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.

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).

- DNICATION AND ESAGE

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and skin rach. (6)
To report SUSPECTED ADVERSE REACTIONS, contact Lupin Pharmaceuticals, Inc. at 1-800-399-2561 or FDA at 1-800-FDA-1088 or wow.kfa gov/medwatch.

PUR-19ER OF brown Min. gov/in redwards.

BRUG INTERACTIONS

See full prescribing information for drugs that after thyroid hormone pharmacolisetics and metabolism (e.g., absorption synthesis, secretion, catalolism, protein binding, and larger tissue response) and may after the therapeutic response to be verifyrous continuables. (r)

levothyroxine sodium tablets, (?)

USE IN SPECIFIC POPULATIONS

Pregnancy may require the use of higher doses of kvothyroxine sodium tablets, (2.3, 8.1)

See 17 for PATINT COUNSELING INFORMATION.

FULL PRESCRIBING INFORMATION: CONTENTS\*
WARNING: NOT FOR TREATMENT OF OBESITY OR FOR WEIGHT LOSS
1 INDICATIONS AND USAGE
2 DOSAGE AND ADMINISTRATION

- 10SAGE AND ACCEPTANCE OF THE PROPERTY OF THE P
- 3 VACAMAN Adverse Reactions in the Enterty man in a management of the Disease
  2.3 Mysedem Comm
  5.2 Mysedem Comm in Inform with Conventions Adread Insufficiency
  3.3 Actes Adversed Facilities and the complex Treatment of Hysothyroidism
  5.5 Worsesting of Diabetic Common facilities and the complex Treatment of Hysothyroidism
  5.5 Worsesting of Diabetic Common facilities and the Common facilities of the Common facilities of the Common facilities of ADVERSE REACTIONS
  4.0 ADVERSE REACTIONS
  7.1 Drugs Konwan Affect Thyroid Hormone Pharmacokinetics
  7.2 Analdadeic Therapy
  7.3 Oral Anticogulation
  7.4 Drugs Konwan Life Common facilities of the Common f

- o Ketamine
  7 Sympathomimetics
  8 Tyrosine-Kinase Inhibitors
  9 Drug-Food Interaction
- .9 Drug-Food Interactions .10 Drug-Laboratory Test Interactions SE IN SPECIFIC POPULATIONS

- 8 USE IN SPECIFIC POPOLATION
  3.1 Pregnary
  3.2 Lactation
  4.4 Pediantic Use
  10 OVERDOSAGE
  10 DESCRIPTION
  12 CLINICAL PHARMACOLOGY
  12.1 Mechanism of Action
  12.2 Pharmacodynamics
- 12.3 Pharmacokinetics
  13 NONCLINICAL TOXICOLOGY

- 13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility
  16 HOW SUPPLIED/STORAGE AND HANDLING
  17 PATIENT COUNSELING INFORMATION
  \* Sections or subsections omitted from the full prescribing information. bing information are not listed.

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 inef for weight reduction.

for weight reduction.

Larger doses may produce serious or even life threatening manifestations of toxicity, particularly when given in as sociation with sympathomimetic amines such as those used for their anorectic effects [see Adverse Reactions [6], Drug Interactions [7.7], and Overdosage [10]].

Hypothysustum

Levodynoxius sodiumalabets are indicated as a replacement therapy in primary (thyroidal), secondary (initiates), and tertapy (hypothalant) congested or acquired hypothyroidstan.

Palmary Thyrotapin (Thyroid-Stimulating Hormane, T831) Suppression

Levodynoxius sodiumalabet are indicated as anadjunct to surgery and radioidne therapy in the management of thyroinpin dependent well-differentiated hypothal carner.

- Limitations of Use:

  Levoltyroxine sodium tablets are not indicated for suppression of berign thyroid nodules and nontoxic diffuse goiter in iodine-sufficient patients as there are no clinical benefits and overtreatment with levoltyroxine sodium tablets may induce hyperthyroidism fee Wurnings and
- overtreatment with revolutyroatme storage and a second precardings (5.64).

   Levolhyroxine sodium tablets are not indicated for treatment of hypothyroidism during the recovery phase of subacute thyroidiis.

### 2 DOSAGE AND ADMINISTRATION

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

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

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

# 2.2 General Principles of Dosing

2.L General Principles of Dosing
The dose of levolutivate sodium blables for hypothyroidism or pinitary TSH suppression depends on a variety of factors including the patient's age, body weight, cardiovascular states, concomiant medical concentration (excluding the specific natural of the condition height greaney) concontains medication, co-administered food and the specific natural of the condition being treated fore Dosage and Administration (2.3), Worthward part Preventions (3), and Type Interaction (3)). Dosage must be individualized as account for these factors and dose adjustmens made based on periodic assessment of the patient's clinical response and laboratory parameters (see Desage and Administration (2.4)).

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

## 2.3 Dosing in Specific Patient Populations

Primary Hypothyroidism in Adults and in Adolescents in Whom Growth and Puberty are Cor Surf levothyroxine sodium tables at the full replacement dose in otherwise healthy, non-elderly individuals who have been hypothyroid for only a short time (such as a few months). The average full replacement dose of levothyroxine sodium tables is approximately 1.6 mcg per kg per day (for example: 100 to 125 mcg per day for a 70 kg adult).

example: 100 to 1.25 mg; per cay tor a /0 sg anutu.

Adjust the dose by 125 to 25 mg; increments every 4 to 6 weeks until the patient is clinically euthyr and the serum TSH returns to normal. Doses greater than 200 mg; per day are seldom required. An inadequate response to daily doses of greater than 300 mg; per day is rare and may indicate poor compliance, malabsorption, drug interactions, or a combination of these factors.

For elderly patients or patients with underlying cardiac disease, start with a dose of 12.5 to 25 mcg per day. Increase the dose every 6 to 8 weeks, as needed until the patient is clinically euthyroid and the

scrimt TSH returns to normal. The full replacement dose of levenlyroxine sodium tablets may be less than large rel age rel day in deflerly painten and the recommendation of the production of the painten production of the production of the painten production of the production of the painten production of the productio

Table 1. Levothyroxine Sodium Tablets Dosing Guidelines for Pediatric Hypothy

AGE	Daily Dose Per Kg Body Weight*
0 to 3 months	10 to 15 mcg/kg/day
3 to 6 months	8 to 10 mcg/kg/day
5 to 12 months	6 to 8 mcg/kg/day
I to 5 years	5 to 6 mcg/kg/day
5 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

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

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

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

Prognancy PreProcessing Hypothyroidin: Levolhyroxine sodium tables dose requirements may increase during 
pregnancy, Messaue serum ISI and free-T-d as soons a pregnancy is confirmed and, at minimum, during 
case thrimster of pregnancy. In patients with primary hypothyroidina, minitian seminal Trian 
the transactive specific reference range. For patients with sevent ISI dhows the normal sinesser-specific 
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transactive specific range. Reduce levolhyroxine sodium tables dose is reached and serum ISI is whithin the normal 
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### 2.4 Monitoring TSH and/or Thyroxine (T4) Levels

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

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

### Pediatrics

In patients with competited hypothyroidium, assess the adequacy of replace oran therapy by resouring, but serum TSTs and used or Free-TA. Solidoner TSTs and used or Free-TA challedness and to those 2 and 4 the extent STs and the present of the contract o

of development, metal and physical growth, and bone minutation, at regular intervals. While the general aim of heragy is to muralize the seurm ISI HeVE, TSI Hawy not normalize in some patients due to in utero hypothyroidstin cassing a resetting of pitultary-thyroid feedback. Failure of the seurm IZ 4 to increase in the upper hald of the normal rage within 2 weeks of initiation. The second is recorded to the resetting of the second TSI to decrease below 20 IU per liter within 4 weeks may indicate the child its or receiving adequate the reput in decrease below 20 IU per liter within 4 weeks may indicate the child its or receiving adequate the reput in the control of the second in the control of the second in the control of the contro

 $Secondary\ and\ Tertiary\ Hypothyroidism$  Monitor serum free-T4 levels and maintain in the upper half of the normal range in the

# 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 supplied as follows:

Tablet Strength	Tablet Color/Shape	Debossing Details
25 mcg	Peach/Round	L15
50 mcg	White/Round	L16
75 mcg	Violet/Round	L17
B8 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
NOO meg	Green/Round	1.27

## 4 CONTRAINDICATIONS

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

### 5 WARNINGS AND PRECAUTIONS

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

Unexase
Over-treatment with levothyroxine may cause an increase in heart rate, cardiac wall thickness, and
cardiac contractility and may precipitate angino or arrhydmias, particularly in patients with
cardiovascular disease and in-elderly patients. Initiate levothyroxine sodium tables therapy in this
population at lower doses than those recommended in jourger individuals or in patients without cardiac
diseases [see Design and Administration (2.3), Use in Specify Populations (8.3).)

unseese per Louing that Amministration (2.5), cost in specify re-positions (cost). 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 therapy. Monitor patients receiving concomitant insufficiency.

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

# 5.2 Myxedema Coma

32. Mysteema Loma
Mysteema com is a life-threatering energency characterized by poor circulation and hypometabolism, and may result in unpredictable absorption of levohyroxine sodium from the gastroinestical tract. Use of oral thyroid hormone drug products is not recommended to treat mysteedena coma. Administer thyroid hormone products formulated for intravenous administration to treat mysteedena coma.

5.3 Acute Adrenal Crisis in Patients with Concomitant Adrenal Insufficiency
Thyroid hormore increases metabolic clearace of glucocorticoids. Initiation of shyroid hormore
therapy prior to initiating glucocorticoid lerga my precipitate as acute adrenal crisis in patients with
adrenal insufficiency. Treat patients with adrenal insufficiency with replacement glucocorticoids prior
to initiating resements with levelopy-toxic southunitables (see Countidactions (st)).

to instanting resument with reconstructions constructions; fore communication (e.g., 24). Prevention of Hypothyroidism of Levolsynoxies codiumable has a merow therapeutic index. Over, or undertreament with levolsynoxies codiumables may have register effects on growth and development, cardiovascular function, have reducibled in register of the construction of the reducible in register of the construction of the reducible in register of the construction of the reducible in register of the reducible in register of the reducible in redu

5.5 Worsening of Diabetic Control
Addition of levothyroxine therapy in patients with diabetes mellitus may worsen glycenic conresult in increased antidiabetic agent or insulin requirements. Carefully monitor glycenic comstarting, changing, or discontinuing levothyroxine sodium tablets [see Drug Interactions (7.3)].

