

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.

PBM-2017-19**DECEMBER 5, 2017**

ITEM: Diphenoxylate Hydrochloride and Atropine Sulfate Tablets : Recall Due to Possible Sub Potent and Super Potent Tablets

SPECIFIC INCIDENT(S): Greenstone is voluntarily recalling multiple lots of diphenoxylate hydrochloride and atropine sulfate tablets, USP due to possible sub potent or super potent tablets.

GENERAL INFORMATION:

- Diphenoxylate hydrochloride and atropine sulfate tablets are indicated as adjunctive therapy in the management of diarrhea in patients 13 years of age and older.
- Patients receiving sub potent product may potentially experience uncontrolled symptoms.
- Over dosage can be life-threatening and symptoms may include respiratory depression, coma, delirium, lethargy, dryness of the skin and mucous membranes, mydriasis or miosis, flushing, hyperthermia, tachycardia, hypotonia, tachypnea, toxic encephalopathy, seizures and incoherent speech.
- Affected lots of diphenoxylate hydrochloride and atropine tablets are listed below:

NDC	Lot Number	Expiration Date	Strength	Configuration/Count
59762-1061-1	R83962	2021 OCT 31	2.5 mg/0.025 mg	Bottle containing 100 tablets
59762-1061-1	R93347	2021 OCT 31	2.5 mg/0.025 mg	Bottle containing 100 tablets
59762-1061-1	R93348	2021 OCT 31	2.5 mg/0.025 mg	Bottle containing 100 tablets
59762-1061-1	R93349	2021 OCT 31	2.5 mg/0.025 mg	Bottle containing 100 tablets
59762-1061-1	R93350	2021 OCT 31	2.5 mg/0.025 mg	Bottle containing 100 tablets
59762-1061-1	R93351	2021 OCT 31	2.5 mg/0.025 mg	Bottle containing 100 tablets
59762-1061-1	R93352	2021 OCT 31	2.5 mg/0.025 mg	Bottle containing 100 tablets
59762-1061-1	S57831	2021 NOV 30	2.5 mg/0.025 mg	Bottle containing 100 tablets
59762-1061-1	S57832	2021 NOV 30	2.5 mg/0.025 mg	Bottle containing 100 tablets
59762-1061-1	S57834	2021 NOV 30	2.5 mg/0.025 mg	Bottle containing 100 tablets
59762-1061-2	R93356	2021 OCT 31	2.5 mg/0.025 mg	Bottle containing 1000 tablets
59762-1061-2	R93357	2021 OCT 31	2.5 mg/0.025 mg	Bottle containing 1000 tablets
59762-1061-2	R93358	2021 OCT 31	2.5 mg/0.025 mg	Bottle containing 1000 tablets
59762-1061-2	R97310	2021 OCT 31	2.5 mg/0.025 mg	Bottle containing 1000 tablets

- Products were distributed nationwide to wholesalers/retailers from November 2016 through June 2017 in the United States.
- To date, there have been no reports of adverse events related to this recall.
- FDA recommends to immediately stop use, distribution, and quarantine immediately.

- This alert is an extension of the product sequestration actions in **Product Recall Office Log #12459** (available at: <http://vaww.recalls.ncps.med.va.gov/WebRecalls/Recalls.html>).
- Providers should continue to report any adverse reactions with the use of diphenoxylate hydrochloride and atropine 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, gastroenterologists, 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 (IRB).

PATIENT NOTIFICATION:

- **Chief of Pharmacy:** Within 10 business days of issue (due 12/19/2017):
 - Determine whether the affected product(s) was administered to any patient(s) for home use. CMOP data will be provided by CMOP representatives to Pharmacy Chiefs.
 - If an affected lot(s) was administered to patient(s) during home administration, then:
 - Identify the patient(s).
 - Contact the patient(s) who may have received the affected product(s) for home use 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) who have received the recalled product with instructions on the following:
 - How to return the product being recalled to the pharmacy.
 - Patients should not continue to take the product until they obtain a new supply of product.

- Patients should contact their provider immediately if experiencing symptoms or other health problems while taking diphenoxylate hydrochloride and atropine tablets.

- 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: FDA

REFERENCE(S):

1. FDA Safety Alerts for Human Medical Products. Diphenoxylate Hydrochloride and Atropine Sulfate Tablets by Greenstone: Recall – Possible Sub Potent and Super Potent Tablets
<https://www.fda.gov/safety/medwatch/safetyinformation/safetyalertsforhumanmedicalproducts/ucm585761.htm> . (Accessed 12/4/2017).
2. FDA Recalls, Market Withdrawals, & Safety Alerts. Greenstone Issues Voluntary Nationwide Recall of Diphenoxylate Hydrochloride and Atropine Sulfate Tablets, USP Due to Possible Sub Potent and Super Potent Tablets.
<https://www.fda.gov/Safety/Recalls/ucm585708.htm> . (Accessed 12/4/2017).

ATTACHMENT(S): None.

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