**Indications and Usage**

Levothyroxine sodium tablets are indicated as an adjunct to surgery and radioiodine therapy in the management of thyrotropin-dependent well-differentiated thyroid cancer. Pituitary Thyrotropin (Thyroid-Stimulating Hormone, TSH) Suppression: As an adjunct to surgery and radioiodine therapy in the management of primary (thyroidal), secondary (pituitary), and tertiary (hypothalamic) congenital or acquired hypothyroidism.

Levothyroxine sodium tablets are indicated as a replacement therapy in primary (thyroidal), secondary (pituitary), and tertiary (hypothalamic) congenital or acquired hypothyroidism.

Levothyroxine sodium tablets are not indicated for treatment of myxedema coma. Do not use oral thyroid hormone drug products to treat myxedema coma.

Levothyroxine sodium tablets are not indicated for suppression of benign thyroid nodules and nontoxic diffuse goiter in iodine-sufficient patients.

Levothyroxine sodium tablets are not indicated for treatment of hypothyroidism during the recovery phase of subacute thyroiditis.

Levothyroxine sodium tablets are not indicated for weight loss.

**Dosage and Administration**

**Overdosage**

**Adverse Reactions**

**Drug Interactions**

**Full Prescribing Information**

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

Thyroid hormones, including levothyroxine sodium tablets, offer no advantage over other strategies (appetite suppressants, diet, and exercise) for a reduction in weight or body weight.

**Compliance**

**Pharmacology**

**Children**

**Pediatric Use**

**Pregnancy**

**Lactation**

**Drug-Laboratory Test Interactions**

**Geriatric Use**

**Arterial Insufficiency**

**Drug Interactions**

**Carcinogenesis, Mutagenesis, Impairment of Fertility**

**Flushing**

**Adult Use**

**Clinical Pharmacology**

**Hypothyroidism**

**Discontinuing Therapy**

**Use During Pregnancy**
Seizures have been reported rarely with the institution of levothyroxine therapy. They include the following:

5.3 Acute Adrenal Crisis in Patients with Concomitant Adrenal Insufficiency

Levothyroxine sodium tablets are contraindicated in patients with uncorrected adrenal insufficiency. If myxedema coma is diagnosed or suspected, treatment with levothyroxine sodium tablets and corticosteroids is necessary. Administration of levothyroxine sodium tablets alone is likely to result in adrenal insufficiency.

3.2 Dosage and Administration

Pediatric Dosage — Congenital or Acquired Hypothyroidism

Table 1. Levothyroxine Sodium Tablets Dosing Guidelines for Pediatric Hypothyroidism

<table>
<thead>
<tr>
<th>Age</th>
<th>Daily Dose Per Kg Body Weight</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 to 5 years</td>
<td>8 to 10 mcg/kg/day</td>
</tr>
<tr>
<td>6 to 12 months</td>
<td>1.6 mcg/kg/day</td>
</tr>
<tr>
<td>Newborns (0 to 3 months)</td>
<td>4 to 5 mcg/kg/day</td>
</tr>
</tbody>
</table>

Children at risk for hyperactivity:

- Monitor children closely and adjust dosing to avoid clinical signs of hyperthyroidism. Refractory hyperactivity generally responds to lower doses of levothyroxine sodium tablets, usually in the range of 4 to 5 mcg/kg/day for the first 6 months of life and 1.6 mcg/kg/day for the 7th to 12th month of life.

- Patients presenting with hyperactivity at or after 12 months of age may require lower starting doses of levothyroxine sodium tablets, and may require increased intervals between dosage adjustments.

- In addition to levothyroxine sodium tablets, appropriate medical management of hyperactivity symptoms, such as behavior modification or counseling, should be considered.

- If a patient with hyperactivity on levothyroxine sodium tablets therapy does not respond to a lower dosage, consider the diagnosis of hyperthyroidism, and treat as appropriate.

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- If a patient with hyperactivity on levothyroxine sodium tablets therapy does not respond to a lower dosage, consider the diagnosis of hyperthyroidism, and treat as appropriate.