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

The created how recording and decreased bone miteral density may occur as a result oil levolityroxine over-replacement, particularly in post-energipane from the first travened how recording may be associated with introduced several levels and training exercision clacking and phosphores, elevation may be associated with introduced several levels and training exercision clacking and phosphores, elevation does of levolityroxine sodium tabless that achieves the desired clinical and biochemical response to misgane this risk.

### 6 ADVERSE REACTIONS

Adverse reactions associated with levothyroxine sodium tablets therapy are primarily those of hyperthyroids and tes to the expectic overdosage fee Warnings and Precondists (5). Overdosage (10)). They include the following:

4 General fatigue, increased appetile, weight loss, heat intolerance, lever, excessives sweating.

4 Control across objeants bedached, hyperactivity, nervousness, andrey, irribablity, emotional lability,

- Central infrarease system: neuroscience, myperactivity, nervousience, naturey, in insulancy, examination and a Mancadoscheine termors, muscle e-positives, muscle appairs
   Confinenciatories pulpitations, techycardia, arrhythmias, increased pulse and blood pressure, heart failure, angian, majorardial infaredion, cardiac arrest a failure, and the contractive of the c

### Adverse Reactions in Children

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

### Hypers ensitivity Reactions

Hypersensitivity reactions to inactive ingredients have occurred in patients treated with thyroid hormone products. These include urticaria, pruritus, skin rash, flushing, angioedema, various gastroinestinal symptoms (abdominal pain, nanees, vomating and daarrhea), fever, arthrafais, serum sickness, and whereign. Hypersensitivity to levoltyrosia itself is not known to occur.

### 7 DRUG INTERACTIONS

A Drugs Koown to Affect Thyroid Hormone Pharmacokinetics

Many drugs can exert effects on thyroid hormore pharmacokinetics and metabolism (e.g., absorption, synthesis, secretion, catabolism, protein binding, and unget tissue response) and mny after the therapeutic response to levolipyroxine sodium tables (see Tables 27 to Stelow).

	Table 2. Drugs That May Decrease T4 Absorption (Hypothyroidism)\
Potential impact: Concurrent use may	reduce the efficacy of levothyroxine sodium tablets by binding and delaying or preventing absorption, potentially resulting in hypothyroidism.
Drug or Drug Class	Effect
	Calcium carbonate may form an insoluble chelate with levothyroxine, and ferrous sulfate likely forms a ferric-thyroxine complex. Administer levothyroxine sodium tablets at least 4 hours apart from these agents.
Ferrous Sulfate	
Orlistat	Monitor patients treated concomitantly with orlistat and levothyroxine sodium tablets for changes in thyroid function.
Bile Acid Sequestrants -Colesevelam -Cholestyramire -Colestipol Ion Exchange Resins -Kayexalate -Sevelamer	Bille acid sequestrans, 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	Castric actidity is an essential requirement for adequate absorption of levolthyroxine. Sucralfate, antacids and proton pump inhibitors may cause hypochlorhydria, affect intragantric pH, and reduce levolthyroxine absorption. Monitor patients appropriately.
Aluminum & Magnesium Hydroxides	

	Table 3. Drugs That May Alter T4 and Triiodothyronine (T3) Serum Transport Without Affecting Free Thyroxine (FT4) Concentration (Euthyroidism)
Drug or Drug Class	Elfect
Clofibrate	These drugs may increase serum thyroxine-binding globulin (TBG) concentration.
Estrogen-	
containing oral contraceptives	
Estrogens (oral)	
Heroin / Methadone	
5-Fluorouracil	
Mitotane Tamoxifen	
	These drugs may decrease serum TBG concentration.
Asparaginase	These units that decrease seculi Fixe concentration.
Glucocorticoids	
Slow-Release Nicotinic Acid	
Potential impact (below): Admi	nistration of these agents with levothyroxine sodium tablets results in an initial transient increase in FT4. Continued administration results in a decrease in serum T4 and normal FT4 and T5H concentrations.
Salicylates (> 2 g/day)	Salicylates inhibit binding of T4 and T3 to TBG and transthyretin. An initial increase in serum FT4 is followed by return of FT4 to normal levels with sustained therapeutic serum salicylate concentrations, although total T4 levels may decrease by as much as 30%.
Other drugs:	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-
Carbamazepine	binding sites on TBG, prealbumin, and albumin, so that a single high dose can accusely 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 hormone parameters.
Furosemide (> 80 mg IV)	
Heparin	
Hydantoins	
Non-Steroidal Anti-	
inflammatory Drugs	
-Fenamates	

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

Potential impact: Stir	mulation 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	s Effect
Phenobarbital	Phenobarbital has been shown to reduce the response to thyroxine. Phenobarbital increases L-thyroxine metabolism by inducing uridine 5'-diphospho-
Rifampin	glucuronosyltransferase (UGT) and leads to a lower T4 serum levels. Changes in thyroid status may occur if barbiturates are added or withdrawn from patients being treated for hypothyroidism. Rifampin has been shown to accelerate the metabolism of levothyroxine.

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

Potential impact: Administration of these enzyme inhibit	ors 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
	In patients treated with large doses of propramolol (> 160 mg/day), T3 and T4 levels change, TSH levels remain normal, and patients are clinically euthyroid. Actions of particular beta-
adrenergic antagonists (e.g., Propranolol > 160 mg/day	adrenergic antagonists may be impaired when a hypothyroid patient is converted to the euthyroid state.
	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 inhibits peripheral conversion of levothyroxine (T4) to triiodothyronine (T3) and may cause isolated biochemical changes (increase in serum free-
Amiodarone	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

Lectorystotic sodius riberta increase the response to real microagular therapy. Therefore, a technique of the control of the control of the popular of the

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.

increase in me once of agains a gyrosmes.

7.5. Andidepressant Therapy

Concurrent use of iricyclic (e.g., mirripylijus) or remayclic (e.g., maprodilius) antidepressants and levolstyroxine solidina malbest may increase the therapeutic and maxic effects of both drugs, possibly due to increased receptor sensitivity to catecholamines. Took: effects may include increased risk of cardia entriphinats and central nervous systems mission. Levoltyposition sodium tables may accelerate the once of action of ircyclics. Administration of servatine in patients sublitized onlevoltyroxine sodium tables may read increased evoltyposities sodium tables may read increased evoltyposities sodium tables to give read increased evoltyposities sodium tables to give read in increased evoltyposities sodium tables requirements.

### 7.6 Ketamine

The sympathonimetics.

Concurrent use of sympathonimetics and levohyvoxine sodium tablets may increase the effects of sympathonimetics or dryord hormone. Thyroid hormones may increase the risk of coronary insufficiency when sympathonimetic agents are administered to patients with coronary artery disease.

### 7.8 Tyrosine-Kinase Inhibitors

Concurrent use of tyrosine-kinase inhibitors such as imutinib 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 doxing feet Dosage and Administration (2.1). Soybean flour, contoneed meal, walnats, and ideary filter may built and decrease the absorption of levothyroxine sodium blacks from the gastrointestinal tract. Grape-fruit juice may delay the absorption of levothyroxine and reduce its bisocratability.

# 7.10 Drug-Laboratory Test Interactions

7.10 Drug-Laboratory Text Interactions
Consider Change in TBG concentration when interpreting T4 and T3 values. Measure and evaluate authorized (free) horizone author determine the free-T4 index (F740) in this circumstance. Pregunery, increase TBG concentration replication, see the value of the concentration replication, see the value of the concentration replication, see review (and control of the concentration replication). The concentration replication re

### 8 USE IN SPECIFIC POPULATIONS

### 8.1 Pregnancy

Risk Summary

Rick Summy

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Data

# Human Data

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

### 8.2 Lactation

Risk Summary

United published studies report that levoltyroxine is present in human milk. However, there is imsufficient information to be entermine the effects of levoltyroxine on the breasted infant and no available information on the effects of levoltyroxine no milk production. Adequate levoltyroxine treatment during laxetion more effects of levoltyroxine normalize production in hypothyroid laxeting mothers. The developmental and shall be right of the reader-desiring should be considered adong with morther's clinical need for levoltyroxine soodium tables and no protential adverse effects on the breasted infant from the underlying material condition.

### 8.4 Pediatric Use

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

In children in whom a diagnosis of permanent hypothyroidism has not been established, discontinue levothyroxine sodium tablets administration for a trial period, but only after the child is at least 3 years of age. Obtain serum T4 and T5H levels at the end of the trial period, and use laboratory test results and clinical assessment to guide diagnosis and treatment, if warranted.

of age. Obtain securit 7 a and 375 to the control for the cont

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

Because of the increased prevalence of cardiovascular disease among the elderly, initiate levolstyroin so dismibilities at less than the full replacement dose [see Wornings and Precontions (5.1) and Dosage and Administration (2.3)]. Artial arrhythmias can occur in elderly quisters. Artial libralliano is the must common the arrhythmias observed with Irvollytoxics overestament in the elderly.

### 10 OVERDOSAGE

10 OVERDOSAGE The signs and symposms of overdosage are those of hyperthyroidism (see Warnings and Precountors (5) and Adverse Rocctions (8)). In addition, confusion and disorteration may occur. Cerebral embolism, about come, and each have been reported. Sections concurred in a Syear old child singering 15 on got leveluly route. Symposm may not necessarily be evident or may not appear until several days after greater than the contraction of the

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

Levohyvoxine sodium tablets USP contain symbetic crystalline L-3,3,5,5 tetraiodothyronine sodium salt (levothyroxine (T4) sodium). Synthetic T4 is chemically identical to that produced in the human thyroid gland. Levothyroxine (T4) sodium) as an empirical formula of C<sub>12</sub>H<sub>10</sub>I<sub>4</sub>N NaO<sub>4</sub>-xH<sub>2</sub>O<sub>5</sub>, molecular weight of 798.85 (mNydows), and structural formula as short all formula of the control of the contro

Levothyroxine sodium tables USP for oral administration are supplied in the following strengths: 25 mg, 50 mg, 75 mg, 80 mg, 100 mg, 112 mg, 125 mg, 137 mg, 150 mg, 175 mg, 200 mg, and 300 mg, Each twothyroxine sodium tables USP contains the inactive ingrediens constant concerning the inactive ingrediens constant concerning the inactive ingrediens constant in the inactive indicates the inactive indicates it in the inactive indicates the inactive indicates it in the inactive indicates in the inactive indicate

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

\* Note - FD&C Yellow No. 6 is peach in color

### 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 transcriptio 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

IL2 Pharmacoknetics

Ahorogian

Ahorogian of orally administered T4 from the gastroinestinal tract ranges from 40% to 80%. The
majority of the levolhycotic sodium tablets dose is absorbed from the jejama and uper ileum. The
levolhycotic sodium solution is approximately 50%. T4 absorption is increased by fasting, and
decreased in malaboration solution is approximately 50%. T4 absorption is increased by fasting, and
decreased in malaboration syndroms and to pertain foods such as sopheans. Dietary fifter decreases
tionwalability of T4. Absorption may also decrease with age. In addition, many drugs and foods affect
T4 absorption for per functions (7).

