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#### 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 tablet, 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).

RECENT MAJOR CHANGESDosage and Administration, Important Considerations for Dosing (2.2)2/2024Dosage and Administration, Monitoring TSH and/or Thyroxine (T4) Levels (2.4)2/2024

Levothyroxine sodium tablet is a L-thyroxine (T4) indicated in adult and pediatric patients, including neonates, 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.
- 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)
- Advise patients to stop biotin and biotin-containing supplements at least 2 days before assessing TSH and/or T4 levels. (2.2)
- 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 to 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)

blets: 25, 50, 75, 88, 100, 112, 125, 137, 150, 175, 200, and 300 mcg (3)	
CONTRAINDICATIONS	
Uncorrected adrenal insufficiency. (4)	

- ------ WARNINGS AND PRECAUTIONS ------
- Serious risks related to overtreatment or undertreatment with levothyroxine sodium tablet: Titrate the dose of levothyroxine sodium tablet carefully and monitor response to titration. (5.1).
- Cardiac adverse reactions in the elderly and in patients with underlying cardiovascular disease:Initiate levothyroxine sodium tablet at less than the full replacement dose because of the increased risk of cardiac adverse reactions, including atrial fibrillation. (2.3, 5.2, 8.5)
- Myxedema coma: Do not use oral thyroid hormone drug products to treat myxedema coma. (5.3)

- Acute adrenal crisis in patients with concomitant adrenal insufficiency: Treat with replacement glucocorticoids prior to initiation of levothyroxine sodium tablet treatment. (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: Overreplacement can increase bone resorption and decrease bone mineral density. Give the lowest effective dose. (5.6)

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) To report SUSPECTED ADVERSE REACTIONS, contact Lupin Pharmaceuticals, Inc. at 1-800-399-2561 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

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)

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

Revised: 3/2025

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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 in adult and pediatric patients, including neonates, 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 in adult and pediatric patients, including neonates, 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 (5.1)].
- Levothyroxine sodium tablets are not indicated for treatment of hypothyroidism during the recovery phase of subacute thyroiditis.

## **2 DOSAGE AND ADMINISTRATION**

## 2.1 Important Administration Instructions

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 dosage adjustments when regularly administering within one hour of certain foods that may affect levothyroxine sodium tablets absorption [see Dosage and Administration (2.2 and 2.3), Drug Interactions (7.9), and Clinical Pharmacology (12.3)].

Administer levothyroxine sodium tablets to pediatric patients who cannot swallow intact tablets by crushing the tablet, suspending the freshly crushed tablet in a small amount (5 to 10 mL) of water and immediately administering the suspension by spoon or dropper. Ensure the patient ingests the full amount of the suspension. 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 Important Considerations for Dosing

The dosage 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 dosage adjustments made based on periodic assessment of the patient's clinical response and laboratory parameters [see Dosage and Administration (2.4)].

For adult patients with primary hypothyroidism, titrate until the patient is clinically euthyroid and the serum TSH returns to normal [see Dosage and Administration (2.3)].

For secondary or tertiary hypothyroidism, serum TSH is not a reliable measure of levothyroxine sodium tablets dosage adequacy and should not be used to monitor therapy. Use the serum free-T4 level to titrate levothyroxine sodium tablets dosing until the patient is clinically euthyroid and the serum free-T4 level is restored to the upper half of the normal range [see Dosage and Administration (2.3)].

Inquire whether patients are taking biotin or biotin-containing supplements. If so, advise

them to stop biotin supplementation at least 2 days before assessing TSH and/or T4 levels [see Dosage and Administration (2.4) and Drug Interactions (7.10)].

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

## 2.3 Recommended Dosage and Titration

## Primary, Secondary, and Tertiary Hypothyroidism in Adults

The recommended starting daily dosage of levothyroxine sodium tablets in adults with primary, secondary, or tertiary hypothyroidism is based on age and comorbid cardiac conditions, as described in Table 1. For patients at risk of atrial fibrillation or patients with underlying cardiac disease, start with a lower dosage and titrate the dosage more slowly to avoid exacerbation of cardiac symptoms. Dosage titration is based on serum TSH or free-T4 [see Dosage and Administration (2.2)].

Table 1. Levothyroxine Sodium Tablets Dosing Guidelines forHypothyroidism in Adults\*

Patient Population	Starting Dosage	Dosage Titration Based on Serum TSH or Free-T4
Adults diagnosed with hypothyroidism	Full replacement dose is 1.6 mcg/kg/day. Some patients require a lower starting dose.	Titrate dosage by 12.5 to 25 mcg increments every 4 to 6 weeks, as needed until the patient is euthyroid.
Adults at risk for atrial fibrillation or with underlying cardiac disease	Lower starting dose (less than 1.6 mcg/kg/day)	Titrate dosage every 6 to 8 weeks, as needed until the patient is euthyroid.
Geriatric patients	Lower starting dose (less than 1.6 mcg/kg/day)	

\* Dosages greater than 200 mcg/day are seldom required. An inadequate response to daily dosages greater than 300 mcg/day is rare and may indicate poor compliance, malabsorption, drug interactions, or a combination of these factors [see Dosage and Administration (2.1) and Drug Interactions (7)].

## Primary, Secondary and Tertiary Hypothyroidism in Pediatric Patients

The recommended starting daily dosage of levothyroxine sodium tablets in pediatric patients with primary, secondary, or tertiary hypothyroidism is based on body weight and changes with age as described in Table 2. Titrate the dosage (every 2 weeks) as needed based on serum TSH or free-T4 until the patient is euthyroid [see Dosage and Administration (2.2)].

Table 2. Levothyroxine Sodium Tablets Dosing Guidelines for	
Hypothyroidism in Pediatric Patients	

Age	Starting Daily Dosage Per Kg Body Weight <sup>a</sup>
0 to 3 months	10 to 15 mcg/kg/day
3 to 6 months	8 to 10 mcg/kg/day
6 to 12 months	6 to 8 mcg/kg/day

1 to 5 years	5 to 6 mcg/kg/day
6 to 12 years	4 to 5 mcg/kg/day
Greater than 12 years but growth and puberty incomplete	2 to 3 mcg/kg/day
Growth and puberty complete	1.6 mcg/kg/day

<sup>a</sup> Adjust dosage based on clinical response and laboratory parameters [see Dosage and Administration (2.4) and Use in Specific Populations (8.4)].

#### Pediatric Patients from Birth to 3 Months of Age at Risk for Cardiac Failure

Start at a lower starting dosage and increase the dosage every 4 to 6 weeks as needed based on clinical and laboratory response.

#### Pediatric Patients at Risk for Hyperactivity

To minimize the risk of hyperactivity, start at one-fourth the recommended full replacement dosage, and increase on a weekly basis by one-fourth the full recommended replacement dosage until the full recommended replacement dosage is reached.

#### Hypothyroidism in Pregnant Patients

For pregnant patients with pre-existing hypothyroidism, measure serum TSH and free-T4 as soon as pregnancy is confirmed and, at minimum, during each trimester of pregnancy. In pregnant patients with primary hypothyroidism, maintain serum TSH in the trimester-specific reference range.

The recommended daily dosage of levothyroxine sodium tablets in pregnant patients is described in Table 3.

Patient Population	Starting Dosage	Dose Adjustment and Titration
Pre-existing primary hypothyroidism with serum TSH above normal trimester- specific range	Pre-pregnancy dosage may increase during pregnancy	Increase levothyroxine sodium tablet dosage by 12.5 to 25 mcg per day. Monitor TSH every 4 weeks until a stable dose is reached and serum TSH is within normal trimester-specific range. Reduce levothyroxine sodium tablet dosage to pre- pregnancy levels immediately after delivery. Monitor serum TSH 4 to 8 weeks postpartum.
New onset hypothyroidism (TSH ≥ 10 mIU per liter)	1.6 mcg/kg/day	Monitor serum TSH every 4 weeks and adjust levothyroxine sodium tablet
New onset hypothyroidism (TSH <	1.0 mcg/kg/day	dosage until serum TSH is within normal trimester-

#### Table 3. Levothyroxine Sodium Tablets Dosing Guidelines for Hypothyroidism in Pregnant Patients

10 mIU per liter)	specific range.
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### TSH Suppression in Well-differentiated Thyroid Cancer in Adult and Pediatric Patients

The levothyroxine sodium tablets dosage is based on the target level of TSH suppression for the stage and clinical status of thyroid cancer.

## 2.4 Monitoring TSH and/or Thyroxine (T4) Levels

Assess the adequacy of therapy by periodic assessment of laboratory tests and clinical evaluation.

Biotin supplementation may interfere with immunoassays for TSH, T4, and T3, resulting in erroneous thyroid hormone test results. Stop biotin and biotin-containing supplements for at least 2 days before assessing TSH and/or T4 levels [see Drug Interactions (7.10)].

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 dosage. In patients on a stable and appropriate replacement dosage, evaluate clinical and biochemical response every 6 to 12 months and whenever there is a change in the patient's clinical status.

#### Pediatric Patients

In patients with 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 pediatric patients 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 dosage 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.

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 mIU per liter within 4 weeks may indicate the patient 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 round, colored, scored and debossed with following debossing details on one side and break-line on other side. They are available as follows (Table 4)

Tablet Strength	Tablet Color/Shape	Debossing Details
25 mcg	Peach/Round	L15
50 mcg	White/Round	L16
75 mcg	Violet/Round	L17
88 mcg	Olive/Round	L19
100 mcg	Yellow/Round	L20
112 mcg	Rose/Round	L21
125 mcg	Tan/Round	L22
137 mcg	Turquoise/Round	L23
150 mcg	Blue/Round	L24
175 mcg	Lilac/Round	L25
200 mcg	Pink/Round	L26
300 mcg	Green/Round	L27

Table 4: Levothyroxine Sodium Tablet Strengths and Identifying Features

## **4 CONTRAINDICATIONS**

Levothyroxine sodium tablets are contraindicated in patients with uncorrected adrenal insufficiency [see Warnings and Precautions (5.4)].

## **5 WARNINGS AND PRECAUTIONS**

# 5.1 Serious Risks Related to Overtreatment or Undertreatment with Levothyroxine sodium tablets

Levothyroxine sodium tablet has a narrow therapeutic index. Overtreatment or undertreatment with Levothyroxine sodium tablets may have negative effects on growth and development, cardiovascular function, bone metabolism, reproductive function, cognitive function, gastrointestinal function, and glucose and lipid metabolism in adult or pediatric patients.

In pediatric patients with congenital and acquired hypothyroidism, undertreatment may adversely

affect cognitive development and linear growth, and overtreatment is associated with craniosynostosis and acceleration of bone age [see Use in Specific Populations (8.4)].

Titrate the dose of Levothyroxine sodium tablets carefully and monitor response to titration to avoid these effects [see Dosage and Administration (2.4)]. Consider the potential for food or drug interactions and adjust the administration or dosage of Levothyroxine sodium tablets as needed [see Dosage and Administration (2.1), Drug Interactions (7.1), and Clinical Pharmacology (12.3)].

# 5.2 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) and 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.

## 5.3 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.

## 5.4 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)].

## 5.5 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) and 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 Pediatric Patients

Pseudotumor cerebri and slipped capital femoral epiphysis have been reported in pediatric patients receiving levothyroxine therapy. Overtreatment may result in craniosynostosis in infants who have not undergone complete closure of the fontanelles, and in premature closure of the epiphyses in pediatric patients still experiencing growth 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 (Tables 5 to 8).

