Tips for Knowing Your LEVOXYL

Take note of your specific LEVOXYL dose
LEVOXYL tablets can be identified by their unique thyroid shape and are color coded by strength. Print and fill out this form to take to the pharmacy so you can make sure you get the brand your doctor has prescribed.

My LEVOXYL dosage(s) strength(s): __________________ My LEVOXYL tablet color(s): __________________

Circle the dosage(s) strength(s) you’ve been prescribed and check to make sure you have received the correct strengths and colors at the pharmacy.

Stand By Your Brand | Generic substitution is possible at the pharmacy
Make sure your doctor indicates “No Substitutions” on your prescription; otherwise the pharmacy may switch you to a generic equivalent.

Below are TIPS to help you get brand-name LEVOXYL:

- **Take the prescription** that your doctor gave you with the following indicated on it: “No Substitutions,” “Dispense As Written (DAW),” or “Brand Medically Necessary,” depending on the state you live in
- **Inform your pharmacist** that you prefer, and your doctor has prescribed, brand-name LEVOXYL
- **Pick up your prescription** and make sure the bottle label says LEVOXYL—look for the unique shape of your LEVOXYL tablet
- **Speak to the pharmacist** right away if you do not receive LEVOXYL

Indications
LEVOXYL is used as replacement or supplemental therapy in low thyroid function (hypothyroidism) of any cause, except transient hypothyroidism during the recovery phase of subacute thyroiditis. It is also used in the treatment or prevention of certain types of goiters and, as additional therapy, in the management of a specific thyroid cancer.

Important Safety Information

**WARNING:** You should not use thyroid hormone, including LEVOXYL, alone or with other drugs to treat obesity or for weight loss. The normal daily doses of thyroid hormone are not effective for weight loss if your thyroid function is normal. If you take larger-than-normal doses of thyroid hormone you may get serious or even life-threatening side effects, particularly if you also take certain stimulant weight loss drugs.

Please see Important Safety Information on the following page, and accompanying full Prescribing Information, including BOXED WARNING.
Important Safety Information (continued)

You should not use LEVOXYL:

• If you have untreated or known overactive thyroid of any cause, heart attack or untreated low adrenal gland function.
• If you are allergic to any of the inactive ingredients in the tablets. Notify your physician if you experience hives, itching, rash, flushing, swelling of the throat, abdominal pain, nausea, vomiting, diarrhea, fever, joint pain, or wheezing, as these may be the symptoms of an allergic reaction.
• For the treatment of male or female infertility unless this condition is due to low thyroid function.
• In a certain type of goiter or for thyroid small masses (particularly in the elderly or those with heart and blood vessel disease), if the TSH level is already lowered. If the TSH level is not lowered, LEVOXYL should be used with caution.

To avoid under- or over-treatment with LEVOXYL, carefully follow the dosage instructions given by your health care provider. Do not discontinue or change the amount you take or how often you take it, unless directed to do so by your physician. Because many drugs interact with levothyroxine sodium, your doctor may need to make adjustments in dosing to maintain therapeutic response.

Long-term therapy with LEVOXYL, especially in women after menopause may decrease bone mineral density.

Tell your physician if you are allergic to any foods or medicines, are pregnant or intend to become pregnant, are breast-feeding or are taking any other medications, including prescription and over-the-counter preparations. If you become pregnant while taking LEVOXYL, it is likely that your dose will need to be increased while you are pregnant.

Tell your physician of any other medical conditions you may have, particularly heart disease, diabetes, clotting disorders, and adrenal or pituitary gland problems. Your dose of medications used to control these other conditions may need to be adjusted while you are taking LEVOXYL.

While taking LEVOXYL, there is a risk of high blood pressure, heart failure, heart attack, and cardiac arrest, as well as growth changes in children.