# Distribution

Distribution:
Circulating thyroid hormones are greater than 99% bound to plasma proteins, including thyroxin-isating globulin (TBCs, thyroxine-Smitting prealbunin (TBPA), and allumin (TBA), whose capacities is the property of the protein of the

### Metabolism

Metabolism T is stowly eliminated (see Table 7). The major pathway of thyroid hormone metabolism is through sequential devolution. Approximately 80% of circulating T 1 is derived from peripheral T 4 by monodelondinuol. The liver is the major is of the graduation from 1 T and T 3, with T 4 decidentian 100 for the daily dose of T 4 is decidented to yield equal amount of T 3 and reverse T 1 (FT.3). T 3 and 171 are further decidentiated to distorbism: Thyroid hormone are also metabolised via conjugation with glucurosides and sulfates and excreted directly into the bile and gut where they undergo emerologistic rectifuation.

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.

Tubic 7.11m	i i i i i i i i i i i i i i i i i i i	01 1 1191010 1101	mones in Luu	iyroid r didents
Hormone	Ratio in Thyroglobulin	Biologic Potency	t <sub>1/2</sub> (days)	Protein Binding (%)*
Levothyroxine (T4)	10 to 20	1	6 to 7 <sup>†</sup>	99.96
Liothyronine (T3)	1	4	≤ 2	99.5

\* Includes TBG, TBPA, and TBA
† 3 to 4 days in hyperthyroidism, 9 to 10 days in hypothyroidism

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

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

### 16 HOW SUPPLIED/STORAGE AND HANDLING

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	Debossing Details	NDC# for bottles of 90	NDC # for bottles of 100	NDC # for bottles of 500	NDC # for bottles of 1000
25	Peach/Round	L15	68180-965-09	68180-965-01	68180+965-02	68180-965-03
50	White/Round	L16	68180-966-09	68180-966-01	68180-966-02	68180-966-03
75	Violet/Round	L17	68180-967-09	68180-967-01	68180-967-02	68180-967-03
88	Olive/Round	L19	68180-968-09	68180-968-01	68180-968-02	68180-968-03
100	Yellow/Round	L20	68180-969-09	68180-969-01	68180-969-02	68180-969-03
112	Rose/Round	L21	68180-970-09	68180-970-01	68180+970+02	68180-970-03
125	Tan/Round	L22	68180-971-09	68180-971-01	68180-971-02	68180-971-03
137	Turquoise/Round	L23	68180-972-09	68180-972-01	68180-972-02	68180-972-03
150	Blue/Round	L24	68180-973-09	68180-973-01	68180-973-02	68180-973-03
175	Lilac/Round	L25	68180+974+09	68180-974-01	68180-974-02	68180-974-03
200	Pink/Round	L26	68180-975-09	68180-975-01	68180+975-02	68180-975-03
300	Cross/Bound	1.27	69190 076 00	69190 076 01	69190 076 07	69190 076 03

Storage Conditions

Store at 25°C (77°F); excursions permitted to 15° to 30° C (59° to 86° F) [see USP Controlled Room Temperature]. Levothyroxine sodium tables 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:

sodium untress.

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 stomeds, one-half to one hour before breadast.
   Inform patients that agers such as iron and calcium supplements and attaction can decrease the absorption of levothyroxine. Instruct patients not to take levothyroxine sodium tablets within a hours of these agents.
   In the control of the control

- thinking of becoming pregnant while taking levothyroxine sodium tables.

  \*\*proprietal information in the several weeks before they notice an improvement in symptoms.

  \*\*Information that it may take several weeks before they notice an improvement in symptoms.

  \*\*Information that the beowhyroxine is oldium their is intended to replace a borrance that is normally produced by the divoid gland. Generally, replacement therapy is to be information that is controlled to the several as a primary or adjustive therapy in as weight control program.

  \*\*Instruct patients not only their bealthcare provider if they are taking any other medications, including prescription and over-the-counter preparations.

  \*\*Provided on the several program of the provider of the provider

prior to any surgery.

Adverse Recording

• Instruct patients to mostly their healthcare provider if they experience any of the following symptoms: rough or irregular heartheat, chest pain, shortness of breath, leg cramps, headache, nervousness, irritability, sleeplessaress, remors, change in appetite, weigh gain or loss, vonting, adarthea, excessive wearing, beat interacter, lever, change in innertual prioris, lives or skin rash, or any other unusual medical event.

and the properties of the

### Manufactured for:

Manufactured for: Lupin Pharmaceuticals, Inc. Baltimore, Maryland 21202 United States Manufactured by: Lupin Limited Pithampur (M.P.) - 454 775 INDIA Revised: April 2019

# PACKAGE LABEL PRINCIPAL DISPLAY PANEL Levothyroxine Sodium Tablets USP

100's Tablets



50 mcg

NDC 68180-966-01 100's Tablets



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

NDC 68180-967-01
Levothyroxine
Sodium Tablets USP
S 75 mcg (0.075 mg) Rx only 100 Tablets 54 x 19 mm

Rx Only 88 mcg

NDC 68180-968-01 100's Tablets



Rx Only

NDC 68180-969-01 100's Tablets



Levothyroxine Sodium Tablets USP



Levothyroxine Sodium Tablets USP RX Orly 125 mcg NDC 68180-971-01 100's Tablets



Levothyroxine Sodium Tablets USP Rx Only 137 mcg NDC 68180-972-01 100's Tablets

NDC 68180-972-01

Levothyroxine
Sodium Tablets USP

13.7 mcg
(0.137-mg)
(1.27-mg)
(1.2

Levothyroxine Sodium Tablets USP Rx Only 150 mcg NDC 68180-973-01 100's Tablets



Levothyroxine Sodium Tablets U Rx Only 175 mcg NDC 68180-974-01 100's Tablets



Levothyroxine Sodium Tablets USP Rx Orly 200 mcg NDC 68180-975-01 100's Tablets



Levothyroxine Sodium Tablets USP Rx Ordy 300 mcg NDC 68180-976-01 100's Tablets



LEVOTHYROXINE S levothyroxine sodium tablet			
Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:68180-965
Route of Administration	ORAL		
	Moiety gredient Name NE 97658129G) (LEVOTIMBOXINE	Basis of Stre	
	NIE 91/65S329G) (LEVO I HIROAINE -	ANINDROUS	0.025 m
UNIEQ51BO43MG4)	NEW / 655329G) (LEVO I III ROANE -		0.025 m
UNIEQ51BO43MG4)			0.025 m
UNRQSIBO43MG4)  Inactive Ingredients	Ingredient Name		0.025 m
Inactive Ingredients  CROSCARMILLOSE SODIUM	Ingredient Name (UNR M28OLIEBHS)		0.025 m
Inactive Ingredients  CROSCARMILLOSE SODIUM FD&C YELLOW NO. 6 (UNIE IE	Ingredient Name (UNE MESOLIBBES) TYLEBASS)		0.025 m
LINOTHYROXINE SORUM (UUNEQSIBOOLIMG)  Inactive Ingredients  CROSCARMILLOSE SODIUM FDMC VELLOW NO. 6 (UNE 16 MAGNISSUM STEART (UNE MAGNISSUM STEART (UNE)	Ingredient Name (UNE MESOL HERB) 770429.348) 7009746500)		0.025 m

