WARNING: NOT FOR TREATMENT OF OBESITY OR FOR WEIGHT LOSS

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

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use Levothyroxine Sodium for Injection safely and effectively. See full prescribing information for Levothyroxine Sodium for Injection.

LEVOTHYROXINE sodium for injection, for intravenous use

INDICATIONS AND USAGE

Levothyroxine Sodium is a L-thyroxine product. Levothyroxine (L-T4) Sodium for injection is indicated for the treatment of hypothyroidism. (1)

Important Limitations of Use:

- The relative bioavailability of this drug has not been established. Use caution when converting patients from oral to intravenous levothyroxine.
- The relative bioavailability of this drug has not been established. Use caution when converting patients from oral to intravenous levothyroxine.

DOSAGE AND ADMINISTRATION

- An initial intravenous loading dose of Levothyroxine sodium for injection between 300 to 500 mcg followed by once daily into

CONTRAINDICATIONS

- Levothyroxine Sodium for injection therapy for patients with previously undiagnosed endocrine disorders, including adrenal

WARNINGS AND PRECAUTIONS

- Thyroid hormones, including Levothyroxine Sodium for Injection, 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 sympathomimetics agents such as those used for their anesthetic effects [See Adverse Reactions (10) and Overdosage (10)].

DRUG INTERACTIONS

- Thyroid hormones and thyroid status have varied effects on the pharmacokinetics and actions of other drugs (See Section 12.3).

- Concurrent use may produce marked hypertension and tachycardia; cautious administration to patients receiving thyroid hormone treatment is recommended.

- Concurrent use of tricyclic (e.g., amitriptyline) or tetracyclic (e.g., maprotiline) antidepressants and levothyroxine may increase their cardiovascular toxicity.

- Levothyroxine increases the response to oral anticoagulant therapy. Therefore, a decrease in the dose of anticoagulant may be necessary when initiating or increasing levothyroxine therapy.

- Careful monitoring of diabetic control is recommended, especially when thyroid therapy is started, changed, or discontinued.

- Concurrent use of tricyclic (e.g., amitriptyline) or tetracyclic (e.g., maprotiline) antidepressants and levothyroxine may increase their cardiovascular toxicity.

- Levothyroxine increases the response to oral anticoagulant therapy. Therefore, a decrease in the dose of anticoagulant may be necessary when initiating or increasing levothyroxine therapy.

- Careful monitoring of diabetic control is recommended, especially when thyroid therapy is started, changed, or discontinued.

Drug-Laboratory Test Interactions

- Thyroid status and laboratory test results may be overshadowed by use of large dose of Levothyroxine Sodium for injection.

- Thyroid hormones, including Levothyroxine Sodium for Injection, 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 sympathomimetics agents such as those used for their anesthetic effects [See Adverse Reactions (10) and Overdosage (10)].

- Concurrent use may produce marked hypertension and tachycardia; cautious administration to patients receiving thyroid hormone treatment is recommended.

- Concurrent use of tricyclic (e.g., amitriptyline) or tetracyclic (e.g., maprotiline) antidepressants and levothyroxine may increase their cardiovascular toxicity.

- Levothyroxine increases the response to oral anticoagulant therapy. Therefore, a decrease in the dose of anticoagulant may be necessary when initiating or increasing levothyroxine therapy.

- Careful monitoring of diabetic control is recommended, especially when thyroid therapy is started, changed, or discontinued.

Drug-Laboratory Test Interactions

- Thyroid status and laboratory test results may be overshadowed by use of large dose of Levothyroxine Sodium for injection.

- Thyroid hormones, including Levothyroxine Sodium for Injection, 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 sympathomimetics agents such as those used for their anesthetic effects [See Adverse Reactions (10) and Overdosage (10)].

- Concurrent use may produce marked hypertension and tachycardia; cautious administration to patients receiving thyroid hormone treatment is recommended.

- Concurrent use of tricyclic (e.g., amitriptyline) or tetracyclic (e.g., maprotiline) antidepressants and levothyroxine may increase their cardiovascular toxicity.

- Levothyroxine increases the response to oral anticoagulant therapy. Therefore, a decrease in the dose of anticoagulant may be necessary when initiating or increasing levothyroxine therapy.

- Careful monitoring of diabetic control is recommended, especially when thyroid therapy is started, changed, or discontinued.

Drug-Laboratory Test Interactions

- Thyroid status and laboratory test results may be overshadowed by use of large dose of Levothyroxine Sodium for injection.

- Thyroid hormones, including Levothyroxine Sodium for Injection, 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 sympathomimetics agents such as those used for their anesthetic effects [See Adverse Reactions (10) and Overdosage (10)].

- Concurrent use may produce marked hypertension and tachycardia; cautious administration to patients receiving thyroid hormone treatment is recommended.