## Table 5. 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
Phosphate Binders (e.g., calcium carbonate, ferrous sulfate, sevelamer, lanthanum)	Phosphate binders may bind to levothyroxine. 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 (e.g., colesevelam, cholestyramine, colestipol) Ion Exchange Resins (e.g., Kayexalate)	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.
Proton Pump Inhibitors Sucralfate Antacids (e.g., 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 6. Drugs That May Alter T4 and Triiodothyronine (T3) Serum TransportWithout 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 the results in an initial transient increase in FT4. C serum T4 and normal FT4 and TSH concentra	ontinued administration results in a decrease in
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 Non-Steroidal Anti-inflammatory Drugs -Fenamates	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. 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

## Table 7. 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	Phenobarbital has been shown to reduce the
Rifampin	response to thyroxine. Phenobarbital
	increases L-thyroxine metabolism by inducing
	uridine 5'-diphospho-glucuronosyltransferase
	(UGT) and leads to 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 8. 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., Propranolo > 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).
Other drugs: Amiodarone	Amiodarone inhibits peripheral conversion of 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 tablet 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

Thyroxine-binding Globulin (TBG)

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.

## <u>Biotin</u>

Biotin supplementation is known to interfere with thyroid hormone immunoassays that are based on a biotin and streptavidin interaction, which may result in erroneous thyroid hormone test results. Stop biotin and biotin-containing supplements for at least 2 days prior to thyroid testing.

## **8 USE IN SPECIFIC POPULATIONS**

## 8.1 Pregnancy

#### **Risk Summary**

The clinical experience, including data from postmarketing studies, in pregnant women treated with oral levothyroxine to maintain euthyroid state have not reported increased rates of major birth defects, miscarriages, or other adverse maternal or fetal outcomes. 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*). Animal reproductive studies have not been conducted with levothyroxine sodium. 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. All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. 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**

## 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)].

## 8.2 Lactation

#### **Risk Summary**

Published studies report that levothyroxine is present in human milk following the administration of oral levothyroxine. No adverse effects on the breastfed infant have been reported and there is no information on the effects of levothyroxine on milk production. Adequate levothyroxine treatment during lactation may normalize milk production in hypothyroid lactating mothers with low milk supply. 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 breastfeed infant from levothyroxine sodium tablets or from the underlying maternal condition.

## 8.4 Pediatric Use

Levothyroxine Sodium Tablets is indicated in patients from birth to less than 17 years of age:

- As a replacement therapy in primary (thyroidal), secondary (pituitary), and tertiary (hypothalamic) congenital or acquired hypothyroidism.
- As an adjunct to surgery and radioiodine therapy in the management of thyrotropindependent well-differentiated thyroid cancer.

Rapid restoration of normal serum T4 concentrations is essential for preventing the adverse effects of congenital hypothyroidism on cognitive 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. *[see Warnings and Precautions (5.1)]*.

Closely monitor infants during the first 2 weeks of levothyroxine sodium tablets therapy for cardiac overload and arrhythmias.

## 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 Dosage and Administration (2.3) and Warnings and Precautions (5.2)]. 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.

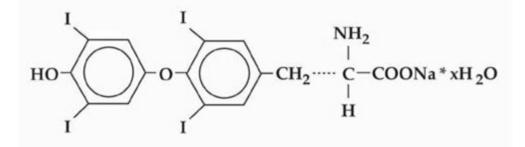
Reduce the levothyroxine sodium tablets dosage or discontinue temporarily if signs or symptoms of overdosage occur. Initiate appropriate supportive treatment as dictated by the patient's medical status.

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 is L-thyroxine (T4) and contains synthetic crystalline L-3,3',5,5' tetraiodothyronine sodium salt. Synthetic T4 is chemically identical to that produced in the human thyroid gland. Levothyroxine (T4) sodium has an empirical formula of  $C_{15}H_{10}I_4N$  NaO<sub>4</sub>•H<sub>2</sub>O, molecular weight of 798.85 (anhydrous), and structural formula as shown:



Levothyroxine sodium tablets USP 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 tablets USP contains the inactive ingredients corn starch, croscarmellose sodium, magnesium stearate, mannitol and sodium bicarbonate. Table 9 provides a listing of the color additives by tablet strength:

Table 9. Levothyroxine	Sodium	Tablets <b>l</b>	USP	Color	Additives
------------------------	--------	------------------	-----	-------	-----------

Strength (mcg)	Color additive(s)
25	FD&C Yellow No. 6 Aluminum Lake*
50	FD&C Blue 1 Aluminum Lake
75	FD&C Red No. 40 Aluminum Lake, FD&C Blue No. 2 Aluminum Lake
88	FD&C Yellow No. 6 Aluminum Lake*, FD&C Blue No. 1 Aluminum Lake, D&C Yellow No. 10 Aluminum Lake
100	FD&C Yellow No. 6 Aluminum Lake*, D&C Yellow No. 10 Aluminum Lake
112	D&C Red No. 27 Aluminum Lake
125	FD&C Yellow No. 6 Aluminum Lake*, FD&C Blue No. 1 Aluminum Lake, FD&C Red No. 40 Aluminum Lake, FD&C Blue No. 2 Aluminum Lake
137	FD&C Blue No. 1 Aluminum Lake
150	FD&C Blue No. 2 Aluminum Lake
175	FD&C Blue No. 1 Aluminum Lake, D&C Red No. 27 Aluminum Lake
200	FD&C Red No. 40 Aluminum Lake
300	FD&C Yellow No. 6 Aluminum Lake*, FD&C Blue No. 1 Aluminum Lake, D&C Yellow No. 10 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**

## <u>Absorption</u>

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 93%. 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**

## Metabolism

T4 is slowly eliminated (see Table 10). 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 10. Pharmacokinetic Parameters of Thyroid Hormones inEuthyroid Patients

Hormone		Biologic Potency		Protein Binding (%) <sup>a</sup>
Levothyroxine (T4)	10 to 20	1	6 to 7 <sup>b</sup>	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

Long-term carcinogenicity studies in animals to evaluate the carcinogenic potential of levothyroxine have not been performed. Studies to evaluate mutagenic potential and animal fertility have not been performed.

## **16 HOW SUPPLIED/STORAGE AND HANDLING**

#### How Supplied

Levothyroxine sodium tablets USP are round, colored, scored and debossed with following debossing details on one side and break-line on other side. They are supplied as follows:

Strength (mcg)	Color/Shape				NDC # for bottles of 1000
25	Peach/Round	115	68180-965- 09	68180-965- 01	68180-965- 03
50	White/Round	116	68180-966- 09	68180-966- 01	68180-966- 03
75	Violet/Round		68180-967- 09	68180-967- 01	68180-967- 03
88	Olive/Round	119	68180-968- 09	68180-968- 01	68180-968- 03

100	Yellow/Round	L20	68180-969- 09	68180-969- 01	68180-969- 03
112	Rose/Round	L21	68180-970- 09	68180-970- 01	68180-970- 03
125	Tan/Round	L22	68180-971- 09	68180-971- 01	68180-971- 03
137	Turquoise/Round	L23	68180-972- 09	68180-972- 01	68180-972- 03
150	Blue/Round	L24	68180-973- 09	68180-973- 01	68180-973- 03
175	Lilac/Round	L25	68180-974- 09	68180-974- 01	68180-974- 03
200	Pink/Round	L26	68180-975- 09	68180-975- 01	68180-975- 03
300	Green/Round	L27	68180-976- 09	68180-976- 01	68180-976- 03

## Storage and Handling

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 USP 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 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 tablet is intended to replace a hormone that is normally produced by the thyroid gland. Generally, replacement therapy is to be taken for life.
- Inform patients that levothyroxine sodium tablets should not be used as a primary or adjunctive therapy in a weight control program.
- Instruct patients to notify their healthcare provider if they are taking any other medications, including prescription and over-the-counter preparations.

- Instruct patients to discontinue biotin or any biotin-containing supplements for at least 2 days before thyroid function testing is conducted.
- 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.

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Manufactured for:

#### Lupin Pharmaceuticals, Inc.

Naples, FL 34108

United States

Manufactured by:

#### Lupin Limited

Pithampur (M.P.) - 454 775

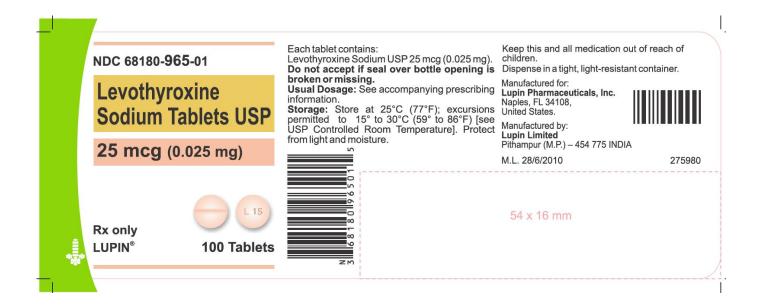
INDIA

Revised: August 2024 276412

ID#:

## PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Levothyroxine Sodium Tablets USP Rx Only 25 mcg



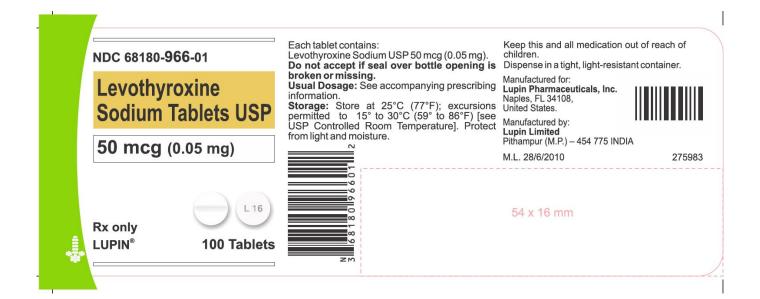
Levothyroxine Sodium Tablets USP

**Rx Only** 

50 mcg

NDC 68180-966-01

100's Tablets



Levothyroxine Sodium Tablets USP

Rx Only

75 mcg



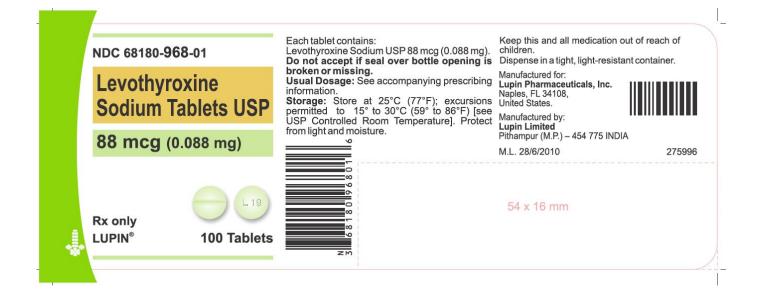
Levothyroxine Sodium Tablets USP

**Rx Only** 

88 mcg

NDC 68180-968-01

100's Tablets



Levothyroxine Sodium Tablets USP Rx Only 100 mcg



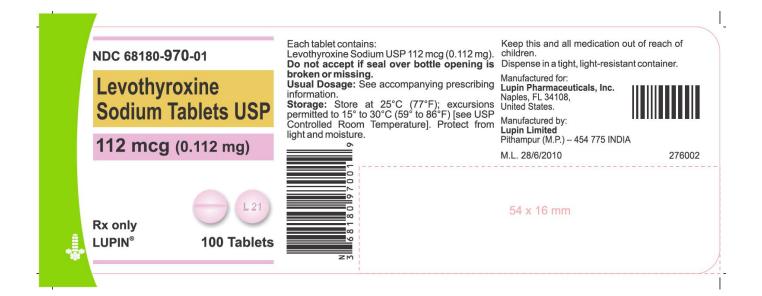
Levothyroxine Sodium Tablets USP

Rx Only

112 mcg

NDC 68180-970-01

100's Tablets



Levothyroxine Sodium Tablets USP

Rx Only

125 mcg



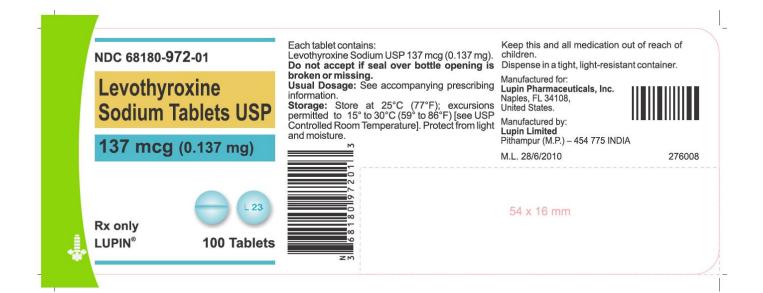
Levothyroxine Sodium Tablets USP

Rx Only

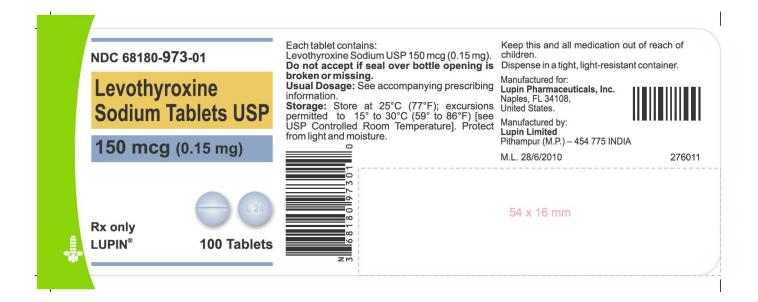
137 mcg

NDC 68180-972-01

100's Tablets



Levothyroxine Sodium Tablets USP Rx Only 150 mcg



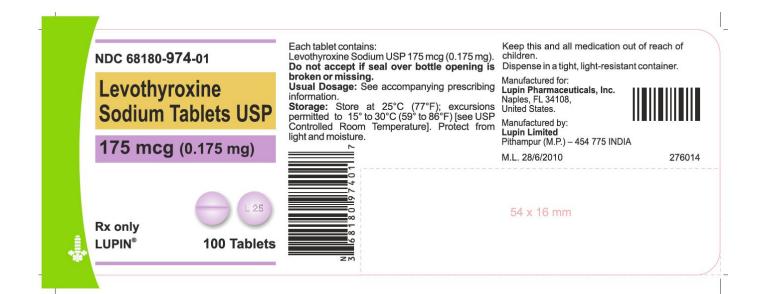
Levothyroxine Sodium Tablets USP

Rx Only

175 mcg

NDC 68180-974-01

100's Tablets



Levothyroxine Sodium Tablets USP Rx Only 200 mcg



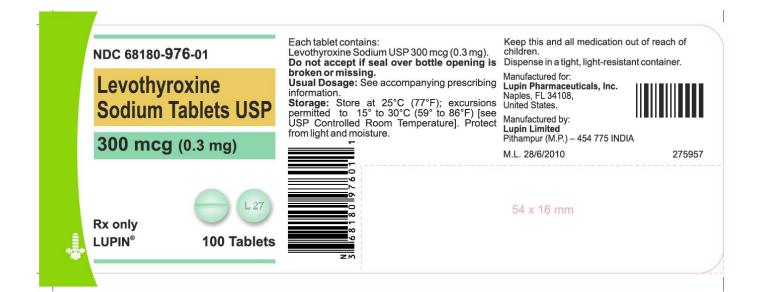
Levothyroxine Sodium Tablets USP

Rx Only

300 mcg

NDC 68180-976-01

100's Tablets



## LEVOTHYROXINE SODIUM

levothyroxine sodium tablet

**Product Information** 

P									
	roduct Type		HUMAN PRESCRIPTION D	RUG	lte	em Code (Source)		NDC:6	8180-965
R	oute of Admini	istration	ORAL						
A	ctive Ingredi	ient/Active	e Moiety						
		Ingred	lient Name			Basis of Stre	ng	th	Strength
	VOTHYROXINE S NII:Q51BO43MG4)	SODIUM (UNI	: 9J765S329G) (LEVOTHYR(	DXINE -		LEVOTHYROXINE SOD ANHYDROUS	IUM	1	0.025 mg
Ir	nactive Ingre	dients							
			Ingredient Name					Str	ength
С	ROSCARMELLOS	E SODIUM (U	NII: M28OL1HH48)						-
FC	O&C YELLOW NO	<b>D. 6</b> (UNII: H77	VEI93A8)						
M	AGNESIUM STEA	RATE (UNII: 7	0097M6I30)						
M	ANNITOL (UNII: 3	OWL53L36A)							
	DDIUM BICARBO								
ST	TARCH, CORN (U	NII: 08232NY3	iSJ)						
Ρ	roduct Chara	acteristics	;						
	olor	ORANG	E (Peach)	Score	•			2 piece	S
	nape	ROUND		Size				6mm	
	avor			Impri	nt (	Code		L15	
C									
	ontains								
P	ackaging								
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#	ackaging Item Code NDC:68180-965- 03	1000 in 1 BC Product		ation	03/2	Date	Ν		
# 1	ackaging Item Code NDC:68180-965- 03 NDC:68180-965- 02	1000 in 1 BC Product 500 in 1 BOT Product	TTLE; Type 0: Not a Comb	ation	03/2 01/0	<b>Date</b> 20/2019	Γ		
# 1 2	ackaging Item Code NDC:68180-965- 03 NDC:68180-965- 02 NDC:68180-965- 09	1000 in 1 BC Product 500 in 1 BOT Product 90 in 1 BOTT Product	TTLE; Type 0: Not a Combi	ation	03/2 01/0 03/2	<b>Date</b> 20/2019 01/2040	η		
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# 1 2 3 4	ackaging Item Code NDC:68180-965- 03 NDC:68180-965- 02 NDC:68180-965- 09 NDC:68180-965- 01	1000 in 1 BC Product 500 in 1 BOT Product 90 in 1 BOT Product 100 in 1 BOT Product	TTLE; Type 0: Not a Combin TLE; Type 0: Not a Combin LE; Type 0: Not a Combina TLE; Type 0: Not a Combin	ation tion ation	03/2 01/0 03/2	Date           20/2019           01/2040           20/2019		Da	

levothyroxine sodium tablet

#### **Product Information**

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	roduct Type		HUMAN PRESCR	IPTION DRUG	Ite	em Code (Source)	NDC	:68180-966
Re	oute of Admini	stration	ORAL					
A	ctive Ingredi	ent/Active	Moiety					
		Ingred	ient Name			Basis of Stre	ength	Strengt
	<b>VOTHYROXINE</b> 9 NII:Q51BO43MG4)	SODIUM (UNII:	9J765S329G) (LE	VOTHYROXINE -		LEVOTHYROXINE SOL ANHYDROUS	DIUM	0.05 mg
In	nactive Ingre	dients						
			Ingredient I	Name			S	trength
CF	ROSCARMELLOS	E SODIUM (UN	III: M28OL1HH48)					
FC	D&C BLUE NO. 1	(UNII: H3R47K	3TBD)					
M	AGNESIUM STEA	RATE (UNII: 70	097M6I30)					
м	ANNITOL (UNII: 3	OWL53L36A)						
sc	DIUM BICARBO	NATE (UNII: 8N	IDF5V39QO)					
ST	TARCH, CORN (U	NII: 08232NY39	5J)					
P	roduct Chara	acteristics						
Сс	olor	WH	ITE	Score			2 pieces	
Sł	hape	RO	UND	Size			6mm	
Fla								
	avor			Imprint Code			L16	
Сс	avor ontains			Imprint Code			L16	
Co				Imprint Code			L16	
				Imprint Code			L16	
Pa	ackaging	Ра	ckage Descri		M	larketing Start Date	Mark	eting End Date
Pa	ackaging Item Code			ption			Mark	
Pa #	ackaging Item Code NDC:68180-966- 03	1000 in 1 BOT Product	ckage Descri	<b>ption</b> a Combination	05/0	Date	Mark	
Pa # 1	ackaging Item Code NDC:68180-966- 03 NDC:68180-966- 02 NDC:68180-966- 02	1000 in 1 BOT Product 500 in 1 BOTT Product 90 in 1 BOTTL Product	<b>ckage Descri</b> TTLE; Type 0: Not TLE; Type 0: Not a E; Type 0: Not a 0	<b>ption</b> a Combination Combination Combination	05/0 01/0	<b>Date</b>	Mark	
Pa # 1	ackaging Item Code NDC:68180-966- 03 NDC:68180-966- 02 NDC:68180-966- 02	1000 in 1 BOT Product 500 in 1 BOTT Product 90 in 1 BOTTL Product	<b>ckage Descri</b> ITLE; Type 0: Not ILE; Type 0: Not a	<b>ption</b> a Combination Combination Combination	05/0 01/0 05/0	Date 02/2019 01/2040	Mark	
Pa # 1 2 3	ackaging Item Code NDC:68180-966- 02 NDC:68180-966- 02 NDC:68180-966- 09 NDC:68180-966-	1000 in 1 BOT Product 500 in 1 BOTT Product 90 in 1 BOTTL Product 100 in 1 BOTT	<b>ckage Descri</b> TTLE; Type 0: Not TLE; Type 0: Not a E; Type 0: Not a 0	<b>ption</b> a Combination Combination Combination	05/0 01/0 05/0	Date 02/2019 01/2040 02/2019	Mark	
Pa # 1 2 3 4	ackaging Item Code NDC:68180-966- 02 NDC:68180-966- 02 NDC:68180-966- 09 NDC:68180-966-	1000 in 1 BOT Product 500 in 1 BOTT Product 90 in 1 BOTTL Product 100 in 1 BOTT Product	<b>ckage Descri</b> ITLE; Type 0: Not ILE; Type 0: Not a E; Type 0: Not a IE; Type 0: Not a	<b>ption</b> a Combination Combination Combination	05/0 01/0 05/0	Date 02/2019 01/2040 02/2019	Mark	
Pa # 1 2 3 4	ackaging Item Code NDC:68180-966- 03 NDC:68180-966- 02 NDC:68180-966- 09 NDC:68180-966- 01	1000 in 1 BOT Product 500 in 1 BOTT Product 90 in 1 BOTTL Product 100 in 1 BOTT Product	<b>ckage Descri</b> ITLE; Type 0: Not ILE; Type 0: Not a E; Type 0: Not a IE; Type 0: Not a	ption a Combination Combination Combination Combination	05/0 01/0 05/0	Date 02/2019 01/2040 02/2019	Mark	