Product Characte	eristics	(Bearly)	Score		2 pieces
Color Shape Flavor	ROUND		Sire	nt Code	6mm
Contains			map/File		
Packaging					
1 NDC:68180-965-01	100 is 1 BO	TTLE; Type 0: Not a	Combination Product	Marketing Start Date	Marketing End Date
2 NDC:68180-965-02 3 NDC:68180-965-03 4 NDC:68180-965-09	300 in 1 BO 30 in 1 BO 30 in 1 BOT	ITLE; Type 0: Not a STTLE; Type 0: Not a ILE; Type 0: Not a	Combination Product a Combination Product Combination Product	03/20/2019 03/20/2019 03/20/2019	
Marketing Inf	y Applica	tion Number or M	Ionograph Citation	Marketing Start Date	Marketing End Date
ANDA LEVOTHYRO	ANDA209	713		03/20/2019	
evothyroxine sodiur	n tablet	DIUM			
Product Informa Product Type Route of Administra	tion	HUMAN PRESC	REPTION DRUG	Item Code (Source)	NDC:68180-966
Houte of Administra	ition	ORAL			
Active Ingredien	Ingr	edient Name	OTIMBOXINE -	Basis of Stree	ngth Strength
UNIEQ51BO43MG4)	omen (con	37.033323G) (EEV	OTHERDARE.	LEVOTINTOXINE SOD ANINUROUS	0.05 mg
Inactive Ingredie		Ingredien	t Name		Strength
CRO SCARMELLOSE MAGNESIUM STEAR: MANNITOL (UNE 30' SODIUM BICARBON STARCE, CORN (UNI	ATE (UNE: 70) WL53L36A) ATE (UNE: 8M	197MSEIO) IDF5V39QO)			
Product Characte	eristics				
Color Shape	WH		Score Size		2 pieces Smm
Flavor Contains			Imprint Code	)	L16
Packaging					
# Item Code 1 NDC:88180-966-01	100 in 1 BO	Package Desc	ription Combination Product	Marketing Start Date 05/02/2019	Marketing End Date
1 NDC:68180-966-01 2 NDC:68180-966-02 3 NDC:68180-966-03 4 NDC:68180-966-09	500 in 1 BO 1000 in 1 BO 90 in 1 BOT	TTLE; Type 0: Not a FTTLE; Type 0: Not TLE; Type 0: Not a	Combination Product a Combination Product Combination Product	05/02/2019 05/02/2019 05/02/2019	
Marketing Inf	ormation	1			
Marketing Categor	y Applica ANDAZ09	tion Number or M	fenograph Citation	Marketing Start Date 05/02/2019	Marketing End Date
LEVOTHYRO ievothyroxine sodiur		DIUM			
Product Informa			REPTION DRUG	Item Code (Source)	NDC:68180-967
Route of Administra					
Active Ingredien	Ingr	edient Name		Basis of Stree	ngth Strength
LEVOTHYROXINE SO UNBQ51BO43MG4)	DDIUM (UNR	91765S329G) (LEV			
			OTIMROXINE -	LEVOTINTOXINE SOD ANINDROUS	0.075 mg
CROSCARMILLOSE	ents SODIUM (UN	Ingredien	rt Name		0.075 mg
Inactive Ingredie CROSCARMILLOSE FDM: C BLUE NO. 2 (U FDM: C BLUE NO. 40 (U MAGNESSIM STEAR. MANNITOL (UNE 30) SO DRUM BICARBO N. STARCE, CORN (UNE	SOBIUM (UN INE LOGKEST INE WZB9 127 ATE (UNE 701 WL53L3GA) ATE (UNE 8M	Ingredien IR MOSOLIEBHS) DQX) XXXA) D97MSID0)	rt Name		
CROSCARMILLOSE FERAC BLUE NO. 2 (U FERAC RED NO. 46 (U MAG RESIÚM STEAR. MANNITOL (UNE 30' SO DRUM BICARBO NI STARCIR, CORN (UNI Product Characte	SOBIUM (UNIVELLOGERED IN WESTERN FOR WESTERN WESTERN WESTERN FOR WESTERN WESTERN FOR WESTE	Ingredien	t Name		Strength
CROSCARMILLOSE FENAC BLUE NO. 2 (U FENAC RED NO. 40 (U MAGNESIUM STEAR, MANNITOL (UNE 30' SO DRUM BICARBON, STARCH, CORN (UNI  Product Characte Color Shape	SOBIUM (UN SOBIUM (UN NNELDEKBEZ NNE WZB9127 ATE (UNE 70 WESSLEGA) ATE (UNE 70 E OB 232NY3S PUBPLE ROUND	Ingredien	t Name		Strength
CROSCARMILLOSE FD&C BLUE NO. 2 (U FD&C RED NO. 46 (U MAGNESIUM STEAR: MANNITOL (UNE 30' SORUM BICARBON: STARCE, CORN (UNE  Product Characte Color	SOBIUM (UN SOBIUM (UN NNELDEKBEZ NNE WZB9127 ATE (UNE 70 E OBZ3ZNY3S PUBPLE ROUND	Ingredien	t Name		Strength
CROSCARMIZLOSE FRAGE BLUE NO. 2 (U FRAGE BLUE NO. 2 (U FRAGE BLUE NO. 48 (U MAGNISHIN FILE MAGNITUM SIO STARCIA CORN (UNE SO STARCIA CORN (UNE Product Characte Celor Shape Flavor Contains Packaging	SOBIUM (UN NEL LORGEST IN NEL LORGEST IN NEL WEB 121 ATE (UNEL 701 WESTLE SEA) ATE (UNEL SEA) E OB ZEENYES FUERTE. ROUND	Ingredient (Ingredient) DQK) XXAA) XXAA) DEREYJSPAQO) (Volet)	Scare Size Imprint	Cade	Strength  2 pieces 6mm L17
CROSCARMIZLOSE FRAGE BLUE NO. 2 (U FRAGE BLUE NO. 2 (U FRAGE BLUE NO. 48 (U MAGNISHIN FILE MAGNITUM SIO STARCIA CORN (UNE SO STARCIA CORN (UNE Product Characte Celor Shape Flavor Contains Packaging	SOBJEM (UNITED EXECUTED IN THE LOCKER FOR WEST 127 ATE (UNITED EXECUTED IN THE CONTROL OF THE CO	Ingredies IR MEMOLIBRED IR MEM	Scare Size Imprint Combination Product Combination Product	Cade  Marketine Start Date	Strength  2 pieces 6mm L17
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CROSCAMMILOSE FIRSC BLIC NO. 2 (0) FIRSC BLIC NO. 2 (0) MANUSCHIN STEAK BLIC NO. 10 MANUSCHIN STEAK MANUSCHI (CRUS STEAK) SORIOUS BLICABON PODIOL STANK CONTROL FOR STANK CONT	SOBIUM (UR NE LOCKERTINE WEB 127 ATE (UNE 70 ME NEED 127 ATE (UNE 70 ME NEED 127 ATE (UNE 70 ME NEED 127 ME NEED 1	Ingredie: In MODILITHIO) IN MODILITHIO MODIL	Scarre Size Size Size Superint	Code  Marketing Start Date 03202019 03202019 03202019	Strength  2 pieces  (mm  L27  Marketing End Date
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CROSCAMMELLOSE TORAC BLAST TOR	SORIM (ICE AND	Ingerdier	Score Size Size Size Size Size Size Size Siz	Code  Marketing Start Date 10000010  Marketing Start Date 10000010  Marketing Start Date 10000010  Reach of Start Date AUVITORIOUS NO.	Strength  2 proces com LT  LT  Marketing End Date  Marketing End Date
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CROSCAMMELLOSE  Product Characte Carlos  Berry  Product Characte Carlos  Berry	SOURM (UNA LEGALES AND	Inguished States of the Control of t	SCOPPERSON PRODUCT  STORMAN CONTINUES PRODUCT  STORMAN CONTINUES	Code  Norketing Start Date (2020207) (2020207) (2020207) (2020207) (2020207) (2020207) (2020207) (2020207) (2020207) (2020207) (2020207) (2020207) (2020207) (2020207) (2020207) (2020207) (2020207)	Strength  J phoes  Load  Marketing End Date  Marketing End Date  NCC-68 200-068  Strength  Strength  Ann  J phoes  Ann  Load og
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CROSCAMMELLOSE TORS. GILL TO J. (1) MANUSCASAM TAGE Product Characte Canada  Product Characte Canada    Inc. Canada   Inc. Canad	SOURMA (UN SAME AND	Package Deck.  Packag	SCOPE STATE OF STATE	Code  Marketing Start Date 15220-20 1  Marketing Start Date 15220-20 1  Marketing Start Date 15220-20 2	Strength  2 pieces  Some  Lay  Marketing End Date  Marketing End Date  NOC-66 280-046  Strength  Strength  Japan  Japan  Strength  Marketing End Date  Marketing End Date  Marketing End Date  Strength  Japan  Japa

Inactive Ingredier	its			
	Ingr	edient Name		Strength
CROSCARMILLOSES	ODIUM (UNE MESOLIN	198)		
D&C YELLOW NO. 10	(UNR 355W5USQ3G)			
FD&C YELLOW NO. 6	(UNB: H77VED3A8)			
MAGNESIUM STEARA	FE (UNE: 70097M5E30)			
MANNITOL (UNE 30W	L53L36A)			
	FE (UNE: 8MDF5V39QO)			
STARCH, CORN (UNE	O8232NY3SJ)			
Product Character	ristics	Score		2 pieces
Shape	ROUND	Size		6mn
Flavor		Imprint Code		1.20
Contains				
Packaging # Item Code	Package	Description	Marketing Start Date	Musication End Dat
	Package Description			
1 NDC:68180-969-09	90 in 1 BOTTLE: Type 0:	Not a Combination Product	03/20/2029	San ar ting Linu Day
		Not a Combination Product : Not a Combination Product	03/20/2019	SHARING LINE DAY
2 NDC:68180-969-01	100 in 1 BOTTLE; Type 0			Jan at ting Life Late
2 NDC:68180-969-01 3 NDC:68180-969-02	100 in 1 BOTTLE; Type 0 500 in 1 BOTTLE; Type 0	: Not a Combination Product	03/20/2019	and the last last last last last last last last
2 NDC:68180-969-01 3 NDC:68180-969-02	100 in 1 BOTTLE; Type 0 500 in 1 BOTTLE; Type 0	: Not a Combination Product : Not a Combination Product	03/20/2019	
2 NDC:s8180-969-01 3 NDC:s8180-969-02 4 NDC:s8180-969-03	100 in 1 BOTTLE; Type 0 500 in 1 BOTTLE; Type 0 1000 in 1 BOTTLE; Type	: Not a Combination Product : Not a Combination Product	03/20/2019	
2 NDC:s8180-969-01 3 NDC:s8180-969-02 4 NDC:s8180-969-03	100 in 1 BOTTLE; Type 0 500 in 1 BOTTLE; Type 0 1000 in 1 BOTTLE; Type	: Not a Combination Product : Not a Combination Product	03/20/2019	Marketing End Date
2 NDC:58180-969-01 3 NDC:58180-969-02 4 NDC:58180-969-03  Marketing Info	100 in 1 BOTTLE; Type 0 500 in 1 BOTTLE; Type 0 1000 in 1 BOTTLE; Type	: Not a Combination Product : Not a Combination Product 0: Not a Combination Product	03/20/20 19 03/20/20 19 03/20/20 19	
2 NDC:58180-969-01 3 NDC:58180-969-02 4 NDC:58180-969-03  Marketing Info Marketing Category	100 in 1 BOTTLE; Type 0 500 in 1 BOTTLE; Type 0 1000 in 1 BOTTLE; Type rmation Application Numbe	: Not a Combination Product : Not a Combination Product 0: Not a Combination Product	03/20/20 29 03/20/20 29 03/20/20 29 Marketing Start Date	
2 NDC:58180-969-01 3 NDC:58180-969-02 4 NDC:58180-969-03 Marketing Info Marketing Category	100 in 1 BOTTLE; Type 0 500 in 1 BOTTLE; Type 0 1000 in 1 BOTTLE; Type rmation Application Numbe	: Not a Combination Product : Not a Combination Product 0: Not a Combination Product	03/20/20 29 03/20/20 29 03/20/20 29 Marketing Start Date	
2 NDC.58 IB0-969-01 3 NDC.58 IB0-969-02 4 NDC.58 IB0-969-03  Marketing Info Marketing Category  ANDA	100 in 1 BOTTLE; Type 0 500 in 1 BOTTLE; Type 0 1000 in 1 BOTTLE; Type 1000 in 1 BOTTLE; Type rmation Application Numbe ANDAZ09713	: Not a Combination Product : Not a Combination Product 0: Not a Combination Product	03/20/20 29 03/20/20 29 03/20/20 29 Marketing Start Date	
2 NDC:58180-969-01 3 NDC:58180-969-02 4 NDC:58180-969-03  Marketing Info Marketing Category	100 in 1 BOTTLE; Type 0 500 in 1 BOTTLE; Type 0 1000 in 1 BOTTLE; Type 1000 in 1 BOTTLE; Type rmation Application Numbe   ANDANO9713	: Not a Combination Product : Not a Combination Product 0: Not a Combination Product	03/20/20 29 03/20/20 29 03/20/20 29 Marketing Start Date	
2 NDC-58 IB0-969-01 3 NDC-58 IB0-969-02 4 NDC-58 IB0-969-03 Marketing Info Marketing Category ANDA LEVOTHYROX	SOO IN HOUTH, Type 0 SOO IN HOUTH, Type 0 1000 IN HOUTH, Type  FMATION  Application Numbe  ANDADO9723  KINE SODIUM tablet	: Not a Combination Product : Not a Combination Product 0: Not a Combination Product	03/20/20 29 03/20/20 29 03/20/20 29 Marketing Start Date	

