

Levothyroxine and Liothyronine – Westminster Pharmaceuticals

On August 9, 2018 the U.S. Food and Drug Administration (FDA) announced that Westminster Pharmaceuticals, LLC is voluntarily recalling all lots, within expiry, of Levothyroxine and Liothyronine 15mg, 30mg, 60mg, 90mg & 120mg. These products are being recalled as a precaution because they were manufactured using active pharmaceutical ingredients that were 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.

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.

See affected products below:

| NDC | Product | Lot / Expiration |
|---------------|---|---|
| 69367-0159-04 | 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 |
| 69367-0155-04 | 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 |
| 69367-0156-04 | Levothyroxine and Liothyronine (Thyroid Tablets, USP) 60mg x 100ct | 15618011 / 3-31-2020 15618009 / 2-29-2020 15618008 / 2-29-2020 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 15617VP02 / 7-31-2019 |
| 69367-0157-04 | Levothyroxine and Liothyronine (Thyroid Tablets, USP) 90mg x 100ct | 15717VP01 / 7-31-2019 15717VP02 / 7-31-2019 15717VP03 / 7-31-2019 15718004 / 3-31-2020 15717002 / 12-31-2019 |
| 69367-0158-04 | Levothyroxine and Liothyronine (Thyroid Tablets, USP) 120mg x 100ct | 15817VP01 / 9-30-2019 15817VP02 / 9-30-2019 15817VP03 / 9-30-2019 15818001 / 3-31-2020 |