PRESCRIPTION MONOGRAPH

Compounded Active Ingredients: Levothyroxine Sodium
Form: Oral Capsule

Drug Class: Synthetic thyroid hormone (T4 analog)

Mechanism of Action[1]:
Levothyroxine is intended to:

- Replace deficient T4 in hypothyroid patients.
- Provide reservoir for T3 conversion by deiodinases into active T3 in peripheral tissues.
- Activate thyroid receptors by regulating transcription of genes involved in metabolism, growth, development, and thermogenesis.
- Normalize hypothalamic–pituitary–thyroid (HPT) axis by lowering elevated TSH and restoring feedback balance.

Indications Commonly Prescribed for:

- Hypothyroidism: Treatment of primary, secondary, or tertiary hypothyroidism (alone or in combination with levothyroxine).
- Thyroid suppression test: As part of diagnostic evaluation of thyroid function.

Before Use: Let your health care provider know if you have any medication allergies before you take this compounded preparation. Let your health care provider know if you have any liver or kidney problems. Let your healthcare provider know of all supplements you are currently taking.

Contraindications:

- Uncorrected adrenal insufficiency.
- Untreated thyrotoxicosis.
- Known hypersensitivity to levothyroxine.

Cautions: Let your Healthcare provider know if you experience any adverse side effects.

How to Use: This compounded preparation is in the form of an oral capsule. Swallow the capsule whole with a glass of water. Do not chew or crush the capsule. If you miss a dose, take as soon as you remember, but not at the time for the next dose. Desired results may take up to several weeks.

Warnings and Precautions:

- Do not use for weight loss: ineffective and potentially life-threatening when combined with sympathomimetics.
- Cardiovascular risk: Use cautiously in patients with CAD, arrhythmias, or elderly; overtreatment can provoke angina, atrial fibrillation, or heart failure.
- Bone health: Chronic overtreatment increases risk of osteoporosis.
- Malabsorption risks: Absorption reduced by GI disorders (celiac disease, atrophic gastritis, IBD) and interfering medications.

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Adverse Reactions:

- Common
  - Headache
  - Insomnia, irritability,
  - Menstrual irregularities
- Signs of Over-Replacement
  - Palpitations, tachycardia, arrhythmias
  - Tremor, anxiety, sweating, chest pain
  - Diarrhea, weight loss.

Interactions:

- Binding/absorption interference:
  - Bile acid sequestrants, iron, calcium, sucralfate, and aluminum hydroxide may lead to decreased absorption.
  - Proton pump inhibitors, H2 blockers may reduce bioavailability.
- Metabolism effects: CYP inducers (phenytoin, carbamazepine, rifampin) can increase hepatic metabolism of levothyroxine, which may reduce its effectiveness.
- Protein-binding changes: Estrogens and oral contraceptives raise thyroxine-binding globulin, which may increase levothyroxine requirements.
- Pharmacodynamic: Potentiates anticoagulants (warfarin), alters insulin/oral hypoglycemic requirements.

Use in Specific Populations:

- Pregnancy: Safe and essential; requirements often increase (monitor every 4 weeks in first half of pregnancy).
- Lactation: Minimal transfer into breast milk; considered safe.
- Elderly/heart disease: Start at low doses (12.5–25 mcg daily), titrate slowly.
- Pediatrics: Critical in congenital hypothyroidism for normal neurodevelopment; dose based on weight.

Storage:

- Store in original container at room temperature (up to 30°C or 86°F)
- Store in a cool dry place away from heat, sunlight, and moisture

Monitoring Parameters:

- TSH and free T4/free T3: Recheck 4–6 weeks after initiation or dose change.
- Cardiac monitoring: Watch for palpitations, tachyarrhythmias, or chest pain.
- Clinical monitoring: Track energy, weight, mood, sleep, menstrual cycles, and symptoms of over/under-treatment.
- Bone health: Consider periodic BMD in long-term therapy (esp. postmenopausal women).

Citations:

1. Duntas LH, Jonklaas J. Levothyroxine Dose Adjustment to Optimise Therapy Throughout a Patient's Lifetime. *Adv Ther*. 2019;36(Suppl 2):30-46. doi:10.1007/s12325-019-01078-2