Marketing Info	rmation	1				
Marketing Category	Applica	tion Number or Monogra	ph Citation	Marketing Start Date	Marketing	End Date
ANDA	ANDA209	713		03/20/2019		
LEVOTHYRO		DIUM				
Product Informat	ion					
Product Type		HUMAN PRESCRIPTION	DRUG	Item Code (Source)	NDC:6818	10-970
Route of Administrat	tion	ORAL				
Active Ingredient	/Active M	oiety				
		edient Name		Basis of Stre	ngth	Strengt
LEVO THYRO XINE SO UNEQ51BO43MG4)		917658329G) (LEVOTIÑRO	XINE -	LEVOTINTOXINE SOE ANIMOROUS		0.112 mg
Inactive Ingredie	nts					
		Ingredient Name			Stre	ngth
CROSCARMELLOSE						
D&C RED NO. 27 (UNI MAGNESIUM STEARA						
MANNITOL (UNE 30)						
SODIUM BICARBONA	TE (UNE: 8M	DF5V39QO)				
STARCH, CORN (UNI:	O8232NY3S	1)				
Product Characte	ristics					
Color	PINK (	Rose)	Score		2 pieces	
Shape	ROUN	D	Size		6mm	
Flavor			Imprint Cod		L21	
Contains						
Packaging						
# Item Code		Package Description		Marketing Start Date	Marketing	End Dat
		TLE; Type 0: Not a Combina TTLE; Type 0: Not a Combin		03/20/2019		
		TTLE; Type 0: Not a Combin		03/20/2019		
		TTLE; Type 0: Not a Combi		03/20/2019		
Manhatina Info						
Marketing Info						
Marketing Category	Applica	tion Number or Monogra	ph Citation	Marketing Start Date	Marketing	End Date
ANDA	ANDAZ09	713		03/20/2019		

LEVOTHYRO levothyroxine sodiu		IUM				
Product Informa	tion					
Product Type		HUMAN PRESCRIPTION	N DRUG	Item Code (Source)	NDC:68	180-971
Route of Administra	ition	ORAL				
Active Ingredien	t/Active Moi	etv				
		ient Name		Basis of Str	ength	Strengtl
LEVO THYRO XINE S UNEQ51BO43MG4)	D DIUM (UNIE 9:	765S329G) (LEVOTIME	OXINE -	LEVOTINTO XINE SO ANIIVOROUS	DIUM	0.125 mg
Inactive Ingredie	ents					
		Ingredient Nam	e		Str	ength
CROSCARMILLOSE	SODIUM (UNE	M28OLIMBW8)				
FD&C BLUE NO. 1 (U	NE HSR47K3TB	D)				
FD&C BLUE NO. 2 (U						
FD&C RED NO. 40 (U						
FD&C YELLOW NO.						
MAGNESIUM STEAR		7M5I30)				
MANNITOL (UNR 30						
SOBUM BICARBON		5V39QD)				
STARCH, CORN (UNI	t 08232NY3SJ)					
Product Charact	eristics					
Color	BROWN (	Tan)	Score		2 pieces	
Shape	ROUND		Size		6mm	
Flavor			Imprint C	ode	1.22	
Contains						
Packaging						
# Item Code		Package Description	n	Marketing Start Date	Marketin	g End Date
1 NDC:68180-971-09	90 in 1 BOTTL	E; Type 0: Not a Combin	ation Product	03/20/2019		
2 NDC:68180-971-01	100 in 1 BOTT	E; Type 0: Not a Combi	sation Product	03/20/2019		
3 NDC:68180-971-02		LE; Type 0: Not a Combi		03/20/2019		
4 NDC:68180-971-03		TLE; Type 0: Not a Comb	bester Berdent	03/20/2019		

		on Number or Monograp		Marketing Sta	rt Date	Marketing	End Date
ANDA	ANDA20971			03/20/2019			
LEVOTHYROX	INE SOL	IUM					
evothyroxine sodium	tablet						
Product Information	on						
Product Type		HEMAN PRESCRIPTION D	muc.	hem Code (So		NDC-681	80,977
				nem Cone (50	urce)		
Route of Administrati	on	ORAL					
Active Ingredient/							
		ient Name			of Stren		Strength
LEVOTHYROXINE SOI UNBOSIBO43MG4)	DIUM (UNIL 9)	765S329G) (LEVOTIMROX	CINE -	LEVOTIMBO: ANIMOROUS	UNE SODI	UM	0.137 mg
UNEQSIBU43MG4)				ANITOROUS			
Inactive Ingredien	ts						
		Ingredient Name				Stre	ngth
CROSCARMELLOSES							
FD&C BLUE NO. 1 (UNI							
MAGNESIUM STEARAT		7M5I30)					
MANNITOL (UNR 30W	L53L36A)						
MANNITOL (UNE 30W) SODIUM BICARBONAT	LS3L36A) FE (UNIE: BMD)						
MAGNESIUM STEARAT MANNITOL (UNE 30W SODIUM BICARBONAT STARCH, CORN (UNE 0	LS3L36A) FE (UNIE: BMD)						
MANNITOL (UNR 30W) SODIUM BICARBONAT	LS3L36A) FE (UNIE: BMD)						
MANNITOL (UNE 3OW SODIUM BICARBONAT STARCH, CORN (UNE 0	LS3L36A) TE (UNIE 8 MDI D8232NY3SJ)						
MANNITOL (UNE 30WI SOBRUM BICARBONAT STARCH, CORN (UNE C Product Character	L53L36A) TE (UNIE 8 MIX D8 Z32NY3SJ)	3Y39QO)					
MANNITOL (UNE 30W SODIUM BICARBONAT STARCH, CORN (UNE C Product Character Color	LSILIGA) TE (UNIE 8 MID D8 ZIZNYISI) TISTICS TURQUO	281 28139QO)	Score			2 pieces	
MANNITOL (UNE 30W SODIUM BICARBONAT STARCE, CORN (UNE C Product Character Color Shape	L53L36A) TE (UNIE 8 MIX D8 Z32NY3SJ)	SE SE	Size			6mm	
MANNITOL (UNE 30W SODIUM BICARBONAT STARCH, CORN (UNE C Product Character Color Shape Flavor	LSILIGA) TE (UNIE 8 MID D8 ZIZNYISI) TISTICS TURQUO	SE SE					
MANNITOL (UNE 30W SODIUM BICARBONAT STARCE, CORN (UNE C Product Character Color Shape	LSILIGA) TE (UNIE 8 MID D8 ZIZNYISI) TISTICS TURQUO	SE SE	Size			6mm	
MANNITOL (UNE 30W SODIUM BICARBONAT STARCH, CORN (UNE C Product Character Color Shape Flavor	LSILIGA) TE (UNIE 8 MID D8 ZIZNYISI) TISTICS TURQUO	SE SE	Size	•		6mm	
MANNITOL (UNE 30WI SO DRUM BICARBONAT STARCH, CORN (UNE 6 Product Character Color Shape Flavor Contains	LSILIGA) TE (UNIE 8 MID D8 ZIZNYISI) TISTICS TURQUO	SE SE	Size	•		6mm	
MANNITOL (UNE SOW SO BRUM BECARBONAT STARCE, CORN (UNE C Product Character Celor Shape Flaver Centains	LSILIGA) TE (UNIE 8 MID D8 ZIZNYISI) TISTICS TURQUO	SE (2019Q0)	Size			6mm L23	
MANNITOL (UNE 30W SO BRUM BECARBO NAT STARCIL CO RN (UNE 6 Product Character Color Shape Flavor Contains Packaging # Item Code	LSSLEGA) TE (UNE: BMEX DB 232NY3SJ) Sistics TURQUE ROUND	SEE  Package Description	Size Imprint Cod	Marketing St.	art Date	6mm L23	g End Date
MANNTOL (UNE 30W SORICH BECAUSO NAT STARCIA CORN (UNE Color	LSSLEGA) TE (UNE SMEX DE ZIZIVYSSJ)  SETICS TURQUE ROUND	SV39QO) SE  Package Description 5: Type 6: No a Combination	Size Imprint Cod	Marketing St. 03/20/2019	art Date	6mm L23	End Date
MANATO I, (1908. 300% SOBIEM BIGABIONAT STARCER CORN (LUNE COLOR CORN (LUNE COLOR COLOR CORN (LUNE COLOR COL	LSILBGA)  TE (UNE: BMEXE  TOR 232NY3SJ)  SETICS  TURQUE  ROUND  100 in 1 BOTTL  100 in 1 BOTTL	SV284QO) SSE  Package Description E; Type 0: Near Combinion	Size Imprint Cod imprint Cod improduct	Marketing St. 03/20/20 19 03/20/20 19	art Date	6mm L23	g End Date
MANNITO, (UNB. 30W SO BILM BICARBONAT STARCIA CORN (UNB. 6 Color Shape Flavor Centains  Packaging    Item Code   I	LSH-86A)  TE (UNE BMEXIBEZIZNYJST)  TISTICS  TURQUE  ROUND  100 in 1 BOTTL  100 in 1 BOTTL  100 in 1 BOTTL	SEE  Package Description 1; Type 0: Next Combination 1; Type 0: Next Combination 1; Type 0: Next Combination	Size Imprint Cod  on Product ion Product ion Product	Marketing St. 03/20/20 19 03/20/20 19 03/20/20 19	art Date	6mm L23	g End Date
MANNTOL (UNB 20W 50 DRIM BICARBONAT STARCEL CORN (UNB 6 Celer Shape Plaver Centains   Tree Cen	LSH-86A)  TE (UNE BMEXIBEZIZNYJST)  TISTICS  TURQUE  ROUND  100 in 1 BOTTL  100 in 1 BOTTL  100 in 1 BOTTL	SV284QO) SSE  Package Description E; Type 0: Near Combinion	Size Imprint Cod  on Product ion Product ion Product	Marketing St. 03/20/20 19 03/20/20 19	art Date	6mm L23	g End Date
MANNTOL (UNB 20W 50 DRIM BICARBONAT STARCEL CORN (UNB 6 Celer Shape Plaver Centains   Tree Cen	LSH-86A)  TE (UNE BMEXIBEZIZNYJST)  TISTICS  TURQUE  ROUND  100 in 1 BOTTL  100 in 1 BOTTL  100 in 1 BOTTL	SEE  Package Description 1; Type 0: Next Combination 1; Type 0: Next Combination 1; Type 0: Next Combination	Size Imprint Cod  on Product ion Product ion Product	Marketing St. 03/20/20 19 03/20/20 19 03/20/20 19	art Date	6mm L23	g End Date
MANNTOL (UNB 20W 50 DRIM BICARBONAT STARCEL CORN (UNB 6 Celer Shape Plaver Centains   Tree Cen	LSH-86A)  TE (UNE BMEXIBEZIZNYJST)  TISTICS  TURQUE  ROUND  100 in 1 BOTTL  100 in 1 BOTTL  100 in 1 BOTTL	SEE  Package Description 1; Type 0: Next Combination 1; Type 0: Next Combination 1; Type 0: Next Combination	Size Imprint Cod  on Product ion Product ion Product	Marketing St. 03/20/20 19 03/20/20 19 03/20/20 19	art Date	6mm L23	g End Date
MANNITOL (UNB 200 SOBREM BACABRO NAT STARCH, CORN (UNB 6 STARCH) C	LSJLEGA)  TE (UNE: 8 MEXE  BE 22 NY JSJ)  Sistics  TURQUE  ROUND  100 in 1 BOTTI	SEE  Package Description 1; Type 0: Next Combination 1; Type 0: Next Combination 1; Type 0: Next Combination	Size Imprint Cod  on Product ion Product ion Product	Marketing St. 03/20/20 19 03/20/20 19 03/20/20 19	art Date	6mm L23	g End Date
MANNITOL (UNB 300 SOBRIM BECARBO NAT STARCEL CORN (UNB CO Color STARCEL CORN (UNB CO Color STARCEL CORN (UNB CO COLOR STARCEL CORN (UNB COLOR STARCEL	ESILIGA)  FE (UNE 8 MEXICO E 2017 STATE OF TURQUE BOUND  100 in 1 BOTTH  100 i	SEE  Package Description E. Type 6: Not a Cambinos LE: Type 0: Not a Cambinos LE: Type 0: Not a Cambinos	Size Imprint Ced imprint Ced imprint Ced imprint Ced improduct improduct improduct improduct improduct improduct	Marketing St. 03/20/20 19 03/20/20 19 03/20/20 19 03/20/20 19		6mn 123 Marketing	
MANNTOL (UNB 200 SOBRIM BLAZABRO NAT STARCIL CORN (UNB CO FOR CORN CORN CORN CORN CORN CORN CORN CO	ESILIGA)  FE (UNE: 8 MAX PER (	SVE Package Description E. Type 0: Not a Combustic E. Type 0: Not a Combust On Number or ar Manageap	Size Imprint Cod I	Marketing St. 03/20/20 19 03/20/20 19 03/20/20 19 03/20/20 19 03/20/20 19 Marketing Sta		6mm L23	
MANNTOL (UNB 200 SORIEM BACABRO NAT STARCIL CORN (UNB 6 Product Character Celer Shape Flavor Centains Packaging Item Code I NDC.68 880-972-02 [2 NDC.68 880-972-02 ] NDC.68 880-972-02 [4 NDC.68 880-972-02 ] Marketing Info	ESILIGA)  FE (UNE 8 MEXICO E 2017 STATE OF TURQUE BOUND  100 in 1 BOTTH  100 i	SVE Package Description E. Type 0: Not a Combustic E. Type 0: Not a Combust On Number or ar Manageap	Size Imprint Cod I	Marketing St. 03/20/20 19 03/20/20 19 03/20/20 19 03/20/20 19		6mn 123 Marketing	

