

Health Awareness

Struggling with Your Thyroid Medication? The Difference may be in the Formulation

Sponsored by YARAL Pharma

(NAPS)—For millions of people managing hypothyroidism, finding the right levothyroxine medication can make all the difference. Not all formulations are the same, and due to some of the inactive ingredients found in other hypothyroid treatments, some patients may have difficulty absorbing or tolerating the medication.

Levothyroxine Sodium Capsules may offer a solution for patients who have trouble tolerating other hypothyroid treatments. These capsules contain only four ingredients¹:

- Levothyroxine (the active ingredient)
- Gelatin
- Glycerin
- Water

This unique formulation is free from common allergens and additives such as sugars, dyes, alcohol, gluten, and lactose.

Who Can Benefit?

Levothyroxine Sodium Capsules may be a good option for patients sensitive to certain inactive ingredients.

Additionally, Levothyroxine Sodium Capsules are available in twelve dosage strengths, providing flexibility to help patients and healthcare providers find



Your doctor can help you select the thyroid medication that may be right for you.

the right dose for individualized treatment plans.

Talk to Your Healthcare Provider

If you're struggling with your current thyroid medication, ask your doctor or pharmacist if YARAL Pharma's Levothyroxine Sodium Capsules, the only generic levothyroxine gel capsules available in the U.S. could be right for you. Learn more at: www.yaralpharma.com.

For Full Prescribing Information, including Important Safety Information and Boxed Warning for Levothyroxine Sodium Capsules, visit: www.yaral-pharma.com/levothyroxine-pi.

IMPORTANT SAFETY INFORMATION for levothyroxine sodium capsules INDICATION AND USAGE

Levothyroxine sodium capsules are L-thyroxine (T4) indicated for adults and pediatric patients 6 years and older with:

- 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:

- Levothyroxine sodium capsules are 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 Levothyroxine sodium capsules may induce hyperthyroidism.
- Levothyroxine sodium capsules are not indicated for treatment of transient hypothyroidism during the recovery phase of subacute thyroiditis

WARNING: NOT FOR THE TREATMENT OF OBESITY OR FOR WEIGHT LOSS

Thyroid hormones, including levothyroxine sodium capsules, 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

Uncorrected adrenal insufficiency

Warnings and Precautions

- Cardiac adverse reactions in the elderly and in patients with underlying cardiovascular disease: Initiate Levothyroxine sodium capsules at less than the full replacement dose because of the increased risk of cardiac adverse reactions, including atrial fibrillation
- Myxedema coma: Do not use oral thyroid hormone drug products to treat myxedema coma
- Acute adrenal crisis in patients with concomitant adrenal insufficiency: Treat with replacement glucocorticoids prior to initiation of levothyroxine sodium capsules treatment
- Prevention of hyperthyroidism or incomplete treatment of hypothyroidism: Proper dose titration and careful monitoring is critical to prevent the persistence of hypothyroidism or the development of hyperthyroidism
- Worsening of diabetic control: 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 thyroid hormone therapy
- Decreased bone mineral density associated with thyroid hormone over-replacement: Over-replacement can increase bone reabsorption and decrease bone mineral density. Give the lowest effective dose

Adverse Reactions

Common adverse reactions with levothyroxine therapy are primarily those of hyperthyroidism due to therapeutic over-dosage. They include the following:

- General: fatigue, increased appetite, weight loss, heat intolerance, fever, excessive sweating
- Central Nervous System: headache, hyperactivity, nervousness, anxiety, irritability, emotional lability, insomnia
- Musculoskeletal: tremors, muscle weakness
- Cardiovascular: palpitations, tachycardia, arrhythmias, increased pulse and blood pressure, heart failure, angina, myocardial infarction, cardiac arrest
- Respiratory: dyspnea
- Gastrointestinal (GI): diarrhea, vomiting, abdominal cramps, elevations in liver function tests
- Dermatologic: hair loss, flushing
- Endocrine: decreased bone mineral density
- Reproductive: menstrual irregularities, impaired fertility

Adverse Reactions in Children

Pseudotumor cerebri and slipped capital femoral epiphysis have been reported in children receiving levothyroxine therapy.

Overtreatment may result in craniosynostosis in infants and premature closure of the epiphyses in children with resultant compromised adult height. Seizures have been reported rarely with the institution of levothyroxine therapy.

Hypersensitivity Reactions

Hypersensitivity reactions to inactive ingredients (in this product or other levothyroxine products) have occurred in patients treated with thyroid hormone products. These include urticaria, pruritis, skin rash, flushing, angioedema, various GI symptoms (abdominal pain, nausea, vomiting and diarrhea), fever, arthralgia, serum sickness and wheezing. Hypersensitivity to levothyroxine itself is not known to occur.

Drug Interactions:

Many drugs and some foods can exert effects on thyroid hormone pharmacokinetics (e.g., absorption, synthesis, secretion, catabolism, protein binding, and target tissue response) and may alter the therapeutic response to Levothyroxine sodium capsules. Administer at least 4 hours before or after drugs that are known to interfere with absorption. See full prescribing information for drugs that affect thyroid hormone pharmacokinetics and metabolism.

To report SUSPECTED ADVERSE REACTIONS, contact YARAL Pharma Inc. at 1-866-218-9009, or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

For Full Prescribing Information, including Boxed Warning, go to www.yaralpharma.com/levothyroxine-pi.

References:

¹Levothyroxine Sodium Capsules [package insert]. Parsippany, NJ: YARAL Pharma Inc; 2024.

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