- If a patient does not respond to lower dosages, consider the diagnosis of hyperactivity, and treat as appropriate.


Adverse Reactions in Children

Prenatal and early childhood exposure to thyroid hormone products has been associated with a range of adverse effects. Thyroid hormone products, if taken too early, can cause hypothyroidism, which can lead to cognitive impairment and growth retardation.

Hypothyroidism

In patients treated with levothyroxine sodium tablets, serum TSH levels should be monitored to determine the effectiveness of treatment. If TSH levels are elevated, the dosage of levothyroxine sodium tablets should be increased. If TSH levels are decreased, the dosage of levothyroxine sodium tablets should be decreased.

Table 2: Drugs That May Decrease T4 Absorption (Hypothyroidism)

<table>
<thead>
<tr>
<th>Drug</th>
<th>Effect</th>
</tr>
</thead>
<tbody>
<tr>
<td>Iodides</td>
<td>May increase serum T4 concentration by changing the T4:T3 ratio.</td>
</tr>
</tbody>
</table>

Table 3: Drugs That May Alter T4 and Triiodothyronine (T3) Absorption Without Allowing Free Thyroxine (T4) Concentration (Hypothyroidism)

<table>
<thead>
<tr>
<th>Drug</th>
<th>Effect</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antacids, Sucralfate</td>
<td>May decrease absorption of levothyroxine sodium tablets.</td>
</tr>
<tr>
<td>Proton Pump Inhibitors</td>
<td>May decrease absorption of levothyroxine sodium tablets.</td>
</tr>
</tbody>
</table>

Table 4: Drugs That May Increase T4 Absorption (Hypothyroidism)

<table>
<thead>
<tr>
<th>Drug</th>
<th>Effect</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ascorbic Acid</td>
<td>May increase absorption of levothyroxine sodium tablets.</td>
</tr>
</tbody>
</table>

Table 5: Drugs That May Decrease Conversion of T3 to T4

<table>
<thead>
<tr>
<th>Drug</th>
<th>Effect</th>
</tr>
</thead>
<tbody>
<tr>
<td>Iodides</td>
<td>May decrease T3 production in the thyroid.</td>
</tr>
</tbody>
</table>

7.2 Antidepressant Therapy

Concurrent use of antidepressants with levothyroxine sodium tablets may decrease serum T4 levels. These drugs may cause protein-binding site displacement. Furosemide has been shown to inhibit the protein binding of T4 to TBG and albumin, causing an increase in free T4 fraction in serum. Furosemide competes for T4-binding sites, and its use may cause an increase in serum T4 levels. Therefore, serum TSH levels should be monitored when furosemide is used in conjunction with levothyroxine sodium tablets.

7.3 Oral Anticoagulants

Concomitant use of oral anticoagulants and levothyroxine sodium tablets may cause fluctuations in the international normalized ratio (INR). Closely monitor coagulation tests to permit necessary dosage adjustments.

7.4 Oral Antidiabetic Therapy

Concomitant use of oral antidiabetic therapy and levothyroxine sodium tablets may cause fluctuations in glycemic control and may increase the risk of hypoglycemia. Closely monitor glycemic control, especially when thyroid therapy is started, changed, or discontinued.

7.5 Antidepressant Therapy

Concurrent use of antidepressants with levothyroxine sodium tablets may decrease serum T4 levels. These drugs may cause protein-binding site displacement. Furosemide has been shown to inhibit the protein binding of T4 to TBG and albumin, causing an increase in free T4 fraction in serum. Furosemide competes for T4-binding sites, and its use may cause an increase in serum T4 levels. Therefore, serum TSH levels should be monitored when furosemide is used in conjunction with levothyroxine sodium tablets.

7.6 Ketamine

Concomitant use of ketamine and levothyroxine sodium tablets may produce hypotension and bradycardia. Closely monitor cardiovascular status and monitor TSH levels.