Product Information
Product Type IRAMAN PRISCRIPTION DRAW Rem Cede (Source) NDC.68180-973

Peckaging	LEVO THYRO XINE SO: UNEQ51BO43MG4)	Ingredient Nam DIUM (UNIE 937658329G)	e ) (LEVOTIMROXINE -	Basis of Strength  LEVOTHYROXINE SODRIM  ANHYDROUS	O.15 mg
Command   Comm	Inactive Ingredien	its			
Transport	CROSCARMILLOSES	Ingre ODIUM (UNR MESOLISE			Strength
SIGNAME CADAPT	FD&C BLUE NO. 2 (UN	II: LOSKSETDQK)			
Political Characteriotics Chier   March   Store   Service   Servic	SODIUM BICARBONAT	FE (UNE: 8MDF5V39QO)			
Cacher	STARCH, CORN (UNE	08232NY3SJ)			
Stage	Product Character	ristics			
Packaging	Shape		Size	6 mm	
Foreign   Continue	Flavor Contains		Imprint Code	124	
Foreign   Continue					
	Packaging	Parkage	Description	Marketing Start Date Market	ting End Da
	1 NDC:68180-973-09	90 in 1 BOTTLE: Type 0: 7	Not a Combination Product	03/20/2019	
	3 NDC:68180-973-02 : 4 NDC:68180-973-03	500 in 1 BOTTLE; Type 0: 1000 in 1 BOTTLE; Type 0	Not a Combination Product 1: Not a Combination Product	03/20/2019	
Product Claracteristics	Marketing Category	Application Number	r or Monograph Citation	Marketing Start Date Marke	ting End Da
Product Information				03/20/2019	
Mode   Part   Mode					
Active Ingredient/Active Naivy  Active Ingredient/Active Naivy  Extractive Ingredient/Active Naivy  Extractive Ingredient/Active Naivy  Ingredient Name  Engredient Name  Engred		on HUMAN P	RESCRIPTION DRUG	Rem Code (Source) NDC	68180-974
LEVOTHYNOXINE SOUTHWAY 1970-1970-1970-1970-1970-1970-1970-1970-	Route of Administrati	ion ORAL			
LEVOTHYNOXINE SOUTHWAY 1970-1970-1970-1970-1970-1970-1970-1970-	Active Ingredient/	Active Moiety			
Inactive Ingredients		Ingredient Nam	e (LEVOTIPROXIPE	Basis of Strength	
Experience   Exp	UNEQSIBO43MG4)			ANINDROUS	0.175 m
Experience   Exp	Inactive Ingredien	ıts			
ACCESSED AND TOTAL CONTROLLED AND THE STANDARD S		Ingre			Strength
MACHINERY DETAILED (100 TOPICS)  Product Characteristics  Product Chara	D&C RED NO. 27 (UNIX FD&C BLUE NO. 1 (UN	: 2LRS IB 5U6K) B: HSR47K3TBD)			
Product Characteristic   Calar	MAGNESIUM STEARAT	FE (UNE: 70097M5E30)			
Product Characteristics  Calve POPULE (Idea) Sever 2 percent Code  Carbon Development Code 2 percent Code 2 per	SO DIUM BICARBO NAT	FE (UNE: 8MDF5V39QO)			
California   NOTICE   California   Store   S					
Store   Stor	Product Character	PURPLE (Liber)	e	7	g1
Parkaging	Shape Flavor	ROUND	Size	6nn	
File Content   Product	Flavor Contains		Imprint	.25	
File Content   Product	Darker 1				
Marketing Information  Marketing Information  Marketing Information  Marketing Information  Marketing Information  Marketing Information  Marketing Start Raw  [Additional Content of the	# Item Code	Package	Description	Marketing Start Date Marke	ting End Da
Marketing Information  Marketing Information  Marketing Information  Marketing Information  Marketing Information  Marketing Information  Marketing Start Raw  [Additional Content of the	1 NDC:68180-974-09 5 2 NDC:68180-974-01	so in 1 BOTTLE; Type 0: 7 100 in 1 BOTTLE; Type 0:	Not a Combination Product	0.5/20/2019 0.3/20/2019	
Marketing Information  Marketing Information  Marketing Information  Marketing Information  Marketing Information  Marketing Information  Marketing Start Raw  [Additional Content of the	a NDC:68180-974-02 1 4 NDC:68180-974-03	ouv is 1 BOTTLE; Type 0: 1000 is 1 BOTTLE; Type 0	not a Combination Product P: Not a Combination Product	U.5/20/2019 1 03/20/2019	
Marketing (Early No. Application Sunder or Memograph Clarine)  EVOCTHYROXINE SODIUM  Product Information    Product Information					
Description	Marketing Info	rmation		W. L	
Product Claracteristic Cales	ANDA	ANDA209713			ong rao Da
LEVOTHYBOURS CORNING (NEW STYRESSPEC) (LEVOTHYBOURNE - LEVOTHYBOURNES ODDINA () 2 mg Annual Control () 2 mg Annual	Product Informati	tablet  on  HUMAN P			68180-975
Insective Ingredients   Ingredient Name	Product Informati Product Type Route of Administrati	ion  HUMAN P  ORAL			58180-975
EDUCAMENTAL DOS 100 (MA) PROTECTION    EDUCAMENTAL DOS 100 (MA) PROTECTION    MANCHARD STRAKET (DR. TESTISTER)    MANCHARD STRAKET (DR. TESTISTER)    MANCHARD STRAKET (DR. TESTISTER)    MANCHARD STRAKET (DR. TESTISTER)    FORMAT (DR. TESTISTER)    FORM	Product Informati Product Type Route of Administrati Active Ingredient/	on HEMAN P	RESCRIPTION DRUG	Rem Code (Source) NDC  Basis of Strength	Streng
EDUCAMENTAL DOS 100 (MA) PROTECTION    EDUCAMENTAL DOS 100 (MA) PROTECTION    MANCHARD STRAKET (DR. TESTISTER)    MANCHARD STRAKET (DR. TESTISTER)    MANCHARD STRAKET (DR. TESTISTER)    MANCHARD STRAKET (DR. TESTISTER)    FORMAT (DR. TESTISTER)    FORM	Product Informati Product Type Reute of Administrati Active Ingredient/	on HEMAN P	RESCRIPTION DRUG	Rem Code (Source) NDC  Basis of Strength	Streng
Product Characteristics  Sing   Section   Sect	Product Informati Product Informati Product Type Reute of Administrati Active Ingredient/ LEVOTHYROXINE SOLUMITQSIEGG43MC4)	IRIMAN P ORAL  Active Moiety Ingredient Nam ORAL  Active Moiety Ingredient Nam ORAL	RESCRIPTION DRING	Rem Code (Source) NDC  Basis of Strength	Streng
SOURCE AND CALLED AND CONTROL OF STATE OF STAT	Product Informati Product Informati Product Type Route of Administrati Active Ingredient/ LEVOTHYROXINE 501 UNRQSIBO-13MC4) Inactive Ingredien	tablet  On  IRAMAN P  ORAL  Active Molety  Ingredient Nam  DRIM (UNI 97755329G)  its	RESCRIPTION DRUG  R (LEVOTTHROXINE -	Rem Cede (Source) NDC  Rasin of Strength LEVOTHROUND SODEM ANITITEOUS	Streng 0.2 mg
Product Characteristics  Cale  Proc.  Start  Continue  Description  Start  Description  Description  Start  Description  D	Product Informati Product Informati Product Type Route of Administrati Active Ing redient/ LEVOTHING NIME SO UNING SIBOLIME() Inactive Ingredien CRO SCARMILLOSES FIAC RED NO. 46 (UM MAGNISHIN STEAKN	Tablet  IRAMAN P  IRAMAN P  ORAL  Active Moiety  Ingredient Nam  BILM (UNR 9)7858329G)  Its  Ingredient Nam  ELEM (UNR 907858329G)  ELEM (UNR 907858329G)	RESCRIPTION DRUG  R (LEVOTTHROXINE -	Rem Cede (Source) NDC  Rasin of Strength LEVOTHROUND SODEM ANIFICEOUS	Streng 0.2 mg
California	Product Informati Product Informati Product Type Route of Administrati Active Ing redient LEVO THYRO XNE 500 UNRIGHED-1996(4) LING SCARMILLOSES FRACE RED NO. 46 (UN MAGNISHM STEAM)	IRAMAN P ORAL  Active Moiety  Ingredient Nam ORAL  Active Moiety  Ingredient Nam ORAM (UNR 97%551296)  tiss  Ingredient Nam OBMAN (UNR MESOLIBE  E WESD 127%AND  FE (UNR MESOLIBE  FE (UNR MESOLIBE  E (UNR MESOLI	RESCRIPTION DRUG  R  (LEVOTHINGXINE -  children Name  86)	Rem Cede (Source) NDC  Rasin of Strength LEVOTHROUND SODEM ANIFICEOUS	Streng 0.2 mg
California	Product Informati Product Informati Product Type Buste of Administrati Active Ingredient/ LEVO THYRO XINE 501 UNIQSIBO-15ME-6) LING SCARMILLOSE S FEAC RED NO. 46 (UNI MACKINESIN STEARM MANNIOL (UNI SORIEM BLARBOWA MANNI	IRDAN P IRDAN P IRDAN P Ingredient Nam DILM (URB 97765529G) Its ODRIM (URB 92780519G) E WZB917ZNOA) FF (URB 98079MED)	RESCRIPTION DRUG  R  (LEVOTHINGXINE -  children Name  86)	Rem Cede (Source) NDC  Rasin of Strength LEVOTHROUND SODEM ANIFICEOUS	Streng 0.2 mg