Tell your physician if you experience any of the following adverse events, or any other unusual medical events:

• 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
• Partial temporary hair loss

Take LEVOXYL in the morning on an empty stomach, at least one-half hour before eating any food. It is very important that you take the tablet with a full glass of water to avoid choking, gagging, tablet getting stuck in your throat or difficulty swallowing.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

Please see accompanying full Prescribing Information, including BOXED WARNING.
Levothyroxine is contraindicated in patients with untreated subclinical (suppressed serum TSH level with normal T4 and T3 levels) or overt thyrotoxicosis of any etiology and in patients with acute myocardial infarction. Levothyroxine is contraindicated in patients with uncontrolled adrenal insufficiency since thyroid hormones may precipitate an acute adrenal crisis by increasing the metabolic clearance of glucocorticoids (see PRECAUTIONS). LEVOXYL® is contraindicated in patients with hypersensitivity to any of the inactive ingredients in LEVOXYL® tablets (see DESCRIPTION, Inactive Ingredients).

Patients with nontoxic diffuse goiter or nodular thyroid disease, particularly the elderly or those with underlying cardiovascular disease, levothyroxine sodium therapy is contraindicated if the serum TSH level is already suppressed due to the potential for precipitating overt thyrotoxicosis (see PRECAUTIONS, CONTRAINDICATIONS). If the serum TSH is already suppressed, LEVOXYL® should be used with caution in conjunction with careful monitoring of thyroid function for evidence of hyperthyroidism and clinical monitoring for potential associated adverse cardiovascular signs and symptoms of hyperthyroidism.

PRECAUTIONS

General
Levothyroxine has a narrow therapeutic index. Regardless of the indication for use, careful dosage titration is necessary to avoid the consequences of over- or under-treatment. These consequences include, among others, effects on growth and development, cardiovascular function, bone metabolism, reproductive function, cognitive function, emotional state, gastrointestinal function, and on glucose and lipid metabolism. Many drugs interact with levothyroxine sodium necessitating adjustments in dosing to maintain therapeutic response (see Drug Interactions).

Effects on bone mineral density — In women, long-term levothyroxine sodium therapy has been associated with decreased bone mineral density, especially in postmenopausal women on greater than replacement doses or in women who are receiving suppressive doses of levothyroxine sodium. Therefore, it is recommended that patients receiving levothyroxine sodium therapy be given the minimum dose necessary to achieve the desired clinical and biochemical response.

Patients with underlying cardiovascular disease — Exercise caution when administering levothyroxine to patients with cardiovascular disorders and to the elderly in whom there is an increased risk of occult cardiac disease. In these patients, levothyroxine therapy should be initiated at lower doses than those recommended in younger individuals or in patients without cardiac disease (see WARNINGS, PRECAUTIONS, Geriatric Use; and DOSAGE AND ADMINISTRATION). If cardiac symptoms develop or worsen, the levothyroxine dose should be reduced or withheld for one week and then cautiously restored at a lower dose. Overtreatment with levothyroxine sodium may have adverse cardiovascular effects such as an increase in heart rate, cardiac wall thickness, and cardiac contractility and may precipitate angina or arrhythmias. Patients with coronary artery disease who are receiving levothyroxine therapy should be monitored closely during surgical procedures, since the possibility of precipitating cardiac arrhythmias may be greater in those treated with levothyroxine. Concomitant administration of levothyroxine and sympathomimetic agents to patients with coronary artery disease may precipitate coronary insufficiency.

Patients with nontoxic diffuse goiter or nodular thyroid disease — Exercise caution when administering levothyroxine to patients with nontoxic diffuse goiter or nodular thyroid disease in order to minimize the risk of precipitating overt thyrotoxicosis (see WARNINGS). If the serum TSH is already suppressed, levothyroxine sodium should not be administered (see CONTRAINDICATIONS).

Associated endocrine disorders
Hypothyroidism and hypothyroidism deficiencies — In patients with secondary or tertiary hypothyroidism, additional hypothyroidism/patulous thyroid hormone deficiencies should be considered, and, if diagnosed, treated (see PRECAUTIONS, Autoimmune polyglandular syndrome) for adrenal insufficiency.