levothyroxine sodium tablet

#### **Product Information**

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Ro	oute of Admini	stration	ORAL					
Aq	ctive Ingredi	ent/Active	e Moiety					
		Ingrea	lient Name			Basis of Stre	ngth	Strengt
	VOTHYROXINE 9 III:Q51BO43MG4)	SODIUM (UNI	: 9J765S329G) (LEVOTHYF	ROXINE -		LEVOTHYROXINE SOD ANHYDROUS	IUM	0.075 mg
In	active Ingre	dients						
			Ingredient Name				Str	ength
			NII: M28OL1HH48)					
	&C BLUE NO. 2							
	&C RED NO. 40							
		•	0097M6I30)					
	ANNITOL (UNII: 3) DIUM BICARBO							
	ARCH, CORN (UI	· ·	· · ·					
_								
	roduct Chara			_				
	olor		E (Violet)	Score			2 piece	es
	ape	ROUNE	)	Size	<b>- C</b> -	-1 -	6mm	
	avor Intains			Imprin	τιο	ae	L17	
Pa	ackaging							
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#	item coue	Pa	ackage Description		Ma	arketing Start Date		ate
1			ackage Description	bination				
1 2	NDC:68180-967- 03 NDC:68180-967- 02	1000 in 1 BC Product 500 in 1 BOT Product	TTLE; Type 0: Not a Coml	ination	03/2	Date		
1 2 3	NDC:68180-967- 03 NDC:68180-967- 02 NDC:68180-967- 09	1000 in 1 BC Product 500 in 1 BOT Product 90 in 1 BOTT Product	TTLE; Type 0: Not a Comb TLE; Type 0: Not a Comb TLE; Type 0: Not a Combin	ination ation	03/2 01/0	<b>Date</b> 0/2019		
1 2 3	NDC:68180-967- 03 NDC:68180-967- 02 NDC:68180-967- 09	1000 in 1 BC Product 500 in 1 BOT Product 90 in 1 BOTT Product	TTLE; Type 0: Not a Coml	ination ation	03/2 01/0 03/2	<b>Date</b> 0/2019 1/2040		
1 2 3 4	NDC:68180-967- 03 NDC:68180-967- 02 NDC:68180-967- 09 NDC:68180-967- 01	1000 in 1 BC Product 500 in 1 BOT Product 90 in 1 BOT Product 100 in 1 BOT Product	TTLE; Type 0: Not a Comb TLE; Type 0: Not a Combi LE; Type 0: Not a Combin TLE; Type 0: Not a Combin	ination ation	03/2 01/0 03/2	Date           0/2019           1/2040           0/2019		
1 2 3 4	NDC:68180-967- 03 NDC:68180-967- 02 NDC:68180-967- 09 NDC:68180-967-	1000 in 1 BC Product 500 in 1 BOT Product 90 in 1 BOT Product 100 in 1 BOT Product	TTLE; Type 0: Not a Comb TLE; Type 0: Not a Combi LE; Type 0: Not a Combin TLE; Type 0: Not a Combin	ination ation	03/2 01/0 03/2	Date           0/2019           1/2040           0/2019		
1 2 3 4	NDC:68180-967- 03 NDC:68180-967- 02 NDC:68180-967- 09 NDC:68180-967- 01	1000 in 1 BC Product 500 in 1 BOT Product 90 in 1 BOT Product 100 in 1 BOT Product	TTLE; Type 0: Not a Comb TLE; Type 0: Not a Combi LE; Type 0: Not a Combin TLE; Type 0: Not a Combin	ination ation ination	03/2 01/0 03/2 03/2	Date           0/2019           1/2040           0/2019	Marke	

levothyroxine sodium tablet

PI	roduct Infor	mation					
Pr	oduct Type		HUMAN PRESCRIPTION DR	RUG	Item Code (S	Source)	NDC:68180-968
Ro	oute of Admini	stration	ORAL				
Ac	tive Ingredi	ent/Active	Moiety				
	<b>J</b>		ent Name		Basis	of Stren	gth Strengt
LEVOTHYROXINE SODIUM (UNII: 9J765S329G) (LEVOTHYROXINE - LEVOTHYROXINE SO UNII:Q51B043MG4) LEVOTHYROXINE - ANHYDROUS							
In	active Ingre	dients					
			Ingredient Name				Strength
CR	OSCARMELLOS	E SODIUM (UN	II: M28OL1HH48)				
D&	C YELLOW NO.	<b>10</b> (UNII: 355V	V5USQ3G)				
FD	&C BLUE NO. 1	(UNII: H3R47K3	STBD)				
FD	&C YELLOW NO	<b>.6</b> (UNII: H77∨	(EI93A8)				
MA	GNESIUM STEA	RATE (UNII: 70	097M6I30)				
MA	NNITOL (UNII: 3	OWL53L36A)					
	DIUM BICARBO ARCH, CORN (UI						
Pr	oduct Chara	acteristics					
	oduct Chara	acteristics GREEN	(Olive) S	Score			2 pieces
Co Sh	lor ape		S	Size			2 pieces 6mm
Co Sh	lor	GREEN	S		Code		
Co Sh Fla	lor ape	GREEN	S	Size	Code		6mm
Co Sh Fla Co	lor ape avor	GREEN	S	Size	Code		6mm
Co Sh Fla Co Pa	lor ape avor ntains	GREEN	S	Size	Code Marketing Date	Start	6mm
Co Sh Fla Co <b>Pa</b> #	lor ape avor ntains ackaging Item Code NDC:68180-968- 09	GREEN ROUND 90 in 1 BOTTL Product	ckage Description E; Type 0: Not a Combinati	Size mprint	Marketing	Start	6mm L19 Marketing End
Co Sh Fla Co Pa # 1	lor ape avor ntains ackaging Item Code NDC:68180-968- 09	GREEN ROUND 90 in 1 BOTTL Product 500 in 1 BOTT Product	ckage Description E; Type 0: Not a Combinati LE; Type 0: Not a Combina	Size Imprint ion	Marketing Date	Start	6mm L19 Marketing End
Co Sh Fla Co Pa # 1 2 3	lor ape avor ntains ackaging Item Code NDC:68180-968- 09 NDC:68180-968- 02 NDC:68180-968- 01	GREEN ROUND 90 in 1 BOTTL Product 500 in 1 BOTT Product 100 in 1 BOTT Product	ckage Description E; Type 0: Not a Combinati LE; Type 0: Not a Combina LE; Type 0: Not a Combina	ion ition	<b>Marketing</b> <b>Date</b> 03/20/2019 01/01/2040 03/20/2019	Start	6mm L19 Marketing End
Co Sh Fla Co Pa # 1 2 3	lor ape avor ntains ackaging Item Code NDC:68180-968- 09 NDC:68180-968- 02 NDC:68180-968- 01	GREEN ROUND 90 in 1 BOTTL Product 500 in 1 BOTT Product 100 in 1 BOTT Product	ckage Description E; Type 0: Not a Combinati LE; Type 0: Not a Combina	ion ition	<b>Marketing</b> <b>Date</b> 03/20/2019 01/01/2040	Start 6	6mm L19 Marketing End
Co Sh Fla Co Pa # 1 2 3 4	lor ape avor ntains ackaging Item Code NDC:68180-968- 02 NDC:68180-968- 01 NDC:68180-968- 01 NDC:68180-968- 01	GREEN ROUND 90 in 1 BOTTL Product 500 in 1 BOTT Product 100 in 1 BOTT Product 1000 in 1 BOTT Product	ckage Description E; Type 0: Not a Combinati LE; Type 0: Not a Combina LE; Type 0: Not a Combina TLE; Type 0: Not a Combina	ion ition	<b>Marketing</b> <b>Date</b> 03/20/2019 01/01/2040 03/20/2019	Start 6	6mm L19 Marketing End
Co Sh Fla Co Pa # 1 2 3 4	lor ape avor ntains ackaging Item Code NDC:68180-968- 02 NDC:68180-968- 01 NDC:68180-968- 01	GREEN ROUND 90 in 1 BOTTL Product 500 in 1 BOTT Product 100 in 1 BOTT Product 1000 in 1 BOTT Product	ckage Description E; Type 0: Not a Combinati LE; Type 0: Not a Combina LE; Type 0: Not a Combina TLE; Type 0: Not a Combina	ion ition	<b>Marketing</b> <b>Date</b> 03/20/2019 01/01/2040 03/20/2019	Start 6	6mm L19 Marketing End
Co Sh Fla Co Pa # 1 2 3 4	lor ape avor ntains ackaging Item Code NDC:68180-968- 02 NDC:68180-968- 01 NDC:68180-968- 01 NDC:68180-968- 01	GREEN ROUND Pace 90 in 1 BOTTL Product 500 in 1 BOTT Product 100 in 1 BOTT Product 1000 in 1 BOTT Product	ckage Description E; Type 0: Not a Combinati LE; Type 0: Not a Combina LE; Type 0: Not a Combina TLE; Type 0: Not a Combina	Size mprint ion ition ation	<b>Marketing</b> <b>Date</b> 03/20/2019 01/01/2040 03/20/2019	g Start	6mm L19 Marketing End

