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 SEQUESTERING ACTIONS

- Affected lot(s) include:

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

- 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 .*