Autoimmune polyglandular syndrome — Occasionally, chronic autoimmune thyroiditis may occur in association with other autoimmune disorders such as adrenal insufficiency, pernicious anemia, and insulin-dependent diabetes mellitus. Patients with concomitant adrenal insufficiency should be treated with replacement glucocorticoids prior to initiation of treatment with levothyroxine sodium. Failure to do so may precipitate an acute adrenal crisis when thyroid hormone therapy is initiated, due to increased metabolic clearance of glucocorticoids by thyroid hormone. Patients with diabetes mellitus may require upward adjustments of their antidiabetic therapeutic regimens when treated with levothyroxine (see PRECAUTIONS, Drug Interactions).

Other associated medical conditions
Infants with congenital hypothyroidism appear to be at increased risk for other congenital anomalies, with cardiovascular anomalies (pulmonary stenosis, atrial septal defect, and ventricular septal defect), being the most common association.

Information for Patients

Patients should be informed of the following information to aid in the safe and effective use of LEVOXYL®:
1. Notify your physician if you are allergic to any foods or medicines, are pregnant or intend to become pregnant, are breast-feeding or are taking any other medications, including prescription and over-the-counter preparations.
2. Notify your physician of any other medical conditions you may have, particularly heart disease, diabetes, clotting disorders, and adrenal or pituitary gland problems. Your dose of medications used to control these other conditions may need to be adjusted while you are taking LEVOXYL®. If you have diabetes, monitor your blood and/or urinary glucose levels as directed by your physician and immediately report any changes to your physician. If you are taking anticoagulants (blood thinners), your clotting status should be checked frequently.
3. Use LEVOXYL® only as prescribed by your physician. Do not discontinue or change the amount you take or how often you take it, unless directed to do so by your physician.
4. The levothyroxine in LEVOXYL® is intended to replace a hormone that is normally produced by your thyroid gland. Generally, replacement therapy is to be taken for life, except in cases of transient hypothyroidism, which is usually associated with an infection of the thyroid gland (thyroiditis).
5. Take LEVOXYL® in the morning on an empty stomach, at least one-half hour before eating any food.
6. LEVOXYL® may rapidly swell and disintegrate resulting in choking, gagging, the tablet getting stuck in your throat or difficulty swallowing. It is very important that you take the tablet with a full glass of water. Most of these problems disappeared when LEVOXYL® tablets were taken with water.
7. It may take several weeks before you notice an improvement in your symptoms.
8. Notify your physician if you experience any of the following symptoms: rapid or irregular heartbeat, chest pain, abnormalities of the heart or blood vessels, nausea, vomiting, hoarseness, headache, fever, chills, change in appetite, weight gain or loss, vomiting, diarrhea, excessive sweating, heat intolerance, fever, changes in menstrual periods, fatigue, depression, anxiety, confusion, or any other unusual medical event.
9. Notify your physician if you become pregnant while taking LEVOXYL®. It is likely that your dose of LEVOXYL® will need to be increased while you are pregnant.
10. Notify your physician or dentist that you are taking LEVOXYL® prior to any surgery.
11. Partial thyroiditis may occur rarely during the first few months of LEVOXYL® therapy, but this is usually temporary.
12. LEVOXYL® should not be used as a primary or adjunctive therapy in a weight control program.

**Laboratory Tests**

**General**
The diagnosis of hypothyroidism is confirmed by measuring TSH levels using a sensitive assay (second generation assay sensitivity ≤0.1 mIU/L, or third generation assay sensitivity ≤0.01 mIU/L) and measurement of free-T4.
The adequacy of therapy is determined by periodic assessment of appropriate laboratory tests and clinical evaluation. The choice of laboratory tests depends on various factors including the etiology of the underlying thyroid disease, the presence of concomitant medical conditions, including pregnancy, and the use of concomitant medications (see **PRECAUTIONS**, **Drug Interactions** and **Drug-Laboratory Test Interactions**). Persistent clinical and laboratory evidence of hypothyroidism despite an apparent adequate replacement dose of LEVOXYL® may be evidence of inadequate absorption, poor compliance, drug interactions, or decreased T3 potency of the drug product.

