

NATIONAL PBM COMMUNICATION · February 11, 2011

Albuterol Sulfate Inhalation Solution 0.083% Recall - Packaging Error with Ipratropium Bromide, 0.5mg and Albuterol Sulfate Inhalation Solution, 3mg (IBAS)

INFORMATION FOR PROVIDERS

- Nephron Pharmaceuticals is voluntarily recalling one lot of Albuterol Inhalation Solution 0.083% due to a potential packaging error.
- Packages of albuterol and ipratropium inhalation solution may be labeled as albuterol inhalation solution, making it possible for a patient to use albuterol plus ipratropium when only albuterol is prescribed.
- Patients with narrow-angle glaucoma, prostatic hypertrophy, or bladder-neck obstruction who are inadvertently administered ipratropium bromide could experience worsening of symptoms due to anticholinergic effects.
- Patients taking other anticholinergic-containing medications who are inadvertently administered ipratropium bromide concomitantly could experience additive anticholinergic effects.
- Hypersensitivity reactions have been reported with ipratropium or its components.

INFORMATION FOR PHARMACY SERVICE

- The following product and lot number is affected:

| Description | Lot# | Exp Date | NDC | UPC | Econo # |
|--------------------------------|--------|----------|-------------|-------------|---------|
| ALBUTEROL INHSOL.083%NEP3MLX60 | A0B17A | 09/2012 | 00487950160 | 30487950160 | 2416964 |

- 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 per the manufacturer's instructions. Please inform your Facility Recall Coordinator when completed.
- Determine whether the affected lot number (refer to lot number provided above) was dispensed to any patient(s) for home administration. It is recommended to start from November 2010 and continue to present for this determination. CMOP confirmed that they did not dispense this affected lot.
- If an affected lot was dispensed to a/multiple patient(s) for home administration, 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:
 - To continue using the medication with the affected lot number, unless contraindicated, until they receive a new supply. When the correct medication is received, patient(s) should begin using the new medication and return the recalled supply as instructed.
 - 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 albuterol and albuterol/ipratropium 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).

REFERENCES:

Ipratropium Bromide 0.5 mg and Albuterol Sulfate 3 mg [package insert]. Orlando, FL: Nephron Pharmaceuticals; October 2007.

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 prescribe this agent (e.g., **primary care providers** and **pulmonary specialists**, 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 2/28/2011), 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.