

NATIONAL PBM COMMUNICATION · October 3, 2014

Creon Delayed-Release Capsules Recall - Possible Presence of Different Strength Capsule(s) Other than Labelled in Bottle

- AbbVie Inc., is conducting a voluntary recall of one lot of Creon Delayed-Release Capsules due to the presence of a capsule of Creon that may be a different strength than labelled. The incorrect strength is not stated.
- The manufacturer states that exposure to the product is not likely to cause adverse health consequences.
- Creon is a combination of porcine-derived lipases, proteases, and amylases indicated for the treatment of exocrine pancreatic insufficiency due to cystic fibrosis, chronic pancreatitis, pancreatectomy, or other conditions.

PRODUCT SEQUESTERING ACTIONS

- This patient level recall involves the following product:

PRODUCT NAME	STRENGTH	NDC NUMBER	LOT NUMBER	EXPIRATION DATE
Creon Delayed-Release Capsules	24,000 USP units of lipase; 76,000 USP units of protease; 120,000 USP units of amylase.	0032-1224-07	1020156	03/21/2016

- This specific lot was packaged on June 21, 2014 and distributed within the U.S. between July 9, 2014 and August 26, 2014.
- Following the action due dates in **Product Recall Office Log # 8644** (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.
- 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>
- 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 Creon Delayed-Release Capsules 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:

1. ABBVIE URGENT CORRECTION: DRUG PRODUCT RECALL. Creon Delayed-Release Capsules. http://www.smithdrug.com/uploads/recalls/creon24_091914.pdf (Accessed 09/30/2014)
2. CREON (pancrelipase) delayed-release capsules for oral use - product package insert. North Chicago, IL: Abbott Laboratories GmbH; March 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, internal medicine, gastrointestinal specialists, 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 10/20/2014), 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.