**Adults**
In adult patients with primary (thyroid) hypothyroidism, serum TSH levels (using a sensitive assay) alone may be used to monitor therapy. The frequency of TSH monitoring during levothyroxine dose titration depends on the clinical situation but it is generally recommended at 6—8 week intervals until normalization. For patients who have recently initiated levothyroxine therapy and whose serum TSH has normalized or in patients who have had their dosage or brand of levothyroxine changed, serum TSH concentration should be measured after 6—12 weeks of the new dose. If the TSH level is optimum replacement dose has been attained, clinical (physiological) examination and biochemical monitoring may be performed every 6—12 months, depending on the clinical situation, and whenever there is a change in the patient’s status. It is important that serum TSH measurement be performed annually in patients receiving LEVOXYL® (see **WARNINGS**, **PRECAUTIONS**, and **DOSAGE AND ADMINISTRATION**).

**Children**
In patients with congenital hypothyroidism, the adequacy of replacement therapy should be assessed by measuring both serum TSH (using a sensitive assay) and total or free-T4. During the first three years of life, the serum TSH level should be maintained at all times in the upper half of the normal range. While the aim of therapy is to also normalize the serum TSH level, this is not always possible in a small percentage of patients, particularly in the first few months of therapy. TSH may not normal due to a mismatch of the pituitary thyroid feedback threshold as a result of a utero hypothyroidism. Failure of the serum TSH to increase into the upper half of the normal range within 2 weeks of initiation of LEVOXYL® therapy and/or of the serum TSH to decrease below 20 mIU/L within 4 weeks should alert the physician to the possibility that the child is not receiving adequate therapy. Careful inquiry should then be made regarding compliance, dose of medication administered, and method of administration prior to raising the dose of LEVOXYL®.

The recommended frequency of monitoring of TSH and total or free T4 in children is as follows: at 2—4 weeks after the initial adjustment, every 6—8 weeks for the first 6 months of life, every 2—3 months between the first year and 3 years of age, and every 3 to 12 months thereafter until growth is completed. More frequent intervals of monitoring may be necessary if poor compliance is suspected or abnormal values are obtained. It is recommended that TSH and T4 levels, and a physical examination, if indicated, be performed 2 weeks after any change in LEVOXYL® dosage. Routine clinical examination, including assessment of mental and physical growth and development, and bone maturation, should be performed at regular intervals (see **PRECAUTIONS**, Pediatric Use and **DOSAGE AND ADMINISTRATION**).

**Secondary (pituicylary) and tertiary (hypothalamic) hypothyroidism**
Adequacy of therapy should be assessed by measuring serum free-T4 levels, which should be maintained in the upper half of the normal range at all times.

**Drug Interactions**
Many drugs affect thyroid hormone pharmacokinetics and metabolism (e.g., absorption, synthesis, secretion, catabolism, protein binding, and target tissue response) and may alter the therapeutic response to LEVOXYL®. The effects of thyroid hormones and thyroid status have varied effects on the pharmacokinetics and action of other drugs. A listing of drug—thyroid axis interactions is included in Table 2.

The list of drug—thyroid axis interactions in Table 2 may not be comprehensive due to the introduction of new drugs that interact with the thyroid axis or the discovery of previously unknown interactions. The prescriber should be aware of this fact and consult appropriate reference sources. (e.g., package inserts of newly approved drugs, medical literature) for additional information if a drug—drug interaction with levothyroxine is suspected.

**Table 2: Drug—Thyroid Axis Interactions**

<table>
<thead>
<tr>
<th>Drug or Drug Class</th>
<th>Effect</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Drugs that may reduce TSH secretion</strong></td>
<td>the reduction is not sustained; therefore, hypothyroidism does not occur</td>
</tr>
<tr>
<td><strong>Drugs that may decrease serum T4 concentration</strong></td>
<td>may result in hypothyroidism</td>
</tr>
<tr>
<td><strong>Drugs that may increase serum T3 and T4 levels</strong></td>
<td>may result in hyperthyroidism</td>
</tr>
</tbody>
</table>

