LEVOTHYROXINE SODIUM- levothyroxine sodium tablet
Lannett Company, Inc

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use LEVOTHYROXINE SODIUM TABLETS safely and effectively. See full prescribing information for LEVOTHYROXINE SODIUM TABLETS.

LEVOTHYROXINE SODIUM tablets, for oral use
Initial U.S. Approval: 2002

WARNING: NOT FOR TREATMENT OF OBESITY OR FOR WEIGHT LOSS

See full prescribing information for complete boxed warning

• Thyroid hormones, including levothyroxine sodium tablets should not be used for the treatment of obesity or for weight loss.
• Doses beyond the range of daily hormonal requirements may produce serious or even life threatening manifestations of toxicity (6, 10).

INDICATIONS AND USAGE

Levothyroxine sodium tablets is L-thyroxine (T4) indicated for:
• Hypothyroidism: As replacement therapy in primary (thyroidal), secondary (pituitary) and tertiary (hypothalamic) congenital or acquired hypothyroidism. (1)
• Pituitary Thyrotropin (Thyroid-Stimulating Hormone, TSH) Suppression: As an adjunct to surgery and radioiodine therapy in the management of thyrotropin-dependent well-differentiated thyroid cancer. (1)
Limitations of Use:
- Not indicated for suppression of benign thyroid nodules and nontoxic diffuse goiter in iodine-sufficient patients.
- Not indicated for treatment of hypothyroidism during the recovery phase of subacute thyroiditis. (1)

DOSAGE AND ADMINISTRATION

• Administer once daily, preferably on an empty stomach, one-half to one hour before breakfast. (2.1)
• Administer at least 4 hours before or after drugs that are known to interfere with absorption. (2.1)
• Evaluate the need for dose adjustments when regularly administering within one hour of certain foods that may affect absorption. (2.1)
• Starting dose depends on a variety of factors, including age, body weight, cardiovascular status and concomitant medications. Peak therapeutic effect may not be attained for 4-6 weeks. (2.2)
• See full prescribing information for dosing in specific patient populations. (2.3)
• Adequacy of therapy determined with periodic monitoring of TSH and/or T4 as well as clinical status. (2.4) (2)

DOSAGE FORMS AND STRENGTHS

Tablets: 25, 50, 75, 88, 100, 112, 125, 137, 150, 175, 200, and 300 mcg (3) (3)

CONTRAINDICATIONS

(4)
- Uncorrected adrenal insufficiency. (4)

(4)

WARNINGS AND PRECAUTIONS

(5)
- *Cardiac adverse reactions in the elderly and in patients with underlying cardiovascular disease:* Initiate levothyroxine sodium tablets at less than the full replacement dose because of the increased risk of cardiac adverse reactions, including atrial fibrillation. (2.3, 5.1, 8.5)
- *Myxedema coma:* Do not use oral thyroid hormone drug products to treat myxedema coma. (5.2)
- *Acute adrenal crisis in patients with concomitant adrenal insufficiency:* Treat with replacement glucocorticoids prior to initiation of levothyroxine sodium tablets treatment. (5.3)
- *Prevention of hyperthyroidism or incomplete treatment of hypothyroidism:* Proper dose titration and careful monitoring is critical to prevent the persistence of hypothyroidism or the development of hyperthyroidism. (5.4)
- *Worsening of diabetic control:* Therapy in patients with diabetes mellitus may worsen glycemic control

and result in increased antidiabetic agent or insulin requirements. Carefully monitor glycemic control after starting, changing, or discontinuing thyroid hormone therapy. (5.5)
- *Decreased bone mineral density associated with thyroid hormone over-replacement:* Over-replacement can increase bone resorption and decrease bone mineral density. Give the lowest effective dose. (5.6)

(5)

ADVERSE REACTIONS

Adverse reactions associated with levothyroxine sodium tablets therapy are primarily those of hyperthyroidism due to therapeutic overdosage: arrhythmias, myocardial infarction, dyspnea, muscle spasm, headache, nervousness, irritability, insomnia, tremors, muscle weakness, increased appetite, weight loss, diarrhea, heat intolerance, menstrual irregularities, and skin rash. (6) (6)
To report SUSPECTED ADVERSE REACTIONS, contact Lannett Company, Inc. at 1-844-834-0530 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch**.** (6)

DRUG INTERACTIONS

See full prescribing information for drugs that 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 levothyroxine sodium tablets. (7) (7)

USE IN SPECIFIC POPULATIONS

Pregnancy may require the use of higher doses of levothyroxine sodium tablets. (2.3, 8.1) (8)
See 17 for PATIENT COUNSELING INFORMATION.

Revised: 7/2020

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FULL PRESCRIBING INFORMATION

WARNING: NOT FOR TREATMENT OF OBESITY OR FOR WEIGHT LOSS

Thyroid hormones, including levothyroxine sodium tablets, either alone or with other therapeutic agents, 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 sympathomimetic amines such as those used for their anorectic effects *[see Adverse Reactions (6), Drug Interactions (7.7) and Overdosage (10)].*

1 INDICATIONS AND USAGE

Hypothyroidism

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

Pituitary Thyrotropin (Thyroid-Stimulating Hormone, TSH) Suppression

Levothyroxine sodium tablets are indicated as an adjunct to surgery and radioiodine therapy in the management of thyrotropin-dependent well-differentiated thyroid cancer.

Limitations of Use:

• Levothyroxine sodium tablets are not indicated for suppression of benign thyroid nodules and nontoxic diffuse goiter in iodine-sufficient patients as there are no clinical benefits and overtreatment with levothyroxine sodium tablets may induce hyperthyroidism [see Warnings and Precautions (5.4)].

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

2 DOSAGE AND ADMINISTRATION

2.1 General Administration Information

Take levothyroxine sodium tablets with a full glass of water as the tablet may rapidly disintegrate.

Administer levothyroxine sodium tablets as a single daily dose, on an empty stomach, one-half to one hour before breakfast.

Administer levothyroxine sodium tablets at least 4 hours before or after drugs known to interfere with levothyroxine sodium tablets absorption *[see Drug Interactions (7.1)].*

Evaluate the need for dose adjustments when regularly administering within one hour of certain foods that may affect levothyroxine sodium tablets absorption *[see Drug Interactions (7.9) and Clinical Pharmacology (12.3)].*

Administer levothyroxine sodium tablets to infants and children who cannot swallow intact tablets by crushing the tablet, suspending the freshly crushed tablet in a small amount (5 to 10 mL or 1 to 2 teaspoons) of water and immediately administering the suspension by spoon or dropper. Do not store the suspension. Do not administer in foods that decrease absorption of levothyroxine sodium tablets, such as soybean-based infant formula *[see Drug Interactions (7.9)].*

2.2 General Principles of Dosing

The dose of levothyroxine sodium tablets for hypothyroidism or pituitary TSH suppression depends on a variety of factors including: the patient's age, body weight, cardiovascular status, concomitant medical conditions (including pregnancy), concomitant medications, co-administered food and the specific nature of the condition being treated *[see Dosage and Administration (2.3), Warnings and Precautions (5)*, and *Drug Interactions (7)].* Dosing must be individualized to account for these factors and dose adjustments made based on periodic assessment of the patient's clinical response

and laboratory parameters *[see Dosage and Administration (2.4)].*

The peak therapeutic effect of a given dose of levothyroxine sodium tablets may not be attained for 4 to 6 weeks.

2.3 Dosing in Specific Patient Populations

Primary Hypothyroidism in Adults and in Adolescents in Whom Growth and Puberty are Complete

Start levothyroxine sodium tablets at the full replacement dose in otherwise healthy, non-elderly individuals who have been hypothyroid for only a short time (such as a few months). The average full replacement dose of levothyroxine sodium tablets is approximately 1.6 mcg per kg per day (for example: 100 to 125 mcg per day for a 70 kg adult).

Adjust the dose by 12.5 to 25 mcg increments every 4 to 6 weeks until the patient is clinically euthyroid and the serum TSH returns to normal. Doses greater than 200 mcg per day are seldom required. An inadequate response to daily doses of greater than 300 mcg per day is rare and may indicate poor compliance, malabsorption, drug interactions, or a combination of these factors.

For elderly patients or patients with underlying cardiac disease, start with a dose of 12.5 to 25 mcg per day. Increase the dose every 6 to 8 weeks, as needed until the patient is clinically euthyroid and the serum TSH returns to normal. The full replacement dose of levothyroxine sodium tablets may be less than 1 mcg per kg per day in elderly patients.

In patients with severe longstanding hypothyroidism, start with a dose of 12.5 to 25 mcg per day. Adjust the dose in 12.5 to 25 mcg increments every 2 to 4 weeks until the patient is clinically euthyroid and the serum TSH level is normalized.