- Concurrent use of tricyclic (e.g., amitriptyline) or tetracyclic (e.g., maprotiline) antidepressants and levothyroxine may increase their cardiovascular toxicity.

- Levothyroxine increases the response to oral anticoagulant therapy. Therefore, a decrease in the dose of anticoagulant may be necessary when initiating or increasing levothyroxine therapy.

- Careful monitoring of diabetic control is recommended, especially when thyroid therapy is started, changed, or discontinued.

Drug-Laboratory Test Interactions

- Thyroid status and laboratory test results may be overshadowed by use of large dose of Levothyroxine Sodium for injection.

- Thyroid hormones, including Levothyroxine Sodium for Injection, 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 sympathomimetics agents such as those used for their anesthetic effects [See Adverse Reactions (10) and Overdosage (10)].

- Concurrent use may produce marked hypertension and tachycardia; cautious administration to patients receiving thyroid hormone treatment is recommended.

- Concurrent use of tricyclic (e.g., amitriptyline) or tetracyclic (e.g., maprotiline) antidepressants and levothyroxine may increase their cardiovascular toxicity.

- Levothyroxine increases the response to oral anticoagulant therapy. Therefore, a decrease in the dose of anticoagulant may be necessary when initiating or increasing levothyroxine therapy.

- Careful monitoring of diabetic control is recommended, especially when thyroid therapy is started, changed, or discontinued.

Drug-Laboratory Test Interactions

- Thyroid status and laboratory test results may be overshadowed by use of large dose of Levothyroxine Sodium for injection.

- Thyroid hormones, including Levothyroxine Sodium for Injection, 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 sympathomimetics agents such as those used for their anesthetic effects [See Adverse Reactions (10) and Overdosage (10)].

- Concurrent use may produce marked hypertension and tachycardia; cautious administration to patients receiving thyroid hormone treatment is recommended.

- Concurrent use of tricyclic (e.g., amitriptyline) or tetracyclic (e.g., maprotiline) antidepressants and levothyroxine may increase their cardiovascular toxicity.

- Levothyroxine increases the response to oral anticoagulant therapy. Therefore, a decrease in the dose of anticoagulant may be necessary when initiating or increasing levothyroxine therapy.

- Careful monitoring of diabetic control is recommended, especially when thyroid therapy is started, changed, or discontinued.

Drug-Laboratory Test Interactions

- Thyroid status and laboratory test results may be overshadowed by use of large dose of Levothyroxine Sodium for injection.

- Thyroid hormones, including Levothyroxine Sodium for Injection, 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 sympathomimetics agents such as those used for their anesthetic effects [See Adverse Reactions (10) and Overdosage (10)].

- Concurrent use may produce marked hypertension and tachycardia; cautious administration to patients receiving thyroid hormone treatment is recommended.

- Concurrent use of tricyclic (e.g., amitriptyline) or tetracyclic (e.g., maprotiline) antidepressants and levothyroxine may increase their cardiovascular toxicity.

- Levothyroxine increases the response to oral anticoagulant therapy. Therefore, a decrease in the dose of anticoagulant may be necessary when initiating or increasing levothyroxine therapy.

- Careful monitoring of diabetic control is recommended, especially when thyroid therapy is started, changed, or discontinued.

Drug-Laboratory Test Interactions

- Thyroid status and laboratory test results may be overshadowed by use of large dose of Levothyroxine Sodium for injection.

- Thyroid hormones, including Levothyroxine Sodium for Injection, 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 sympathomimetics agents such as those used for their anesthetic effects [See Adverse Reactions (10) and Overdosage (10)].

- Concurrent use may produce marked hypertension and tachycardia; cautious administration to patients receiving thyroid hormone treatment is recommended.

- Concurrent use of tricyclic (e.g., amitriptyline) or tetracyclic (e.g., maprotiline) antidepressants and levothyroxine may increase their cardiovascular toxicity.

- Levothyroxine increases the response to oral anticoagulant therapy. Therefore, a decrease in the dose of anticoagulant may be necessary when initiating or increasing levothyroxine therapy.

- Careful monitoring of diabetic control is recommended, especially when thyroid therapy is started, changed, or discontinued.
USE IN SPECIFIC POPULATIONS

9.1 Pregnancy

Pregnancy Category A: There are no reported cases of Levotyramine Sodium for injection used to treat myxedema coma in patients who were pregnant or lactating. Studies in animals with thyroxine have not shown an increased risk of fetal abnormalities. Therefore, pregnant patients who develop myxedema should be treated with Levotyramine Sodium for injection as the risk of non-treatment is associated with a high probability of significant or severe mental retardation or mortality to the maternal patient and fetus.

