MedChoice
Endocrine

Levothyroxine Sodium

Thydin

12.5 mcg • 25 mcg • 50 mcg • 100 mcg • 150 mcg Tablet

THYROID HORMONE REPLACEMENT

PRODUCT DESCRIPTION:
Levothyroxine Sodium 12.5 mcg Tablet (Thydin) is a white, oval-shaped biconvex tablet, scored on one side and plain on the other.
Levothyroxine Sodium 25 mcg Tablet (Thydin) is a light pink mottled, oval-shaped biconvex tablet, scored on one side and plain on the other.
Levothyroxine Sodium 50 mcg Tablet (Thydin) is a light blue mottled, oval-shaped tablet, scored on one side and plain on the other.
Levothyroxine Sodium 100 mcg Tablet (Thydin) is a light yellow mottled, oval-shaped tablet, scored on one side and plain on the other.
Levothyroxine Sodium 150 mcg Tablet (Thydin) is a light green mottled, oval-shaped tablet, scored on one side and plain on the other.

FORMULATION:
Each Tablet contains:
Levothyroxine Sodium, USP ..... 12.5 mcg
Levothyroxine Sodium, USP ..... 25 mcg
Levothyroxine Sodium, USP ..... 50 mcg
Levothyroxine Sodium, USP ..... 100 mcg
Levothyroxine Sodium, USP ..... 150 mcg

CLINICAL PHARMACOLOGY:
Pharmacodynamics:
Thyroid hormones influence most body systems as they are responsible for regulating growth and development, affecting metabolic processes, stimulating calorigenesis and having a positive chronotropic and inotropic effect on the heart. These systems may slow down when shortage of thyroid hormones occur leading to fatigue, cold intolerance, sleepiness, dry skin, constipation and menstrual cycle disorder. In children, growth is delayed. Levothyroxine, the active ingredient in Levothyroxine Sodium Tablet (Thydin) is a synthetically prepared sodium salt of the natural hormone thyroxine. The major component of normal thyroid gland secretion is Thyroxine (T4), but it has a very small pharmacologic effect itself. The amount of inactive T4 that is converted into the active triiodothyronine (T3) in the peripheral tissues is approximately 30%. The precise mechanisms by which the thyroid hormones exert their physiologic action are not well understood. However, the physiological effect mediating at the cellular level primarily by T3 is known.

Pharmacokinetics:
Levothyroxine Sodium is variably but adequately absorbed from the gastrointestinal tract following oral administration. Fasting increases absorption. Only 0.03% of total thyroxine in plasma is free. Metabolism and excretion is reduced since thyroxine is bound to plasma proteins (Thyroxine Binding Globulin [TBG], Thyroxine-Binding-Pre-Albumin [TBPA] and albumin). Thyroxine has an elimination half-life of 6 to 7 days. In patients with hyperthyroidism, it is shortened to 3 to 4 days, whereas in patient with hypothyroidism and in elderly, half-life may be 9 to 10 days. In the liver, thyroid hormones are primarily degraded and their metabolites are excreted in the bile. Since thyroid hormones are released by hydrolysis in the intestine and reabsorbed, enterohepatic circulation occurs. Due to the long half-life of the T4, one single daily dose of Levothyroxine Sodium Tablet (Thydin) can result to a steady state blood level of the biologically active T3. When the oral dose is increased or decreased, the change in thyroxine levels is slow. The steady state level of thyroxine is reached in about a month.

INDICATIONS:
Levothyroxine Sodium Tablet (Thydin) is used as a replacement therapy for hypothyroidism of any etiology or as an adjuvant with anti-thyroid preparations to prevent hypothyroidism. It is used to suppress Thyroid Stimulating Hormone (TSH) in simple non-toxic goiter, such as thyroid nodules and Hashimoto's thyroiditis, and post therapeutic treatment for radiological or surgical operation. Levothyroxine Sodium Tablet (Thydin) is concomitantly given to patients undergoing thyroid suppression test and to patients taking drugs with goitrogenic effects such as lithium.

DOSAGE AND MODE OF ADMINISTRATION:
Levothyroxine Sodium Tablet (Thydin) is taken orally as a single daily dose, preferably one-half to one hour before breakfast. It should be taken at least 4 hours apart from drugs that are known to interfere with its absorption. Replacement dose should not be administered in a large volume of water for infants being breastfed. A tablet may be crushed in small amount of water to give a paste which may be given to an infant for sucking.