levothyroxine sodium tablet  Product Information Product Type HUMAN PRESCRIPTION DRUG Route of Administration ORAL  Active Ingredient/Active Moiety Ingredient Name Easis of Strength LEVOTHYROXINE SODIUM (UNII: 9)7655329() (LEVOTHYROXINE - EVOTHYROXINE SODIUM (UNII: 9)7655329() (LEVOTHYROXINE - UNII: 0518043MG4)  Inactive Ingredients Ingredient Name Ingredient Nam									
Product Type       HUMAN PRESCRIPTION DRUG       Item Code (Source)       NDC:68180-969         Route of Administration       ORAL       NDC:68180-969       NDC:68180-969         Active Ingredient/Active Moiety       Ingredient Name       Basis of Strength       Strength         LEVOTHYROXINE SODUM (UNII: 9/7655329G) (LEVOTHYROXINE -       LEVOTHYROXINE SODUM (UNII: 9/7655329G) (LEVOTHYROXINE -       LEVOTHYROXINE SODUM (UNII: 9/7655329G) (LEVOTHYROXINE -       Strength         Inactive Ingredients       Ingredient Name       Strength       Strength         CR05CARMELLOSE SODUM (UNII: 8/70/YEI93A8)       AntHYDROUS       0.1 mg         MANITOL (UNII: 30x453128A)       Sodium BicARBONATE (UNII: 700/97MG30)       AntHYDROUS       2 pieces         Sodium BicARBONATE (UNII: 800/5939Q0)       Strength       Ingredient Strength       2 pieces         Sodium BicARBONATE (UNII: 800/5939Q0)       Size       Gmm       2 pieces         Shape       ROUND       Size       Gmm       End         Product Characteristics       Imprint Code       2 pieces       Ingredient Date         Product Characteristics       Size       Gmm       2 pieces       Ingredient Date         Product Characteristics       Size       Gmm       Ingredient Date       2 pieces       Ingredient Date       Ingredient Date	levothyroxine soc	dium tablet							
Product Type       HUMAN PRESCRIPTION DRUG       Item Code (Source)       NDC:68180-969         Route of Administration       ORAL       NDC:68180-969       NDC:68180-969         Active Ingredient/Active Moiety       Ingredient Name       Basis of Strength       Strength         LEVOTHYROXINE SODUM (UNII: 9/7655329G) (LEVOTHYROXINE -       LEVOTHYROXINE SODUM (UNII: 9/7655329G) (LEVOTHYROXINE -       LEVOTHYROXINE SODUM (UNII: 9/7655329G) (LEVOTHYROXINE -       Strength         Inactive Ingredients       Ingredient Name       Strength       Strength         CR05CARMELLOSE SODUM (UNII: 8/70/YEI93A8)       AntHYDROUS       0.1 mg         MANITOL (UNII: 30x453128A)       Sodium BicARBONATE (UNII: 700/97MG30)       AntHYDROUS       2 pieces         Sodium BicARBONATE (UNII: 800/5939Q0)       Strength       Ingredient Strength       2 pieces         Sodium BicARBONATE (UNII: 800/5939Q0)       Size       Gmm       2 pieces         Shape       ROUND       Size       Gmm       End         Product Characteristics       Imprint Code       2 pieces       Ingredient Date         Product Characteristics       Size       Gmm       2 pieces       Ingredient Date         Product Characteristics       Size       Gmm       Ingredient Date       2 pieces       Ingredient Date       Ingredient Date	Product Infor	mation							
ORAL         Active Ingredient/Active Moiety         Ingredient Name       Basis of Strength       Strength         LEVOTHYROXINE SODIUM (UNI: 9)7655329G) (LEVOTHYROXINE -       LEVOTHYROXINE SODIUM (UNI: 9)7655329G) (LEVOTHYROXINE -         Ingredient Name       Executive Ingredients       Strength         Ingredient Name       LEVOTHYROXINE SODIUM (UNI: 9)7655329G) (LEVOTHYROXINE -       Strength         Ingredient Name       LEVOTHYROXINE SODIUM (UNI: 9)7655329G) (LEVOTHYROXINE -       Strength         CROSCARMELLOSE SODIUM (UNI: M280L1H480)       Strength         Strength       Strength         MANNTOCI (UNI: 30X5315(a)       Strength         SoDIUM (UNII: M2805114630)       MANNTOCI (UNII: 30X5315(a)         SoDIUM BICARBONATE (UNII: 800F5V39QO)       Strength         Strength       Solum       Strength         Product Char=Ceristics       2       Size       2       Size         Fackaging       Marketing Start       Marketing End       Marketing Start <th c<="" th=""><th></th><th></th><th>HUMAN PRESCRI</th><th></th><th>lter</th><th>n Code (Source)</th><th>NDO</th><th>C:68180-969</th></th>	<th></th> <th></th> <th>HUMAN PRESCRI</th> <th></th> <th>lter</th> <th>n Code (Source)</th> <th>NDO</th> <th>C:68180-969</th>			HUMAN PRESCRI		lter	n Code (Source)	NDO	C:68180-969
Active Ingredient/Active Moiety Ingredient Name EVOTHYROXINE SODIUM (UNII: 9)7655329G) (LEVOTHYROXINE - UNII: Q318043MG4) 0.1 mg ANHYDROUS 0.1 mg ANHYDROUS 0.1 mg ANHYDROUS 0.1 mg ANHYDROUS 0.1 mg CROSCARMELLOSE SODIUM (UNII: 9)7655329G) (LEVOTHYROXINE - LEVOTHYROXINE SODIUM CROSCARMELLOSE SODIUM (UNII: 9)7655329G) (LEVOTHYROXINE - CROSCARMELLOSE SODIUM (UNII: 9)76553929G) (LEVOTHYROXINE - CROSCARMELLOSE SODIUM (UNII: 9)76553929G) (LEVOTHYROXINE - CROSCARMELLOSE SODIUM (UNII: 70037M6130) MANNTOL (UNII: 355M505936) FD&C YELLOW NO. 10 (UNII: 355M505930) SODIUM BICARBONATE (UNII: 80DF5V3900) STARCH, CORN (UNII: 00232NY35)) Product Characteristics Color YELLOW Score 2 pieces Shape ROUND Size Grim E Flavor 1 20 120 120 120 120 120 120 120 120 12					itei	li code (Source)	NBC	2.00100 505	
Ingredient Name         Basis of Strength         Strength           LEVOTHYROXINE SODIUM (UNII: 9)7655329G) (LEVOTHYROXINE - UNII:0518043MG4)         0.1 mg         0.1 mg           Inactive Ingredients         Ingredient Name         Strength         Strength           CROSCARMELLOSE SODIUM (UNII: 9)7655329G) (LEVOTHYROXINE - MANHYDROUS         Strength         0.1 mg           Inactive Ingredients         Strength         Strength           CROSCARMELLOSE SODIUM (UNII: M280L1HH48)         Strength         Strength           DeC YELLOW NO. 10 (UNII: 305%DUG (3G)         Strength         Strength           MacMESIUM STEARATE (UNII: 70097M6I30)         Mannitol (UNII: 70097M6I30)         Strength           MacMeSIUM STEARATE (UNII: 800F5V39Q0)         Strength         Strength           SoDIUM BICARBONATE (UNII: 80455336A)         Score         2 pieces           Shape         ROUND         Size         6mm           Flavor         Imprint Code         L20         Contains           Packaging         Into In BOTTLE; Type 0: Not a Combination Product         03/20/2019         Strength           100 in 1 BOTTLE; Type 0: Not a Combination Product         03/20/2019         Strength         Strength           1 NDC:68180-969         Strength         Strength         Strength         Strength	Route of Admini	stration	UKAL						
Ingredient Name         Basis of Strength         Strength           LEVOTHYROXINE SODIUM (UNII: 9)7655329G) (LEVOTHYROXINE - UNII:0518043MG4)         0.1 mg         0.1 mg           Inactive Ingredients         Ingredient Name         Strength         Strength           CROSCARMELLOSE SODIUM (UNII: 9)7655329G) (LEVOTHYROXINE - MANHYDROUS         Strength         0.1 mg           Inactive Ingredients         Strength         Strength           CROSCARMELLOSE SODIUM (UNII: M280L1HH48)         Strength         Strength           DeC YELLOW NO. 10 (UNII: 305%DUG (3G)         Strength         Strength           MacMESIUM STEARATE (UNII: 70097M6I30)         Mannitol (UNII: 70097M6I30)         Strength           MacMeSIUM STEARATE (UNII: 800F5V39Q0)         Strength         Strength           SoDIUM BICARBONATE (UNII: 80455336A)         Score         2 pieces           Shape         ROUND         Size         6mm           Flavor         Imprint Code         L20         Contains           Packaging         Into In BOTTLE; Type 0: Not a Combination Product         03/20/2019         Strength           100 in 1 BOTTLE; Type 0: Not a Combination Product         03/20/2019         Strength         Strength           1 NDC:68180-969         Strength         Strength         Strength         Strength									
LEVOTHYROXINE SODIUM (UNII: 9)7655329G) (LEVOTHYROXINE - MHYDROUS         LEVOTHYROXINE SODIUM ANHYDROUS         0.1 mg           Inactive Ingredients         Strength           Inactive IngredientS         Ingredient Name         Strength           CROSCARMELLOSE SODIUM (UNII: M280L1HH48)         Strength           Dac YELLOW NO. 10 (UNII: M280L1HH48)         Strength           MacMesium StreARTE (UNII: 70097M6/30)           MACMESIUM STREARTE (UNII: 800F5V39QO)           STARCH, CORN (UNII: 800L55339QO)           Strect Street Stre	Active Ingredi	ent/Active	Moiety						
UNINEQSIBO43MG4)         Ingredient Name         ANHYDROUS         UTING           Inactive Ingredients         Ingredient Name         Strength           CROSCARMELLOSE SODIUM (UNIE: M28011H48)         Strength         Improvide Strength         Improvide Strength           DBC YELLOW NO. 10 (UNIE: 355/05030)         BGC VELLOW NO. 10 (UNIE: 70097/06130)         Improvide Strength         Improvide Strength           MARNESIUM STEARATE (UNIE: 70097/06130)         MARNITOL (UNIE: 08232NY35)         Improvide Strength         Improvide Strength           StarCH, CORN (UNIE: 08232NY35)         Store         2 pieces           Shape         ROUND         Size         Gmm           Flavor         Imprint Code         L20           Contains         Imprint Code         L20           Packaging         Package Descripton         Marketing Start         Marketing End           1         NDC:68180-969- 100 in 1 BOTTLE; Type 0: Not a Combination 03/20/2019         03/20/2019         Imprint Code           1         NDC:68180-969- 300 in 1 BOTTLE; Type 0: Not a Combination 03/20/2019         03/20/2019         Imprint Code           1         NDC:68180-969- 90 in 1 BOTTLE; Type 0: Not a Combination 03/20/2019         03/20/2019         Imprint Code           1         NDC:68180-969- 90 in 1 BOTTLE; Type 0: Not a Combination 03/20/2019         <		Ingredi	ent Name			Basis of Stre	ength	Strength	
Ingredient Name       Strength         CROSCARMELLOSE SODIUM (UNII: M280L1HH48)       Strength         Dac YELLOW NO. 10 (UNII: S35W5USQ3G)		SODIUM (UNII:	9J765S329G) (LEV	OTHYROXINE -			DUM	0.1 mg	
CROSCARMELLOSE SODIUM (UNII: M280L1HH48)         Image: Croscard (UNI: Signature)         Image: Croscard (UNI: Croscard (UNI: Signature))         Image: Croscard (UNI: Croscard (UNI: Signature))         Image: Croscard (UNI: Croscard (UNI: Croscard (UNI: Signature)))         Image: Croscard (UNI: Croscard (UNI	Inactive Ingre	dients							
D≼C YELLOW NO. 10 (UNII: 35SW5US03G)       Image: Simple Si			Ingredient N	lame			S	trength	
FD-6C YELLOW NO. 6 (UNII: H77VEI93A8)       Image: Second S		-	-						
MaGNESIUM STEARATE (UNII: 3004/53L36A)       Image: Start (UNII: 3004/53L36A)         SODIUM BICARBONATE (UNII: 800/55399(O)       Image: Start (UNII: 800/55399(O))         STARCH, CORN (UNII: 08232NY35))       Image: Start (UNII: 800/55399(O))         Product Characteristics       2 pieces         Color       YELLOW       Score       2 pieces         Shape       ROUND       Size       6mm         Flavor       Imprint Code       Imprint Code       120         Ontains       Imprint Code       Marketing End       Date       120         V       V       Stare       Stare       Stare       Stare         I       NDC:68180-969-       100 in 1 BOTTLE; Type 0: Not a Combination 01/01/2040       01/01/2040       Stare       Stare         2       NDC:68180-969-       20 in 1 BOTTLE; Type 0: Not a Combination 03/20/2019       01/01/2040       Stare       Stare       Stare         3       NDC:68180-969-       90 in 1 BOTTLE; Type 0: Not a Combination 03/20/2019       03/20/2019       Stare       Stare       Stare         4       NDC:68180-969-       90 in 1 BOTTLE; Type 0: Not a Combination 03/20/2019       03/20/2019       Stare       Stare       Stare         3       NDC:68180-969-       90 in 1 BOTTLE; Type 0: Not a Combination 03/20/2019									
MANNITOL (UNII: 30WL53L36A)       Image: Starch, CORN (UNII: 80DF5V39QO)       Image: Starch, CORN (UNII: 08232NY3S)         Starch, CORN (UNII: 08232NY3S)         Product Characteristics         VELLOW       Score       2 pieces         Size       6mm         Imprint Code       L20         Contains         VelLoW       Size       6mm         Imprint Code       L20         Contains         Vertice Site Site Site Site Site Site Site Sit									
SOLUM BICARBONATE (UNII: 8MDF5V39QO)STARCH, CORN (UNII: 08232NY3SI)Product CharscreteristicsVELLOWScore2 piecesSize6mmFlavorQUNDSize6mmContainsMarkting EndDateProductSizeSizeSizeFlavorContainsMarkting EndPackage DescriptionMarketing EndDatePolici8180-969- 01100 in 1 BOTTLE; Type 0: Not a Combination 01/2040Olyc0/2019GateGotNDC:68180-969- 02Sion in 1 BOTTLE; Type 0: Not a Combination 03Olyc0/2019GateGotNDC:68180-969- 03Sion in 1 BOTTLE; Type 0: Not a Combination 03Olyc0/2019GateGotMarketing End DateNDC:68180-969- 03Sion in 1 BOTTLE; Type 0: Not a Combination 03Olyc0/2019GateGotNDC:68180-969- 90Sion in 1 BOTTLE; Type 0: Not a Combination 03/20/2019Olyc0/2019GateGotMarketing End DateNDC:68180-969- 90Ol in 1 BOTTLE; Type 0: Not a Combination 03/20/2019Olyc0/2019<			097M6I30)						
STARCH, CORN (UNII: 08232NY35J)VICLOW S0232NY35J)VICLOW S0232NY35J)Marketing Start D01 1 B OTTLE; Type 0: Not a Combination Product03/20/2019001 1 B OTTLE; Type 0: Not a Combination Product03/20/201901/01/2040OUCLOW IN BOTTLE; Type 0: Not a Combination Product03/20/20190100 in 1 B OTTLE; Type 0: Not a Combination Product03/20/201901/01/204001/01/204001/01/204001/01/204001/01/204001/01/204001/01/204001/01/204001/01/204001/01/2040 <th colsp<="" td=""><td></td><td></td><th></th><td></td><td></td><td></td><td></td><th></th></th>	<td></td> <td></td> <th></th> <td></td> <td></td> <td></td> <td></td> <th></th>								
VelLOW       Score       2 pieces         Colspan="4">Colspan="4"Colspan="4">Colspan="4"Colspan="4"Colspan="4">Colspan="4"Colspan="4"Colspan="4">Colspan="4"Colspan=									
Size			LOW	Score			2 pieces	5	
Imprint Code       Iz0         Imprint Code         V V V V V V V V V V V V V V V V V V V	Shape	ROU	IND						
Marketing Start Date       Marketing End Date         #       Item Code       Package Description       Marketing Start Date       Marketing End Date         1       NDC:68180-969-       100 in 1 BOTTLE; Type 0: Not a Combination Product       03/20/2019       01/01/2040         2       NDC:68180-969-       500 in 1 BOTTLE; Type 0: Not a Combination Product       01/01/2040       03/20/2019         3       NDC:68180-969-       1000 in 1 BOTTLE; Type 0: Not a Combination Product       03/20/2019       03/20/2019         4       NDC:68180-969-       90 in 1 BOTTLE; Type 0: Not a Combination Product       03/20/2019       03/20/2019         Freduct         Marketing Category         Marketing Start Date	-			Imprint Code			L20		
#Item CodePackage DescriptionMarketing Start DateMarketing End Date1NDC:68180-969- 01100 in 1 BOTTLE; Type 0: Not a Combination Product03/20/201903/20/20192NDC:68180-969- 02500 in 1 BOTTLE; Type 0: Not a Combination Product01/01/204001/01/20403NDC:68180-969- 021000 in 1 BOTTLE; Type 0: Not a Combination Product03/20/201903/20/20194NDC:68180-969- 0990 in 1 BOTTLE; Type 0: Not a Combination Product03/20/201903/20/20195NDC:68180-969- 0990 in 1 BOTTLE; Type 0: Not a Combination Product03/20/201903/20/2019Harketing Tormation Marketing CategoryApplication Number or Monograph CitationMarketing Start DateMarketing End Date	Contains								
#Item CodePackage DescriptionMarketing Start DateMarketing End Date1NDC:68180-969- 01100 in 1 BOTTLE; Type 0: Not a Combination Product03/20/201903/20/20192NDC:68180-969- 02500 in 1 BOTTLE; Type 0: Not a Combination Product01/01/204001/01/20403NDC:68180-969- 021000 in 1 BOTTLE; Type 0: Not a Combination Product03/20/201903/20/20194NDC:68180-969- 0990 in 1 BOTTLE; Type 0: Not a Combination Product03/20/201903/20/20195NDC:68180-969- 0990 in 1 BOTTLE; Type 0: Not a Combination Product03/20/201903/20/2019Harketing Tormation Marketing CategoryApplication Number or Monograph CitationMarketing Start DateMarketing End Date									
# Item CodePackage DescriptionDateDate1NDC:68180-969100 in 1 BOTTLE; Type 0: Not a Combination Product03/20/201901/01/20402NDC:68180-969500 in 1 BOTTLE; Type 0: Not a Combination Product03/20/201901/01/20403NDC:68180-969000 in 1 BOTTLE; Type 0: Not a Combination Product03/20/201903/20/20194NDC:68180-96900 in 1 BOTTLE; Type 0: Not a Combination Product03/20/201903/20/20195Marketing End DateMarketing End DateMarketing End Date	Packaging								
1       01       Product       05/2012019       05/2012019         2       NDC:68180-969- 02       500 in 1 BOTTLE; Type 0: Not a Combination Product       01/01/2040       03/20/2019         3       NDC:68180-969- 03       1000 in 1 BOTTLE; Type 0: Not a Combination Product       03/20/2019       03/20/2019         4       NDC:68180-969- 09       90 in 1 BOTTLE; Type 0: Not a Combination Product       03/20/2019       03/20/2019	# Item Code	Pa	ckage Descrip	otion	Ma		Mark	-	
2       Product       01/01/2040         3       NDC:68180-969- 03       1000 in 1 BOTTLE; Type 0: Not a Combination Product       03/20/2019         4       NDC:68180-969- 09       90 in 1 BOTTLE; Type 0: Not a Combination Product       03/20/2019         Marketing Tromation         Marketing Category         Application Number or Monograph Citation       Marketing Start Date       Marketing End Date			LE; Type 0: Not a	Combination	03/20	)/2019			
3       03       Product       03/20/2019         4       NDC:68180-969- 09       90 in 1 BOTTLE; Type 0: Not a Combination Product       03/20/2019         Marketing Information         Marketing Category         Application Number or Monograph Citation       Marketing Start Date       Marketing End Date			LE; Type 0: Not a	Combination	01/01	L/2040			
4     09     Product     03/20/2019       OS/20/2019       OS/20/2019 <td< td=""><td></td><td></td><th>TLE; Type 0: Not a</th><td>a Combination</td><td>03/20</td><td>)/2019</td><td></td><th></th></td<>			TLE; Type 0: Not a	a Combination	03/20	)/2019			
Marketing CategoryApplication Number or Monograph CitationMarketing Start DateMarketing End Date	4		E; Type 0: Not a C	Combination	03/20	)/2019			
Marketing CategoryApplication Number or Monograph CitationMarketing Start DateMarketing End Date									
Marketing CategoryApplication Number or Monograph CitationMarketing Start DateMarketing End Date	Marketing	Informat	ion						
	Marketing		tion Number o	r Monograph	r		Mar		
			Citation			Date		Date	