| **Dopamine / Dopamine Agonists Glicentin (Glicentin)** | Use of these agents may result in a transient reduction in TSH secretion when administered at the following doses: Dopamine (10-20 mcg/kg/day); Glucocorticoids (hydrocortisone >100 mg/day or equivalent). Glicentin (> 100 mcg/day). |
| **Drugs that may increase thyrotoxic symptoms** | may result in hypothyroidism |
| **Amiodarone** | Long term TSH therapy can result in growth in up to 50% of patients, and either subclinical or overt hypothyroidism, each in up to 20% of patients. The fetus, neonate, elderly and euthyroid patients with underlying thyroid disease (e.g., Hashimoto’s thyroiditis) or with Grave’s disease previously treated with radioactive iodine or surgery are among those subgroups who are particularly susceptible to iodine-induced hypothyroidism. Oral cholecystographic agents and amiodarone are slowly excreted, producing prolonged hypothyroidism than parenterally administered iodinated contrast agents. Long term amiodarone therapy may minimally decrease T3 and T4 levels and increase TSH, although all values remain within normal limits in most patients. |

**Drugs that may increase serum T3 and T4 levels** | may result in hyperthyroidism |
| **Potassium** | Therapy with potassium—rich fluids has been associated with the development of antithyroid microsomal antibodies in 20% of patients and some have transient hypothyroidism, hyperthyroidism, or both. Patients who have antithyroid antibodies before treatment are at higher risk for thyroid dysfunction during treatment, Particularly has been associated with transient painless thyroiditis in 20% of patients. Interferon—γ and — and have not been reported to cause thyroid dysfunction. |
| **Growth Hormones** | Serum digitalis glycoside levels may be reduced in hyperthyroidism or when the hypothyroid patient is converted to the euthyroid state. Therapeutic effect of digitalis glucosides may be reduced. |
| **Antithyroid Agents** | Concurrent use of 5-Fluorouracil and levothyroxine may increase the therapeutic and toxic effects of both drugs, possibly due to increased receptor sensitivity to catecholamines. Toxic effects may include increased risk of cardiac arrhythmias and CNS stimulation; onset of action of triyocyclics may be accelerated. Administration of sertraline in patients stabilized on levothyroxine may result in increased levothyroxine requirements. |
| **Antihistamines** | Concurrent use of antihistamines and levothyroxine may increase the therapeutic and toxic effects of both drugs, possibly due to increased receptor sensitivity to catecholamines. Toxic effects may include increased risk of cardiac arrhythmias and CNS stimulation; onset of action of triyocyclics may be accelerated. |
| **Drugs that alter TSH secretion** | may result in hypothyroidism |
| **Drugs that may alter T3 and T4 serum concentration** | may result in hypothyroidism |

**Concurrent use of agents with levothyroxine results in a transient increase in FT4. Continued administration results in a decrease in serum T3 and normal FT3 and TSH concentrations and, therefore, patients are clinically euthyroid. Serum digitalis glycoside levels may be reduced in hyperthyroidism or when the hypothyroid patient is converted to the euthyroid state. Short-term administration of large doses of glucocorticoids may decrease serum T4 concentrations by 30% with minimal change in serum T3 concentrations. However, long-term glucocorticoid therapy may result in slightly decreased T4 and T3 levels due to decreased TSH production (see above).|

**Drugs that may alter T3 and T4 metabolism** | may result in hypothyroidism |
| **Antacids** | Concurrent use of non-steroidal anti-inflammatory agents and levothyroxine may increase the therapeutic and toxic effects of both drugs, possibly due to increased receptor sensitivity to catecholamines. Toxic effects may include increased risk of cardiac arrhythmias and CNS stimulation; onset of action of triyocyclics may be accelerated. Administration of sertraline in patients stabilized on levothyroxine may result in increased levothyroxine requirements. |
Hypothyroidism in Adults and in Children in Whom Growth and Puberty are Complete (see PRECAUTIONS).

The goal of replacement therapy is to achieve and maintain a clinical and biochemical euthyroid state. The goal of suppressive therapy is to inhibit growth and/or function of abnormal thyroid tissue. The dose of LEVOXYL® that is adequate to achieve these goals depends on a variety of factors including the patient’s age, body weight, cardiovascular status, concomitant medical conditions, including pregnancy, concomitant medications, and the specific nature of the condition being treated (see PRECAUTIONS and PRECAUTIONS, Laboratory Tests). Hence, the following recommendations serve only as guidelines. Dosing must be individualized and adjustments made based on periodic assessment of the patient’s clinical response and laboratory parameters (see PRECAUTIONS, Laboratory Tests).

