THE 1ST FDA-APPROVED
orally administered levothyroxine sodium treatment for hypothyroidism[1]

TREATMENT FOR HYPOTHYROIDISM THAT'S

THERE AT EVERY TURN

By delivering quality, consistency, and affordability, all in one, UNITHROID can help get your patients where they need to be no matter which way life turns.

IMPORTANT SAFETY INFORMATION

WARNING: NOT FOR TREATMENT OF OBESITY OR FOR WEIGHT LOSS

Thyroid hormones, including UNITHROID, either alone or with other therapeutic agents, should not be used for the treatment of obesity or for weight loss. In euthyroid patients, doses within the range of daily hormonal requirements are ineffective for weight reduction. Larger doses may produce serious or even life-threatening manifestations of toxicity, particularly when given in association with sympathomimetic amines such as those used for their anorectic effects.

Please see Boxed Warning above, Important Safety Information throughout this piece, and accompanying Full Prescribing Information.

UNITHROID®
(Levothyroxine Sodium Tablets, USP)

A STEP BEYOND

HIGH QUALITY AND CONSISTENCY

QUALITY

MADE IN 1 FACILITY
Manufactured in the same state-of-the-art facility for more than 2 decades[2]

MADE IN THE USA
Tablets are manufactured exclusively in New York[2]

GLUTEN-FREE
Contains no ingredient made from a gluten-containing grain (wheat, barley, or rye)[2]

UNITHROID production adheres to Current Good Manufacturing Practices (CGMP)
The CGMP is an FDA initiative that helps ensure the quality of drug products. The regulations make sure that a product has the ingredients and strength it claims to, and is safe.[3]

INDICATION

UNITHROID is L-thyroxine (T4) indicated in pediatric and adult patients for:

- Hypothyroidism: As replacement therapy in primary (thyroidal), secondary (pituitary), and tertiary (hypothalamic) congenital or acquired hypothyroidism
- Pituitary Thyrotropin (Thyroid-Stimulating Hormone, TSH) Suppression: As an adjunct to surgery and radioiodine therapy in the management of thyrotropin-dependent well-differentiated thyroid cancer

Limitations of Use:
UNITHROID is not indicated for suppression of benign thyroid nodules and nontoxic diffuse goiter in iodine-sufficient patients as there are no clinical benefits and overtreatment with UNITHROID may induce hyperthyroidism. UNITHROID is not indicated for treatment of hypothyroidism during the recovery phase of subacute thyroiditis.

AT EVERY TURN

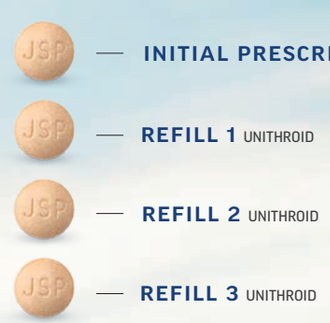
CONSISTENCY

NO HISTORY OF RECALLS OR REFORMULATIONS

UNITHROID has been manufactured for more than 20 years with no recalls, reformulations, or gaps in availability.[2]

WRITE BY NAME

Prescribing UNITHROID by name—and writing dispense as written (DAW)—provides assurance that patients consistently receive the same levothyroxine preparation with every refill instead of various generic substitutes.*



Tablets shown not actual size.

American Association of Clinical Endocrinologists Guidelines
Because levothyroxine has a narrow therapeutic range, small differences in absorption can result in subclinical or clinical hypothyroidism or hyperthyroidism.[4]

*Or equivalent language in your state.

IMPORTANT SAFETY INFORMATION

Contraindication
UNITHROID is contraindicated in patients with uncorrected adrenal insufficiency.

Warnings and Precautions

- Overtreatment with UNITHROID may cause an increase in heart rate, cardiac wall thickness, and cardiac contractility and may precipitate angina or arrhythmias particularly in patients with cardiovascular disease and in elderly patients. Initiate UNITHROID therapy at lower doses than those recommended in younger individuals or in patients without cardiac disease.
- Coronary artery disease: Patients receiving UNITHROID should be monitored closely during surgical procedures for cardiac arrhythmias. Also, monitor patients during concomitant administration of UNITHROID and sympathomimetic agents for signs and symptoms of coronary insufficiency.

Please see Important Safety Information throughout this piece, including Boxed Warning on cover, and accompanying Full Prescribing Information.

