The United States: Greenstone issues voluntary nationwide recall of Diphenoxylate Hydrochloride and Atropine Sulfate Tablets, USP due to possible sub potent and super potent tablets

The US Food and Drug Administration (FDA) announces that Greenstone LLC, a wholly owned subsidiary of Pfizer Inc., is voluntarily recalling multiple lots of diphenoxylate hydrochloride and atropine sulfate tablets, USP to the consumer level. Greenstone initiated this recall because product from these lots has the potential to be super potent or sub potent.

Diphenoxylate hydrochloride and atropine sulfate tablets are packaged in bottles of 100-count (NDC 59762-1061-1) and 1000-count (NDC 59762-1061-2). The affected diphenoxylate hydrochloride and atropine sulfate lots include the following lot numbers and expiration dates:

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.

The use of this 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.

Please refer to the following website in FDA for details:
https://www.fda.gov/Safety/Recalls/ucm585708.htm

In Hong Kong, the above product is not a registered pharmaceutical product.

Ends/Friday, Nov 17, 2017
Issued at HKT 16:00