	VOTHYRC		DIUM						
ev	othyroxine soc	num tablet							
Р	roduct Infor	mation							
	oduct Type		HUMAN PRESCRIPTIO		lta	m Code (Source)	NDC	8180-970	
		atration	ORAL		ite	in code (source)	NDC.C	0100-970	
R	oute of Admini	stration	ORAL						
۸.	ctive Ingredi	ont/Activo	Mojety						
~	cuve mgrea		-			Basis of Strer	ath	Strength	
						LEVOTHYROXINE SODI	-	0.112 mg	
In	active Ingre	dients							
			Ingredient Nam	е			Str	ength	
CF	OSCARMELLOS	E SODIUM (UN	III: M28OL1HH48)						
	C RED NO. 27 (								
	AGNESIUM STEA		097M6I30)						
	ANNITOL (UNII: 3								
	DIUM BICARBO ARCH, CORN (UI								
D	roduct Chara	octoristics							
	olor		(Rose)	Score			2 pieces		
	ape	ROUN		Size			6mm		
	avor			Imprint Co	ode		L21		
Co	ontains			•					
Pa	ackaging								
#	ltem Code	Pa	ckage Description	n	Μ	arketing Start Date		ting End ate	
1	NDC:68180-970- 01	100 in 1 BOTT Product	TLE; Type 0: Not a Com	bination	03/2	0/2019			
2	NDC:68180-970- 02	500 in 1 BOTT Product	TLE; Type 0: Not a Com	bination	01/0	1/2040			
3	03	Product	TLE; Type 0: Not a Cor		03/2	0/2019			
4	NDC:68180-970- 09	90 in 1 BOTTL Product	.E; Type 0: Not a Comb	ination	03/2	0/2019			
Μ	larketing	Informat	ion						
	Marketing Category	Applica	tion Number or Mo	onograph		Marketing Start Date		eting End Date	
	category		Citation					ace	
AN	DA	ANDA20971			03	8/20/2019			