Adults
For adults with hypothyroidism, the initial daily dose is 50 mcg to 100 mcg increased by increments of 25 mcg to 50 mcg every 14 days to achieve a euthyroid state. Maintenance dose is usually 100 mcg to 200 mcg daily.
For adults who had undergone radiological or surgical treatment, rapid replacement therapy must be achieved.
To suppress Thyroid Stimulating Hormone (TSH) in adults, daily dose of 2.6 mcg per kilogram body weight is given.

Elderly
For elderly patients with cardiovascular disorder, initial dose is 12.5 mcg daily increased by increments of 12.5 mcg to 25 mcg every four weeks.
For patients over 60 years of age, the maintenance dose is about 25 percent lower than in younger adults.

Children
For neonates, the treatment is given in full replacement dose for rapid replacement. Treatment in children over 1 year old starts with 2.5 mcg to 5 mcg per kg body weight daily. The dose is gradually increased to achieve a euthyroid state.
For children less than 6 months old, 8 mcg to 10 mcg per kilogram body weight is usually given with daily replacement dose of 25 mcg to 50 mcg.
For 6 to 12 months old, 6 mcg to 8 mcg per kilogram body weight is given usually comprising of about 50 mcg to 75 mcg daily.
For children 1 to 5 years of age, about 75 mcg to 100 mcg daily replacement dose is given calculated at 5 mcg to 6 mcg per kilogram body weight.
For children 6 to 12 years of age, about 100 mcg to 150 mcg daily replacement dose is given calculated at 4 mcg to 5 mcg per kilogram body weight.
For children over 12 years of age, 2 mcg to 3 mcg per kilogram body weight is given with usual dose of 100 mcg to 200 mcg daily.
Or as prescribed by the physician.

CONTRAINDICATIONS:
Levothyroxine Sodium Tablet (Thydin) is contraindicated in patients with rare hereditary problems of galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption. It is also contraindicated in patients hypersensitive to levothyroxine or one of the ingredients of the tablet.

PRECAUTIONS:
Dose must be carefully monitored and titrated as it is necessarily given to a certain patient. When given to elderly and in patients with cardiovascular disease, high initial dose or rapid dose titration may exacerbate symptoms of cardiovascular disease. For patients with myxedema, low dose should initiate replacement therapy with slow dosing increments since these patients have increased sensitivity for thyroid hormones.

In pituitary hypothyroidism (secondary hypothyroidism), institute corticosteroid replacement therapy prior to Levothyroxine replacement therapy to prevent acute adrenal insufficiency.

Levothyroxine therapy affects thyroid function test; however, Thyroid Stimulating Hormone (TSH) test should be performed to check the levels of T3 and T4 for dose titration of Levothyroxine Sodium Tablet (Thydin). It should be noted that slight increase of T4 level is required to guarantee a normal level of T3.

Patients with euthyroid non-autonomous goiter can only be treated if the TSH response is not affected.

WARNING:
Thyroid hormones, including Levothyroxine Sodium Tablet (Thydin), should not be used either alone or with other therapeutic agents for the treatment of obesity or 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.

"For suspected adverse drug reaction, report to FDA: www.fda.gov.ph.
Seek medical attention immediately at first sign of any adverse drug reaction."

PREGNANCY AND LACTATION:
Although thyroid hormones cross the placenta, Levothyroxine Sodium Tablet (Thydin) can still be administered during pregnancy without hazard to the fetus if recommended dosage is applied. Readjustment of the dosage may be necessary since more thyroid hormone is bound to plasma proteins during pregnancy. Interference during neonatal screening for hypothyroidism may be expected since thyroxine is excreted in small quantities in breast milk. No effect has been observed in breastfed infants whose mothers were taking levothyroxine and as such it is considered to be comparable with breastfeeding.