9.2 Labor and Delivery

Patients in labor who develop myxedema have not been reported in the literature. However, patients should be treated with Levotyramine Sodium for injection as the risk of non-treatment is associated with a high probability of significant or severe mental retardation or mortality to the maternal patient and fetus.

9.3 Nursing Mothers

Administrative changes of thyroid hormones are required to maintain normal function. There are no reported cases of Levotyramine Sodium for injection used to treat thyrotoxicosis in women who are lactating. However, since Levotyramine Sodium for injection is used to treat with Levotyramine Sodium for injection for the risk of non-treatment is associated with a high probability of significant or severe mental retardation or mortality to the maternal patient and fetus.

9.4 Pediatric Use

Mycxedema in the presence of thyroid failure. An approved, and dosage form of levotyramine should be used in the pediatric patient population for maintaining euthyroid state in neonatal hypothyroidism.

9.5 Geriatric Use

The Geriatric and Adult with Endocrine and Metabolic Disease See Section 2. Safety and Tolerance, for full prescribing information in the geriatric patient population. Because of the increased prevalence of comorbidities in the elderly, cautious use of Levotyramine Sodium for injection in the elderly and in patients with serious cardiac risk factors is advised. Atrial fibrillation is a common side effect associated with levotyramine in the elderly (See Safety and Administration (2.1) and Warnings and Precautions (5.1).

10 OVSIDRAE

In general, the signs and symptoms of ovidonaldamiento with levotyramine are those of hyperthyroidism (See Warnings and Precautions (5.2) and畜恶), and any underlying condition that may cause the signs and symptoms of ovidonaldamiento. Any underlying condition that may cause the signs and symptoms of ovidonaldamiento should be treated before definitive treatment with levotyramine is instituted. Atrial fibrillation is a common side effect associated with levotyramine in the elderly (See Safety and Administration (2.1) and Warnings and Precautions (5.1)).

11 DESCRIPTION

Levotyramine Sodium for injection is a sterile, preservative-free liquid consisting of the active ingredient, levotyramine sodium, and the excipients, sodium chloride, sodium hydroxide, sodium citrate, and sodium carbonate. The action of levotyramine sodium is the result of its ability to increase the production of thyroid hormones and to decrease the size of the pituitary gland.

The sodium salts of levotyramine sodium have as its active moiety 3,3'-dimethyl-4-phenyl-2-isopropyl-1-pyrroline, an amino-acid-like substance, and the following structural formula:

\[ \text{C}_{10}\text{H}_{19}\text{N}_{3}\text{O}\]

Table 3: Drags That May Alter Hypothesis of T4 (Hyperthyroidism)

<table>
<thead>
<tr>
<th>Drug or Drug Class</th>
<th>Potential Impact</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antidepressants</td>
<td>May increase T4 levels</td>
<td>Consider with caution.</td>
</tr>
<tr>
<td>Antihypertensives</td>
<td>May decrease T4 levels</td>
<td>Monitor closely.</td>
</tr>
<tr>
<td>Anticoagulants</td>
<td>May decrease T4 levels</td>
<td>Monitor closely.</td>
</tr>
</tbody>
</table>

Table 4: Drugs That May Decrease Conversion of T4 to T3

<table>
<thead>
<tr>
<th>Drug or Drug Class</th>
<th>Potential Impact</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antiretrovirals</td>
<td>May decrease T3 levels</td>
<td>Consider with caution.</td>
</tr>
<tr>
<td>Antifungal</td>
<td>May decrease T3 levels</td>
<td>Consider with caution.</td>
</tr>
</tbody>
</table>

Table 5: Other Drugs

<table>
<thead>
<tr>
<th>Drug or Drug Class</th>
<th>Potential Impact</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Corticosteroids</td>
<td>May increase T3 levels</td>
<td>Consider with caution.</td>
</tr>
<tr>
<td>Antipsychotics</td>
<td>May increase T3 levels</td>
<td>Consider with caution.</td>
</tr>
</tbody>
</table>

Table 6: Drugs That May Decrease Conversion of T4 to T3

<table>
<thead>
<tr>
<th>Drug or Drug Class</th>
<th>Potential Impact</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antiretrovirals</td>
<td>May decrease T3 levels</td>
<td>Consider with caution.</td>
</tr>
<tr>
<td>Antifungal</td>
<td>May decrease T3 levels</td>
<td>Consider with caution.</td>
</tr>
</tbody>
</table>

Table 7: Other Drugs

<table>
<thead>
<tr>
<th>Drug or Drug Class</th>
<th>Potential Impact</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Corticosteroids</td>
<td>May increase T3 levels</td>
<td>Consider with caution.</td>
</tr>
<tr>
<td>Antipsychotics</td>
<td>May increase T3 levels</td>
<td>Consider with caution.</td>
</tr>
</tbody>
</table>