

LIOMNY™ (liothyronine sodium tablets, USP)

Hypothyroidism affects millions of individuals, many of whom continue to experience persistent symptoms despite available treatment options. These diagnoses particularly impact middle-aged women among others. Thyroid symptoms differ between people and may be experienced for a multitude of reasons. Although there is no definitive cure for thyroid diseases, maintenance medications may lessen symptom severity. While developing LIOMNY™, Sigmapharm Laboratories ensured it gave consideration to patient needs, listened to inquiries from endocrinologists, and understood advocacy group concerns. Taken in totality, Sigmapharm Laboratories utilized all of these different perspectives in combination with its technology platforms to provide patients with a stable, reliable, and consistent product.

LIOMNY™ is a **gluten free tablet** indicated as a replacement therapy for hypothyroidism. At Sigmapharm, LIOMNY™ is viewed as a catalyst for helping hypothyroid patients manage their T3 levels. Sigmapharm is most proud of the stability, assay, and uniformity of LIOMNY™.

1. **Stability:** A drug's ability to remain effective and potent for a specific period of time.
2. **Assay:** A measurement to describe the amount of active ingredient present in a pharmaceutical dosage form.
3. **Uniformity:** A measurement describing the homogeneity of active ingredient dispersed consistently within a drug product.

The ability for LIOMNY™ to remain potent and effective for **five years** after its manufacturing date may help handle diverse administration schedules. During Sigmapharm's blending, compression, and post packaging process, LIOMNY™ is tested for its imposed distribution standard of liothyronine sodium in all batches. Sigmapharm anticipates consistent therapeutic outcomes and is tightening the assay acceptance criteria from the USP/NF general standards as indicated below:

**USP/NF Assay
Acceptance Criteria:**

90.0% - 110.0%

**LIOMNY™ Assay
Acceptance Criteria:**

95.0% - 105.0%

The FDA defines liothyronine sodium as a narrow therapeutic index (NTI) drug, meaning that both over-treatment and under-treatment of this medicine can lead to negative effects. To demonstrate product uniformity and consistency, Sigmapharm Laboratories has tightened the compendial content uniformity requirements by ten percent.

Compendial Uniformity Acceptance Range Tightened by 10.0%

Sigmapharm has been in the pharmaceutical industry for 20 years with liothyronine sodium serving as its largest manufacturing segment since its approval, and is proud to offer LIOMNY™ to the thyroid community.



Boxed Warning:

Thyroid hormones, including LIOMNY™, 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.

Warnings and Precautions:

- LIOMNY™ may cause irregular heartbeat, especially in older adults or those with heart disease. It is recommended to start at a less than the full replacement dose.
- Do not use LIOMNY™ for myxedema coma.
- Acute adrenal crisis in patients with concomitant adrenal insufficiency should be treated before starting LIOMNY™.
- Too much or too little of LIOMNY™ can cause thyroid problems. Proper dose titration and careful monitoring is critical to avoid under treatment or over treatment.
- LIOMNY™ may worsen glycemic control for diabetes. Monitor while starting, changing, or discontinuing therapy.
- High doses may weaken bones. Use the lowest effective dose.

Adverse Reactions:

The most common adverse reactions for LIOMNY™ are primarily those of hyperthyroidism due to therapeutic overdose: arrhythmias, myocardial infarction, dyspnea, headache, nervousness, irritability, insomnia, tremors, muscle weakness, increased appetite, weight loss, diarrhea, heat intolerance, menstrual irregularities, and skin rash.

Contraindications:

LIOMNY™ should not be taken with uncorrected adrenal cortical insufficiency.

The risk information provided here is not comprehensive.

To learn more about LIOMNY™, talk with a health care provider or pharmacist. The full FDA-approved product labeling can be found at www.liomny.com

Have Questions?

Contact Us

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