

Levothyroxine Sodium Injection

Ready-to-use vials from Fresenius Kabi

Available strengths:

- 100 mcg per 5 mL
- 200 mcg per 5 mL
- 500 mcg per 5 mL



Levothyroxine Sodium Injection

WARNING: NOT FOR TREATMENT OF OBESITY OR FOR WEIGHT LOSS

Thyroid hormones, including Levothyroxine Sodium Injection, should not be used for the treatment of obesity or for weight loss. Larger doses may produce serious or even life threatening manifestations of toxicity.



Ready-to-use (RTU) for optimal care

Helps promote safe medication practices

- RTU presentation may help reduce the potential for human error during reconstitution
- The Joint Commission recommends using manufacturer-prepared presentations when available¹

May improve operational efficiency

- RTU eliminates the need for reconstitution
- Less coordination may be required between pharmacy and nurse

Reduces waste

- Fewer preparation materials required compared to lyophilized presentations²
- Lyophilized presentations must be administered within four hours of reconstitution or discarded³



1 The Joint Commission, Revisions to the Medication Management Standards Regarding Sample Medications, .03.01.01; 2013

2 Shuster, Keith P. "Increase Use of Ready-to-Administer Prefilled Injectables." *Pharmacy Purchasing & Products*, Mar. 2014, pp. S6-S7.

3 Levothyroxine Sodium for Injection Package Insert. Fresenius Kabi USA; 2024.

Levothyroxine Sodium Injection

INDICATIONS AND USAGE

Levothyroxine Sodium Injection is L-thyroxine (T4) indicated in adult patients for the treatment of myxedema coma.

Limitations of Use:

Not recommended as a substitute for oral levothyroxine sodium because the relative bioavailability of Levothyroxine Sodium Injection to oral levothyroxine sodium has not been established and there is a risk of inaccurate dose conversion.

IMPORTANT SAFETY INFORMATION

WARNING: NOT FOR TREATMENT OF OBESITY OR FOR WEIGHT LOSS

Thyroid hormones, including Levothyroxine Sodium Injection, should not be used for the treatment of obesity or for weight loss.

Larger doses may produce serious or even life threatening manifestations of toxicity.

Levothyroxine Sodium Injection is contraindicated in uncorrected adrenal insufficiency.

Cardiac Adverse Reactions in the Elderly and in Patients with Underlying Cardiovascular Disease:

Overtreatment may cause arrhythmias, tachycardia, myocardial ischemia and infarction, or worsening of congestive heart failure and death, particularly in patients with cardiovascular disease and in elderly patients. Start with lower doses in elderly patients and in patients with underlying cardiovascular disease and monitor patients after administration.

Acute Adrenal Crisis in Patients with Concomitant Adrenal Insufficiency: Initiation of thyroid hormone therapy prior to initiating glucocorticoid therapy may precipitate an acute adrenal crisis in patients with adrenal insufficiency. Treat patients with adrenal insufficiency with replacement glucocorticoids prior to initiating treatment.

Worsening of Diabetic Control: May worsen glycemic control and result in increased antidiabetic agent or insulin requirements. Carefully monitor glycemic control.

Adverse reactions associated with Levothyroxine Sodium Injection are primarily those of hyperthyroidism due to therapeutic overdosage: fatigue, increased appetite, weight loss, heat intolerance, fever, excessive sweating, headache, hyperactivity, nervousness, anxiety, irritability, emotional lability, insomnia, tremors, muscle weakness, muscle spasm, palpitations, tachycardia, arrhythmias, increased pulse and blood pressure, heart failure, angina, myocardial infarction, cardiac arrest, dyspnea, diarrhea, vomiting, abdominal cramps, elevations in liver function tests, flushing, and rash.




To report SUSPECTED ADVERSE REACTIONS, contact Fresenius Kabi USA, LLC at 1-800-551-7176, option 5, or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

See full prescribing information for drugs that affect thyroid hormone pharmacokinetics and metabolism (e.g., synthesis, secretion, catabolism, protein binding, and target tissue response) that may alter the therapeutic response to Levothyroxine Sodium Injection.

This Important Safety Information does not include all the information needed to use Levothyroxine Sodium Injection safely and effectively. Please see the full prescribing information, including BOXED WARNING, for Levothyroxine Sodium Injection at www.forcriticalmoments.com.

Levothyroxine Sodium Injection



Strength	100 mcg per 5 mL	200 mcg per 5 mL	500 mcg per 5 mL
Concentration	20 mcg per mL	40 mcg per mL	100 mcg per mL
Fill volume	5 mL	5 mL	5 mL
Description	Single Dose Vial	Single Dose Vial	Single Dose Vial
Ready-to-use	Yes	Yes	Yes
Preservative free	Yes	Yes	Yes
Unit of sale NDC	63323-885-10	63323-890-10	63323-895-10
Unit of sale bar code	 3 63323-885-10 6	 3 63323-890-10 0	 3 63323-895-10 5
Unit of sale	1	1	1
Wholesale numbers			
AmerisourceBergen	1022-5479	1022-5478	1022-5640
Cardinal	5544366	5544374	5544382
McKesson	3966892	3966926	3966959
Morris & Dickson	732180	732198	734004

To place an order, contact your Sales Representative or call Customer Service at
1.888.386.1300 | www.forcriticalmoments.com



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Three Corporate Drive
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Please see full prescribing information, including BOXED WARNING, for Levothyroxine Sodium Injection at www.forcriticalmoments.com.
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