The LEVOXYL® should be taken in the morning on an empty stomach, at least one-half hour before any food is eaten. LEVOXYL® should be taken at least 4 hours apart from drugs that are known to interfere with its absorption (see PRECAUTIONS, Drug Interactions).

LEVOXYL® should be taken with water (see Information for Patients and ADVERSE REACTIONS).

Due to the long half-life of levothyroxine, the peak therapeutic effect at a given dose of levothyroxine sodium may not be attained for 4—6 weeks.

Caution should be exercised when administering LEVOXYL® to patients with underlying cardiovascular disease, to the elderly, and to those with concomitant adrenal insufficiency (see PRECAUTIONS, Specific Patient Populations).
In patients with severe hypothyroidism, the recommended initial levothyroxine sodium dose is 12.5—25 mcg/day with increases of 25 mcg/day every 2—4 weeks, accompanied by clinical and laboratory assessment, until the TSH level is normalized.

In patients with secondary (pituitary) or tertiary (hypothalamic) hypothyroidism, the levothyroxine sodium dose should be titrated until the patient is clinically euthyroid and the serum free-T₄ level is restored to the upper half of the normal range.

Pediatric Dosage — Congenital or Acquired Hypothyroidism (see PRECAUTIONS, Laboratory Tests)

General Principles

In general, levothyroxine therapy should be instituted at full replacement doses as soon as possible. Delays in diagnosis and institution of therapy may have deleterious effects on the child’s intellectual and physical growth and development.

Under-treatment and overtreatment should be avoided (see PRECAUTIONS, Pediatric Use).

LEVOTHYROXINE® may be administered to infants and children who cannot swallow intact tablets by crushing the tablet and suspending the freshly crushed tablet in a small amount (5—10 mL or 1—2 teaspoons) of water. This suspension can be administered by spoon or dropper. DO NOT STORE THE SUSPENSION.

Foods that decrease absorption of levothyroxine, such as soybean infant formula, should not be used for administering levothyroxine sodium tablets. (see PRECAUTIONS, Drug-Food Interactions).

Newborns

The recommended starting dose of levothyroxine sodium in newborn infants is 10—15 mcg/kg/day. A lower starting dose (e.g., 25 mcg/day) should be considered in infants at risk for cardiac failure, and the dose should be increased in 4—6 weeks as needed based on clinical and laboratory response to treatment. In infants with very low (< 5 mcg/dL) or undetectable serum T4 concentrations, the recommended initial starting dose is 50 mcg/day of levothyroxine sodium.

Infants and Children

Levothyroxine therapy is usually initiated at full replacement doses, with the recommended dose per body weight decreasing with age (see TABLE 3). However, in children with chronic or severe hypothyroidism, an initial dose of 25 mcg/kg/day of levothyroxine sodium is recommended with increments of 25 mcg every 2—4 weeks until the desired effect is achieved.

Hyperactivity in an older child can be minimized if the starting dose is one-fourth of the recommended full replacement dose, and the dose is then increased on a weekly basis by an amount equal to one-fourth the full recommended replacement dose until the full recommended replacement dose is reached.