	dium tablet							
Product Infor	mation							
Product Type		HUMAN PRESCRIPTION	DRUG	ltem	Code (Source)	NDC:	68180-971	
Route of Admini	istration	ORAL						
Active Ingredi	ient/Active	e Moiety						
J		lient Name			Basis of Stre	nath	Strengt	
<b>LEVOTHYROXINE</b> UNII:Q51BO43MG4)	SODIUM (UNII	: 9J765S329G) (LEVOTHYF	ROXINE -		/OTHYROXINE SOD HYDROUS	-	0.125 mg	
Inactive Ingre	dients							
		Ingredient Name				St	rength	
CROSCARMELLOS	E SODIUM (U	-						
FD&C BLUE NO. 1	UNII: H3R47k	(3TBD)						
FD&C BLUE NO. 2	(UNII: L06K8R	7DQK)						
FD&C RED NO. 40	(UNII: WZB91	27XOA)						
FD&C YELLOW NO	<b>). 6</b> (UNII: H77	VEI93A8)						
MAGNESIUM STEA	RATE (UNII: 7	0097M6I30)						
MANNITOL (UNII: 3	OWL53L36A)							
SODIUM BICARBO	NATE (UNII: 8	MDF5V39QO)						
STARCH, CORN (U	NII: 08232NY3	SJ)						
Product Chara	acteristics	i						
Color	BROW	N (Tan)	Score			2 piece	S	
Shape	ROUN		Size			6mm		
Flavor			Imprint C					
Contains								
Packaging	_	- akawa Decemintian		Mar	keting Start Date		ting End ate	
	Pi	ackage Description						
# Item Code		TLE; Type 0: Not a Combi	ination (	)3/20/2	019			
#         Item Code           1         NDC:68180-971- 01           2         NDC:68180-971- 02	100 in 1 BOT Product 500 in 1 BOT Product	TLE; Type 0: Not a Combi	ination (	)3/20/2 )1/01/2				
<ul> <li># Item Code</li> <li>1 NDC:68180-971- 01</li> <li>2 NDC:68180-971- 02</li> <li>3 NDC:68180-971- 03</li> </ul>	100 in 1 BOT Product 500 in 1 BOT Product 1000 in 1 BO Product	TLE; Type 0: Not a Combi TLE; Type 0: Not a Combi TTLE; Type 0: Not a Combi	ination (		.040			
<ul> <li># Item Code</li> <li>1 NDC:68180-971- 01</li> <li>2 NDC:68180-971- 02</li> <li>3 NDC:68180-971- 03</li> <li>1 NDC:68180-971- 03</li> </ul>	100 in 1 BOT Product 500 in 1 BOT Product 1000 in 1 BO Product	TLE; Type 0: Not a Combi	ination (	)1/01/2	040			
<ul> <li># Item Code</li> <li>1 NDC:68180-971- 01</li> <li>2 NDC:68180-971- 02</li> <li>3 NDC:68180-971- 03</li> <li>4 NDC:68180-971- 09</li> </ul>	100 in 1 BOT Product 500 in 1 BOT Product 1000 in 1 BO Product 90 in 1 BOTT Product	TLE; Type 0: Not a Combi TLE; Type 0: Not a Combi TTLE; Type 0: Not a Combi TE; Type 0: Not a Combin	ination (	)1/01/2 )3/20/2	040			
<ul> <li>NDC:68180-971- 01</li> <li>NDC:68180-971- 02</li> <li>NDC:68180-971- 03</li> <li>NDC:68180-971- 03</li> </ul>	100 in 1 BOT Product 500 in 1 BOT Product 1000 in 1 BO Product 90 in 1 BOTT Product	TLE; Type 0: Not a Combi TLE; Type 0: Not a Combi TTLE; Type 0: Not a Combi TE; Type 0: Not a Combin	ination (	)1/01/2 )3/20/2	040			

03/20/2019

Marketing	Informa	tion						
03								
	FIGUULL							
03 4 NDC:68180-972		LE; Type 0: Not a Comb	pination	03/20/2019				
NDC:68180-972		TTLE; Type 0: Not a Co	mbination	03/20/2019				
		TLE; Type 0: Not a Com	bination	01/01/2040				
<b>1</b> NDC:68180-972	- 100 in 1 BOT Product	TLE; Type 0: Not a Com	bination	03/20/2019				
# Item Code	Pa	ackage Descriptio	n		ing Start ate		ing End ate	
Packaging								
Contains								
Flavor			Imprint Co	ode		L23		
Shape	ROUN		Size			6mm		
Product Chai Color		UOISE	Score			2 pieces		
STARCH, CORN (	JNII: 08232NY3	SJ)						
SODIUM BICARB								
MANNITOL (UNII:								
FD&C BLUE NO. MAGNESIUM STE								
	•							
		Ingredient Nam	e			Stre	ength	
Inactive Ingr	edients							
LEVOTHYROXINE UNII:Q51BO43MG4		: 9J765S329G) (LEVOTH	TROXINE -	LEVOT ANHYD	HYROXINE SODII ROUS	UM	0.137 mg	
	-	lient Name			asis of Stren	-	Strengt	
Active Ingred	lient/Active	Moiety						
Route of Admir	nistration	ORAL						
Product Type		HUMAN PRESCRIPTION DRUG		Item Code (Source)		NDC:68	NDC:68180-972	
<b>Product Info</b>	rmation							
evothyroxine so	dium tablet							

03/20/2019

	thyroxine soo		·				
Pro	oduct Infor	mation					
Pro	duct Type		HUMAN PRESC	RIPTION DRUG	Item Code (Sourc	e) NC	DC:68180-973
Rou	ite of Admini	stration	ORAL				
Act	ive Ingredi	ent/Activ	e Moiety				
		Ingree	dient Name		Basis of S	Strengt	
	VOTHYROXINE SODIUM (UNII: 9J765S329G) (LEVOTHYROXINE - LEVOTHYROXINE SODIUM II:Q51B043MG4) ANHYDROUS			ODIUM	0.15 mg		
Ina	ctive Ingre	dients					
	g		Ingredient	Name			Strength
CRO	SCARMELLOS	E SODIUM (L	JNII: M28OL1HH48				
	C BLUE NO. 2						
MAG	NESIUM STEA	RATE (UNII: 7	70097M6I30)				
	INITOL (UNII: 3						
	IUM BICARBO						
STA	RCH, CORN (UI	NII: 08232NY:	351)				
			,				
Colo		В	s LUE	Score		2 piece	25
Colo Sha	or pe	В	5	Size		6mm	25
Colo Sha Flav	pe vor	В	s LUE			-	25
Cold Sha Flav Con	or pe or tains	В	s LUE	Size		6mm	25
Cold Sha Flav Con	pe vor	В	s LUE	Size		6mm L24	
Cold Sha Flav Con Pac	or pe or tains	B	s LUE	Size Imprint Code	Marketing Start Date	6mm L24	es keting End Date
Cold Sha Flav Con Pac	or pe vor tains :kaging Item Code DC:68180-973-	P	<b>S</b> LUE OUND	Size Imprint Code	-	6mm L24	keting End
Cold Sha Flav Con Pac # 1 Not State	or pe vor tains ckaging Item Code DC:68180-973- 1 DC:68180-973- 2	B R P 100 in 1 BO Product 500 in 1 BO Product	S LUE OUND Package Descr TTLE; Type 0: Not TTLE; Type 0: Not	Size Imprint Code Imprint Code imprint Code Code Code Code Code Code Code Code	Date	6mm L24	keting End
Cold Sha Flav Con Pac # 1 $\stackrel{\text{No}}{}_{0}$ 2 $\stackrel{\text{No}}{}_{0}$ 3 $\stackrel{\text{No}}{}_{0}$	or pe vor tains :kaging Item Code DC:68180-973- 1 DC:68180-973- 2 DC:68180-973- 3	B R R 100 in 1 BO Product 500 in 1 BO Product	S LUE OUND Package Descr TTLE; Type 0: Not TTLE; Type 0: Not DTTLE; Type 0: Not	Size Imprint Code Imprint Code Imprint Code Code Imprint	<b>Date</b> 03/20/2019	6mm L24	keting End
Cold Sha Flav Con Pac # 1 $\stackrel{\text{No}_1}{\text{O}_2}$ 3 $\stackrel{\text{No}_2}{\text{O}_2}$	or pe vor tains :kaging Item Code DC:68180-973- 1 DC:68180-973- 2 DC:68180-973- 3 DC:68180-973-	B R R 100 in 1 BO Product 500 in 1 BO Product	S LUE OUND Package Descr TTLE; Type 0: Not TTLE; Type 0: Not	Size Imprint Code Imprint Code Imprint Code Code Imprint	Date 03/20/2019 01/01/2040	6mm L24	keting End
Cold Sha Flav Con Pac # 1 No 2 No 3 No 3 No 9	or pe vor tains ckaging ltem Code DC:68180-973- 1 DC:68180-973- 2 DC:68180-973- 3 DC:68180-973- 3	B R R 100 in 1 BO Product 500 in 1 BO Product 1000 in 1 BO Product 90 in 1 BO Product	S LUE OUND Package Descr TTLE; Type 0: Not TTLE; Type 0: Not DTTLE; Type 0: Not DTTLE; Type 0: Not TLE; Type 0: Not a	Size Imprint Code Imprint Code Imprint Code Code Imprint	Date           03/20/2019           01/01/2040           03/20/2019	6mm L24	keting End
Cold Sha Flav Con Pac # 1 0: 2 0: 3 0: 3 0: 4 0: 9 4 0: 9	or pe vor tains :kaging Item Code DC:68180-973- 1 DC:68180-973- 2 DC:68180-973- 3 DC:68180-973-	B R P 100 in 1 BO Product 500 in 1 BO Product 1000 in 1 BO Product 90 in 1 BO Product	S LUE OUND Package Descr TTLE; Type 0: Not TTLE; Type 0: Not DTTLE; Type 0: Not DTTLE; Type 0: Not TLE; Type 0: Not a	Size Imprint Code Imprint Code Combination Combination Combination	Date           03/20/2019           01/01/2040           03/20/2019	6mm L24 Mar	keting End