Secondary or Tertiary Hypothyroidism

Start levothyroxine sodium tablets at the full replacement dose in otherwise healthy, non-elderly individuals. Start with a lower dose in elderly patients, patients with underlying cardiovascular disease or patients with severe longstanding hypothyroidism as described above. Serum TSH is not a reliable measure of levothyroxine sodium tablets dose adequacy in patients with secondary or tertiary hypothyroidism and should not be used to monitor therapy. Use the serum free-T4 level to monitor adequacy of therapy in this patient population. Titrate levothyroxine sodium tablets dosing per above instructions 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

The recommended daily dose of levothyroxine sodium tablets in pediatric patients with hypothyroidism is based on body weight and changes with age as described in Table 1. Start levothyroxine sodium tablets at the full daily dose in most pediatric patients. Start at a lower starting dose in newborns (0-3 months) at risk for cardiac failure and in children at risk for hyperactivity (see below). Monitor for clinical and laboratory response *[see Dosage and Administration (2.4)].*

Table 1. Levothyroxine Sodium Tablets Dosing Guidelines

for Pediatric Hypothyroidism

AGE	Daily Dose Per Kg Body Weight *
0-3 months	10-15 mcg/kg/day
3-6 months	8-10 mcg/kg/day
6-12 months	6-8 mcg/kg/day
1-5 years	5-6 mcg/kg/day
6-12 years	4-5 mcg/kg/day
Greater than 12 years but growth and puberty incomplete	2-3 mcg/kg/day
Growth and puberty complete	1.6 mcg/kg/day

a. The dose should be adjusted based on clinical response and laboratory parameters *[see Dosage and Administration (2.4) and Use in Specific Populations (8.4)]* .

*

Newborns (0-3 months) at risk for cardiac failure: Consider a lower starting dose in newborns at risk for cardiac failure. Increase the dose every 4 to 6 weeks as needed based on clinical and laboratory response.

Children at risk for hyperactivity: To minimize the risk of hyperactivity in children, start at one- fourth the recommended full replacement dose, and increase on a weekly basis by one-fourth the full recommended replacement dose until the full recommended replacement dose is reached.

Pregnancy

Pre-existing Hypothyroidism: Levothyroxine sodium tablets dose requirements may increase during pregnancy. Measure serum TSH and free-T4 as soon as pregnancy is confirmed and, at minimum, during each trimester of pregnancy. In patients with primary hypothyroidism, maintain serum TSH in the trimester-specific reference range. For patients with serum TSH above the normal trimester-specific range, increase the dose of levothyroxine sodium tablets by 12.5 to 25 mcg/day and measure TSH every 4 weeks until a stable levothyroxine sodium tablets dose is reached and serum TSH is within the normal trimester-specific range. Reduce levothyroxine sodium tablets dosage to pre-pregnancy levels immediately after delivery and measure serum TSH levels 4 to 8 weeks postpartum to ensure levothyroxine sodium tablets dose is appropriate.

New Onset Hypothyroidism: Normalize thyroid function as rapidly as possible. In patients with moderate to severe signs and symptoms of hypothyroidism, start levothyroxine sodium tablets at the full replacement dose (1.6 mcg per kg body weight per day). In patients with mild hypothyroidism (TSH < 10 IU per liter) start levothyroxine sodium tablets at 1.0 mcg per kg body weight per day. Evaluate serum TSH every 4 weeks and adjust levothyroxine sodium tablets dosage until a serum TSH is within the normal trimester specific range *[see Use in Specific Populations (8.1)]*.

TSH Suppression in Well-differentiated Thyroid Cancer

Generally, TSH is suppressed to below 0.1 IU per liter, and this usually requires a levothyroxine sodium tablets dose of greater than 2 mcg per kg per day. However, in patients with high-risk tumors, the target level for TSH suppression may be lower.

2.4 Monitoring TSH and/or Thyroxine (T4) Levels

Assess the adequacy of therapy by periodic assessment of laboratory tests and clinical evaluation. Persistent clinical and laboratory evidence of hypothyroidism despite an apparent adequate replacement dose of levothyroxine sodium tablets may be evidence of inadequate absorption, poor compliance, drug interactions, or a combination of these factors.

Adults

In adult patients with primary hypothyroidism, monitor serum TSH levels after an interval of 6 to 8 weeks after any change in dose. In patients on a stable and appropriate replacement dose, evaluate clinical and biochemical response every 6 to 12 months and whenever there is a change in the patient's clinical status.

Pediatrics

In patients with congenital hypothyroidism, assess the adequacy of replacement therapy by measuring both serum TSH and total or free-T4. Monitor TSH and total or free-T4 in children as follows: 2 and 4 weeks after the initiation of treatment, 2 weeks after any change in dosage, and then every 3 to 12 months thereafter following dose stabilization until growth is completed. Poor compliance or abnormal values may necessitate more frequent monitoring. Perform routine clinical examination, including assessment of development, mental and physical growth, and bone maturation, at regular intervals.

While the general aim of therapy is to normalize the serum TSH level, TSH may not normalize in some patients due to in utero hypothyroidism causing a resetting of pituitary-thyroid feedback. Failure of the serum T4 to increase into the upper half of the normal range within 2 weeks of initiation of levothyroxine sodium tablets therapy and/or of the serum TSH to decrease below 20 IU per liter within 4 weeks may indicate the child is not receiving adequate therapy. Assess compliance, dose of medication administered, and method of administration prior to increasing the dose of levothyroxine sodium tablets *[see Warnings and Precautions (5.1) and Use in Specific Populations (8.4).*

Secondary and Tertiary Hypothyroidism

Monitor serum free-T4 levels and maintain in the upper half of the normal range in these patients.

3 DOSAGE FORMS AND STRENGTHS

Levothyroxine Sodium Tablets, USP are available as follows:

Tablet Strength	Tablet Color/Shape	Tablet Markings
25 mcg	Orange/Caplet	"25" and "GG/331"
50 mcg	White/ Caplet	"50" and "GG/332"
75 mcg	Violet/ Caplet	"75" and "GG/333"
88 mcg	Olive Green/ Caplet	"88" and "GG/334"
100 mcg	Yellow/ Caplet	"100" and "GG/335"
112 mcg	Rose/ Caplet	"112" and "GG/336"

125 mcg	Brown/ Caplet	"125" and "GG/337"
137 mcg	Turquoise/ Caplet	"137" and "GG/330"
150 mcg	Blue/ Caplet	"150" and "GG/338"
175 mcg	Lilac/ Caplet	"175" and "GG/339"
200 mcg	Pink/ Caplet	"200" and "GG/340"
300 mcg	Green/ Caplet	"300" and "GG/341"

4 CONTRAINDICATIONS

Levothyroxine sodium tablets is contraindicated in patients with uncorrected adrenal insufficiency *[see Warnings and Precautions (5.3)]* .

5 WARNINGS AND PRECAUTIONS

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

Over-treatment with levothyroxine may cause an increase in heart rate, cardiac wall thickness, and cardiac contractility and may precipitate angina or arrhythmias, particularly in patients with cardiovascular disease and in elderly patients. Initiate levothyroxine sodium tablets therapy in this population at lower doses than those recommended in younger individuals or in patients without cardiac disease *[see Dosage and Administration (2.3), Use in Specific Populations (8.5).*

Monitor for cardiac arrhythmias during surgical procedures in patients with coronary artery disease receiving suppressive levothyroxine sodium tablets therapy. Monitor patients receiving concomitant levothyroxine sodium tablets and sympathomimetic agents for signs and symptoms of coronary insufficiency.

If cardiac symptoms develop or worsen, reduce the levothyroxine sodium tablets dose or withhold for one week and restart at a lower dose.

5.2 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. Use of oral thyroid hormone drug products is not recommended to treat myxedema coma. Administer thyroid hormone products formulated for intravenous administration to treat myxedema coma.

5.3 Acute Adrenal Crisis in Patients with Concomitant Adrenal Insufficiency

Thyroid hormone increases metabolic clearance of glucocorticoids. 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 with levothyroxine sodium tablets *[see Contraindications (4)].*

5.4 Prevention of Hyperthyroidism or Incomplete Treatment of Hypothyroidism

Levothyroxine sodium tablets has a narrow therapeutic index. Over- or undertreatment with levothyroxine sodium tablets may have negative effects on growth and development, cardiovascular function, bone metabolism, reproductive function, cognitive function, emotional state, gastrointestinal function, and glucose and lipid metabolism. Titrate the dose of levothyroxine sodium tablets carefully and monitor response to titration to avoid these effects *[see Dosage and Administration (2.4).* Monitor for the presence of drug or food interactions when using levothyroxine sodium tablets and adjust the dose as necessary *[see Drug Interactions (7.9) and Clinical Pharmacology (12.3).*

5.5 Worsening of Diabetic Control

Addition of levothyroxine therapy in patients with diabetes mellitus may worsen glycemic control and result in increased antidiabetic agent or insulin requirements. Carefully monitor glycemic control after starting, changing, or discontinuing levothyroxine sodium tablets *[see Drug Interactions (7.2)].*

5.6 Decreased Bone Mineral Density Associated with Thyroid Hormone Over-Replacement

Increased bone resorption and decreased bone mineral density may occur as a result of levothyroxine over-replacement, particularly in post-menopausal women. The increased bone resorption may be associated with increased serum levels and urinary excretion of calcium and phosphorous, elevations in bone alkaline phosphatase, and suppressed serum parathyroid hormone levels. Administer the minimum dose of levothyroxine sodium tablets that achieves the desired clinical and biochemical response to mitigate this risk.