7.7 Sympathomimetics

Concomitant use of sympathomimetics and levothyroxine sodium tablets may increase the risk of arrhythmias and cardiovascular collapse. Closely monitor cardiovascular status and monitor TSH levels.

7.8 Tyrosine-Kinase Inhibitors

Concomitant use of tyrosine-kinase inhibitors and levothyroxine sodium tablets may increase the risk of hypothyroidism. Closely monitor thyroid hormone parameters.

8.1 Carbohydrate-Restricted Diet

Pregnancy may increase levothyroxine sodium tablets requirements. Serum TSH levels should be monitored to determine the effectiveness of treatment. If TSH levels are elevated, the dosage of levothyroxine sodium tablets should be increased. If TSH levels are decreased, the dosage of levothyroxine sodium tablets should be decreased.

8.2 Lactation

Breastfeeding women who are being treated for hypothyroidism should be monitored for the presence of thyroid hormone excess. If there is no evidence of excess thyroid hormone, breastfeeding can be continued. If there is evidence of excess thyroid hormone, breastfeeding should be discontinued.

8.3 Pediatric Use

The safety and efficacy of levothyroxine sodium tablets in children have not been established. Therefore, levothyroxine sodium tablets should not be administered to children until at least 3 years of age. TSH levels in children at this age are primarily determined by the hypothalamic-pituitary-thyroid axis.

8.4 Pregnancy

Pregnancy may increase levothyroxine sodium tablets requirements. Serum TSH levels should be monitored to determine the effectiveness of treatment. If TSH levels are elevated, the dosage of levothyroxine sodium tablets should be increased. If TSH levels are decreased, the dosage of levothyroxine sodium tablets should be decreased.

8.5 Nursing Mothers

Breastfeeding women who are being treated for hypothyroidism should be monitored for the presence of thyroid hormone excess. If there is no evidence of excess thyroid hormone, breastfeeding can be continued. If there is evidence of excess thyroid hormone, breastfeeding should be discontinued.

8.6 Contraindications

In patients treated with levothyroxine sodium tablets, serum TSH levels should be monitored to determine the effectiveness of treatment. If TSH levels are elevated, the dosage of levothyroxine sodium tablets should be increased. If TSH levels are decreased, the dosage of levothyroxine sodium tablets should be decreased.

8.7 Cautions

In patients treated with levothyroxine sodium tablets, serum TSH levels should be monitored to determine the effectiveness of treatment. If TSH levels are elevated, the dosage of levothyroxine sodium tablets should be increased. If TSH levels are decreased, the dosage of levothyroxine sodium tablets should be decreased.

8.8 Adverse Reactions

The safety and efficacy of levothyroxine sodium tablets in children have not been established. Therefore, levothyroxine sodium tablets should not be administered to children until at least 3 years of age. TSH levels in children at this age are primarily determined by the hypothalamic-pituitary-thyroid axis.

8.9 Overdosage

In patients treated with levothyroxine sodium tablets, serum TSH levels should be monitored to determine the effectiveness of treatment. If TSH levels are elevated, the dosage of levothyroxine sodium tablets should be increased. If TSH levels are decreased, the dosage of levothyroxine sodium tablets should be decreased.

9. DESCRIPTION

Levothyroxine sodium tablets are a synthetic thyroid hormone. Levothyroxine sodium tablets are indicated for the replacement therapy of hypothyroidism and as a full dose to achieve euthyroidism in patients with hypothyroidism. Levothyroxine sodium tablets are indicated for the treatment of hypothyroidism in patients with hypothyroidism. Levothyroxine sodium tablets are indicated for the treatment of hypothyroidism in patients with hypothyroidism. Levothyroxine sodium tablets are indicated for the treatment of hypothyroidism in patients with hypothyroidism.
Dosing and Administration

Dosage and Administration (13.1) Levothyroxine sodium tablets USP should be protected from light and moisture.

Levothyroxine sodium tablets USP are round, colored, scored and debossed with following debossing potential or effects on fertility of levothyroxine.

