Levothyroxine Sodium for Injection

Initial U.S. Approval 1969

Levothyroxine Sodium is a synthetic form of L-thyroxine product. Levothyroxine (T3) Sodium for Injection is indicated for the treatment of hypothyroidism in adults and children. It is not indicated for the treatment of obesity or weight loss. Levothyroxine Sodium should be used to maintain a euthyroid state, and dosing should be individualized based on the clinical response of the patient. Levothyroxine Sodium should be used with caution in patients with underlying cardiovascular disease, as it can potentially exacerbate cardiac complications.

INDICATIONS AND USAGE
Levothyroxine Sodium is administered for the treatment of hypothyroidism in adults and children. It is not indicated for the treatment of obesity or weight loss. Levothyroxine Sodium should be used to maintain a euthyroid state, and dosing should be individualized based on the clinical response of the patient.

CONTRAINDICATIONS
Levothyroxine Sodium should be administered to patients who are hypersensitive to L-thyroxine. It should not be administered to patients with undiagnosed endocrine disorders, including adrenal insufficiency, hypopituitarism, and disseminated intravascular coagulation (DIC), or with hyperthyroidism. Levothyroxine Sodium should not be used to treat obesity or weight loss. Levothyroxine Sodium should not be used in patients with underlying cardiovascular disease, as it can potentially exacerbate cardiac complications.

ADVERSE REACTIONS
Adverse reactions to Levothyroxine Sodium include arrhythmias, tachycardia, myocardial ischemia and infarction, or worsening of congestive heart failure and death. The most common adverse reactions associated with Levothyroxine Sodium therapy are fever, headache, nausea, vomiting, diarrhea, abdominal cramps, sweating, tachycardia, increased pulse and blood pressure, weight loss, increased appetite, palpitations, nervousness, heat intolerance, tremor, anxiety, nervousness, heat intolerance, and nervousness.

DOSE AND ADMINISTRATION
An initial intravenous loading dose of Levothyroxine Sodium for Injection between 50 to 100 mcg should be administered, as clinically indicated, until serum TSH levels have been established. Caution should be used when switching patients from oral to intravenous levothyroxine.

CONTRAINDICATIONS
Levothyroxine Sodium is contraindicated in patients with hyperthyroidism, undiagnosed endocrine disorders, including adrenal insufficiency, hypopituitarism, DIC, and disseminated intravascular coagulation.

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after adenogen or corticosteroid therapy. Familial hyper or hyperthyroidism arising from single or multiple somatic or tissue changes in this context may be associated with a high risk of malignancy or mortality in the maternal patient and the fetus.

1.2 Labor and Delivery

Patients in labor who develop myxedema have not been reported in the literature. However, the neonate should be treated with Levothyroxine Sodium for injection as the risk of non-treatment is associated with a high risk of malformations or mortality to the maternal patient and the fetus.

1.3 Nursing Mothers

Adverse replacement doses of thyroid hormones are required to maintain normal maternal and fetal health. In the reported cases of Levothyroxine Sodium for injection used to treat myxedema coma in patients who are lactating, such caution can be taken. However, certain caution can be taken before use of Levothyroxine Sodium for injection as the risk of non-treatment is associated with a high risk of malformations or mortality to the maternal patient and the fetus.

1.4 Pediatric Use

Myxedema is a disease of the elderly. An approved, oral dosing form of levothyroxine should be used in the pediatric patient population for maintaining normal thyroid function in a non-complicated hypothyroidism.

1.5 Geriatric Use and Patients with Underlying Cardiovascular Disease

See Section 2, Dosage and Administration, for full prescribing information in the section on impaired renal function. Because of the increased prevalence of cardiovascular disease in the elderly, caution should be used in Levothyroxine Sodium for injection in the elderly, and in patients with cardiovascular disease on active treatment. Atherosclerosis is a common side effect associated with levothyroxine treatment in the elderly. Atrial fibrillation and tachycardia are rare to impeded, and Cerebrovascular accidents and peripheral vascular disease are known in these patients with underlying cardiovascular disease.

1.6 Treatment of Overdose

Levothyroxine Sodium for injection should be reduced in dose or temporarily discontinued if signs or symptoms of overdose occur. To obtain up-to-date information about the treatments of excesses, a good resource is the Therapeutic Appalachian Poison Control Center. In managing overdose, consider the possibility of multiple drug overdoses, interactions, and unusual drug interactions in the patient in the event of an overdose, appropriate supportive treatment should be initiated as dictated by the patient’s medical status.

1.7 DESCRIPTION

Levothyroxine Sodium for injection contains synthetic crystalline levothyroxine (L-T4). Levothyroxine Sodium for injection is a sterile, preservative-free, lyophilized powder containing 1 mg levothyroxine sodium. The product contains sodium phosphate buffer, NaCl, sodium lactate, and sodium hydroxide, pH adjustment is achieved with sodium hydroxide. In accordance with this, Levothyroxine Sodium for injection is available in a dose of 100 mg via:

2 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Thyroid hormones that act on their physiologic actions through control of DNA transcription and protein synthesis. T3 or L-thyroxine (T4) stimulates the thyroid stimulating hormone (TSH) receptor and reduces and increases the number of TSH receptors to TSH. The physiological actions of thyroid hormones are produced predominantly by T3, the majority of which is 3′0-dihydroxy-difluoro-iodothyronine from T3 by deiodination in peripheral tissues.

12.2 Pharmacodynamics

Thyroid hormone synthesis and secretion is regulated by the hypothalamic pituitary-thyroid axis. Thyrotropin releasing hormone (TRH) released from the hypothalamic paraventricular nucleus stimulates the pituitary gland located within the hypothalamic gland. The TSH is secreted by the anterior pituitary gland. TSH, in turn, is the physiologic stimulus for the synthesis and secretion of thyroid hormones. T3 and T4 by the thyroid gland.

2.12 Cautions

Levothyroxine Sodium for injection is a sterile, preservative-free lyophilized powder containing 1 mg levothyroxine sodium. The product contains sodium phosphate buffer, NaCl, sodium lactate, and sodium hydroxide, pH adjustment is achieved with sodium hydroxide. Levothyroxine Sodium for injection is available in a dose of 100 mg via:

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