6 ADVERSE REACTIONS

Adverse reactions associated with levothyroxine sodium tablets therapy are primarily those of hyperthyroidism due to therapeutic overdosage *[see Warnings and Precautions (5), Overdosage (10)]*. They include the following:

- *General:* fatigue, increased appetite, weight loss, heat intolerance, fever, excessive sweating
- *Central nervous system:* headache, hyperactivity, nervousness, anxiety, irritability, emotional lability, insomnia
- *Musculoskeletal:* tremors, muscle weakness, muscle spasm
- *Cardiovascular:* palpitations, tachycardia, arrhythmias, increased pulse and blood pressure, heart failure, angina, myocardial infarction, cardiac arrest
- *Respiratory:* dyspnea
- *Gastrointestinal:* diarrhea, vomiting, abdominal cramps, elevations in liver function tests
- *Dermatologic:* hair loss, flushing, rash
- *Endocrine:* decreased bone mineral density
- *Reproductive:* menstrual irregularities, impaired fertility

Seizures have been reported rarely with the institution of levothyroxine therapy.

Adverse Reactions in Children

Pseudotumor cerebri and slipped capital femoral epiphysis have been reported in children receiving levothyroxine therapy. Overtreatment may result in craniosynostosis in infants and premature closure of the epiphyses in children with resultant compromised adult height.

Hypersensitivity Reactions

Hypersensitivity reactions to inactive ingredients have occurred in patients treated with thyroid hormone products. These include urticaria, pruritus, skin rash, flushing, angioedema, various gastrointestinal symptoms (abdominal pain, nausea, vomiting and diarrhea), fever, arthralgia, serum sickness, and wheezing. Hypersensitivity to levothyroxine itself is not known to occur.

7 DRUG INTERACTIONS

7.1 Drugs Known to Affect Thyroid Hormone Pharmacokinetics

Many drugs can exert effects on thyroid hormone pharmacokinetics and metabolism (e.g., absorption, synthesis, secretion, catabolism, protein binding, and target tissue response) and may alter the therapeutic response to levothyroxine sodium tablets (see **Tables 2-5** below).

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

Potential impact: Concurrent use may reduce the efficacy of levothyroxine sodium tablets by binding and delaying or preventing absorption, potentially resulting in hypothyroidism.	
Drug or Drug Class	**Effect**
Calcium Carbonate Ferrous Sulfate	Calcium carbonate may form an insoluble chelate with levothyroxine, and ferrous sulfate likely forms a ferric-thyroxine complex. Administer levothyroxine sodium tablets at least 4 hours apart from these agents.
Orlistat	Monitor patients treated concomitantly with orlistat and levothyroxine sodium tablets for changes in thyroid function.
Bile Acid Sequestrants -Colesevelam -Cholestyramine -Colestipol Ion Exchange Resins -Kayexalate -Sevelamer	Bile acid sequestrants and ion exchange resins are known to decrease levothyroxine absorption. Administer levothyroxine sodium tablets at least 4 hours prior to these drugs or monitor TSH levels.
Other drugs: Proton Pump	

Proton Pump Inhibitors Sucralfate Antacids - Aluminum & Magnesium Hydroxides - Simethicone	Gastric acidity is an essential requirement for adequate absorption of levothyroxine. Sucralfate, antacids and proton pump inhibitors may cause hypochlorhydria, affect intragastric pH, and reduce levothyroxine absorption. Monitor patients appropriately.

Table 3. Drugs That May Alter T4 and Triiodothyronine (T3) Serum Transport Without Affecting Free Thyroxine (FT4) Concentration (Euthyroidism)

Drug or Drug Class	Effect
Clofibrate Estrogen-containing oral contraceptives Estrogens (oral) Heroin / Methadone 5-Fluorouracil Mitotane Tamoxifen	These drugs may increase serum thyroxine-binding globulin (TBG) concentration.
Androgens / Anabolic Steroids Asparaginase Glucocorticoids Slow-Release Nicotinic Acid	These drugs may decrease serum TBG concentration.
Potential impact (below): Administration of these agents with levothyroxine sodium tablets results in an initial transient increase in FT4. Continued administration results in a decrease in serum T4 and normal FT4 and TSH concentrations.	
Salicylates (> 2 g/day)	Salicylates inhibit binding of T4 and T3 to TBG and transthyretin. An initial increase in serum FT4 is followed by return of FT4 to normal levels with sustained therapeutic serum salicylate concentrations, although total T4 levels may decrease by as much as 30%.
Other drugs: Carbamazepine Furosemide (> 80 mg IV) Heparin Hydantoins	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 free T4 fraction in serum. Furosemide competes for T4-binding sites on TBG, prealbumin, and albumin, so that a single high dose can acutely lower the total T4 level.

Non-Steroidal Anti-inflammatory Drugs -Fenamates	Phenytoin and carbamazepine reduce serum protein binding of levothyroxine, and total and free T4 may be reduced by 20% to 40%, but most patients have normal serum TSH levels and are clinically euthyroid. Closely monitor thyroid hormone parameters.

Table 4. Drugs That May Alter Hepatic Metabolism of T4 (Hypothyroidism)

Potential impact: Stimulation of hepatic microsomal drug-metabolizing enzyme activity may cause increased hepatic degradation of levothyroxine, resulting in increased levothyroxine sodium tablets requirements.	
Drug or Drug Class	**Effect**
Phenobarbital Rifampin	Phenobarbital has been shown to reduce the response to thyroxine. Phenobarbital increases L-thyroxine metabolism by inducing uridine 5'-diphospho-glucuronosyltransferase (UGT) and leads to a lower T4 serum levels. Changes in thyroid status may occur if barbiturates are added or withdrawn from patients being treated for hypothyroidism. Rifampin has been shown to accelerate the metabolism of levothyroxine.

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

Potential impact: Administration of these enzyme inhibitors decreases the peripheral conversion of T4 to T3, leading to decreased T3 levels. However, serum T4 levels are usually normal but may occasionally be slightly increased.	
Drug or Drug Class	**Effect**
Beta-adrenergic antagonists (e.g., Propranolol > 160 mg/day)	In patients treated with large doses of propranolol (> 160 mg/day), T3 and T4 levels change, TSH levels remain normal, and patients are clinically euthyroid. Actions of particular beta-adrenergic antagonists may be impaired when a hypothyroid patient is converted to the euthyroid state.
Glucocorticoids (e.g., Dexamethasone ≥ 4 mg/day)	Short-term administration of large doses of glucocorticoids may decrease serum T3 concentrations by 30% with minimal change in serum T4 levels. However, long-term glucocorticoid therapy may result in slightly decreased T3 and T4 levels due to decreased TBG production (See above).
	Amiodarone inhibits peripheral conversion of

Other drugs: Amiodarone	levothyroxine (T4) to triiodothyronine (T3) and may cause isolated biochemical changes (increase in serum free-T4, and decreased or normal free-T3) in clinically euthyroid patients.

7.2 Antidiabetic Therapy

Addition of levothyroxine sodium tablets therapy in patients with diabetes mellitus may worsen glycemic control and result in increased antidiabetic agent or insulin requirements. Carefully monitor glycemic control, especially when thyroid therapy is started, changed, or discontinued *[see Warnings and Precautions (5.5)].*

7.3 Oral Anticoagulants

Levothyroxine sodium tablets increases the response to oral anticoagulant therapy. Therefore, a decrease in the dose of anticoagulant may be warranted with correction of the hypothyroid state or when the levothyroxine sodium tablets dose is increased. Closely monitor coagulation tests to permit appropriate and timely dosage adjustments.

7.4 Digitalis Glycosides

Levothyroxine sodium tablets may reduce the therapeutic effects of digitalis glycosides. Serum digitalis glycoside levels may decrease when a hypothyroid patient becomes euthyroid, necessitating an increase in the dose of digitalis glycosides.

7.5 Antidepressant Therapy

Concurrent use of tricyclic (e.g., amitriptyline) or tetracyclic (e.g., maprotiline) antidepressants and levothyroxine sodium tablets 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 central nervous system stimulation. Levothyroxine sodium tablets may accelerate the onset of action of tricyclics. Administration of sertraline in patients stabilized on levothyroxine sodium tablets may result in increased levothyroxine sodium tablets requirements.

7.6 Ketamine

Concurrent use of ketamine and levothyroxine sodium tablets may produce marked hypertension and tachycardia. Closely monitor blood pressure and heart rate in these patients.

7.7 Sympathomimetics

Concurrent use of sympathomimetics and levothyroxine sodium tablets may increase the effects of sympathomimetics or thyroid hormone. Thyroid hormones may increase the risk of coronary insufficiency when sympathomimetic agents are administered to patients with coronary artery disease.

7.8 Tyrosine-Kinase Inhibitors

Concurrent use of tyrosine-kinase inhibitors such as imatinib may cause hypothyroidism. Closely monitor TSH levels in such patients.

7.9 Drug-Food Interactions

Consumption of certain foods may affect levothyroxine sodium tablets absorption thereby necessitating adjustments in dosing *[see Dosage and Administration (2.1)].* Soybean flour, cottonseed meal, walnuts, and dietary fiber may bind and decrease the absorption of levothyroxine sodium tablets from the gastrointestinal tract. Grapefruit juice may delay the absorption of levothyroxine and reduce its bioavailability.

