

## Company Announcement

When a company announces a recall, market withdrawal, or safety alert, the FDA posts the company's announcement as a public service. FDA does not endorse either the product or the company.

# Virtus Pharmaceuticals Opco II, LLC Issues Voluntary Nationwide Recall of Hyoscyamine sulfate Due to Superpotent and Subpotent Results

## For Immediate Release

September 14, 2016

## Contact

### Consumers

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### Media

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## Announcement

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Virtus Pharmaceuticals Opco II, LLC (Virtus) is voluntarily recalling seven batches of Hyoscyamine sulfate (0.125mg) listed in the table below, 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.

Hyoscyamine Sulfate 0.125 mg Recalled Batches				
Form	NDC	Package Size	Batch #	Expiry
Sublingual Tablets	76439-309-10	100-count	30051601	Jan-18
			30051602	Jan-18 Jan-28*
			30051603	Jan-18
			30051604	Jan-18
Oral Disintegrating Tablets	76439-307-10	100-count	30011601	Jan-18
Tablets	76439-308-10	100-count	30031601	Jan-18
			30031602	Jan-18

\*A small number of bottles from this lot have the incorrect expiration date printed on them.

Taking a product that is superpotent could result in hot/dry skin, fever, blurred vision, sensitivity to light, dry mouth, unusual excitement, fast or irregular heartbeat, dizziness, an inability to completely empty the bladder, and seizures. The severity of the adverse event would depend on how superpotent the tablet was. Adverse events such as clotted blood within the tissues and fractures could occur, as a result of falls from dizziness or seizures if the strength is particularly high. 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.

Hyoscyamine sulfate is an anticholinergic agent which blocks the action of acetylcholine and is used to treat diseases like asthma, incontinence, stomach cramps, peptic ulcers, control gastric secretion, intestinal spasm and other bowel disturbances. These products were distributed Nationwide in the U.S. and Puerto Rico starting on March 11, 2016, to distributors, hospitals, and retail pharmacies.

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.

Consumers with questions regarding this recall can contact Virtus at 1-855-255-6076 on Monday through Friday from 8 am to 5 pm EST or [rxrecalls@inmar.com](mailto:rxrecalls@inmar.com). (mailto:rxrecalls@inmar.com) Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using these drug products.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report Online: [www.fda.gov/medwatch/report.htm](http://www.fda.gov/medwatch/report.htm) (<http://www.fda.gov/MedWatch/report.htm>)
- Regular Mail or Fax: Download form [www.fda.gov/MedWatch/getforms.htm](http://www.fda.gov/MedWatch/getforms.htm) (<http://www.fda.gov/MedWatch/getforms.htm>) or call 1-800-332-1088 to request a reporting form, then

complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178.

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

### About Virtus

Virtus Pharmaceuticals is a specialty niche pharmaceutical company focused on the development and marketing of prescription products to pharmaceutical wholesalers, distributors and retailers across the United States. Virtus offers its customers a diversified product portfolio covering a broad range of therapeutic areas, including prenatal vitamins, women's health, vitamin supplements, anti-bacterials, and others, in a variety of dosage forms. Virtus is headquartered in Tampa, FL.

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