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

Inadvertently taking Meclizine HCI 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 (SGR) 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](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 by any appropriate method, then:
  - Identify the patient(s).
  - Contact patient(s) who may have received the affected product(s) for home administration.

  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](https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm), or by mail).

**REFERENCES**


**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](https://vaww.cmopnational.va.gov/cmop/PBM/visn_drug_recalls_alerts/default.aspx).