7.10 Drug-Laboratory Test Interactions

Consider changes in TBG concentration when interpreting T4 and T3 values. Measure and evaluate unbound (free) hormone and/or determine the free-T4 index (FT4I) in this circumstance. Pregnancy, infectious hepatitis, estrogens, estrogen-containing oral contraceptives, and acute intermittent porphyria increase TBG concentration. Nephrosis, severe hypoproteinemia, severe liver disease, acromegaly, androgens, and corticosteroids decrease TBG concentration. Familial hyper- or hypo-thyroxine binding globulinemias have been described, with the incidence of TBG deficiency approximating 1 in 9000.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

Experience with levothyroxine use in pregnant women, including data from post-marketing studies, have not reported increased rates of major birth defects or miscarriages *[see Data].* There are risks to the mother and fetus associated with untreated hypothyroidism in pregnancy. Since TSH levels may increase during pregnancy, TSH should be monitored and levothyroxine sodium tablets dosage adjusted during pregnancy *[see Clinical Considerations]* . There are no animal studies conducted with levothyroxine during pregnancy. Levothyroxine sodium tablets should not be discontinued during pregnancy and hypothyroidism diagnosed during pregnancy should be promptly treated.

The estimated background risk of major birth defects and miscarriage for the indicated population is unknown. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2 to 4% and 15 to 20%, respectively.

Clinical Considerations

Clinical Considerations

Disease-Associated Maternal and/or Embryo/Fetal Risk

Maternal hypothyroidism during pregnancy is associated with a higher rate of complications, including spontaneous abortion, gestational hypertension, pre-eclampsia, stillbirth, and premature delivery. Untreated maternal hypothyroidism may have an adverse effect on fetal neurocognitive development.

Dose Adjustments During Pregnancy and the Postpartum Period

Pregnancy may increase levothyroxine sodium tablets requirements. Serum TSH levels should be monitored and the levothyroxine sodium tablets dosage adjusted during pregnancy. Since postpartum TSH levels are similar to preconception values, the levothyroxine sodium tablets dosage should return to the pre-pregnancy dose immediately after delivery *[see Dosage and Administration (2.3)].*

Data

Data

Human Data

Levothyroxine is approved for use as a replacement therapy for hypothyroidism. There is a long experience of levothyroxine use in pregnant women, including data from post-marketing studies that have not reported increased rates of fetal malformations, miscarriages or other adverse maternal or fetal outcomes associated with levothyroxine use in pregnant women.

8.2 Lactation

Risk Summary

Limited published studies report that levothyroxine is present in human milk. However, there is insufficient information to determine the effects of Levothyroxine on the breastfed infant and no available information on the effects of levothyroxine on milk production. Adequate levothyroxine treatment during lactation may normalize milk production in hypothyroid lactating mothers. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for levothyroxine sodium tablets and any potential adverse effects on the breastfed infant from levothyroxine sodium tablets or from the underlying maternal condition.

8.4 Pediatric Use

The initial dose of levothyroxine sodium tablets varies with age and body weight. Dosing adjustments are based on an assessment of the individual patient's clinical and laboratory parameters *[see Dosage and Administration (2.3, 2.4)]* .

In children in whom a diagnosis of permanent hypothyroidism has not been established, discontinue levothyroxine sodium tablets administration for a trial period, but only after the child is at least 3 years of age. Obtain serum T4 and TSH levels at the end of the trial period, and use laboratory test results and clinical assessment to guide diagnosis and treatment, if warranted.

Congenital Hypothyroidism [See Dosage and Administration (2.3, 2.4)]

Rapid restoration of normal serum T4 concentrations is essential for preventing the adverse effects of congenital hypothyroidism on intellectual development as well as on overall physical growth and maturation. Therefore, initiate levothyroxine sodium tablets therapy immediately upon diagnosis. Levothyroxine is generally continued for life in these patients.

Closely monitor infants during the first 2 weeks of levothyroxine sodium tablets therapy

for cardiac overload, arrhythmias, and aspiration from avid suckling.

Closely monitor patients to avoid undertreatment or overtreatment. Undertreatment may have deleterious effects on intellectual development and linear growth. Overtreatment is associated with craniosynostosis in infants, may adversely affect the tempo of brain maturation, and may accelerate the bone age and result in premature epiphyseal closure and compromised adult stature.

Acquired Hypothyroidism in Pediatric Patients

Closely monitor patients to avoid undertreatment and overtreatment. Undertreatment may result in poor school performance due to impaired concentration and slowed mentation and in reduced adult height. Overtreatment may accelerate the bone age and result in premature epiphyseal closure and compromised adult stature.

Treated children may manifest a period of catch-up growth, which may be adequate in some cases to normalize adult height. In children with severe or prolonged hypothyroidism, catch-up growth may not be adequate to normalize adult height.

8.5 Geriatric Use

Because of the increased prevalence of cardiovascular disease among the elderly, initiate levothyroxine sodium tablets at less than the full replacement dose *[see Warnings and Precautions (5.1)* and *Dosage and Administration (2.3)]* . Atrial arrhythmias can occur in elderly patients. Atrial fibrillation is the most common of the arrhythmias observed with levothyroxine overtreatment in the elderly.

10 OVERDOSAGE

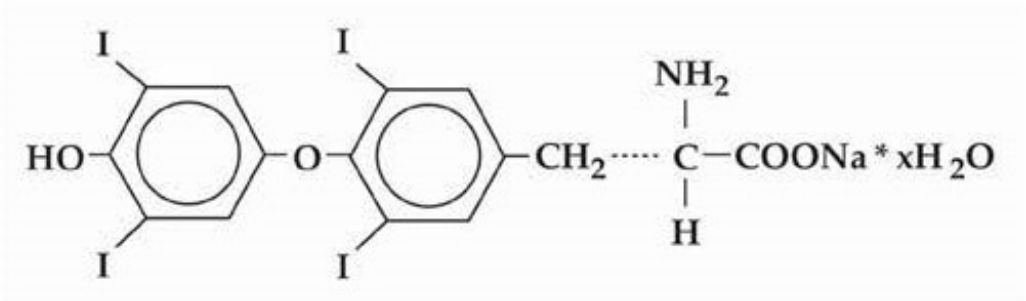
The signs and symptoms of overdosage are those of hyperthyroidism *[see Warnings and Precautions (5)* and *Adverse Reactions (6)]*. In addition, confusion and disorientation may occur. Cerebral embolism, shock, coma, and death have been reported. Seizures occurred in a 3-year-old child ingesting 3.6 mg of levothyroxine. Symptoms may not necessarily be evident or may not appear until several days after ingestion of levothyroxine sodium.

Reduce the levothyroxine sodium tablets dose or discontinue temporarily if signs or symptoms of overdosage occur. Initiate appropriate supportive treatment as dictated by the patient's medical status.

For current information on the management of poisoning or overdosage, contact the National Poison Control Center at 1-800-222-1222 or www.poison.org.

11 DESCRIPTION

Levothyroxine sodium tablets, USP contain synthetic crystalline L-3,3',5,5'-tetraiodothyronine sodium salt [levothyroxine (T4) sodium]. Synthetic T4 is chemically identical to that produced in the human thyroid gland. Levothyroxine (T4) sodium has an empirical formula of $C_{15}H_{10}I_4NNaO_4 \cdot xH_2O$ (where x = 5), molecular weight of 798.86 g/mol (anhydrous) and structural formula as shown:



Levothyroxine sodium tablets for oral administration are supplied in the following strengths: 25 mcg, 50 mcg, 75 mcg, 88 mcg, 100 mcg, 112 mcg, 125 mcg, 137 mcg, 150 mcg, 175 mcg, 200 mcg and 300 mcg. Each levothyroxine sodium tablet contains the inactive ingredients Magnesium Stearate, NF; Microcrystalline Cellulose, NF; Colloidal Silicone Dioxide, NF; and Sodium Starch Glycolate, NF. Each tablet strength meets USP Dissolution Test 2. **Table 6** provides a listing of the color additives by tablet strength:

Table 6. Levothyroxine Sodium Tablets Color Additives

Strength (mcg)	**Color additive(s)**
25	FD&C Yellow No. 6 Aluminum Lake
50	None
75	FD&C Blue No. 2 Aluminum Lake, D&C Red No. 27 Aluminum Lake
88	FD&C Blue No. 1 Aluminum Lake, D&C Yellow No. 10 Aluminum Lake, D&C RedNo. 30 Aluminum Lake
100	D&C Yellow No. 10 Aluminum Lake, D&C Red Lake Blend (D&C Red No. 27 Lake and D&C Red No. 30 Lake)
112	D&C Red No. 27 Aluminum Lake, D&C Red No. 30 Aluminum Lake
125	FD&C Yellow No. 6 Aluminum Lake, FD&C Red No. 40 Aluminum Lake, FD&C Blue No. 1 Aluminum Lake
137	FD&C Blue No. 1 Aluminum Lake
150	FD&C Blue No. 2 Aluminum Lake
175	D&C Red No. 27 Aluminum Lake, D&C Red No. 30 Aluminum Lake, FD&C Blue No. 1 Aluminum Lake
200	D&C Yellow No. 10 Aluminum Lake, D&C Red No. 27 Aluminum Lake
300	D&C Yellow No. 10 Aluminum Lake, FD&C Yellow No. 6 Aluminum Lake, FD&C Blue No. 1 Aluminum Lake

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Thyroid hormones exert their physiologic actions through control of DNA transcription and protein synthesis. Triiodothyronine (T3) and L-thyroxine (T4) diffuse into the cell

nucleus and bind to thyroid receptor proteins attached to DNA. This hormone nuclear receptor complex activates gene transcription and synthesis of messenger RNA and cytoplasmic proteins.