Parkaging   Parkage Description   Parkage	Product Informati Product Informati Product Type Busts of Administrati Active Ingredient/ LEVO TIWKO NNE 50 UNREQ\$IBO-64ME-10 Inactive Ingredien CRO SCARMELLOSES FROC EED NO. 48 (UN MAGNISHIS STEAKS SORGEM BICARRO NAT STARCEL CORN (UNE 6)	Active Moiety Ingredient Nam UMM (NR 197553276)  Is seen to seen to see	RESCRIPTION DRUG  R  (LEVOTHINGXINE -  children Name  86)	Rem Cede (Source) NDC  Rasin of Strength LEVOTHROUND SODEM ANIFICEOUS	Streng 0.2 mg
Packaging  # June Cade  # June	Product Informati Product Type Bases of Administrati Active Ingredient LEOTHING MEDICAL LEOTHING LE	INDAMA PORAL  Active Moiety  Ingredient Namo  ORAL  Active Moiety  Ingredient Namo  ORAL  Active Moiety  Ingredient Namo  ORAL  CONT. (CONT. (	NESCRIPTON ISSUE  R  R  R  R  R  R  R  R  R  R  R  R  R	Nom Code (Source) NOC  Rasks of Strength LEVOTHNOLOUS SOIEM ANNERSOUS	Streng 0.2 mg
Size Carlot   Package Description   Number of Strength   Number of Str	Product Informati Product Informati Product Type Buse of Administratory Buse of Administrat	INDAMA PORAL  Active Moiety  Ingredient Namo  ORAL  Active Moiety  Ingredient Namo  ORAL  Active Moiety  Ingredient Namo  ORAL  CONT. (CONT. (	Seere Size	New Code (Searce) POC  Basis of Strength  Accordance Stocks  Accordanc	Streng 0.2 mg
Security of the Content of the Con	Product Informati Product Informati Product Type Bases of Administrati Rases of Rases of Rases Rases Rases of Rases Ras	INDAMA PORAL  Active Moiety  Ingredient Namo  ORAL  Active Moiety  Ingredient Namo  ORAL  Active Moiety  Ingredient Namo  ORAL  CONT. (CONT. (	Seere Size	New Code (Searce) POC  Basis of Strength  Accordance Stocks  Accordanc	Streng 0.2 mg
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Product Information  Product Type  BOAN PERSON TORSO  Boar of Administration  Onto.  Stock  Boar of Administration  Onto.  Active Ingredient/Active Meisty  Ingredient/Active	Product Type  Rose of Administration  Active Ingredient  Active Ingredient  LECTIFICATION  LECTI	OR INDAMY PARKETS  INDAMY PARKETS  INDIGATE OF THE PARKETS  INDIGATE OF	SCORE SOURCE STORY OR SOURCE SO	Man Code (Saure) NOC  Mask of Strength LAVOTIMOSONS SIGNA AMERICA  2 pers Loss Loss Loss Loss Loss Loss Loss Lo	Streng 0.2 mg
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	Product Informati Product Informati Product Informati Product Informati Active Ingredient LECTIFICATION LECTIFICAT	IN EDUTIL Type 0  IN EDUTL TYPE	Seere Suppose Code Description	Man Code (Searce) 2000  Rasis of Strength Lawrences Stotch Accordances  2 Agency Accordances Accordanc	Strength 0.2 mg
Active IngredientActive Noisy  Active IngredientActive Noisy  Exportinate Noisy  Exportin	Product Informati Information	MANAGE   M	Seere Suppose Code Description	Man Code (Searce) 2000  Rasis of Strength Lawrences Stotch Accordances  2 Agency Accordances Accordanc	Strength 0.2 mg
LECOTORIO XANA SODIAM (URB STANSASSOC) (LECOTORIO XANA SODIAM (URB STANSASSOC)	Product Character Cabe Shape Castles Cabe Shape Castles Castle	155001 F	Seary State Colonian Profess Nat Combinion P	Basis of Strength  Assume Code (Searce)  Basis of Strength  Assume Stock  Assume Stock	Strength  1 2 = g  1 2 = g  1 2 = g  1 2 = g  1 3 = g  1
LECOTORIO XANA SODIAM (URB STANSASSOC) (LECOTORIO XANA SODIAM (URB STANSASSOC)	Product Character Cabe Shape Castles Cabe Shape Castles Castle	155001 F	Seary State Colonian Profess Nat Combinion P	Basis of Strength  Assume Code (Searce)  Basis of Strength  Assume Stock  Assume Stock	Strength  1 2 = g  1 2 = g  1 2 = g  1 2 = g  1 3 = g  1
Inactive Ingredients   Ingredient Name	Product Informati Product Informati Product Informati Product Informati Product Informati Product Informati Active Ingredient LINOTITING NUMBER LINOTITING N	IN THE STATE OF TH	Seary State Colonian Profess Nat Combinion P	Mara Code (Season) NOC.  Basis of Strength  John Code (Season)  2 proces  Season Strength  ANNOTATION  ANNOTATION  ANNOTATION  Season Strength  ANNOTATION  ANNOTA	Strength  0.2 mg  0.2
Engredient Name   Strength   St	Product Character Cabe Manyon Caracter Cabe Dispute Code Caracter Cabe Dispute Code	INSOLVE PROPERTY OF THE PROPER	SCORPTION COLIG  SCORPTION COLIG  SCORPTION COLIG  SCORPTION COLIG  May coli Carle  May colicide to Public  MAY COLICIDE TO MAY	Man Cade (Saures) NCC  Rasis of Strength LANOTHROUGH SOLDM ANDERSOLS  2 pers loss loss 2020 10 2020000 10 2020000 10 2020000 10 2020000 10 20200000 10 20200000 10 20200000 10 202000000 10 2020000000000	Strength  0.2 mg  0.2 mg  End Da  Strength  Strength
Engredient Name   Strength   St	Product Character Cabe Manyon Caracter Cabe Dispute Code Caracter Cabe Dispute Code	INSOLVE PROPERTY OF THE PROPER	SCORPTION COLIG  SCORPTION COLIG  SCORPTION COLIG  SCORPTION COLIG  May coli Carle  May colicide to Public  MAY COLICIDE TO MAY	Man Cade (Saures) NCC  Rasis of Strength LANOTHROUGH SOLDM ANDERSOLS  2 pers loss loss 2020 10 2020000 10 2020000 10 2020000 10 2020000 10 20200000 10 20200000 10 20200000 10 202000000 10 2020000000000	Strength  0.2 mg  0.2 mg  End Da  Strength  Strength
Dec.   March	Product Information of the Control o	IN INDIVIDUAL STREET, TO THE STREET,	SCORPTION COLIG  SCORPTION COLIG  SCORPTION COLIG  SCORPTION COLIG  May coli Carle  May colicide to Public  MAY COLICIDE TO MAY	Man Cade (Saures) NCC  Rasis of Strength LANOTHROUGH SOLDM ANDERSOLS  2 pers loss loss 2020 10 2020000 10 2020000 10 2020000 10 2020000 10 20200000 10 20200000 10 20200000 10 202000000 10 2020000000000	Strength  0.2 mg  0.2 mg  End Da  Strength  Strength
TRACE YELLOW NO. 6 (10 NO INTERDATA)  MANNENDER STANDARD (10 NO 10	Product Tops  Base of Administration  Active Ingredient  LECTRONAME LOVE  Brown of Administration  LECTRONAME LOVE  FIRE CROSS AND ACTIVE INCREMENT  CONTROL TOPS  PRODUCT TOPS  PRODUCT TOPS  Brown  Product Character  Carlo  Ca	IN THE SOUTH TO THE STATE THE SOUTH TO THE S	SCAPTION ORAG  SCAPT SAME SAME SAME SAME SAME SAME SAME SAME	Marie Cade (Saures) NOC.  Mask of Strength LEVOTRODUSE SOLDM ANDERSOLS  2 press Lan Date Cade (Saures)  Marketing Start Date Market (Saures)  Mark	Strength  0.2 mg 0.2 mg 10.2 m
	Product Informati Product Type Bases of Administration Active Ingredient LECTIFICATION LECTIFICATION LECTIFICATION LINESTRATE LINEST	IN THE SOUTH AND THE STATE OF THE SOUTH AND	SCAPTION ORAG  SCAPT SAME SAME SAME SAME SAME SAME SAME SAME	Marie Cade (Saures) NOC.  Mask of Strength LEVOTRODUSE SOLDM ANDERSOLS  2 press Lan Date Cade (Saures)  Marketing Start Date Market (Saures)  Mark	Strength  0.2 mg 0.2 mg 10.2 m
Parket Characteristics	Product Character Cabe Marketing Cargary Parket Office of the Control of the Cont	IN SAGALY PARENTS OF THE PARENTS OF	SCAPTION ORAG  SCAPT SAME SAME SAME SAME SAME SAME SAME SAME	Marie Cade (Saures) NOC.  Mask of Strength LEVOTRODUSE SOLDM ANDERSOLS  2 press Lan Date Cade (Saures)  Marketing Start Date Market (Saures)  Mark	Strength  0.2 mg 0.2 mg 10.2 m
Caliar	Product Information of the Control o	IN STATE OF THE ST	SECRETION DRIG  ( LEVOTHOROUNE -  SECRETION DRIG  SECRETION DR	Marie Cade (Saures) NOC.  Mask of Strength LEVOTRODUSE SOLDM ANDERSOLS  2 press Lan Date Cade (Saures)  Marketing Start Date Market (Saures)  Mark	Strength  0.2 mg 0.2 mg 10.2 m
