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.

Westminster Pharmaceuticals, LLC. Issues Voluntary Nationwide Recall of Levothyroxine and Liothyronine (Thyroid Tablets, USP) Due to Risk of Adulteration

For Immediate Release

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Contact

Consumers

Jonathan H. Olive
recalls@wprx.com (mailto: recalls@wprx.com)
888-354-9939

Announcement

Westminster Pharmaceuticals, LLC is voluntarily recalling all lots, within expiry, of Levothyroxine and Liothyronine (Thyroid Tablets, USP) 15 mg, 30 mg, 60 mg, 90 mg, & 120 mg to the wholesale level. These products are being recalled as a precaution because they were manufactured using active pharmaceutical ingredients that were sourced prior to the FDA's Import Alert of Sichuan Friendly Pharmaceutical Co., Ltd., which as a result of a 2017 inspection were found to have deficiencies with Current Good Manufacturing Practices (cGMP). Substandard cGMP practices could represent the possibility of risk being introduced into the manufacturing process.

To date, Westminster Pharmaceuticals has not received any reports of adverse events related to this product.

Levothyroxine and Liothyronine (thyroid tablets, USP) for oral use is a natural preparation derived from porcine thyroid glands. Thyroid tablets contain both tetraiodothyronine sodium (T4 levothyroxine) and liothyronine sodium (T3 liothyronine). Levothyroxine and Liothyronine tablets (thyroid tablets, USP) are indicated as replacement or

supplemental therapy in patients with hypothyroidism. Appropriate adjustments of the various therapeutic measures directed at these concomitant endocrine diseases are required. Thyroid is not associated with serious adverse reactions and does not have a known tumorigenic potential.

Because these products may be used in the treatment of serious medical conditions, patients taking the recalled medicines should continue taking their medicine until they have a replacement product.

The products subject to recall are packed in 100-count bottles. To best identify the product the NDC's, Product Description, Lot numbers and Expiration dates are listed below. These lots were distributed nationwide in the USA to Westminster's direct accounts.

NDC	Product	Lot	Expiration
69367-159-04	Levothyroxine and Liothyronine (Thyroid Tablets, USP) 15mg X 100ct	15918VP03	2/29/2020
		15918VP02	2/29/2020
		15918VP01	2/29/2020
		15918007	3/31/2020
		15918006	3/31/2020
		15918005	2/29/2020
		15918004	12/31/2019
		15918003	12/31/2019
		15918002	12/31/2019
		15918001	12/31/2019
		15917VP03	10/31/2019
		15917VP02	10/31/2019
		15917VP01	10/31/2019
69367-155-04	Levothyroxine and Liothyronine (Thyroid Tablets, USP) 30mg X 100ct	15517VP01	8/31/2019
		15517VP02	8/31/2019
		15517VP03	8/31/2019
		15518001	12/31/2019
		15518002	3/31/2020
69367-156-04	Levothyroxine and Liothyronine (Thyroid Tablets, USP) 60mg X 100ct	15618011	3/31/2020
		15618009	2/29/2020
		15618008	2/29/2020

NDC	Product	Lot	Expiration
		15618004	12/31/2019
		15618002	12/31/2019
		15617VP06	11/30/2019
		15617VP05	11/30/2019
		15617VP04	12/31/2019
		15617VP03	7/31/2019
		15617VP01	7/31/2019
		15617VP-02	7/31/2019
69367-157-04	Levothyroxine and Liothyronine (Thyroid Tablets, USP) 90mg X 100ct	15717VP-01	7/31/2019
		15717VP-02	7/31/2019
		15717VP-03	7/31/2019
		15718004	3/31/2020
		15717002	12/31/2019
69367-158-04	Levothyroxine and Liothyronine (Thyroid Tablets, USP) 120mg X 100ct	15817VP-01	9/30/2019
		15817VP-02	9/30/2019
		15817VP-03	9/30/2019
		15818001	3/31/2020

Westminster is notifying its direct accounts by email and by phone to immediately discontinue distribution of the product being recalled and to notify their sub-wholesale accounts of this product recall and make arrangements for impacted product to be returned to Westminster. Instructions for returning recalled products are given in the Recall Notice Letter and Recall Response Form. Consumers that have these products which are being recalled should not discontinue use before contacting their physician for further guidance.

Customers and patients with medical-related questions, information about an adverse event or other questions about the Westminster's product's being recalled should contact Westminster's Regulatory Affairs department by phone at: 888-354-9939

- Live calls are received Monday-Friday, 9:00AM - 5:00PM EST with voicemail available 24 hours/day, 7 days/week or email **recalls@wprx.com. (mailto:recalls@wprx.com)**

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)**

- **Regular Mail or Fax**: Download form **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

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