The physiological actions of thyroid hormones are produced predominantly by T3, the majority of which (approximately 80%) is derived from T4 by deiodination in peripheral tissues.

12.2 Pharmacodynamics

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.

12.3 Pharmacokinetics

Absorption

Absorption of orally administered T4 from the gastrointestinal tract ranges from 40% to 80%. The majority of the levothyroxine sodium tablets dose is absorbed from the jejunum and upper ileum. The relative bioavailability of levothyroxine sodium tablets, compared to an equal nominal dose of oral levothyroxine sodium solution, is approximately 99%. T4 absorption is increased by fasting, and decreased in malabsorption syndromes and by certain foods such as soybeans. Dietary fiber decreases bioavailability of T4. Absorption may also decrease with age. In addition, many drugs and foods affect T4 absorption *[see Drug Interactions (7)]* .

Distribution

Circulating thyroid hormones are greater than 99% bound to plasma proteins, including thyroxine-binding globulin (TBG), thyroxine-binding prealbumin (TBPA), and albumin (TBA), whose capacities and affinities vary for each hormone. The higher affinity of both TBG and TBPA for T4 partially explains the higher serum levels, slower metabolic clearance, and longer half-life of T4 compared to T3. Protein-bound thyroid hormones exist in reverse equilibrium with small amounts of free hormone. Only unbound hormone is metabolically active. Many drugs and physiologic conditions affect the binding of thyroid hormones to serum proteins *[see Drug Interactions (7)]*. Thyroid hormones do not readily cross the placental barrier *[see Use in Specific Populations (8.1)]*.

Elimination

Elimination

Metabolism

T4 is slowly eliminated (see **Table 7**). The major pathway of thyroid hormone metabolism is through sequential deiodination. Approximately 80% of circulating T3 is derived from peripheral T4 by monodeiodination. The liver is the major site of degradation for both T4 and T3, with T4 deiodination also occurring at a number of additional sites, including the kidney and other tissues. Approximately 80% of the daily dose of T4 is deiodinated to yield equal amounts of T3 and reverse T3 (rT3). T3 and rT3 are further deiodinated to diiodothyronine. Thyroid hormones are also metabolized via conjugation with glucuronides and sulfates and excreted directly into the bile and gut

where they undergo enterohepatic recirculation.

Excretion

Thyroid hormones are primarily eliminated by the kidneys. A portion of the conjugated hormone reaches the colon unchanged and is eliminated in the feces. Approximately 20% of T4 is eliminated in the stool. Urinary excretion of T4 decreases with age.

Table 7. Pharmacokinetic Parameters of Thyroid Hormones in Euthyroid Patients

Hormone	Ratio in Thyroglobulin	Biologic Potency	$t_{1/2}$ (days)	Protein Binding (%) [a*]
Levothyroxine (T4)	10 - 20	1	6-7 [b†]	99.96
Liothyronine (T3)	1	4	≤ 2	99.5
a - Includes TBG, TBPA, and TBA b - 3 to 4 days in hyperthyroidism, 9 to 10 days in hypothyroidism †				

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Standard animal studies have not been performed to evaluate the carcinogenic potential, mutagenic potential or effects on fertility of levothyroxine.

16 HOW SUPPLIED/STORAGE AND HANDLING

Levothyroxine Sodium Tablets, USP are supplied as follows:

Strength (mcg)	Color/Shape	Tablet Markings	NDC# for bottles of 90	NDC # for bottles of 1000
25	Orange/Caplet	"25" and "GG/331"	0527-3280-46	0527-3280-43
50	White/ Caplet	"50" and "GG/332"	0527-3281-46	0527-3281-43
75	Violet/ Caplet	"75" and "GG/333"	0527-3282-46	0527-3282-43
88	Olive Green/ Caplet	"88" and 'GG/334"	0527-3283-46	0527-3283-43
100	Yellow/ Caplet	"100" and "GG/335"	0527-3284-46	0527-3284-43
112	Rose/ Caplet	"112" and "GG/336"	0527-3285-46	0527-3285-43
125	Brown/ Caplet	"125" and "GG/337"	0527-3286-46	0527-3286-43

137	Turquoise/ Caplet	"137" and "GG/330"	0527-3287-46	0527-3287-43
150	Blue/ Caplet	"150" and "GG/338"	0527-3288-46	0527-3288-43
175	Lilac/ Caplet	"175" and "GG/339"	0527-3289-46	0527-3289-43
200	Pink/ Caplet	"200" and "GG/340"	0527-3290-46	0527-3290-43
300	Green/ Caplet	"300" and "GG/341"	0527-3291-46	0527-3291-43

Storage Conditions

Store at 25°C (77°F); excursions permitted to 15° to 30° C (59° to 86° F) [see USP Controlled Room Temperature]. Levothyroxine sodium tablets should be protected from light and moisture.

17 PATIENT COUNSELING INFORMATION

Inform the patient of the following information to aid in the safe and effective use of *levothyroxine sodium tablets*:

Dosing and Administration

- Instruct patients that levothyroxine sodium tablets should be taken with a full glass of water since the tablet may rapidly disintegrate.
- Instruct patients to take levothyroxine sodium tablets only as directed by their healthcare provider.
- Instruct patients to take levothyroxine sodium tablets as a single dose, preferably on an empty stomach, one-half to one hour before breakfast.
- Inform patients that agents such as iron and calcium supplements and antacids can decrease the absorption of levothyroxine. Instruct patients not to take levothyroxine sodium tablets within 4 hours of these agents.
- 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 tablets 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.

Dosing and Administration

- Instruct patients that levothyroxine sodium tablets should be taken with a full glass of water since the tablet may rapidly disintegrate.
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Important Information

- Inform patients that it may take several weeks before they notice an improvement in symptoms.
- Inform patients that the levothyroxine in levotyhroxine sodium tablets 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 levotyhroxine sodium tablets should not be used as a primary or adjunctive therapy in a weight control program.
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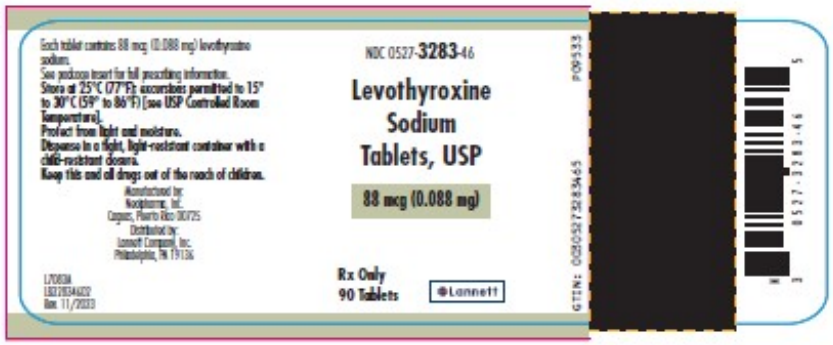
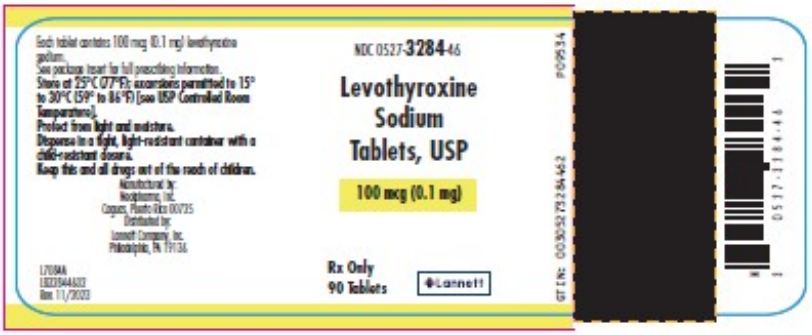
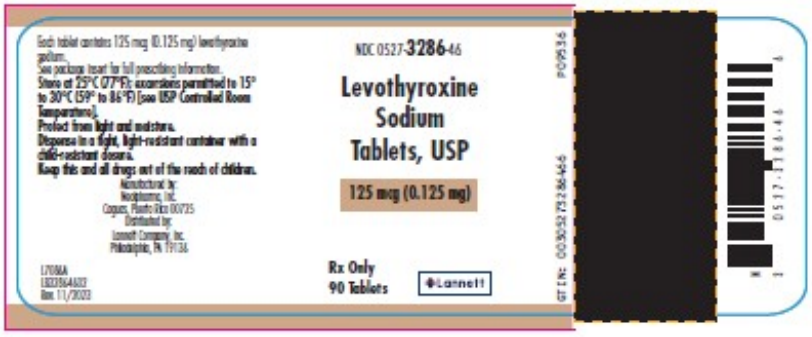
Principal Display Panel







Each tablet contains 88 mcg (0.088 mg) levothyroxine sodium.
See package insert for full prescribing information.
Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].
Protect from light and moisture.
Dispense in a tight, light-resistant container with a child-resistant closure.
Keep this and all drugs out of the reach of children.

