NATIONAL PBM COMMUNICATION · November 22, 2013

Imitrex STATdose System and Sumatriptan Succinate Injection Refill - Recall Due to Loss of Sterility

- GlaxoSmithKline (GSK) has issued a voluntary recall for one lot of Imitrex STATdose System injection distributed by GSK and one lot of Sumatriptan Injection Refill cartridges distributed by Sandoz.
- The medication comes in pre-filled syringes with a sterile needle for injection; however, needles in the affected lots may be protruding through their protective plastic shields which may compromise sterility.
- There is a potential risk of infection when using the product because of the protrusion.

PRODUCT SEQUESTRING ACTIONS

- Affected lot(s) include:

<table>
<thead>
<tr>
<th>PRODUCT DESCRIPTION</th>
<th>NDC</th>
<th>LOT NUMBER</th>
<th>EXPIRY</th>
</tr>
</thead>
<tbody>
<tr>
<td>GSK Imitrex STATdose System – Each unit contains one autoinjector pen, two 6mg single-dose prefilled syringe cartridges and one carrying case</td>
<td>0173-0479-00</td>
<td>C636293</td>
<td>Jun-15</td>
</tr>
<tr>
<td>Sandoz Sumatriptan Injection Refill – Each unit contains two 6mg single-dose prefilled syringe cartridges</td>
<td>0781-3173-07</td>
<td>C636242</td>
<td>Jun-15</td>
</tr>
</tbody>
</table>

- Following the action due dates in Product Recall Office Log # 7556 and 7557 (available at: http://vaww.recalls.ncps.med.va.gov/WebRecalls/Recalls.html), sequester and then return all remaining affected product at the CMOP/facility per manufacturer’s instructions. Please inform your Facility Recall Coordinator when completed.

PATIENT NOTIFICATION ACTIONS

- Determine whether the affected product(s) was dispensed to any patient(s) for home administration. CMOP data (if available) will be provided by a CMOP representative to Pharmacy Chiefs. Recalled product was distributed between August 27, 2013 and October 14, 2013.
- If an affected lot(s) was dispensed to a patient(s) for home administration, then:
  - Identify the patient(s).
  - Contact patient(s) who may have received the affected product(s) for home administration by any appropriate method.
    - A sample letter can be found at: https://vaww.cmopnational.va.gov/cmop/PBM/Other%20Documents%20and%20Resources/Recall%20Patient%20Letter%20Template.doc
      This template can be altered according to site-specific needs.
  - Provide patient(s) in possession of the recalled product with instructions on the following:
    - How to return the product being recalled to the pharmacy.
    - How to obtain a new supply of product.
    - When the correct product is received, patients should begin using the new product and return the recalled supply as instructed.
- Providers should continue to report any adverse reactions with the use of Imitrex STATdose System injection and Sumatriptan Succinate Injection Refill cartridges by entering the information into CPRS’ Allergies/Adverse Reactions field and/or via local reporting mechanisms. Adverse events should also be reported, as appropriate, to the VA ADERS program and FDA MedWatch (1-800-FDA-1088, fax 1-800-FDA-0178, online at https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm, or by mail).

FEEDBACK NOTIFICATION 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, neurologists, and 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 issue (due 12/06/2013), communicate to PBM/VAMedSAFE that all product sequestration actions have been completed via the Feedback tool: https://vaww.cmopnational.va.gov/cmop/PBM/visn_drug_recalls_alerts/default.aspx.