

Alerts are based on the clinical evidence available at the time of publication. Recommendations are intended to assist practitioners in providing consistent, safe, high quality, and cost effective drug therapy. They are not intended to interfere with clinical judgment. When using dated material, the clinician should consider new clinical information, as available and applicable.

NATIONAL PBM PATIENT LEVEL RECALL COMMUNICATION

PBM-2017-02

MARCH 7, 2017

**ITEM:
SPECIFIC
INCIDENT(S):**

**GENERAL
INFORMATION:**

Mirtazapine Tablets, USP 45mg – Recall Due to Potential of Commingled Tablets

- Mylan Pharmaceuticals Inc. is voluntarily recalling three batches of mirtazapine tablets, USP 45 milligrams (mg) packaged in bottles of 30, 100, and 500 due to the potential for commingled tablets within the batches.
- Mirtazapine tablets are indicated for the treatment of major depressive disorder.
- Per manufacturer, “A risk to the patient population may be present if ingestion of the foreign tablet were to occur”. However, upon contact, Mylan was not able to provide any information on the type of “foreign” tablets that were commingled in the batches.
- Risk of suboptimal symptom control, clinical worsening, or unusual changes in behavior may become an issue if a patient does not receive their intended dose(s) of mirtazapine.
- Affected products include:

NDC	NAME AND STRENGTH	SIZE	BATCH #	EXPIRES
0378-3545-05	Mirtazapine Tablets, USP 45mg	Bottles of 500	3078936	August 2019
0378-3545-93	Mirtazapine Tablets, USP 45mg	Bottles of 30	3078937	August 2019
0378-3545-01	Mirtazapine Tablets, USP 45mg	Bottles of 100	3078937	August 2019
0378-3545-93	Mirtazapine Tablets, USP 45mg	Bottles of 30	3078938	August 2019

- The affected lots were distributed in the US between October 2016 and December 2016.
- This recall is an extension of the product sequestration actions in **Product Recall Office Log # 11717** (available at: <http://vaww.recalls.ncps.med.va.gov/WebRecalls/Recalls.html>).
- Providers should continue to report any adverse reactions with the use of mirtazapine tablets 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).

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, mental health 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

NATIONAL PBM PATIENT LEVEL RECALL COMMUNICATION

authority to practice at the facility and to your respective Institutional Review Board (IRB).

PATIENT NOTIFICATION:

- **Chief of Pharmacy:** Within 10 business days of issue (due 03/20/2017):
 - Determine whether the affected product(s) was dispensed to any patient(s) for home administration. CMOP data will be provided by CMOP representatives to Pharmacy Chiefs.
 - 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:
 - 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.
 - Mylan-manufactured mirtazapine tablets, USP 45mg are film-coated with the following characteristics:
 - ✓ Shape: ROUND
 - ✓ Size: 10mm
 - ✓ Color: BROWN
 - ✓ Scored: 1 side
 - ✓ Imprint: M;545
- 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: Manufacturer

REFERENCE(S): Mylan Notice of Voluntary Drug Recall [Data on file, Date 01/25/17]. Head of Pricing and Contracts, Generics, written communication, February 21, 2017.

ATTACHMENT(S): None.

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