Euthyrox®
(levothyroxine sodium tablets, USP)

World's most dispensed levothyroxine brand with more than 53 million patients treated annually[1]

The Treatment Advantage of EUTHYROX® Blister-packaged Levothyroxine Sodium Tablets, USP, Over Bottled Levothyroxine

EUTHYROX offers your patients levothyroxine with precise and protected potency[2,3]

Light and moisture rob levothyroxine of potency[2]

Levothyroxine has a narrow therapeutic index. It requires a precise, consistent dosage[4]

EUTHYROX tablets are blister packaged to protect potency until the moment they are taken[3]

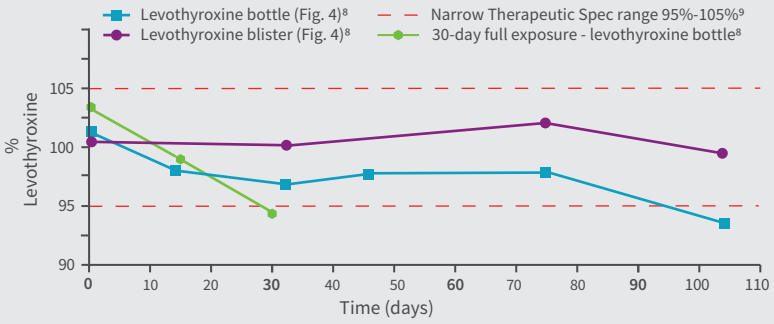
EUTHYROX is a brand product at a generic price. Patients have low out-of-pocket costs[5,6]

Dye-free, lactose-free, and gluten-free [3,7]
Reduces the potential for adverse effects in patients with associated sensitivites.

THE STUDY: Stability of levothyroxine tablets in blister packaging versus bottles and vials under simulated in-use conditions[8]

STUDY RESULTS

- EUTHYROX blister packaging preserved the physicochemical properties and potency of levothyroxine tablets.
- Bottled levothyroxine showed a measurable decrease in potency over 105 days. At baseline, the average levothyroxine content was 101.4% of the stated strength. Values for 14 through 90 days ranged from 96.9% to 97.7%, and, at 105 days, the potency was 93.9%, which was outside of the USP specifications.
- Bottled tablets in the 30-day full exposure experiment showed an observable decline in potency. Bottled tablets had 103.0% average levothyroxine potency at baseline; however, potency fell to 98.4% after 15 days and to 94.5% at 30 days.



"Blister packages preserved physicochemical properties and potency better than bulk bottles."[8]

Prescribe EUTHYROX by name

Indicate Dispense as Written (DAW) to ensure patients receive levothyroxine with safeguarded potency.

Get the full study here:

INDICATIONS[3]

Hypothyroidism
EUTHYROX is indicated in pediatric and adult patients as a replacement therapy in primary (thyroidal), secondary (pituitary), and tertiary (hypothalamic) congenital or acquired hypothyroidism.

Pituitary Thyrotropin (Thyroid Stimulating Hormone, TSH) Suppression
EUTHYROX is indicated in pediatric and adult patients as an adjunct to surgery and radioiodine therapy in the management of thyrotropin-dependent well-differentiated thyroid cancer.

Please see Important Safety Information on page 2.
Please see accompanying Package Insert (PI) for Full Prescribing Information.

IMPORTANT SAFETY INFORMATION[3] (*continued*)

Limitations of Use:

- EUTHYROX 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 EUTHYROX may induce hyperthyroidism.
- EUTHYROX is not indicated for treatment of hypothyroidism during the recovery phase of subacute thyroiditis.

WARNING: NOT FOR TREATMENT OF OBESITY OR FOR WEIGHT-LOSS
Thyroid hormones, including EUTHYROX, 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.

CONTRAINDICATIONS

EUTHYROX is contraindicated in patients with uncorrected adrenal insufficiency.

