

# Nature-Throid® and WP Thyroid® Recall Alert

Date of Notice: 09/03/2020

## **Brief Description of Recall Alert**

RLC Labs, Inc. is voluntarily recalling a total of 483 lots of Nature-Throid® and WP Thyroid® in all strengths and counts within current expiry to the consumer level. The products are being recalled because testing of samples from six (6) lots by the U.S. Food and Drug Administration found the samples to be sub potent. The product may have as low as 87% of the labeled amount of Liothyronine (T3) or Levothyroxine(T4).

Risk Statement: Patients being treated for hypothyroidism (underactive thyroid), who receive sub potent Nature-Throid® or WP Thyroid®, may experience signs and symptoms of hypothyroidism (underactive thyroid) 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 in 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, such as cardiac pain, palpitations, or cardiac arrhythmia may occur. RLC Labs, Inc. has not received any reports of adverse events related to this recall.

Nature-Throid® and WP Thyroid® (thyroid tablets, USP) are composed of liothyronine and levothyroxine, and are used to treat hypothyroidism (underactive thyroid). The products subject to recall are packaged in 30, 60, 90, 100 and 1,000 count bottles.

#### **Affected Products**

Drug Name & Strength	NDC	Lot	Expiration Date
Nature-Throid™ (Thyroid USP) 32.5 mg (0.5 Grain)	64727-3299-4	All lots	All dates
Nature-Throid™ (Thyroid USP) 32.5 mg (0.5 Grain)	64727-3299-5	All lots	All dates
Nature-Throid™ (Thyroid USP) 32.5 mg (0.5 Grain)	64727-3299-6	All lots	All dates
Nature-Throid™ (Thyroid USP) 32.5 mg (0.5 Grain)	64727-3299-1	All lots	All dates
Nature-Throid™ (Thyroid USP) 32.5 mg (0.5 Grain)	64727-3299-2	All lots	All dates
Nature-Throid™ (Thyroid USP) 48.75 mg (0.75 Grain)	64727-3302-4	All lots	All dates
Nature-Throid™ (Thyroid USP) 48.75 mg (0.75 Grain)	64727-3302-5	All lots	All dates

This document is designed to be an informational resource to facilitate discussion and should be used neither as a basis for clinical decision-making or treatment nor as a substitute for reading original literature. RxAdvance makes every effort to ensure that the information provided is up-to-date, accurate, and complete, but no guarantee is made to that effect. If this information is provided to clients or vendors, it is subject to any contractual confidentiality provisions. Third-party disclosures are in violation of confidentiality provisions.

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64727-3302-6	All lots	All dates
64727-3302-1	All lots	All dates
64727-3302-2	All lots	All dates
64727-3300-4	All lots	All dates
64727-3300-5	All lots	All dates
64727-3300-6	All lots	All dates
64727-3300-1	All lots	All dates
64727-3300-2	All lots	All dates
64727-3303-4	All lots	All dates
64727-3303-5	All lots	All dates
64727-3303-6	All lots	All dates
64727-3303-1	All lots	All dates
64727-3303-2	All lots	All dates
64727-3305-4	All lots	All dates
64727-3305-5	All lots	All dates
64727-3305-6	All lots	All dates
64727-3305-1	All lots	All dates
64727-3305-2	All lots	All dates
64727-3307-4	All lots	All dates
64727-3307-5	All lots	All dates
64727-3307-6	All lots	All dates
	64727-3302-1 64727-3302-2 64727-3300-4 64727-3300-5 64727-3300-6 64727-3300-1 64727-3303-4 64727-3303-5 64727-3303-1 64727-3303-2 64727-3305-4 64727-3305-5 64727-3305-6 64727-3305-1 64727-3305-2 64727-3307-4 64727-3307-5	64727-3302-1 All lots 64727-3302-2 All lots 64727-3300-4 All lots 64727-3300-5 All lots 64727-3300-6 All lots 64727-3300-1 All lots 64727-3303-2 All lots 64727-3303-5 All lots 64727-3303-5 All lots 64727-3303-1 All lots 64727-3303-2 All lots 64727-3305-4 All lots 64727-3305-5 All lots 64727-3305-5 All lots 64727-3305-1 All lots 64727-3305-2 All lots 64727-3305-2 All lots 64727-3307-4 All lots