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

NONCLINICAL TOXICOLOGY

Thyroid hormones are primarily eliminated by the kidneys. A portion of the conjugated hormone is excreted as T3 and T4 glucuronides. Approximately 80% of the daily dose of T4 is deiodinated to yield equal amounts of T3 and reverse T3 (rT3). T3 and T4 are also occurring at a number of additional sites, including the kidney and other tissues. Approximately 80% of circulating T3 is derived from peripheral T4 by sequential deiodination. Approximately 80% of circulating T3 is derived from peripheral T4 by sequential deiodination. Approximately 80% of circulating T3 is derived from peripheral T4 by sequential deiodination. Approximately 80% of circulating T3 is derived from peripheral T4 by sequential deiodination.

Circulating thyroid hormones are greater than 99% bound to plasma proteins, including thyroxine-binding globulin (TBG), transthyretin (prealbumin), albumin, and other proteins. Only unbound hormone is metabolically active. Many drugs and physiologic conditions affect the binding of thyroid hormones to serum proteins.

Levothyroxine (T4) is a synthetic hormone that exerts the same physiologic effect as endogenous T4, thereby maintaining normal T4 levels when a deficiency is present. Oral levothyroxine sodium is a synthetic T4 hormone that exerts the same physiologic effect as endogenous T4, thereby maintaining normal T4 levels when a deficiency is present.

The physiological actions of thyroid hormones are produced predominantly by T3, the majority of T3 being produced in peripheral tissues, including the liver, brain, heart, skeletal muscle, and adipose tissue. T3 and T4 are also occurring at a number of additional sites, including the kidney and other tissues. Approximately 80% of circulating T3 is derived from peripheral T4 by sequential deiodination. Approximately 80% of circulating T3 is derived from peripheral T4 by sequential deiodination. Approximately 80% of circulating T3 is derived from peripheral T4 by sequential deiodination. Approximately 80% of circulating T3 is derived from peripheral T4 by sequential deiodination.
Instruct patients to notify their healthcare provider if they are pregnant or breastfeeding or are thinking of becoming pregnant while taking levothyroxine sodium tablets.

Important Information

Inform patients that it may take several weeks before they notice an improvement in symptoms.

Inform patients that the levothyroxine in levothyroxine sodium tablet is intended to replace a hormone that is normally produced by the thyroid gland. Generally, replacement therapy is to be taken for life.

Inform patients that levothyroxine sodium tablets should not be used as a primary or adjunctive therapy in a weight control program.

Instruct patients to notify their healthcare provider if they are taking any other medications, including prescription and over-the-counter preparations.

Instruct patients to notify their physician of any other medical conditions they may have, particularly heart disease, diabetes, clotting disorders, and adrenal or pituitary gland problems, as the dose of medications used to control these other conditions may need to be adjusted while they are taking levothyroxine sodium tablets. If they have diabetes, instruct patients to monitor their blood and/or urinary glucose levels as directed by their physician and immediately report any changes to their physician. If patients are taking anticoagulants, their clotting status should be checked frequently.

Instruct patients to notify their physician or dentist that they are taking levothyroxine sodium tablets prior to any surgery.

Adverse Reactions

Instruct patients to notify their healthcare provider if they experience any of the following symptoms: rapid or irregular heartbeat, chest pain, shortness of breath, leg cramps, headache, nervousness, irritability, sleeplessness, tremors, change in appetite, weight gain or loss, vomiting, diarrhea, excessive sweating, heat intolerance, fever, changes in menstrual periods, hives or skin rash, or any other unusual medical event.

Inform patients that partial hair loss may occur rarely during the first few months of levothyroxine sodium tablets therapy, but this is usually temporary.