03/20/2019

Pr	oduct Infor	mation							
Pr	oduct Type		HUMAN PRESCRIPT	ION DRUG	lte	m Code (Source)	NDC:68180-974		
	ute of Admini	stration	ORAL						
Ac	tive Ingredi	ent/Active	Moiety						
		Ingredi	ent Name			Basis of Stre	ength	Strengt	
	VOTHYROXINE S II:Q51BO43MG4)	SODIUM (UNII:	9J765S329G) (LEVO	THYROXINE -		LEVOTHYROXINE SOI ANHYDROUS	NUIC	0.175 mg	
Ina	active Ingre	dients							
			Ingredient Na	me			S	trength	
CR	OSCARMELLOS								
		UNII: 2LRS185U	6K)						
	-			FD&C BLUE NO. 1 (UNII: H3R47K3TBD)					
FD	&C BLUE NO. 1		STBD)						
FD MA	&C BLUE NO. 1 GNESIUM STEA	RATE (UNII: 70	STBD)						
F D MA MA	&C BLUE NO. 1 GNESIUM STEA NNITOL (UNII: 3	<b>RATE</b> (UNII: 70 OWL53L36A)	097M6I30)						
FD MA MA SO	&C BLUE NO. 1 GNESIUM STEA	RATE (UNII: 70 OWL53L36A) NATE (UNII: 8M	DF5V39QO)						
FD MA MA SO	&C BLUE NO. 1 GNESIUM STEA NNITOL (UNII: 3 DIUM BICARBO	RATE (UNII: 70 OWL53L36A) NATE (UNII: 8M	DF5V39QO)						
FD MA MA SO ST	&C BLUE NO. 1 GNESIUM STEA NNITOL (UNII: 3 DIUM BICARBO	RATE (UNII: 70 OWL53L36A) NATE (UNII: 8M NII: 08232NY3S	DF5V39QO)						
FD MA MA SO ST	&C BLUE NO. 1 IGNESIUM STEA INNITOL (UNII: 3 DIUM BICARBO ARCH, CORN (UI	RATE (UNII: 70 OWL53L36A) NATE (UNII: 8M NII: 08232NY3S	DF5V39QO)	Score			2 piec	ces	
FD MA SO ST/ Pr Co	&C BLUE NO. 1 GNESIUM STEA INNITOL (UNII: 3 DIUM BICARBO ARCH, CORN (UI	RATE (UNII: 70         OWL53L36A)         NATE (UNII: 8M         NII: 08232NY3S         Acteristics	DF5V39QO)	Score Size			2 piec 6mm	ces	
FD MA SO ST Pr Co Sh Fla	&C BLUE NO. 1 AGNESIUM STEA INNITOL (UNII: 3 DIUM BICARBO ARCH, CORN (UI COduct Chara Ior ape	RATE (UNII: 70 OWL53L36A) NATE (UNII: 8M NII: 08232NY3S Acteristics PURPLE	DF5V39QO)		t Coc	le		ces	
FD MA SO ST Pr Co Sh Fla	&C BLUE NO. 1 GNESIUM STEA INNITOL (UNII: 3 DIUM BICARBO ARCH, CORN (UI Oduct Chara Ior ape	RATE (UNII: 70 OWL53L36A) NATE (UNII: 8M NII: 08232NY3S Acteristics PURPLE	DF5V39QO)	Size	t Coc	le	6mm	:es	
FD MA SO ST Co Sh Fla Co	&C BLUE NO. 1 AGNESIUM STEA INNITOL (UNII: 3 DIUM BICARBO ARCH, CORN (UI COduct Chara Ior ape	RATE (UNII: 70 OWL53L36A) NATE (UNII: 8M NII: 08232NY3S Acteristics PURPLE	DF5V39QO)	Size			6mm L25		
FDA MA SO STA Co Sh Fla Co	&C BLUE NO. 1 GNESIUM STEA INNITOL (UNII: 3 DIUM BICARBO ARCH, CORN (UI oduct Chara lor ape ivor ntains	ARATE (UNII: 70) OWL53L36A) NATE (UNII: 8M NII: 08232NY3S ACTERISTICS PURPLE ROUND	DF5V39QO)	Size Imprint		le arketing Start Date	6mm L25 Mark	ting End	
FD MA SO ST Co Sh Fla Co Pa #	&C BLUE NO. 1 AGNESIUM STEA ANNITOL (UNII: 3 DIUM BICARBO ARCH, CORN (UNI CODUCT Chara Ior ape Ivor Intains ACKaging Item Code	RATE (UNII: 70) OWL53L36A) NATE (UNII: 8M NII: 08232NY3S ACTERISTICS PURPLE ROUND	TBD) 097M6I30) DF5V39QO) J) (Lilac)	Size Imprint	M	arketing Start	6mm L25 Mark	eting End	
FD MA SO ST/ Co Sh Fla Co Pa # 1	&C BLUE NO. 1 AGNESIUM STEA INNITOL (UNII: 3 DIUM BICARBO ARCH, CORN (UNII: 3 CODUCT Chara Ior ape ivor ntains ACKaging Item Code NDC:68180-974- 01 NDC:68180-974- 02	RATE (UNII: 70) OWL53L36A) NATE (UNII: 8M NII: 08232NY3S ACTERISTICS PURPLE ROUND 100 in 1 BOTT Product 500 in 1 BOTT Product	TBD)         097M6I30)         IDF5V39QO)         J)         (Lilac)         ckage Descripti         LE; Type 0: Not a Co         LE; Type 0: Not a Co	Size Imprint	<b>M</b> 03/2	arketing Start Date	6mm L25 Mark	eting End	
FD MA SO ST Co Sh Fla Co Pa # 1	&C BLUE NO. 1 AGNESIUM STEA ANNITOL (UNII: 3 DIUM BICARBO ARCH, CORN (UNII: 3 CODUCT Chara Ior ape Nor ntains ACKaging Item Code NDC:68180-974- 01 NDC:68180-974- 02 NDC:68180-974- 03	RATE (UNII: 70) OWL53L36A) NATE (UNII: 8M NII: 08232NY3S ACTERISTICS PURPLE ROUND 100 in 1 BOTT Product 1000 in 1 BOTT Product 1000 in 1 BOTT Product	TBD) 097M6I30) DF5V39QO) J) (Lilac) ckage Descripti LE; Type 0: Not a Co	ion ombination Combination	<b>M</b> 03/2 01/0	arketing Start Date 0/2019	6mm L25 Mark	eting End	

ANI	Marketing Category	Applic	ation Number Citatio		Marketing Start Date		eting End Date
	DA	ANDA2097	713		03/20/2019		
.E	VOTHYRC	DXINE S	ODIUM				
eve	othyroxine so	dium tablet					
Pr	roduct Infor	mation					
Product Type		HUMAN PRESCI	RIPTION DRUG	Item Code (Source)	NDC:	68180-975	
Route of Administration		ORAL					
Λ.	tivo Ingradi	ont/Activ	o Moioty				
AC	tive Ingredi		dient Name		Basis of Stre	nath	Strengt
LE،		-	ll: 9J765S329G) (LE	EVOTHYROXINE -		-	
	II:Q51BO43MG4)				ANHYDROUS		0.2 mg
In	active Ingre	dients					
			Ingredient	Name		St	rength
CR	OSCARMELLOS	E SODIUM (L	JNII: M28OL1HH48				
FD	&C RED NO. 40	(UNII: WZ B91	L27XOA)				
MA	GNESIUM STEA	RATE (UNII: 7	70097M6I30)				
MA	NNITOL (UNII: 3	OWL53L36A)					
	DIUM BICARBO						
ST	ARCH, CORN (U	NII: 08232NY3	3SJ)				
Pr	oduct Chara	acteristics	5				
	lor	D		Score			
	Color PIN		INK	JUIE		2 pieces	
Co	ape		OUND	Size		2 pieces 6mm	
Co Sh						-	
Co Sh Fla	ape			Size		6mm	
Co Sh Fla	ape avor			Size		6mm	
Co Sh Fla Co	ape avor ntains			Size		6mm	
Co Sh Fla Co <b>P</b> a	ape avor	R	OUND	Size Imprint Code	Marketing Start	6mm L26 Marke	eting End
Co Sh Fla Co <b>P</b> a	ape avor intains ackaging Item Code	P		Size Imprint Code iption	Marketing Start Date	6mm L26 Marke	eting End Date
Co Sh Fla Co <b>Pa</b> 1	ape avor intains ackaging Item Code NDC:68180-975- 03	R P 1000 in 1 BC Product	OUND P <b>ackage Descr</b> DTTLE; Type 0: Not	Size Imprint Code iption t a Combination	Marketing Start Date 03/20/2019	6mm L26 Marke	
Co Sh Fla Co Pa #	ape avor intains ackaging Item Code NDC:68180-975- 03 NDC:68180-975- 02	P 1000 in 1 BC Product 500 in 1 BO Product	OUND P <b>ackage Descr</b> DTTLE; Type 0: Not TTLE; Type 0: Not	Size Imprint Code iption t a Combination a Combination	Marketing Start Date	6mm L26 Marke	
Co Sh Fla Co Pa # 1 2 3	ape avor intains ackaging Item Code NDC:68180-975- 03 NDC:68180-975- 02	P 1000 in 1 BC Product 500 in 1 BO Product	OUND P <b>ackage Descr</b> DTTLE; Type 0: Not	Size Imprint Code iption t a Combination a Combination	Marketing Start Date 03/20/2019	6mm L26 Marke	
Co Sh Fla Co Pa # 1 2 3 4	ape avor intains ackaging Item Code NDC:68180-975- 03 NDC:68180-975- 02 NDC:68180-975- 01	P 1000 in 1 BC Product 500 in 1 BC Product 100 in 1 BC Product	OUND P <b>ackage Descr</b> DTTLE; Type 0: Not TTLE; Type 0: Not	Size Imprint Code iption t a Combination a Combination a Combination	Marketing Start           Date           03/20/2019           01/01/2040	6mm L26 Marke	
Co Sh Fla Co Pa # 1 2 3 4	ape avor intains ackaging Item Code NDC:68180-975- 02 NDC:68180-975- 01 NDC:68180-975- 01 NDC:68180-975-	P 1000 in 1 BC Product 500 in 1 BO Product 100 in 1 BO Product 90 in 1 BOT	OUND <b>ackage Descr</b> DTTLE; Type 0: Not TTLE; Type 0: Not TTLE; Type 0: Not	Size Imprint Code iption t a Combination a Combination a Combination	Marketing Start         03/20/2019         01/01/2040         03/20/2019	6mm L26 Marke	
Co 5h Fla Co Pa #	ape avor intains ackaging Item Code NDC:68180-975- 02 NDC:68180-975- 01 NDC:68180-975- 01 NDC:68180-975-	P 1000 in 1 BC Product 500 in 1 BO Product 100 in 1 BO Product 90 in 1 BOT	OUND <b>ackage Descr</b> DTTLE; Type 0: Not TTLE; Type 0: Not TTLE; Type 0: Not	Size Imprint Code iption t a Combination a Combination a Combination	Marketing Start         03/20/2019         01/01/2040         03/20/2019	6mm L26 Marke	

	Marketing Category	Applica	tion Number ( Citatior	or Monograph า	Μ	larketing Start Date	Mark	eting End Date
٩N	DA	ANDA20971	3		03/	20/2019		
_E	VOTHYRC	OXINE SO	DIUM					
ev	othyroxine soc	dium tablet						
P	roduct Infor	mation						
Pr	oduct Type		HUMAN PRESCR	RIPTION DRUG	lten	n Code (Source)	NDC	:68180-976
Rc	oute of Admini	stration	ORAL					
Ac	tive Ingredi	ent/Active	Moiety					
		Ingredi	ent Name			Basis of Stre	ength	Strengt
	VOTHYROXINE S III:Q51BO43MG4)	SODIUM (UNII:	9J765S329G) (LE	VOTHYROXINE -		EVOTHYROXINE SOI NHYDROUS	NUM	0.3 mg
In	active Ingre	dients						
			Ingredient				St	rength
	OSCARMELLOS							
	C YELLOW NO.							
	&C BLUE NO. 1							
	&C YELLOW NO		· · ·					
			097M6I30)					
	ANNITOL (UNII: 3							
	DIUM BICARBO							
51	ARCH, CORN (UI	NII: 08232NY35	])					
Pr	roduct Chara	acteristics						
Co	lor	GRE	EEN	Score			2 pieces	
Sh	ape	ROU	JND	Size			6mm	
	avor			Imprint Code			L27	
	ontains							
Pa	ackaging							
#	ltem Code	Pa	ckage Descri	iption	Ma	rketing Start Date		eting End Date
1	NDC:68180-976- 01	100 in 1 BOTT Product	LE; Type 0: Not a	a Combination	03/20	/2019		
2	NDC:68180-976- 02	500 in 1 BOTT Product	LE; Type 0: Not a	a Combination	01/01	/2040		
3	NDC:68180-976- 03	1000 in 1 BOT Product	TLE; Type 0: Not	a Combination	03/20	/2019		
4	NDC:68180-976- 09	90 in 1 BOTTL Product	E; Type 0: Not a	Combination	03/20	/2019		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA209713	03/20/2019		

Labeler - Lupin Pharmaceuticals, Inc. (089153071)

Registrant - Lupin Atlantis Holdings SA (483965500)

Esta	Establishment					
Name	Address	ID/FEI	Business Operations			
LUPIN LIMITED		650582310	MANUFACTURE(68180-965, 68180-966, 68180-967, 68180-968, 68180-969, 68180-970, 68180-971, 68180-972, 68180-973, 68180-974, 68180-975, 68180-976), PACK(68180-965, 68180-966, 68180-967, 68180-968, 68180-969, 68180-970, 68180-971, 68180-972, 68180-973, 68180-974, 68180-975, 68180-976)			

Revised: 3/2025

Lupin Pharmaceuticals, Inc.