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Nature-Throid™ (Thyroid USP) 113.75 mg (1.75 Grain)	64727-3307-1	All lots	All dates
Nature-Throid™ (Thyroid USP) 113.75 mg (1.75 Grain)	64727-3307-2	All lots	All dates
Nature-Throid™ (Thyroid USP) 130 mg (2 Grain)	64727-3308-4	All lots	All dates
Nature-Throid™ (Thyroid USP) 130 mg (2 Grain)	64727-3308-5	All lots	All dates
Nature-Throid™ (Thyroid USP) 130 mg (2 Grain)	64727-3308-6	All lots	All dates
Nature-Throid™ (Thyroid USP) 130 mg (2 Grain)	64727-3308-1	All lots	All dates
Nature-Throid™ (Thyroid USP) 130 mg (2 Grain)	64727-3308-2	All lots	All dates
Nature-Throid™ (Thyroid USP) 146.25 mg (2.25 Grain)	64727-3309-4	All lots	All dates
Nature-Throid™ (Thyroid USP) 146.25 mg (2.25 Grain)	64727-3309-5	All lots	All dates
Nature-Throid™ (Thyroid USP) 146.25 mg (2.25 Grain)	64727-3309-6	All lots	All dates
Nature-Throid™ (Thyroid USP) 146.25 mg (2.25 Grain)	64727-3309-1	All lots	All dates
Nature-Throid™ (Thyroid USP) 146.25 mg (2.25 Grain)	64727-3309-2	All lots	All dates
Nature-Throid™ (Thyroid USP) 162.5 mg (2.5 Grain)	64727-3310-4	All lots	All dates
Nature-Throid™ (Thyroid USP) 162.5 mg (2.5 Grain)	64727-3310-5	All lots	All dates
Nature-Throid™ (Thyroid USP) 162.5 mg (2.5 Grain)	64727-3310-6	All lots	All dates
Nature-Throid™ (Thyroid USP) 162.5 mg (2.5 Grain)	64727-3310-1	All lots	All dates
Nature-Throid™ (Thyroid USP) 162.5 mg (2.5 Grain)	64727-3310-2	All lots	All dates
Nature-Throid™ (Thyroid USP) 195 mg (3 Grain)	64727-3312-4	All lots	All dates
Nature-Throid™ (Thyroid USP) 195 mg (3 Grain)	64727-3312-5	All lots	All dates
Nature-Throid™ (Thyroid USP) 195 mg (3 Grain)	64727-3312-6	All lots	All dates
Nature-Throid™ (Thyroid USP) 195 mg (3 Grain)	64727-3312-1	All lots	All dates

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Nature-Throid™ (Thyroid USP) 195 mg (3 Grain)	64727-3312-2	All lots	All dates
WP Thyroid® (Thyroid USP) 16.25 mg (0.25 Grain)	64727-5450-4	All lots	All dates
WP Thyroid® (Thyroid USP) 16.25 mg (0.25 Grain)	64727-5450-5	All lots	All dates
WP Thyroid® (Thyroid USP) 16.25 mg (0.25 Grain)	64727-5450-6	All lots	All dates
WP Thyroid® (Thyroid USP) 16.25 mg (0.25 Grain)	64727-5450-1	All lots	All dates
WP Thyroid® (Thyroid USP) 16.25 mg (0.25 Grain)	64727-5450-2	All lots	All dates
WP Thyroid® (Thyroid USP) 32.5 mg (0.5 Grain)	64727-5550-4	All lots	All dates
WP Thyroid® (Thyroid USP) 32.5 mg (0.5 Grain)	64727-5550-5	All lots	All dates
WP Thyroid® (Thyroid USP) 32.5 mg (0.5 Grain)	64727-5550-6	All lots	All dates
WP Thyroid® (Thyroid USP) 32.5 mg (0.5 Grain)	64727-5550-1	All lots	All dates
WP Thyroid® (Thyroid USP) 32.5 mg (0.5 Grain)	64727-5550-2	All lots	All dates
WP Thyroid® (Thyroid USP) 48.75 mg (0.75 Grain)	64727-5650-4	All lots	All dates
WP Thyroid® (Thyroid USP) 48.75 mg (0.75 Grain)	64727-5650-5	All lots	All dates
WP Thyroid® (Thyroid USP) 48.75 mg (0.75 Grain)	64727-5650-6	All lots	All dates
WP Thyroid® (Thyroid USP) 48.75 mg (0.75 Grain)	64727-5650-1	All lots	All dates
WP Thyroid® (Thyroid USP) 48.75 mg (0.75 Grain)	64727-5650-2	All lots	All dates
WP Thyroid® (Thyroid USP) 65 mg (1.0 Grain)	64727-5750-4	All lots	All dates
WP Thyroid® (Thyroid USP) 65 mg (1.0 Grain)	64727-5750-5	All lots	All dates
WP Thyroid® (Thyroid USP) 65 mg (1.0 Grain)	64727-5750-6	All lots	All dates
WP Thyroid® (Thyroid USP) 65 mg (1.0 Grain)	64727-5750-1	All lots	All dates
WP Thyroid® (Thyroid USP) 65 mg (1.0 Grain)	64727-5750-2	All lots	All dates

