Drug recall notice for Nature-Throid and WP Thyroid tablets

To assist you in the care of your patients, we would like to alert you to the recall of 483 lots of Nature-Throid® and WP Thyroid® (thyroid tablets, USP) in all strengths and all counts of unexpired product.[1] We recommend you review your medical records and contact all patients for whom you have prescribed these medications to warn them of the recall. We have listed alternative options below.

The drug manufacturer, RLC Labs, is voluntarily recalling these products because testing of samples by the U.S. Food and Drug Administration (FDA) has found the samples to be subpotent. The product may have as low as 87% of the labeled amount of liothyronine (T3) or levothyroxine (T4).

Nature-Throid and WP Thyroid are composed of liothyronine and levothyroxine, and are used to treat hypothyroidism (underactive thyroid). Patients who receive these subpotent drugs may experience signs and symptoms of hypothyroidism, which may include fatigue, increased sensitivity to cold, constipation, dry skin, puffy face, hair loss, slow heart rate, depression, swelling of the thyroid gland, and/or unexplained weight gain or difficulty losing weight. There is reasonable risk of serious injury to newborn infants or pregnant women with hypothyroidism, including early miscarriage, fetal hyperthyroidism, and/or impairments to fetal neural and skeletal development. In elderly patients and patients with underlying cardiac disease, toxic cardiac manifestations of hyperthyroidism may occur, such as cardiac pain, palpitations or cardiac arrhythmia. To date, RLC Labs has not received any reports of adverse events related to this recall.

Medications included in this recall:

Visit the FDA website for specific details about the recalled medications.

Recommendations:

To reduce impact to your patients, please consider the following alternative options.

Preferred alternatives
levothyroxine tablets (all strengths)
liothyronine tablets (all strengths)

- To access the CarePlus formulary drug list search, go to www.CarePlusHealthPlans.com/medicare-plans/2021-prescription-drug-guides

Information for providers:[1]

- We have sent a letter to your patients who have had a claim for Nature-Throid or WP Thyroid and asked them to contact their physicians or healthcare providers if their medication is included in the recall and if they have experienced problems that may be related to using these drug products.

- Healthcare providers with questions can contact RLC Labs at 877-797-7997, Monday – Thursday, 7 a.m. – 4 p.m., and Friday, 7 a.m. – 3 p.m., Mountain time; or email recall@rlclabs.com.
- Patients may report adverse reactions or quality problems experienced with the use of these products to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.
    - **Online:** Complete and submit the report.
        - Select "Consumer/Patient (FDA Form 3500B)."
    - **Regular mail or fax:** Download the form.
        - Select "Form FDA 3500B – Voluntary Reporting for Consumers" and submit by mail to the address on the form or by fax to 800-FDA-0178.

Reference:

1. "RLC Labs, Inc., Issues Voluntary Nationwide Recall of All Lots of Nature-Throid® and WP Thyroid® with Current Expiry Due to Sub Potency." U.S. Food and Drug Administration. Sept. 3, 2020. www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/rlc-labs-inc-issues-voluntary-nationwide-recall-all-lots-nature-throidr-and-wp-thyroidr-current