

#### **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



A STEP BEYOND

#### 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.

#### 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.

#### Contraindication

UNITHROID is contraindicated in patients with uncorrected adrenal insufficiency.

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

# SOME PATIENTS MAY BE HAVING ISSUES WITH

### **INCONSISTENT LEVOTHYROXINE TREATMENT**

ATA/TES/AACE Guidelines recommend that patients should be maintained on the same levothyroxine preparation<sup>1,2</sup> Minor changes in levothyroxine administration may cause significant changes in TSH serum concentrations.<sup>1</sup>

A survey of members of the AACE, ATA, and TES was conducted to assess experience regarding safety of substituting levothyroxine products. This study showed\*:

- 89% of adverse events were associated with a change in levothyroxine preparation<sup>3</sup>
- Of the reports indicating a formulation change,
   88% were from brand to generic preparation<sup>3</sup>
- In 92% of cases, prescribers were unaware of the switch at the pharmacy<sup>3,†</sup>

#### PATIENTS MAY RECEIVE DIFFERENT PREPARATIONS

DAW NOT SPECIFIED



# INITIAL PRESCRIPTION



Ger



Generic LT,



RFFIII 2

Generic LT,

**REFILL 3** 

25 mcg 25 mcg

Tablets not shown at actual size.

AACE=American Association of Clinical Endocrinologists; ATA=American Thyroid Association; DAW=Dispense as written; TES=The Endocrine Society. \*A total of 1536 responses were received.

 $^{\dagger}$ Details about switching of preparations were provided in 167 of the 177 reported cases. $^{3}$ 

#### **IMPORTANT SAFETY INFORMATION** (continued)

#### **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.
- 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.

# FOR BRAND CONSISTENCY, TURN TO UNITHROID

Prescribing UNITHROID by name—and writing dispense as written (DAW)<sup>‡</sup>—provides assurance that patients, like Emma, consistently receive the same levothyroxine preparation with every refill instead of various generic substitutes. This consistency may be especially important when treating a lifelong condition like hypothyroidism.



UNITHROID has been manufactured in New York for more than

20 years with no recalls, reformulations, or gaps in availability.

Learn more at UNITHROIDHCP.com/CONSISTENCY

#### IMPORTANT SAFETY INFORMATION (continued)

A BRAND YOU

CAN COUNT ON

#### **Warnings and Precautions** (continued)

- 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 overreplacement, particularly in post-menopausal women. To minimize this risk, administer the minimum dose of UNITHROID that achieves the desired clinical and biochemical response.

#### **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.
- 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.

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



A STEP BEYOND

# UNITHROID DELIVERS CONSISTENCY, QUALITY, AND AFFORDABILITY FOR PATIENTS LIKE EMMA

CONSISTENCY

QUALITY

AFFORDABILITY

Prescribing UNITHROID by name and writing DAW ensures product **consistency with every fill**.

UNITHROID has been manufactured in New York for more than 2 decades with **no recalls, reformulations, or gaps in availability**.<sup>4</sup>

Eligible patients may pay as little as

\$3\* for their 30-day UNITHROID prescription.4

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 Eligibility Criteria and Terms and Conditions at UNITHROIDHCP.com/savings.

#### GET YOUR PATIENTS STARTED ON UNITHROID

UNITHROID is available in 2-week samples in 7 strengths. For more information, talk to your UNITHROID representative or visit

UNITHROIDHCP.com/OrderSamples.

\*Of commercially insured UNITHROID patients, 90% paid a \$3 co-pay for a 30-day supply from December 2019-December 2020.4

Actor portrayal.

VISIT UNITHROIDHCP.com/CONSISTENCY FOR MORE INFORMATION

#### **IMPORTANT SAFETY INFORMATION** (continued)

#### **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.

References: 1. Jonklaas J, Bianco AC, Bauer AJ, et al. *Thyroid*. 2014;24(12):1670-1751. 2. Garber JR, Cobin RH, Gharib H, et al. *Endocr Pract*. 2012;18(6):988-1028. 3. Hennessey JV, Malabanan AO, Haugen BR, et al. *Endocr Pract*. 2010;16:357-370. 4. Data on file. Amneal Pharmaceuticals LLC.



(Levothyroxine Sodium Tablets, USP)

A STEP BEYOND