WARNINGS AND PRECAUTIONS

- EUTHYROX has a narrow therapeutic index. Overtreatment or undertreatment with EUTHYROX may have negative effects on growth and development, cardiovascular function, bone metabolism, reproductive function, cognitive function, emotional state, gastrointestinal function, and glucose and lipid metabolism in adult or pediatric patients. Titrate the dose of EUTHYROX carefully and monitor response to titration to avoid these effects. Monitor for the presence of drug or food interactions when using EUTHYROX and adjust the dose as necessary.
- In the elderly and in patients with cardiovascular disease, initiate EUTHYROX at lower doses than those recommended in younger individuals or in patients without cardiac disease.
- Patients with coronary artery disease who are receiving EUTHYROX should be monitored closely during surgical procedures for cardiac arrhythmias. Monitor patients during concomitant administration of EUTHYROX and sympathomimetic agents for signs and symptoms of coronary insufficiency. If cardiovascular symptoms develop or worsen, reduce or withhold the EUTHYROX dose for one week and restart at a lower dose.
- Use of oral thyroid hormone is not recommended to treat myxedema coma. Use products formulated for IV administration to treat myxedema coma.
- Treat patients with adrenal insufficiency with replacement glucocorticoids prior to initiating treatment with EUTHYROX. Failure to do so may precipitate an acute adrenal crisis when thyroid hormone therapy is initiated.
- 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 EUTHYROX.
- Increased bone resorption and decreased bone mineral density may occur as a result of levothyroxine over-replacement, particularly in postmenopausal women. To mitigate this risk, administer the minimum dose of EUTHYROX that achieves the desired response.

ADVERSE REACTIONS

- Adverse reactions associated with EUTHYROX therapy 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.*
- In pediatric patients receiving levothyroxine therapy, pseudotumor cerebri and slipped capital femoral epiphysis have been reported. Overtreatment may result in craniosynostosis in infants and premature closure of the epiphyses in pediatric patients with resultant compromised adult height.
- Seizures have been reported rarely with levothyroxine therapy.

DRUG INTERACTIONS

- Many drugs and some foods affect thyroid hormone pharmacokinetics and metabolism and may alter the therapeutic response to EUTHYROX. In addition, thyroid hormones and thyroid status have varied effects on the pharmacokinetics and actions of other drugs. Administer at least 4 hours before or after drugs that are known to interfere with absorption. Evaluate the need for dose adjustments when regularly administering within one hour of certain foods that may affect absorption. Prescribers should consult appropriate reference sources for additional information on drug or food interactions with EUTHYROX.

USE IN SPECIFIC POPULATIONS

- EUTHYROX should not be discontinued during pregnancy, and hypothyroidism diagnosed during pregnancy should be promptly treated. TSH levels may increase during pregnancy, so TSH should be monitored and EUTHYROX dose adjusted as needed.

Please see accompanying Package Insert (PI) for Full Prescribing Information.

References: **1.** Data on File. Merck KGaA, Darmstadt, Germany. **2.** Malinowski H. Bioavailability/bioequivalence studies in evaluation of new levothyroxine sodium products. FDA.gov. Accessed January 9, 2023. https://www.fda.gov/media/77811/download **3.** EUTHYROX package insert. Provell Pharmaceuticals, LLC; 2022. **4.** FDA.gov. Real-world evidence from a narrow therapeutic index product (levothyroxine) reflects the therapeutic equivalence of generic drug products. Accessed January 6, 2023. https://www.fda.gov-/drugs/new-events-human-drugs/real-world-evidence-narrow-therapeutic-index-product-levothyroxine-reflects-therapeutic-equivalence **5.** Data on File. Managed Markets Insight & Technology LLC database; August 25, 2022. **6.** Feldman R. The devil in the tiers. J Law Biosci. 2021;8(1):lsaa081. https://doi.org/10.1093/jlb/lsaa081 **7.** Data on File. Provell Pharmaceuticals, LLC. **8.** Chun J. Stability of levothyroxine tablets in blister packaging versus bottles and vials under simulated in-use conditions. AAPS Open. 2022;8:15. https://-doi.org/10.1186/s41120-022-00062-5 **9.** Jiang, Ph.D. W. FDA Drug Topics: Understanding Generic Narrow Therapeutic Index Drugs. FDA.gov. Accessed May 18, 2023, https://fda.gov/-media/162779/download

Euthyrox®
(levothyroxine sodium tablets, USP)

www.euthyrox-us.com
Manufactured by Merck KGaA, Darmstadt, Germany
for Provell Pharmaceuticals, LLC

PROVELL
PHARMACEUTICALS LLC