Manufactured for:
Lupin Pharmaceuticals, Inc.
Baltimore, Maryland 21202

Manufactured by:
Lupin Limited
Pithampur (M.P.) - 454 775

Revised: November 2020

PACKAGE LABEL--PRINCIPAL DISPLAY PANEL

Levothyroxine Sodium Tablets USP
Rx Only
25 mcg
NDC 68180-965-01
100's Tablets

Levothyroxine Sodium Tablets USP
Rx Only
50 mcg
NDC 68180-966-01
100's Tablets

Levothyroxine Sodium Tablets USP
Rx Only
75 mcg
NDC 68180-967-01
100's Tablets

Levothyroxine Sodium Tablets USP
Rx Only
88 mcg
NDC 68180-968-01
100's Tablets

Levothyroxine Sodium Tablets USP
Rx Only
100 mcg
NDC 68180-969-01
100's Tablets

Levothyroxine Sodium Tablets USP
Rx Only
112 mcg
NDC 68180-970-01
100's Tablets

Levothyroxine Sodium Tablets USP
Rx Only
125 mcg
NDC 68180-971-01
100's Tablets

Levothyroxine Sodium Tablets USP
Rx Only
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100's Tablets

Levothyroxine Sodium Tablets USP
Rx Only
175 mcg
NDC 68180-973-01
100's Tablets
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<tr>
<td>300 mcg</td>
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</table>

**Product Information**

- **Product Type**: HUMAN PRESCRIPTION DRUG
- **Item Code (Source)**: NDC:68180-965
- **Route of Administration**: ORAL

**Active Ingredient/Active Moiety**

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<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
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<tbody>
<tr>
<td>LEVOTHYROXINE SODIUM</td>
<td>LEVOTHYROXINE ANHYDROUS</td>
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**Inactive Ingredients**

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<td>CROSCARMELLOSE SODIUM</td>
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<tr>
<td>FD&amp;C YELLOW NO. 6</td>
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<tr>
<td>MAGNESIUM STEARATE</td>
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</tr>
<tr>
<td>MANNITOL</td>
<td></td>
</tr>
<tr>
<td>SODIUM BICARBONATE</td>
<td></td>
</tr>
</tbody>
</table>
levothyroxine sodium tablet

**Ingredient Name**
- **LEVOTHYROXINE SODIUM**

**Route of Administration**
- ORAL

**Product Type**
- HUMAN PRESCRIPTION DRUG

**Marketing Category**
- ANDA

**Basis of Strength**
- ANHYDROUS

---

**Ingredient Name**
- **SODIUM BICARBONATE**

**Description**
- Inactive Ingredient

**Package Description**
- In 1 BOTTLE; Type 0: Not a Combination Product

**Strength**
- 0.175 mg, 0.3 mg

**Size**
- 6 mm, 5 mm

**Score**
- 2 pieces

**Imprint Code**
- L24, L25

**Marketing Start Date**
- 03/20/2019

**Marketing End Date**
- 03/20/2019

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**Ingredient Name**
- **MANNITOL**

**Description**
- Inactive Ingredient

**Package Description**
- In 1 BOTTLE; Type 0: Not a Combination Product

**Strength**
- 500 mg

**Size**
- 6 mm

**Score**
- 2 pieces

**Imprint Code**
- L26

**Marketing Start Date**
- 03/20/2019

**Marketing End Date**
- 03/20/2019

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**Ingredient Name**
- **FD&C BLUE NO. 1**

**Description**
- Inactive Ingredient

**Package Description**
- In 1 BOTTLE; Type 0: Not a Combination Product

**Strength**
- 100 mg

**Size**
- 6 mm

**Score**
- 1 piece

**Imprint Code**
- L25

**Marketing Start Date**
- 03/20/2019

**Marketing End Date**
- 03/20/2019

---

**Ingredient Name**
- **FD&C RED NO. 27**

**Description**
- Inactive Ingredient

**Package Description**
- In 1 BOTTLE; Type 0: Not a Combination Product

**Strength**
- 500 mg

**Size**
- 6 mm

**Score**
- 2 pieces

**Imprint Code**
- L26

**Marketing Start Date**
- 03/20/2019

**Marketing End Date**
- 03/20/2019
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Lupin Pharmaceuticals, Inc.