UNITHROID®
(Levothyroxine Sodium Tablets, USP)

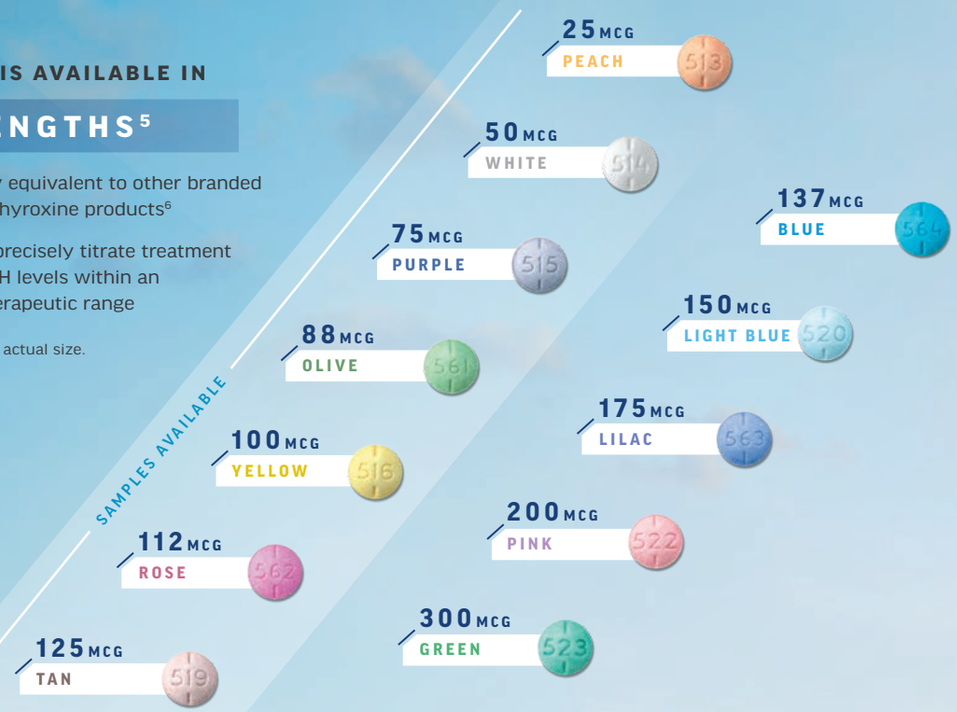
A FULL ARRAY OF **DOSAGE STRENGTHS**

UNITHROID IS AVAILABLE IN

12 STRENGTHS[5]

- Therapeutically equivalent to other branded synthetic levothyroxine products[6]
- Allows you to precisely titrate treatment and achieve TSH levels within an appropriate therapeutic range

Tablets shown not actual size.



GETTING PATIENTS STARTED TODAY

UNITHROID is available in 2-week samples in 7 strengths

- Allows patients to begin their treatment without delay
- Gives pharmacies time to obtain a patient's specific dose in case UNITHROID is out of stock

IMPORTANT SAFETY INFORMATION *(continued)*

Warnings and Precautions *(continued)*

- Myxedema coma: is a life-threatening emergency characterized by poor circulation and hypometabolism, and may result in unpredictable absorption of UNITHROID from the gastrointestinal tract. Use of oral thyroid hormone drug products is not recommended. Administer intravenous thyroid hormone products to treat myxedema coma.
- Acute adrenal crisis in patients with concomitant adrenal insufficiency: thyroid hormone increases metabolic clearance of glucocorticoids. Initiation of thyroid hormone therapy prior to initiating glucocorticoid therapy may precipitate an acute adrenal crisis in patients with adrenal insufficiency.
- UNITHROID has a narrow therapeutic index. Titrate the dose of UNITHROID carefully and monitor response to titration to avoid effects of over or under treatment with UNITHROID. Monitor for the presence of drug or food interactions when using UNITHROID and adjust the dose as necessary.
- Addition of levothyroxine therapy in patients with diabetes mellitus may worsen glycemic control and result in increased antidiabetic agent or insulin requirements. Carefully monitor glycemic control after starting, changing, or discontinuing UNITHROID.
- Increased bone resorption and decreased bone mineral density may occur as a result of levothyroxine over-replacement, particularly in post-menopausal women. To minimize this risk, administer the minimum dose of UNITHROID that achieves the desired clinical and biochemical response

TURN TO UNITHROID TO HELP YOUR **PATIENTS SAVE**

MORE THAN 90% OF COMMERCIALLY INSURED PATIENTS MAY PAY AS LITTLE AS

$3 FOR A 30-DAY PRESCRIPTION[2,*]

This allows eligible patients to save on their co-pay costs for this chronic condition.

eVOUCHER Rx™ PROGRAM

Most eligible patients with commercial insurance will receive an automatic co-pay reduction when picking up a UNITHROID prescription.[†]

No cards or coupons are needed.

See a list of pharmacies that participate in the eVoucherRx™ Program at **UNITHROID.com/savings**.

*Of commercially insured UNITHROID patients, 90% paid a $3 co-pay for a 30-day supply from December 2019–November 2020.[2]

[†]Subject to eligibility. Individual out-of-pocket costs may vary. Not valid for patients covered under Medicare, Medicaid, or other federal or state programs. Please see full Terms, Conditions, and Eligibility Criteria at UNITHROID.com/savings.

