    - How to obtain a new supply of medication.
    - How to return the medication being recalled to the pharmacy.
- Providers should continue to report any adverse events with dexamethasone sodium phosphate injection by entering the information into CPRS’ Allergies/Adverse Reactions field and/or via local reporting mechanisms. Facilities should continue to report adverse events into VA ADERS and to the FDA (as appropriate).

ACTIONS:

- **Facility Director** (or physician designee): Report completion of actions to the VISN Director.
- **Facility COS and Chief Nurse Executives**: Forward this document to all appropriate providers who handle this agent (e.g., 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. Report completion of actions to the Facility Director.
- **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).
- **VISN Directors**: Within 10 business days of receipt (due 4/5/2011), communicate to PBM/VAMedSAFE that all actions have been completed via the Feedback tool: [http://vaww.national.cmop.va.gov/PBM/visn_drug_recalls_alerts/default.aspx](http://vaww.national.cmop.va.gov/PBM/visn_drug_recalls_alerts/default.aspx)
ATTACHMENT: AFFECTED LOTS - Dexamethasone Sodium Phosphate Injection, USP, 4mg/mL: Voluntary Recall Due to Particulate Formation [NDC# 0517-4901-25 (1mL Single Dose Vial), NDC# 0517-4905-25 (5mL Multiple Dose Vial), NDC# 0517-4930-25 (30mL Multiple Dose Vial)]

DEXAMETHASONE SODIUM PHOSPHATE INJECTION, USP
STRENGTH: 4MG/ML

SIZE: 1 mL SINGLE DOSE VIAL, NDC#: 0517-4901-25

Lot # 9153, Exp Date 03/2011 Lot # 9565, Exp Date 08/2011 Lot # 0245, Exp Date 04/2011 Lot # 0678, Exp Date 10/2011
Lot # 9170, Exp Date 03/2011 Lot # 9605, Exp Date 09/2011 Lot # 0271, Exp Date 04/2011 Lot # 0710, Exp Date 10/2011
Lot # 9182, Exp Date 03/2011 Lot # 9615, Exp Date 09/2011 Lot # 0277, Exp Date 04/2011 Lot # 0736, Exp Date 10/2011
Lot # 9254, Exp Date 04/2011 Lot # 9656, Exp Date 09/2011 Lot # 0296, Exp Date 04/2011 Lot # 0792, Exp Date 11/2011
Lot # 9295, Exp Date 04/2011 Lot # 9668, Exp Date 09/2011 Lot # 0302, Exp Date 05/2011 Lot # 0803, Exp Date 11/2011
Lot # 9329, Exp Date 05/2011 Lot # 9690, Exp Date 10/2011 Lot # 0305, Exp Date 05/2011 Lot # 0819, Exp Date 11/2011
Lot # 9352, Exp Date 05/2011 Lot # 9710, Exp Date 10/2011 Lot # 0324, Exp Date 05/2011 Lot # 0836, Exp Date 12/2011
Lot # 9368, Exp Date 05/2011 Lot # 9722, Exp Date 10/2011 Lot # 0331, Exp Date 05/2011 Lot # 0846, Exp Date 12/2011
Lot # 9385, Exp Date 06/2011 Lot # 9743, Exp Date 10/2011 Lot # 0342, Exp Date 05/2011 Lot # 0853, Exp Date 12/2011
Lot # 9422, Exp Date 06/2011 Lot # 0135, Exp Date 03/2011 Lot # 0409, Exp Date 06/2011 Lot # 0879, Exp Date 12/2011
Lot # 9425, Exp Date 06/2011 Lot # 0138, Exp Date 03/2011 Lot # 0444, Exp Date 06/2011 Lot # 092679
Lot # 9441, Exp Date 06/2011 Lot # 0164, Exp Date 03/2011 Lot # 0593, Exp Date 09/2011 Lot # 093761
Lot # 9512, Exp Date 07/2011 Lot # 0215, Exp Date 03/2011 Lot # 0599, Exp Date 09/2011 Lot # 102307
Lot # 9549, Exp Date 08/2011 Lot # 0229, Exp Date 04/2011 Lot # 0639, Exp Date 09/2011

SIZE: 5 mL MULTIPLE DOSE VIAL, NDC#: 0517-4905-25

Lot # 9210, Exp Date 03/2011 Lot # 9571, Exp Date 08/2011 Lot # 0317, Exp Date 05/2011 Lot # 0704, Exp Date 10/2011
Lot # 9335, Exp Date 05/2011 Lot # 9667, Exp Date 09/2011 Lot # 0404, Exp Date 06/2011 Lot # 0805, Exp Date 11/2011
Lot # 9393, Exp Date 05/2011 Lot # 0157, Exp Date 03/2011 Lot # 0407, Exp Date 06/2011 Lot # 0878, Exp Date 12/2011
Lot # 9417, Exp Date 06/2011 Lot # 0217, Exp Date 03/2011 Lot # 0556, Exp Date 08/2011 Lot # 1055, Exp Date 01/2012
Lot # 9516, Exp Date 08/2011 Lot # 0269, Exp Date 04/2011 Lot # 0624, Exp Date 09/2011 Lot # 092115

SIZE: 30 mL MULTIPLE DOSE VIAL, NDC#: 0517-4930-25

Lot # 0213, Exp Date 03/2011 Lot # 0387, Exp Date 06/2011 Lot # 0679, Exp Date 10/2011 Lot # 0840, Exp Date 12/2011
Lot # 0306, Exp Date 05/2011 Lot # 0565, Exp Date 08/2011 Lot # 0771, Exp Date 11/2011