Manufactured by:
Neopharma, Inc.
Caguas, Puerto Rico 00725
Distributed by:
Lannett Company, Inc.
Philadelphia, PA 19136

L7083A
L8238A4622
Rev. 11/2023

NDC 0527-**3283**-46

Levothyroxine Sodium Tablets, USP

88 mcg (0.088 mg)

Rx Only
90 Tablets

Lannett

P09533

GTIN: 00305273283465

0527-3283-46

Each tablet contains 100 mcg (0.1 mg) levothyroxine sodium.
See package insert for full prescribing information.
Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].
Protect from light and moisture.
Dispense in a tight, light-resistant container with a child-resistant closure.
Keep this and all drugs out of the reach of children.

Manufactured by:
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Distributed by:
Lannett Company, Inc.
Philadelphia, PA 19136

L7084A
L8238A4622
Rev. 11/2023

NDC 0527-**3284**-46

Levothyroxine Sodium Tablets, USP

100 mcg (0.1 mg)

Rx Only
90 Tablets

Lannett

P09534

GTIN: 00305273284462

0527-3284-46

Each tablet contains 112 mcg (0.112 mg) levothyroxine sodium.
See package insert for full prescribing information.
Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].
Protect from light and moisture.
Dispense in a tight, light-resistant container with a child-resistant closure.
Keep this and all drugs out of the reach of children.

Manufactured by:
Neopharma, Inc.
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Distributed by:
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L7085A
L8238A4622
Rev. 11/2023

NDC 0527-**3285**-46

Levothyroxine Sodium Tablets, USP

112 mcg (0.112 mg)

Rx Only
90 Tablets

Lannett

P09535

GTIN: 00305273285469

0527-3285-46

Each tablet contains 125 mcg (0.125 mg) levothyroxine sodium.
See package insert for full prescribing information.
Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].
Protect from light and moisture.
Dispense in a tight, light-resistant container with a child-resistant closure.
Keep this and all drugs out of the reach of children.

Manufactured by:
Neopharma, Inc.
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L7086A
L8238A4622
Rev. 11/2023

NDC 0527-**3286**-46

Levothyroxine Sodium Tablets, USP

125 mcg (0.125 mg)

Rx Only
90 Tablets

Lannett

P09536

GTIN: 00305273286466

0527-3286-46

Each tablet contains 137 mcg (0.137 mg) levothyroxine sodium.
See package insert for full prescribing information.
Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].
Protect from light and moisture.
Dispense in a tight, light-resistant container with a child-resistant closure.
Keep this and all drugs out of the reach of children.

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L7087A
L8238A4622
Rev. 11/2023

NDC 0527-**3287**-46

Levothyroxine Sodium Tablets, USP

137 mcg (0.137 mg)

Rx Only
90 Tablets

Lannett

P09537

GTIN: 00305273287463

0527-3287-46

Each tablet contains 150 mcg (0.150 mg) levothyroxine sodium.
See package insert for full prescribing information.
Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].
Protect from light and moisture.
Dispense in a tight, light-resistant container with a child-resistant closure.
Keep this and all drugs out of the reach of children.
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Caguas, Puerto Rico 00725
Distributed by:
Lannett Company, Inc.
Philadelphia, PA 19136
L70188
LB03884603
Rev. 11/2023
NDC 0527-3288-46
Levothyroxine Sodium Tablets, USP
150 mcg (0.150 mg)
Rx Only
90 Tablets
Lannett
P09538
GTIN: 00305273288460
0527-3288-46

Each tablet contains 175 mcg (0.175 mg) levothyroxine sodium.
See package insert for full prescribing information.
Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].
Protect from light and moisture.
Dispense in a tight, light-resistant container with a child-resistant closure.
Keep this and all drugs out of the reach of children.
Manufactured by:
Neopharma, Inc.
Caguas, Puerto Rico 00725
Distributed by:
Lannett Company, Inc.
Philadelphia, PA 19136
L70189
LB03884603
Rev. 11/2023
NDC 0527-3289-46
Levothyroxine Sodium Tablets, USP
175 mcg (0.175 mg)
Rx Only
90 Tablets
Lannett
P09539
GTIN: 00305273289467
0527-3289-46

Each tablet contains 200 mcg (0.2 mg) levothyroxine sodium.
See package insert for full prescribing information.
Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].
Protect from light and moisture.
Dispense in a tight, light-resistant container with a child-resistant closure.
Keep this and all drugs out of the reach of children.
Manufactured by:
Neopharma, Inc.
Caguas, Puerto Rico 00725
Distributed by:
Lannett Company, Inc.
Philadelphia, PA 19136
L70190
LB03904603
Rev. 11/2023
NDC 0527-3290-46
Levothyroxine Sodium Tablets, USP
200 mcg (0.2 mg)
Rx Only
90 Tablets
Lannett
P09540
GTIN: 00305273290463
0527-3290-46

Each tablet contains 300 mcg (0.3 mg) levothyroxine sodium.
See package insert for full prescribing information.
Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].
Protect from light and moisture.
Dispense in a tight, light-resistant container with a child-resistant closure.
Keep this and all drugs out of the reach of children.
Manufactured by:
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Lannett Company, Inc.
Philadelphia, PA 19136
L70191A
LB03914603
Rev. 11/2023
NDC 0527-3291-46
Levothyroxine Sodium Tablets, USP
300 mcg (0.3 mg)
Rx Only
90 Tablets
Lannett
P09541
GTIN: 00305273291460
0527-3291-46

Each tablet contains 25 mcg (0.025 mg) levothyroxine sodium.
See package insert for full prescribing information.
Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].
Protect from light and moisture.
Dispense in a tight, light-resistant container with a child-resistant closure.
Keep this and all drugs out of the reach of children.

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Philadelphia, PA 19136

L7092A
LB32804302
Rev. 11/2023

NDC 0527-**3280**-43

Levothyroxine Sodium Tablets, USP

25 mcg (0.025 mg)

Rx Only
1000 Tablets

Lannett

N 3 0527-3280-43 3

GTIN: 00305273280433

P09542
LOT: / EXP:

[redacted]

Each tablet contains 50 mcg (0.050 mg) levothyroxine sodium.
See package insert for full prescribing information.
Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].
Protect from light and moisture.
Dispense in a tight, light-resistant container with a child-resistant closure.
Keep this and all drugs out of the reach of children.

Manufactured by:
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Caguas, Puerto Rico 00725
Distributed by:
Lannett Company, Inc.
Philadelphia, PA 19136

L7093A
LB32814302
Rev. 11/2023

NDC 0527-**3281**-43

Levothyroxine Sodium Tablets, USP

50 mcg (0.050 mg)

Rx Only
1000 Tablets

Lannett

N 3 0527-3281-43 0

GTIN: 00305273281430

P09543
LOT: / EXP:

[redacted]

Each tablet contains 75 mcg (0.075 mg) levothyroxine sodium.
See package insert for full prescribing information.
Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].
Protect from light and moisture.
Dispense in a tight, light-resistant container with a child-resistant closure.
Keep this and all drugs out of the reach of children.

Manufactured by:
Neolpharma, Inc.
Caguas, Puerto Rico 00725
Distributed by:
Lannett Company, Inc.
Philadelphia, PA 19136

L7094A
LB32824302
Rev. 11/2023

NDC 0527-**3282**-43

Levothyroxine Sodium Tablets, USP

75 mcg (0.075 mg)

Rx Only
1000 Tablets

Lannett

N 3 0527-3282-43 7

GTIN: 00305273282437

PO9544
LOT: / EXP:

[redacted]

Each tablet contains 88 mcg (0.088 mg) levothyroxine sodium.
See package insert for full prescribing information.
Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].
Protect from light and moisture.
Dispense in a tight, light-resistant container with a child-resistant closure.
Keep this and all drugs out of the reach of children.

Manufactured by:
Neolpharma, Inc.
Caguas, Puerto Rico 00725
Distributed by:
Lannett Company, Inc.
Philadelphia, PA 19136

L7095A
LB32834302
Rev. 11/2023

NDC 0527-**3283**-43

Levothyroxine Sodium Tablets, USP

88 mcg (0.088 mg)

Rx Only
1000 Tablets

Lannett

N 3 0527-3283-43 4

GTIN: 00305273283434

PO9545
LOT: / EXP:

[redacted]

Each tablet contains 100 mcg (0.1 mg) levothyroxine sodium.
See package insert for full prescribing information.
Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].
Protect from light and moisture.
Dispense in a tight, light-resistant container with a child-resistant closure.
Keep this and all drugs out of the reach of children.

Manufactured by:
Neolpharma, Inc.
Caguas, Puerto Rico 00725
Distributed by:
Lannett Company, Inc.
Philadelphia, PA 19136

L7096A
LB32844302
Rev. 11/2023

NDC 0527-**3284**-43

Levothyroxine Sodium Tablets, USP

100 mcg (0.1 mg)

Rx Only
1000 Tablets

Lannett

N 3 0527-3284-43 1

GTIN: 00305273284431

P09546
LOT: / EXP:

[redacted]

Each tablet contains 112 mcg (0.112 mg) levothyroxine sodium.
See package insert for full prescribing information.
Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].
Protect from light and moisture.
Dispense in a tight, light-resistant container with a child-resistant closure.
Keep this and all drugs out of the reach of children.

