NATIONAL PBM COMMUNICATION · January 31, 2013

Ferrous Sulfate Tablets, 325 mg Labeled as Rugby Natural Iron Supplement: Recall - Bottle May Contain Meclizine HCl 25 mg Tablets

- On January 18, 2013, Advance Pharmaceutical Inc. recalled one lot of Ferrous Sulfate Tablets 325 mg because of a report that the bottle incorrectly contains Meclizine HCl 25 mg tablets instead.
- Inadvertently taking Meclizine HCl 25 mg instead of the intended Ferrous Sulfate 325 mg may pose risks of serious side effects in patients who use alcohol or other sedatives; patients with CNS conditions; patients with kidney or liver impairment; elderly patients; nursing infants whose lactating mothers received the drug; and newborns whose mothers received the drug immediately before childbirth.
- Dose-related and potentially life-threatening toxicities resulting from Meclizine accumulation include impaired alertness, drowsiness, confusion, low blood pressure, coma, and respiratory depression.

PRODUCT SEQUESTERING ACTIONS

- Details of affected lot include:
  - Product(s): Ferrous Sulfate 325mg (5GR) 100 Count.
  - Product Identification No(s): NDC 00536-5890-01.
  - Serial/Lot No(s): 12G468.
  - Expiration date for the lot: 07/14.
  - Manufacturer: Advance Pharmaceutical for Rugby Laboratories.
- Following the action due dates in **Product Recall Office Log # 3347** (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 FRC when completed.

PATIENT NOTIFICATION ACTIONS

- Determine whether the affected product(s) was dispensed to any patient(s) for home administration. Affected product was shipped between 09/21/2012 and 10/03/2012. VISNs with PPV purchases include: 1, 2, 3, 11, 17, 20, and 21. PPV sales data does not include lot number. VISNs 16, 17, and 18 had medical centers with prescriptions dispensed from CMOP with the affected lot number.
- 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:
      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.
  - If necessary, provide patient(s) in possession of the recalled product with instructions on the following:
    - How to obtain a new supply of product.
    - How to return the product being recalled to the pharmacy.
    - When the correct product is received, patients should begin using the new product and return the recalled supply as instructed.
    - Patients should not continue to take the product until they obtain replacement product.
- Providers should continue to report any adverse reactions with the use of any iron supplement product(s) 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).

REFERENCES

FDA Drug Safety Communication: Ferrous Sulfate Tablets, 325 mg Labeled as Rugby Natural Iron Supplement: Recall - Bottle May Contain Meclizine HCl 25 mg Tablets. http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm336137.htm . (Accessed 01/25/2013).

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 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 02/14/2013), 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 .*