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:

http://vaww.national.cmop.va.gov/PBM/Other%20Documents%20and%20Resources/Recall%20Patient%20Letter%20Template.doc

    - 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.*

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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 # 9218, Exp Date 03/2011	Lot # 9615A, Exp Date 09/2011	Lot # 0282, Exp Date 04/2011	Lot # 0773, Exp Date 11/2011
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 # 9250, Exp Date 04/2011	Lot # 9620, Exp Date 09/2011	Lot # 0392, Exp Date 06/2011	Lot # 0765, Exp Date 11/2011
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	