DRUG INTERACTIONS:
Cholestyramine, Aluminum, Magnesium and Ferrous Preparations and Ciprofloxacin: Decrease the absorption of levothyroxine resulting to decrease effectiveness. Levothyroxine Sodium Tablet (Thydin) should be taken 4 hours apart from these medications.
Phenytoin, Carbamazepine, Rifampicin and Barbiturates: Increase the biotransformation and elimination of levothyroxine.
Estrogens: Increase the serum concentration of thyroxine-binding globulin (TEG).
Lithium and Iodide: Decrease thyroid hormone secretion from the thyroid gland.
Propranolol, Amiodarone, some X-ray-imaging fluids and Dexamethasone: Inhibit enzyme responsible for the conversion of T4 to T3 causing decrease in T3 level; thus, therapeutic effect also decrease. For patients with hypothyroidism continuously taking Propranolol with Levothyroxine Sodium Tablet (Thydin), plasma level of Propranolol may decrease.
Antidiabetics: Require an increase dose of Insulin or other oral anti-diabetic drugs when taken with Levothyroxine Sodium Tablet (Thydin). Hypoglycemia may occur if the dose of Levothyroxine Sodium Tablet (Thydin) is lowered and the insulin or oral antidiabetics remain unchanged.
Anticoagulants: Increase the anticoagulant activity and therefore dosing of anticoagulant should be adjusted based on plasma protein binding. Dose may be re-adjusted if necessary.

ADVERSE DRUG REACTIONS:
During Levothyroxine Sodium (Thydin) therapy, undesirable effects are not expected to occur if recommended dosage is followed and laboratory parameters are monitored. Symptoms of hyperthyroidism only result from a dose that is too high or too rapid increments of the dose.
Gastrointestinal disorders: Vomiting, diarrhea
Cardiovascular disorders: Tachycardia, arrhythmia, angina pectoris, hypertension
Musculoskeletal disorders: Muscular weakness, muscular cramp
Central Nervous System disorders: Headache
Nervous System disorder: Benign intracranial disorder
Menstrual disorder: Irregular menstruation
Metabolism disorder: Weight loss
Endocrine side effect: Hyperhidrosis, Hyperthyroidism
Neurological side effects: Restlessness, insomnia, tremors
Others: palpitations, flushing, fever

OVERDOSAGE AND TREATMENT:
Massive or chronic Levothyroxine intoxication will result to thyrotoxicosis that may lead to cardiac arrhythmia, heart failure and coma. In acute over dosage, gastric lavage, induction of emesis, or administration of activated charcoal may be initiated to reduce gastrointestinal absorption of Levothyroxine. Symptomatic and supportive treatment is given along with hospitalization during Levothyroxine intoxication. Symptomatic treatment for sympathetic over activity includes the administration of Propranolol. It is highly recommended to have extended follow-up check up on Levothyroxine intoxication since symptoms of toxicity may be delayed. This is due to gradual peripheral conversion of T4 to its active form T3.

CAUTION:
Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.

STORAGE CONDITION:
Store at temperatures not exceeding 30°C. Protect from light and moisture.
Keep out of reach of children.

AVAILABILITY:
Levothyroxine Sodium 12.5 mcg Tablet (Thydin) ..... Alu-PVDC White Opaque Blister x 10's (Box x 100's)
Registration No.: DRP - 7790
Date of First Authorization: January 2015
Renewal of Authorization: January 2020

Levothyroxine Sodium 25 mcg Tablet (Thydin) ..... Alu-PVDC White Opaque Blister x 10's (Box x 100's)
Registration No.: DRP - 7791
Date of First Authorization: December 2014
Renewal of Authorization: December 2019

Levothyroxine Sodium 50 mcg Tablet (Thydin) ..... Alu-PVDC White Opaque Blister x 10's (Box x 100's)
Registration No.: DRP - 7792
Date of First Authorization: January 2015
Renewal of Authorization: January 2020

Levothyroxine Sodium 100 mcg Tablet (Thydin) ..... Alu-PVDC White Opaque Blister x 10's (Box x 100's)
Registration No.: DRP - 7793
Date of First Authorization: February 2016
Renewal of Authorization: February 2021

Levothyroxine Sodium 150 mcg Tablet (Thydin) ..... Alu-PVDC White Opaque Blister x 10's (Box x 100's)
Registration No.: DRP - 7794
Date of First Authorization: January 2015
Renewal of Authorization: January 2020

Date of Revision: July 2018

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