Caliar	Product Character  Capacity Type  Base of Administration  LENOTHING NESS  Base of Administration  LENOTHING NESS  Base of Administration  Marketing Category  Base of Administration  Marketing Category  Base of Administration  Base of Administration  LEVOTHYROX  ELEVOTHYROX  ELEVOTHYROX  ELEVOTHYROX  Base of Administration  Base VELLOW NESS  Base VELLOW	MANON PRO   MANO	SECRETION DRIG  ( LEVOTHOROUNE -  SECRETION DRIG  SECRETION DR	Marie Cade (Saures) NOC.  Mask of Strength LEVOTRODUSE SOLDM ANDERSOLS  2 press Lan Date Cade (Saures)  Marketing Start Date Market (Saures)  Mark	Strength  0.2 mg 0.2 mg 10.2 m
Reser	Product Character  Carbon San Car	IN THE STATE TO THE STATE OF TH	SECRETION DRIG  ( LEVOTHOROUNE -  SECRETION DRIG  SECRETION DR	Marie Cade (Saures) NOC.  Mask of Strength LEVOTRODUSE SOLDM ANDERSOLS  2 press Lan Date Cade (Saures)  Marketing Start Date Market (Saures)  Mark	Strength  0.2 mg 0.2 mg 10.2 m
Centains  Parkaging  Parkage Description  Parkage Description  Marketing Start Date  Marketing Start Date  Marketing End Date  1,000,000,000,000,000,000,000,000,000,	Product Character  Capacity Type  Base of Administrati  LENOTHING NESS  Base of Administrati  LENOTHING NESS  Base of Administrati  Base values of Administra	MARCH	SECRETION ORAG   SECRETION ORAG  SECRETION ORAGINA  SECRETION  SEC	Basis of Strength LANDITIONS SIGNA  Applicating Start Date  Marketing Start Date  Market	Strength  0.2 mg 0.2 mg 10.2 m
## Item Code Package Description Marketing Start Date Marketing End Di (INCASH189-978-9) 90 is 1 2017111; 1790 - 5 Nist Cambination Product 02/20/2019 2 NICASH189-978-91 1990 is 1 2077112; 1790 0 Nist Cambination Product 02/20/2019 3 NICASH189-978-22 2090 is 1 1007112; 1790 0 Nist Cambination Product 02/20/2019 1990 1 NIST CAMBINATION PRODUCT 02/20/2019 1 NIST CAMBINATI	Product Character Cabe Shape Castles Cabe Castles Castles Cabe Castles Cabe Castles Cabe Castles Cast	IN STANCE PER CONTROL TO THE CONTROL	SCAPTION ORAG  SCAPTION ORAG  SCAPT  SCAPT  SCAPT  SALE  SCAPT  SALE  SA	Basis of Strength  2 process  Basis of Strength  2 process  Basis of Strength  Basis of Strength  Basis of Strength  Basis of Strength  LEVOTTIME DATE SHEET  Basis of Strength  Basis of Strength  LEVOTTIME DATE SHEET  Basis of Strength	Strength  0.2 mg 0.2 mg 10.2 m
## Item Code Package Description Marketing Start Date Marketing End Di (NCC68180-978-0) 90 is 1 2017LE; 1ypo - Nisa L combination Product 02/20/2019 2 NCC68180-978-01 390 is 1 207TLE; 1ypo - Nisa Combination Product 02/20/2019 3 NCC68180-978-02 200 is 1 1007TLE; 1ypo - Nisa Combination Product 02/20/2019 3 NCC68180-978-02 200 is 1 1007TLE; 1ypo - Nisa Combination Product 02/20/2019 3 NCC68180-978-02 200 is 1 1007TLE; 1ypo - Nisa Combination Product 02/20/2019 3 NCC68180-978-02 200 is 1 1007TLE; 1ypo - Nisa Combination Product 02/20/2019 3 NCC68180-978-02 200 is 1 1007TLE; 1ypo - Nisa Combination Product 02/20/2019 3 NCC68180-978-02 200 is 1 1007TLE; 1ypo - Nisa Combination Product 02/20/2019 3 NCC68180-978-02 200 is 1 1007TLE; 1ypo - Nisa Combination Product 02/20/2019 3 NCC68180-978-02 200 is 1 1007TLE; 1ypo - Nisa Combination Product 02/20/2019 3 NCC68180-978-02 200 is 1 1007TLE; 1ypo - Nisa Combination Product 02/20/2019 3 NCC68180-978-02 200 is 1 1007TLE; 1ypo - Nisa Combination Product 02/20/2019 3 NCC68180-978-02 200 is 1 1007TLE; 1ypo - Nisa Combination Product 02/20/2019 3 NCC68180-978-02 200 is 1 1007TLE; 1ypo - Nisa Combination Product 02/20/2019 3 NCC68180-978-02 200 is 1 1007TLE; 1ypo - Nisa Combination Product 02/20/2019 3 NCC68180-978-02 200 is 11007TLE; 1ypo - Nisa Combination Product 02/20/2019 3 NCC68180-978-02 200 is 11007TLE; 1ypo - Nisa Combination Product 02/20/2019 3 NCC68180-978-02 200 is 11007TLE; 1ypo - Nisa Combination Product 02/20/2019 3 NCC68180-978-02 200 is 11007TLE; 1ypo - Nisa Combination Product 02/20/2019 3 NCC68180-978-02 200 is 11007TLE; 1ypo - Nisa Combination Product 02/20/2019 3 NCC68180-978-02 200 is 11007TLE; 1ypo - Nisa Combination Product 02/20/2019 3 NCC68180-978-02 200 is 11007TLE; 1ypo - Nisa Combination Product 02/20/2019 3 NCC68180-978-02 200 is 11007TLE; 1ypo - Nisa Combination Product 02/20/2019 3 NCC68180-978-02 200 is 11007TLE; 1ypo - Nisa Combination Product 02/20/2019 3 NCC68180-02 200 is 11007TLE; 1ypo - Nisa Combination Product 02/20/2019 3 NCC68180-02 20	Product Character Cabe Shape Castles Cabe Castles Castles Cabe Castles Cabe Castles Cabe Castles Cast	IN STANCE PER CONTROL TO THE CONTROL	SCAPTION ORAG  SCAPTION ORAG  SCAPT  SCAPT  SCAPT  SALE  SCAPT  SALE  SA	Basis of Strength  2 process  Basis of Strength  2 process  Basis of Strength  Basis of Strength  Basis of Strength  Basis of Strength  LEVOTTIME DATE SHEET  Basis of Strength  Basis of Strength  LEVOTTIME DATE SHEET  Basis of Strength	Strength  0.2 mg 0.2 mg 10.2 m
2 NDC:58180-976-01 100 in 1 BOTTLE; Type 0: Not a Combination Product 03/20/2019 3 NDC:58180-976-02 500 in 1 BOTTLE; Type 0: Not a Combination Product 03/20/2019	Product Character  Case Case Case Case Case Case Case Case	IN STANCE PER CONTROL TO THE CONTROL	SCAPTION ORAG  SCAPTION ORAG  SCAPT  SCAPT  SCAPT  SALE  SCAPT  SALE  SA	Basis of Strength  2 process  Basis of Strength  2 process  Basis of Strength  Basis of Strength  Basis of Strength  Basis of Strength  LEVOTTIME DATE SHEET  Basis of Strength  Basis of Strength  LEVOTTIME DATE SHEET  Basis of Strength	Strength  0.2 mg 0.2 mg 10.2 m
4 NDC-68 ISO-976-93 3000 is 1 BOTTLE; Type 0: Not a Combination Product 03/20/20 19	Product Character Cabre Shape Packet Directive Ingredien CHONGROUND IN CONTROL OF THE CONTROL OF THE CHORACTER CHONGROUND IN CONTROL OF THE CHORACTER CHORACTER PRODUCT CHARACTER CHORACTER C	IN STANCE OF THE	SCENTION ORIGINAL STATES OF THE STATES OF TH	Man Code (Source) 900  Rasis of Strength LEVERTHOUSE STREET LEVERTHOUS	Strength    0.2 mg
	Product Character Cabre Shape Packet Directive Ingredien CHONGROUND IN CONTROL OF THE CONTROL OF THE CHORACTER CHONGROUND IN CONTROL OF THE CHORACTER CHORACTER PRODUCT CHARACTER CHORACTER C	IN STANCE OF THE	SCENTION ORIGINAL STATES OF THE STATES OF TH	Man Code (Source) 900  Rasis of Strength LEVERTHOUSE STREET LEVERTHOUS	Strength    0.2 mg
	Product Informati Product Type Buste of Administration Active Ingredient LEVOTHYNO NES SOLITION Buste of Administration LEVOTHYNO NES SOLITION Buste of Administration Inscribe Ingredient LEVOTHYNO NES SOLITION MICHIGAN STATE MICHIG	Service Servic	SCEPTION ORAG  Serv  Ser	Mark Code (Sauces) POC.  Raids of Strength Lacotromocome contact ANDORROUS  2 proces Lacotromocome contact ANDORROUS  Society Lacotromocome contact Lacotr	Strength    0.2 mg
	Product Character  Cale State Control of the Contro	IN STANCE PROPERTY NAME OF THE	SCOPTION ORAG  SCOPTI	Mark Code (Sauces) POC.  Raids of Strength Lacotromocome contact ANDORROUS  2 proces Lacotromocome contact ANDORROUS  Society Lacotromocome contact Lacotr	Strength  0.2 mg  0.2 mg  End Do  Strength  End Do  Strength  Strength

Labeler - Lupin Pharmaceuticals, Inc. (089153071)

Registrant - Lupin Atlantis Holdings SA (483965509)

Establishment

None Mderes DSEI

MANUFACTURED 2010-04: Embero Operation

MANUFACTURED 2010-04: Embero Corporation

MANUFACTURED 2010-04: Embero Corporation