

PBM-2015-02

June 24, 2015

ITEM: NEXIUM® Delayed-Release Capsules 20mg, Recall for containing SEROQUEL XR® 150 MG tablets

SPECIFIC INCIDENT(S): AstraZeneca is voluntarily recalling NEXIUM (esomeprazole magnesium) Delayed-Release 20mg [thirty (30)-capsule containers] due to the discovery that a small quantity of bottles within this lot may contain sixty (60) SEROQUEL XR (quetiapine fumarate) 150 mg tablets instead.

GENERAL INFORMATION:

- NEXIUM Delayed-Release Capsules, 20 mg are opaque, hard gelatin, amethyst colored capsules with two radial bars in yellow on the cap and NEXIUM 20 mg in yellow on the body
- SEROQUEL XR® 150 mg tablets are white, capsule shaped, biconvex, intagliated with 'XR 150' on one side and plain on the other.
- The following lot has been identified:

| Description | Lot #, Exp Date, Ship Dates | NDC | UPC | Econo # |
|---|---|--------------|---------------|---------|
| NEXIUM® (esomeprazole magnesium) Delayed-Release Capsules, 20mg packaged in one (1) bottle containing 30 capsules | FC0064, EXP: 5/2017 Shipped: 3/16/2015-5/27/2015 | 0186-5020-31 | 3-01865-02031 | 1295799 |

- VA PBM has identified that at least eight facilities have purchased the affected product and that CMOP has dispensed the affected lot to at least 55 patients. There may be other facilities that have also dispensed the affected lot. Hence, a patient level recall is being initiated across VA.
- This alert is an extension of the product sequestration actions in **Product Recall Office Log # 9741** (available at: <http://vaww.recalls.ncps.med.va.gov/WebRecalls/Recalls.html>).
- Providers should report any adverse outcomes relating to this inadvertent switching of NEXIUM and SEROQUEL via local reporting mechanisms. Adverse events should also be reported, as appropriate, to the VA ADERS program and FDA MedWatch.

ACTIONS:

PROVIDER NOTIFICATION:

- **Facility Director** (or physician designee): Forward this document to the Facility Chief of Staff (COS).
- **Facility COS** (and Chief Nurse Executives): Forward this document to all appropriate providers who prescribe this agent (e.g., **primary care providers, gastroenterology 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.
- **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.



PATIENT NOTIFICATION:

- **Chief of Pharmacy:** Within 10 business days of issue (due 07/8/2015):
 - 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. Affected product started shipping March 2015.
 - If an affected lot 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 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:
 - 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.
 - Communicate to PBM/VAMedSAFE that all patient notification actions have been completed via the VHA Alerts and Recalls Website:
<http://vaww.recalls.ncps.med.va.gov/WebRecalls/Recalls.html>.

SOURCE: AstraZeneca

REFERENCE(S): AstraZeneca – Urgent Drug Recall.

ATTACHMENT(S): None.

CONTACTS: Pharmacy Benefits Management Services (PBM) at (708)786-7862.