Manufactured by:
Neolpharma, Inc.
Caguas, Puerto Rico 00725
Distributed by:
Lannett Company, Inc.
Philadelphia, PA 19136

L7097A
LB32854302
Rev. 11/2023

NDC 0527-**3285**-43

Levothyroxine Sodium Tablets, USP

112 mcg (0.112 mg)

Rx Only
1000 Tablets

Lannett

N 3 0527-3285-43 8

GTIN: 00305273285438

P09547
LOT: / EXP:

[redacted]

Each tablet contains 125 mcg (0.125 mg) levothyroxine sodium.
See package insert for full prescribing information.
Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].
Protect from light and moisture.
Dispense in a tight, light-resistant container with a child-resistant closure.
Keep this and all drugs out of the reach of children.

Manufactured by:
Neolpharma, Inc.
Caguas, Puerto Rico 00725
Distributed by:
Lannett Company, Inc.
Philadelphia, PA 19136

L7098A
LB32864302
Rev. 11/2023

NDC 0527-**3286**-43

Levothyroxine Sodium Tablets, USP

125 mcg (0.125 mg)

Rx Only
1000 Tablets

Lannett

N 3 0527-3286-43 5

GTIN: 00305273286435

P09548
LOT: / EXP:

Each tablet contains 137 mcg (0.137 mg) levothyroxine sodium.
See package insert for full prescribing information.
Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].
Protect from light and moisture.
Dispense in a tight, light-resistant container with a child-resistant closure.
Keep this and all drugs out of the reach of children.

Manufactured by:
Neolpharma, Inc.
Caguas, Puerto Rico 00725
Distributed by:
Lannett Company, Inc.
Philadelphia, PA 19136

L7099A
LB32874302
Rev. 11/2023

NDC 0527-**3287**-43

Levothyroxine Sodium Tablets, USP

137 mcg (0.137 mg)

Rx Only
1000 Tablets

Lannett

N 3 0527-3287-43 2

GTIN: 00305273287432

P09549
LOT: / EXP:

Each tablet contains 150 mcg (0.150 mg) levothyroxine sodium.
See package insert for full prescribing information.
Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].
Protect from light and moisture.
Dispense in a tight, light-resistant container with a child-resistant closure.
Keep this and all drugs out of the reach of children.

Manufactured by:
Neolpharma, Inc.
Caguas, Puerto Rico 00725
Distributed by:
Lannett Company, Inc.
Philadelphia, PA 19136

L7100A
LB32884302
Rev. 11/2023

NDC 0527-**3288**-43

Levothyroxine Sodium Tablets, USP

150 mcg (0.150 mg)

Rx Only
1000 Tablets

Lannett

N 3 0527-3288-43 9

GTIN: 00305273288439

P09550
LOT: / EXP:

[redacted]

Each tablet contains 175 mcg (0.175 mg) levothyroxine sodium.
See package insert for full prescribing information.
Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].
Protect from light and moisture.
Dispense in a tight, light-resistant container with a child-resistant closure.
Keep this and all drugs out of the reach of children.

Manufactured by:
Neolpharma, Inc.
Caguas, Puerto Rico 00725
Distributed by:
Lannett Company, Inc.
Philadelphia, PA 19136

L7101A
LB32894302
Rev. 11/2023

NDC 0527-**3289**-43

Levothyroxine Sodium Tablets, USP

175 mcg (0.175 mg)

Rx Only
1000 Tablets

Lannett

N 3 0527-3289-43 6

GTIN: 00305273289436

P09551
LOT: / EXP:

[redacted]

Each tablet contains 200 mcg (0.2 mg) levothyroxine sodium.
See package insert for full prescribing information.
Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].
Protect from light and moisture.
Dispense in a tight, light-resistant container with a child-resistant closure.
Keep this and all drugs out of the reach of children.

Manufactured by:
Neolpharma, Inc.
Caguas, Puerto Rico 00725
Distributed by:
Lannett Company, Inc.
Philadelphia, PA 19136

L7102A
LB32904302
Rev. 11/2023

NDC 0527-**3290**-43

Levothyroxine Sodium Tablets, USP

200 mcg (0.2 mg)

Rx Only
1000 Tablets

Lannett

N 3 0527-3290-43 2

GTIN: 00305273290432

P09552
LOT: / EXP:

Each tablet contains 300 mcg (0.3 mg) levothyroxine sodium.
See package insert for full prescribing information.
Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].
Protect from light and moisture.
Dispense in a tight, light-resistant container with a child-resistant closure.
Keep this and all drugs out of the reach of children.

Manufactured by:
Neolpharma, Inc.
Caguas, Puerto Rico 00725
Distributed by:
Lannett Company, Inc.
Philadelphia, PA 19136

L7103A
LB32914302
Rev. 11/2023

NDC 0527-**3291**-43

Levothyroxine Sodium Tablets, USP

300 mcg (0.3 mg)

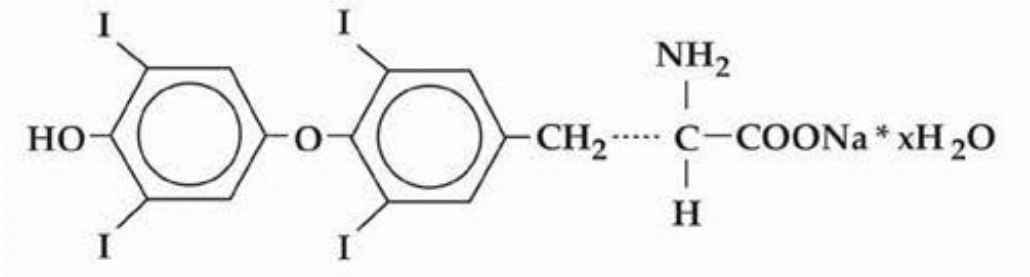
Rx Only
1000 Tablets

Lannett

N 3 0527-3291-43 9

GTIN: 00305273291439

P09553
LOT: / EXP:



LEVOTHYROXINE SODIUM

levothyroxine sodium tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0527-3281
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
LEVOTHYROXINE SODIUM (UNII: 9J765S329G) (LEVOTHYROXINE - UNII:Q51BO43MG4)	LEVOTHYROXINE SODIUM ANHYDROUS	50 ug

Inactive Ingredients	
Ingredient Name	**Strength**
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	

Product Characteristics			
Color	white	**Score**	2 pieces
Shape	CAPSULE (Caplet)	**Size**	9mm
Flavor		**Imprint Code**	50;GG;332
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0527-3281-46	90 in 1 BOTTLE; Type 0: Not a Combination Product	08/03/2020	
2	NDC:0527-3281-43	1000 in 1 BOTTLE; Type 0: Not a Combination Product	08/03/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA authorized generic	NDA021342	08/03/2020	

LEVOTHYROXINE SODIUM

levothyroxine sodium tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0527-3282
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
LEVOTHYROXINE SODIUM (UNII: 9J765S329G) (LEVOTHYROXINE - UNII:Q51BO43MG4)	LEVOTHYROXINE SODIUM ANHYDROUS	75 ug

Inactive Ingredients	
Ingredient Name	**Strength**
FD&C BLUE NO. 2--ALUMINUM LAKE (UNII: 4AQJ3LG584)	
D&C RED NO. 27 ALUMINUM LAKE (UNII: ZK64F7XSTX)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	

Product Characteristics			
Color	purple ((violet))	**Score**	2 pieces
Shape	CAPSULE (Caplet)	**Size**	9mm
Flavor		**Imprint Code**	75;GG;333
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0527-3282-46	90 in 1 BOTTLE; Type 0: Not a Combination Product	08/03/2020	
2	NDC:0527-3282-43	1000 in 1 BOTTLE; Type 0: Not a Combination Product	08/03/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA authorized generic	NDA021342	08/03/2020	

LEVOTHYROXINE SODIUM

levothyroxine sodium tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0527-3280
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
LEVOTHYROXINE SODIUM (UNII: 9J765S329G) (LEVOTHYROXINE - UNII:Q51BO43MG4)	LEVOTHYROXINE SODIUM ANHYDROUS	25 ug

Inactive Ingredients	
Ingredient Name	**Strength**
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	

Product Characteristics			
Color	orange	**Score**	2 pieces
Shape	CAPSULE (caplet)	**Size**	9mm
Flavor		**Imprint Code**	25;GG;331
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0527-3280-46	90 in 1 BOTTLE; Type 0: Not a Combination Product	08/03/2020	
2	NDC:0527-3280-43	1000 in 1 BOTTLE; Type 0: Not a Combination Product	08/03/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA authorized generic	NDA021342	08/03/2020	

LEVOTHYROXINE SODIUM

levothyroxine sodium tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0527-3284

Route of Administration	ORAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
LEVOTHYROXINE SODIUM (UNII: 9J765S329G) (LEVOTHYROXINE - UNII:Q51BO43MG4)	LEVOTHYROXINE SODIUM ANHYDROUS	100 ug

