NATIONAL PBM COMMUNICATION · July 1, 2013

Rugby Aspirin Lot Recalled for Containing Acetaminophen Tablets

- On June 19, 2013, Advance Pharmaceuticals Inc., initiated a recall of one lot of Rugby label Enteric Coated Aspirin Tablets, 81mg, due to the discovery of one bottle erroneously containing Acetaminophen 500mg tablets instead.
- Patients who inadvertently take Acetaminophen 500mg instead of Enteric Coated Aspirin 81mg may be at risk of hepatotoxicity, especially those with:
  - Concomitant therapy with other drugs containing acetaminophen;
  - Consumption of ≥ 3 alcoholic beverages every day;
  - Liver disease.
- In addition, patients who use Enteric Coated Aspirin 81mg as primary or secondary cardioprophylaxis or post-stroke prophylaxis may have an increased risk of developing a myocardial infarction, cerebrovascular accident, or other vascular event if they do not receive adequate dosing for prevention.

PRODUCT SEQUESTERING ACTIONS

- Details of affected lot (s)include:

PRODUCT	NDC	UPC	LOT NUMBER	EXPIRATION DATE	DISTRIBUTION DATE
ENTERIC-COATED ASPIRIN TABLETS, 81 MG, BOTTLE SIZE: 120 TABLETS, RUGBY LABEL	0536-3086-41	3 0536-3086-41 9	13A026	01/2015	02/25/2013

- Product label image is available at: http://www.fda.gov/Safety/Recalls/ucm357917.htm .
- Following the action due dates in **Product Recall Office Log # 7035** (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. Affected product was shipped to VISNs 1, 7, 8, 12, 16, 17, 18, 21, 22, and 23 on 02/25/2013.
- If an affected lot(s) was dispensed to a patient(s) for home administration, then:
  - Identify the patient(s).
  - Contact the patient(s) who may have received the affected product(s) for home administration by letter (or other means).
    - A sample letter can be found at:

https://vaww.cmopnational.va.gov/cmop/PBM/Other%20Documents%20and%20Resources/ASA%20Recall%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:
    - Patients should observe if their aspirin medication bottles contain any pills that do not look like aspirin. **Aspirin should be a small yellow tablet**. In the case that they find tablets that do not fit the description of the correct product, patients should alert the facility immediately.
    - How to return the product being recalled to the pharmacy.
    - How to obtain a new supply of product.
    - Patients should not continue to take the product until they obtain replacement 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 any aspirin 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).

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 07/15/2013), 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 .*