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WP Thyroid® (Thyroid USP) 81.25 mg (1.25 Grain)	64727-6050-4	All lots	All dates
WP Thyroid® (Thyroid USP) 81.25 mg (1.25 Grain)	64727-6050-5	All lots	All dates
WP Thyroid® (Thyroid USP) 81.25 mg (1.25 Grain)	64727-6050-6	All lots	All dates
WP Thyroid® (Thyroid USP) 81.25 mg (1.25 Grain)	64727-6050-1	All lots	All dates
WP Thyroid® (Thyroid USP) 81.25 mg (1.25 Grain)	64727-6050-2	All lots	All dates
WP Thyroid® (Thyroid USP) 97.5 mg (1.5 Grain)	64727-5850-4	All lots	All dates
WP Thyroid® (Thyroid USP) 97.5 mg (1.5 Grain)	64727-5850-5	All lots	All dates
WP Thyroid® (Thyroid USP) 97.5 mg (1.5 Grain)	64727-5850-6	All lots	All dates
WP Thyroid® (Thyroid USP) 97.5 mg (1.5 Grain)	64727-5850-1	All lots	All dates
WP Thyroid® (Thyroid USP) 97.5 mg (1.5 Grain)	64727-5850-2	All lots	All dates
WP Thyroid® (Thyroid USP) 113.75 mg (1.75 Grain)	64727-6150-4	All lots	All dates
WP Thyroid® (Thyroid USP) 113.75 mg (1.75 Grain)	64727-6150-5	All lots	All dates
WP Thyroid® (Thyroid USP) 113.75 mg (1.75 Grain)	64727-6150-6	All lots	All dates
WP Thyroid® (Thyroid USP) 113.75 mg (1.75 Grain)	64727-6150-1	All lots	All dates
WP Thyroid® (Thyroid USP) 113.75 mg (1.75 Grain)	64727-6150-2	All lots	All dates
WP Thyroid® (Thyroid USP) 130 mg (2 Grain)	64727-5950-4	All lots	All dates
WP Thyroid® (Thyroid USP) 130 mg (2 Grain)	64727-5950-5	All lots	All dates
WP Thyroid® (Thyroid USP) 130 mg (2 Grain)	64727-5950-6	All lots	All dates
WP Thyroid® (Thyroid USP) 130 mg (2 Grain)	64727-5950-1	All lots	All dates
WP Thyroid® (Thyroid USP) 130 mg (2 Grain)	64727-5950-2	All lots	All dates

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## **Prescriber Information**

To best identify the product, the NDCs, Lot Numbers, and Expiration Dates are listed. These lots were distributed nationwide in the USA to RLC Labs, Inc.'s direct accounts, including healthcare professionals and retail pharmacies.

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
- Regular Mail or Fax: <u>Download form</u> 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

## **Member Information**

RLC Labs, Inc. is proactively notifying its wholesalers by email, mail, and phone to discontinue distribution of the product being recalled and is arranging for the return of all recalled products. Patients who are currently taking Nature-Throid® and WP Thyroid® should not discontinue use without contacting their healthcare provider for further guidance and/or replacement prescription.

Consumers with questions about the recall can email RLC Labs, Inc. at <a href="mailto:recall@rlclabs.com">recall@rlclabs.com</a> or contact RLC Labs, Inc. Customer Service at 1-877-797-7997, Monday through Thursday from 7:00 am to 4:00 pm MST (AZ) and Friday from 7:00 am to 3:00 pm MST (AZ).

Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

### **RxAdvance Response**

RxAdvance is in the process of contacting members and prescribers to advise those impacted by this recall.

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