Inactive Ingredients	
Ingredient Name	**Strength**
D&C RED NO. 27 (UNII: 2LRS185U6K)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

Product Characteristics			
Color	yellow	**Score**	2 pieces
Shape	CAPSULE (Caplet)	**Size**	9mm
Flavor		**Imprint Code**	100;GG;335
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0527-3284-46	90 in 1 BOTTLE; Type 0: Not a Combination Product	08/03/2020	
2	NDC:0527-3284-43	1000 in 1 BOTTLE; Type 0: Not a Combination Product	08/03/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA authorized generic	NDA021342	08/03/2020	

LEVOTHYROXINE SODIUM

levothyroxine sodium tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0527-3283

Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LEVOTHYROXINE SODIUM (UNII: 9J765S329G) (LEVOTHYROXINE - UNII:Q51BO43MG4)	LEVOTHYROXINE SODIUM ANHYDROUS	88 ug

Inactive Ingredients

Ingredient Name	Strength
FD&C BLUE NO. 1--ALUMINUM LAKE (UNII: J9EQA3S2JM)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

Product Characteristics

Color	green ((olive))	**Score**	2 pieces
Shape	CAPSULE (caplet)	**Size**	9mm
Flavor		**Imprint Code**	88;GG;334
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0527-3283-46	90 in 1 BOTTLE; Type 0: Not a Combination Product	08/03/2020	
2	NDC:0527-3283-43	1000 in 1 BOTTLE; Type 0: Not a Combination Product	08/03/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA authorized generic	NDA021342	08/03/2020	

LEVOTHYROXINE SODIUM

levothyroxine sodium tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0527-3285

Route of Administration	ORAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
LEVOTHYROXINE SODIUM (UNII: 9J765S329G) (LEVOTHYROXINE - UNII:Q51BO43MG4)	LEVOTHYROXINE SODIUM ANHYDROUS	112 ug

Inactive Ingredients	
Ingredient Name	**Strength**
D&C RED NO. 30 (UNII: 2S42T2808B)	
D&C RED NO. 27 ALUMINUM LAKE (UNII: ZK64F7XSTX)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	

Product Characteristics			
Color	pink ((Rose))	**Score**	2 pieces
Shape	CAPSULE (caplet)	**Size**	9mm
Flavor		**Imprint Code**	112;GG;336
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0527-3285-46	90 in 1 BOTTLE; Type 0: Not a Combination Product	08/03/2020	
2	NDC:0527-3285-43	1000 in 1 BOTTLE; Type 0: Not a Combination Product	08/03/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA authorized generic	NDA021342	08/03/2020	

LEVOTHYROXINE SODIUM

levothyroxine sodium tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0527-3290
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
LEVOTHYROXINE SODIUM (UNII: 9J765S329G) (LEVOTHYROXINE - UNII:Q51BO43MG4)	LEVOTHYROXINE SODIUM ANHYDROUS	200 ug

Inactive Ingredients	
Ingredient Name	**Strength**
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
D&C RED NO. 27 ALUMINUM LAKE (UNII: ZK64F7XSTX)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	

Product Characteristics			
Color	pink	**Score**	2 pieces
Shape	CAPSULE (caplet)	**Size**	9mm
Flavor		**Imprint Code**	200;GG;340
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0527-3290-46	90 in 1 BOTTLE; Type 0: Not a Combination Product	08/03/2020	
2	NDC:0527-3290-43	1000 in 1 BOTTLE; Type 0: Not a Combination Product	08/03/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA authorized generic	NDA021342	08/03/2020	

LEVOTHYROXINE SODIUM

levothyroxine sodium tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0527-3291
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
LEVOTHYROXINE SODIUM (UNII: 9J765S329G) (LEVOTHYROXINE - UNII:Q51BO43MG4)	LEVOTHYROXINE SODIUM ANHYDROUS	300 ug

Inactive Ingredients	
Ingredient Name	**Strength**
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
FD&C BLUE NO. 1--ALUMINUM LAKE (UNII: J9EQA3S2JM)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	

Product Characteristics			
Color	green	**Score**	2 pieces
Shape	CAPSULE (caplet)	**Size**	9mm
Flavor		**Imprint Code**	300;GG;341
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0527-3291-46	90 in 1 BOTTLE; Type 0: Not a Combination Product	08/03/2020	
2	NDC:0527-3291-43	1000 in 1 BOTTLE; Type 0: Not a Combination Product	08/03/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA authorized generic	NDA021342	08/03/2020	

LEVOTHYROXINE SODIUM

levothyroxine sodium tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0527-3288
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
LEVOTHYROXINE SODIUM (UNII: 9J765S329G) (LEVOTHYROXINE - UNII:Q51BO43MG4)	LEVOTHYROXINE SODIUM ANHYDROUS	150 ug

Inactive Ingredients	
Ingredient Name	**Strength**
FD&C BLUE NO. 2--ALUMINUM LAKE (UNII: 4AQJ3LG584)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	

Product Characteristics			
Color	blue	**Score**	2 pieces
Shape	CAPSULE (caplet)	**Size**	9mm
Flavor		**Imprint Code**	150;GG;338
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0527-3288-46	90 in 1 BOTTLE; Type 0: Not a Combination Product	08/03/2020	
2	NDC:0527-3288-43	1000 in 1 BOTTLE; Type 0: Not a Combination Product	08/03/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA authorized generic	NDA021342	08/03/2020	

LEVOTHYROXINE SODIUM

levothyroxine sodium tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0527-3289
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**

LEVOTHYROXINE SODIUM (UNII: 9J765S329G) (LEVOTHYROXINE - UNII:Q51BO43MG4)	LEVOTHYROXINE SODIUM ANHYDROUS	175 ug

Inactive Ingredients	
Ingredient Name	**Strength**
D&C RED NO. 27 ALUMINUM LAKE (UNII: ZK64F7XSTX)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
FD&C BLUE NO. 1--ALUMINUM LAKE (UNII: J9EQA3S2JM)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	

Product Characteristics			
Color	purple ((lilac))	**Score**	2 pieces
Shape	CAPSULE (caplet)	**Size**	9mm
Flavor		**Imprint Code**	175;GG;339
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0527-3289-46	90 in 1 BOTTLE; Type 0: Not a Combination Product	08/03/2020	
2	NDC:0527-3289-43	1000 in 1 BOTTLE; Type 0: Not a Combination Product	08/03/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA authorized generic	NDA021342	08/03/2020	

LEVOTHYROXINE SODIUM

levothyroxine sodium tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0527-3287
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**

LEVOTHYROXINE SODIUM (UNII: 9J765S329G) (LEVOTHYROXINE - UNII:Q51BO43MG4)	LEVOTHYROXINE SODIUM ANHYDROUS	137 ug

Inactive Ingredients

Ingredient Name	Strength
FD&C BLUE NO. 1--ALUMINUM LAKE (UNII: J9EQA3S2JM)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	

Product Characteristics

Color	turquoise	**Score**	2 pieces
Shape	CAPSULE (Caplet)	**Size**	9mm
Flavor		**Imprint Code**	137;GG;330
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0527-3287-46	90 in 1 BOTTLE; Type 0: Not a Combination Product	08/03/2020	
2	NDC:0527-3287-43	1000 in 1 BOTTLE; Type 0: Not a Combination Product	08/03/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA authorized generic	NDA021342	08/03/2020	

LEVOTHYROXINE SODIUM

levothyroxine sodium tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0527-3286
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LEVOTHYROXINE SODIUM (UNII: 9J765S329G) (LEVOTHYROXINE - UNII:Q51BO43MG4)	LEVOTHYROXINE SODIUM ANHYDROUS	125 ug

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
FD&C BLUE NO. 1--ALUMINUM LAKE (UNII: J9EQA3S2JM)	

Product Characteristics

Color	brown	**Score**	2 pieces
Shape	CAPSULE (caplet)	**Size**	9mm
Flavor		**Imprint Code**	125;GG;337
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0527-3286-46	90 in 1 BOTTLE; Type 0: Not a Combination Product	08/03/2020	
2	NDC:0527-3286-43	1000 in 1 BOTTLE; Type 0: Not a Combination Product	08/03/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA authorized generic	NDA021342	08/03/2020	

Labeler - Lannett Company, Inc (002277481)

Registrant - Neolpharma, Inc. (078709787)

Establishment

Name	Address	ID/FEI	Business Operations
Neolpharma, Inc.		078709787	manufacture(0527-3287, 0527-3281, 0527-3282, 0527-3284, 0527-3286, 0527-3280, 0527-3283, 0527-3285, 0527-3288, 0527-3289, 0527-3290, 0527-3291) , analysis(0527-3287, 0527-3280, 0527-3281, 0527-3282, 0527-3284, 0527-3286, 0527-3283, 0527-3285, 0527-3288, 0527-3289, 0527-3290, 0527-3291) , pack(0527-3287, 0527-3280, 0527-3281, 0527-3282, 0527-3284, 0527-3286, 0527-3283, 0527-3285, 0527-3288, 0527-3289, 0527-3290, 0527-3291) , label(0527-3280, 0527-3281, 0527-3282, 0527-3284, 0527-3286, 0527-3283, 0527-3285, 0527-3287, 0527-3288, 0527-3289, 0527-3290, 0527-3291)