INSTANT SAVINGS CARD

If a pharmacy doesn't participate in the eVoucherRx™ Program, eligible patients can download an Instant Savings Card at **UNITHROID.com/savings** and their pharmacist will apply the co-pay reduction at the counter.[†]

IMPORTANT SAFETY INFORMATION *(continued)*

Adverse Reactions

- Common adverse reactions for UNITHROID are primarily those of hyperthyroidism due to therapeutic overdosage: arrhythmias, myocardial infarction, dyspnea, muscle spasm, headache, nervousness, irritability, insomnia, tremors, muscle weakness, increased appetite, weight loss, diarrhea, heat intolerance, menstrual irregularities, and skin rash.

Please see Important Safety Information throughout this piece, including Boxed Warning on cover, and accompanying Full Prescribing Information.

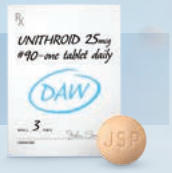
UNITHROID®
(Levothyroxine Sodium Tablets, USP)

HIGH QUALITY

UNITHROID tablets have been manufactured in the same state-of-the-art facility in New York for more than 2 decades.[2]

UNITHROID production adheres to Current Good Manufacturing Practices (CGMP).[3]

BRAND CONSISTENCY



Prescribing UNITHROID by name—and writing DAW—ensures product consistency with every refill.

AFFORDABLE CO-PAY

Eligible patients may pay as little as

$3 FOR A 30-DAY PRESCRIPTION*

12 DOSAGE STRENGTHS[5]

All therapeutically equivalent to other branded synthetic levothyroxine products.[6]

Tablets shown not actual size.

***Subject to eligibility. Individual out-of-pocket costs may vary. Not valid for patients covered under Medicare, Medicaid, or other federal or state programs. Please see full Terms, Conditions, and Eligibility Criteria at UNITHROID.com/savings.**

IMPORTANT SAFETY INFORMATION *(continued)*

Adverse Reactions *(continued)*

- Pediatric Patients: Pseudotumor cerebri and slipped capital femoral epiphysis have been reported in pediatric patients receiving levothyroxine therapy. Overtreatment may result in craniosynostosis in infants and premature closure of the epiphyses in pediatric patients with resultant compromised adult height.

Drug Interactions

- Many drugs can exert effects on thyroid hormone pharmacokinetics and may alter the therapeutic response to UNITHROID. Administer at least 4 hours before or after drugs that are known to interfere with absorption. Consumption of certain foods may affect absorption of UNITHROID, resulting in the need for dose adjustment. Consult appropriate sources of information on drug or food interactions for additional information relative to drug or food interactions with UNITHROID.
- Drug-Laboratory test interactions: Consider changes in TBG concentration when interpreting T4 and T3 values. Measure and evaluate unbound (free) hormone and/or determine the free T4 index (FT4I) in this circumstance.

Use in Specific Populations

- Pregnancy: Since thyroid-stimulating hormone (TSH) levels may increase during pregnancy, TSH should be monitored and UNITHROID dosage adjusted during pregnancy. UNITHROID should not be discontinued during pregnancy and hypothyroidism diagnosed during pregnancy should be promptly treated.

To report SUSPECTED ADVERSE REACTIONS, contact Amneal Specialty, a division of Amneal Pharmaceuticals LLC at 1-877-835-5472 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see Important Safety Information throughout this piece, including Boxed Warning on cover, and accompanying Full Prescribing Information.

Visit UNITHROIDHCP.com for more information.

References: 1. US Food and Drug Administration. Guidance for Industry: levothyroxine sodium products enforcement of August 14, 2001, compliance date and submission of new applications. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/levothyroxine-sodium-products-enforcement-august-14-2001-compliance-date-and-submission-new. Updated July 2001. Accessed November 10, 2020. **2.** Data on file. Amneal Pharmaceuticals LLC. **3.** US Food and Drug Administration. Current good manufacturing practice (CGMP) regulations. www.fda.gov/drugs/pharmaceutical-quality-resources/current. Accessed November 10, 2020. **4.** Baskin HJ, Cobin RH, Duick DS, et al; for American Association of Clinical Endocrinologists. American Association of Clinical Endocrinologists medical guidelines for clinical practice for the evaluation and treatment of hyperthyroidism and hypothyroidism. *Endocr Pract*. 2002;8(6):457-469. **5.** UNITHROID [package insert]. **6.** US Department of Health and Human Services. *Orange Book: Approved drugs with therapeutic equivalence evaluations, 39th ed.* https://www.fda.gov/media/71474/download. Published 2019. Accessed November 10, 2020.

amneal

PP-HCP-UNI-US-0014 11/2020

UNITHROID®
(Levothyroxine Sodium Tablets, USP)
A STEP BEYOND