Table 3: Levothyroxine Sodium Dosing Guidelines for Pediatric Hypothyroidism

<table>
<thead>
<tr>
<th>AGE</th>
<th>Daily Dose Per Kg Body Weight</th>
<th>Strength (mcg)</th>
<th>Color</th>
<th>NDC # for bottles of 100</th>
<th>NDC # for bottles of 1000</th>
</tr>
</thead>
<tbody>
<tr>
<td>0—3 months</td>
<td>0—15 mcg/kg/day</td>
<td>25</td>
<td>Orange</td>
<td>NDC 60793-850-01</td>
<td>NDC 60793-850-10</td>
</tr>
<tr>
<td>3—6 months</td>
<td>8—10 mcg/kg/day</td>
<td>50</td>
<td>White</td>
<td>NDC 60793-851-01</td>
<td>NDC 60793-851-10</td>
</tr>
<tr>
<td>6—12 months</td>
<td>6—8 mcg/kg/day</td>
<td>75</td>
<td>Purple</td>
<td>NDC 60793-852-01</td>
<td>NDC 60793-852-10</td>
</tr>
<tr>
<td>1—4 years</td>
<td>5—6 mcg/kg/day</td>
<td>100</td>
<td>Olive</td>
<td>NDC 60793-853-01</td>
<td>NDC 60793-853-10</td>
</tr>
<tr>
<td>6—12 years</td>
<td>4—5 mcg/kg/day</td>
<td>112</td>
<td>Yellow</td>
<td>NDC 60793-854-01</td>
<td>NDC 60793-854-10</td>
</tr>
<tr>
<td>&gt;12 years</td>
<td>3—4 mcg/kg/day</td>
<td>125</td>
<td>Rose</td>
<td>NDC 60793-855-01</td>
<td>NDC 60793-855-10</td>
</tr>
<tr>
<td></td>
<td>1.7 mcg/kg/day</td>
<td>137</td>
<td>Light Brown</td>
<td>NDC 60793-856-01</td>
<td>NDC 60793-856-10</td>
</tr>
<tr>
<td></td>
<td></td>
<td>150</td>
<td>Dark Blue</td>
<td>NDC 60793-857-01</td>
<td>NDC 60793-857-10</td>
</tr>
<tr>
<td></td>
<td></td>
<td>175</td>
<td>Turquoise</td>
<td>NDC 60793-858-01</td>
<td>NDC 60793-858-10</td>
</tr>
<tr>
<td></td>
<td></td>
<td>200</td>
<td>Pink</td>
<td>NDC 60793-859-01</td>
<td>NDC 60793-859-10</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>NDC 60793-860-01</td>
<td>NDC 60793-860-10</td>
<td></td>
</tr>
</tbody>
</table>

Growth and puberty complete 1.7 mcg/kg/day

a - The dose should be adjusted based on clinical response and laboratory parameters (see PRECAUTIONS, Laboratory Tests and Pediatric Use).

Pregnancy — Pregnancy may increase levothyroxine requirements (see PREGNANCY).

Subclinical Hypothyroidism — If this condition is treated, a lower levothyroxine sodium dose (e.g., 1 mcg/kg/day) than that used for full replacement may be adequate to normalize the serum TSH level. Patients who are not treated should be monitored yearly for changes in clinical status and thyroid laboratory parameters.

TSH Suppression in Well-differentiated Thyroid Cancer and Thyroid Nodules — The target level for TSH suppression in these conditions has not been established with controlled studies. In addition, the efficacy of TSH suppression for benign nodular disease is controversial. Therefore, the dose of LEVOXYL® used for TSH suppression should be individualized based on the specific disease and the patient being treated.

In the treatment of well-differentiated (papillary and follicular) thyroid cancer, levothyroxine is used as an adjunct to surgery and radioactive iodine therapy. Generally, TSH is suppressed to <0.1 mU/L, and this usually requires a levothyroxine sodium dose of greater than 2 mcg/kg/day. However, in patients with high-risk tumors, the target level for TSH suppression may be <0.01 mU/L.

In the treatment of benign nodules and nontoxic multinodular goiter, TSH is generally suppressed to a higher target (e.g., 0.1—0.5 mU/L for nodules and 0.5—1.0 mU/L for multinodular goiter) than that used for the treatment of thyroid cancer. Levothyroxine sodium is contraindicated if the serum TSH is already suppressed due to the risk of precipitating overt thyrotoxicosis (see CONTRAINDICATIONS, WARNINGS and PRECAUTIONS).

Myxedema Coma — Myxedema coma is a life-threatening emergency characterized by poor circulation and hypometabolism, and may result in unpredictable absorption of levothyroxine sodium from the gastrointestinal tract. Therefore, oral thyroid hormone drug products are not recommended to treat this condition. Thyroid hormone products formulated for intravenous administration should be administered.

HOW SUPPLIED

— LEVOXYL®(levothyroxine sodium tablets, USP) are supplied as oval, color-coded, potency marked tablets in bottles of 100.

STORAGE CONDITIONS


Distributed by:

Pfizer Inc New York, NY 10017

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