Greenstone – Recall of diphenoxylate/atropine

- On November 16, 2017, the FDA announced a consumer-level recall of some lots of Greenstone's diphenoxylate/atropine tablets because product from these lots has the potential to be super potent or sub potent.

- The recalled products were distributed nationwide to wholesalers/retailers from November 2016 through June 2017.

Product Description	NDC #	Lot # (Expiration Date)
Diphenoxylate/atropine 2.5 mg/0.025 mg tablets, 1000-count bottle	59762-1061-02	R97310 (10/31/21); R93358 (10/31/21); R93357 (10/31/21); R93356 (10/31/21)
Diphenoxylate/atropine 2.5 mg/0.025 mg tablets, 100-count bottle	59762-1061-01	S57834 (11/30/21); S57832 (11/30/21) S57831 (11/30/21); R93352 (10/31/21); R93351 (10/31/21); R93350 (10/31/21); R93349 (10/31/21); R93348 (10/31/21); R93347 (10/31/21); R83962 (10/31/21)

- Diphenoxylate/atropine tablets are indicated as adjunctive therapy in the management of diarrhea in patients ≥ 13 years of age.

- The use of the recalled product in patients with uncontrolled diarrhea due to chronic medical conditions may predispose the patient to toxicity from either the diphenoxylate or atropine components.

- The product label states that over dosage can be life-threatening and symptoms may include opioid and/or anticholinergic effects including 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.

- Respiratory depression has been reported up to 30 hours after ingestion and may recur despite an initial response to narcotic antagonists.

- The use of the impacted super potent product when used as labeled has a low probability of being associated with adverse events of limited severity such as lethargy, skin flush, and drowsiness. Serious adverse events such as coma and respiratory depression are improbable. If a patient was to receive a sub potent tablet, symptoms may not be controlled.

- To date, there have been no reports of adverse events related to this recall.

- Anyone with an existing inventory of the recalled products should stop use and distribution and quarantine immediately.

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- For recall assistance, contact Stericycle at **1-855-215-4982**. For any clinical questions regarding this recall, contact Pfizer at **1-800-438-1985**.

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