ProCare Rx

URGENT NOTICE

TYPE: Drug Recall

Possible Risk to Public Safety

Drug Name: **Hyoscyamine Sulfate**

Audience: Pharmacy, Patient

Date: **09/14/16**

ISSUE

Virtus Pharmaceuticals Opco II, LLC (Virtus) is voluntarily recalling seven batches of hyoscyamine sulfate (0.125mg) to the consumer level which include the tablet, sublingual, and orally disintegrating tablet form. This recall is being initiated due to both superpotent and subpotent test results. All of these batches were manufactured by Pharmatech LLC for distribution by Virtus throughout the United States and Puerto Rico.

This includes lot numbers 30051601-30051604, 30011601, and 30031601-30031602, which expire January 31, 2018. A small number of bottles from lot 30051602 have the incorrect expiration date printed on them, January 2028.

To date, Virtus has received three adverse event reports involving hallucinations, stroke-like symptoms, confusion, dizziness, blurred vision, dry mouth, slurred speech, imbalance, and disorientation. These symptoms were reported to be resolved are all believed to be temporary. None of the adverse events were life threatening, and the patients who reported the incidents were treated and released.

BACKGROUND

Treating certain stomach or bowel problems (eg, ulcers, spasms or cramping, irritable bowel syndrome, symptoms of colic), certain bladder problems (eg, spastic bladder, cystitis), and excessive secretions caused by inflammation of the pancreas, and for aiding in certain medical procedures or surgery. It may also be used for other conditions as determined by your doctor.

RECOMMENDATION

Virtus is notifying its distributors and retailers by letter and email and is arranging for return of all recalled drug product. Consumers, distributors, and retailers that have the hyoscyamine sulfate product lots listed above should stop using/distributing and return to place of purchase.

Complete the response form and send to rxrecalls@inmar.com to be issued return authorization labels. If you have any questions or need additional information, please contact recalls@virtusrx.com.