

Synroid®

Levothyroxine Sodium

Tablet

Description

Synroid® contains synthetic Levothyroxine Sodium which is identical to the natural hormone, produced in the thyroid gland. Thyroid hormones regulate multiple metabolic processes and play an essential role in normal growth and development, and normal maturation of the central nervous system and bone. The metabolic actions of thyroid hormones include augmentation of cellular respiration and thermogenesis, as well as metabolism of proteins, carbohydrates and lipids.

Indications

- As replacement therapy in hypothyroidism of any etiology.
- For the suppression of Thyroid Stimulating Hormone (TSH) levels in the presence of goiters, nodules and after radiological and/or surgical treatment of thyroid cancer.
- For the suppression of the goitrogenic effects of other drugs such as lithium.
- As a diagnostic aid in suppression tests.

Dosage and Administration

Oral Administration

Administer orally on an empty stomach, preferably one hour before breakfast or the first food of the day.

Pediatric Patients

Hypothyroidism

Initiate therapy at full replacement dosages as soon as possible after diagnosis of hypothyroidism to prevent deleterious effects on intellectual and physical growth and development; initiate dosage at a lower level in children with long-standing or severe hypothyroidism. The following dosages have been recommended:

Age	Daily Dose
0-3 months	10-15 µg/kg
3-6 months	25-50 µg or 8-10 µg/kg
6-12 months	50-75 µg or 6-8 µg/kg
1-5 years	75-100 µg or 5-6 µg/kg
6-12 years	100-150 µg or 4-5 µg/kg
Older than 12 years (growth and puberty incomplete)	>150 µg or 2-3 µg/kg
Growth and puberty complete	1.6-1.7 µg/kg

Alternatively, 25-50 µg once daily has been recommended for otherwise healthy children <1 year of age; after 1 year of age, children may be given 3-5 µg/kg daily until the adult dosage of about 150 µg daily is reached in early or mid-adolescence.

When transient hypothyroidism is suspected, therapy may be temporarily discontinued when the child is older than 3 years of age to reassess the condition.

Adults

Hypothyroidism

In otherwise healthy individuals <50 years of age and in those >50 years of age who have been recently treated for hyperthyroidism or who have been hypothyroid for only a short time (i.e., several months), usual initial oral dosage (full replacement dosage) is 1.7 µg/kg daily (e.g., 100-125 µg daily for a 70-kg adult) given as a single dose. Older patients may require <1 µg/kg daily.

For most patients >50 years of age, usual initial dosage is 25-50 µg daily given as a single dose; increase dosage at intervals of 6-8 weeks.

For management of severe or long-standing hypothyroidism, usual initial dosage is 12.5-25 µg daily given as a single dose. Increase by increments of 25 µg at intervals of 2-4 weeks until serum TSH concentrations return to normal.

Thyroid Cancer

Dosages >2 µg/kg daily given as a single dose usually required to suppress TSH concentrations to <0.1 mU/L. In patients with high-risk tumors, target level for TSH suppression may be <0.01 mU/L.

Benign Nodules or Nontoxic Multinodular Goiter

Suppress TSH concentrations to 0.1-0.5 mU/L for nodules and to 0.5-1 mU/L for multinodular goiter

Contraindications

- Untreated subclinical (suppressed serum TSH concentrations with normal T₃ [triiodothyronine] and T₄ concentrations) or overt thyrotoxicosis of any etiology.
- Acute Myocardial Infarction (AMI)
- Untreated adrenal insufficiency.
- Known hypersensitivity to any ingredient in the formulation.

Precautions

Levothyroxine Sodium should be used with caution in patients with cardiovascular disorders, including angina, coronary artery disease and hypertension.

Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

Thyroid replacement therapy may cause an increase in dosage requirements of insulin or other antidiabetic therapy.

Parents of children receiving thyroid agent should be advised that partial loss of hair may occur during the first few months of therapy, but this effect is usually transient and subsequent re-growth usually occurs.

Care is required when Levothyroxine Sodium is administered to patients with known history of epilepsy.

Subclinical hyperthyroidism may be associated with bone loss. To minimise the risk of osteoporosis, dosage of Levothyroxine Sodium should be titrated to the lowest possible effective level.

Drug Interaction

Anticoagulants: Levothyroxine Sodium increases the effect of anticoagulants and it may be necessary to reduce the anticoagulation dosage if excessive, hypoprothrombinaemia and bleeding are to be avoided.

Anti-convulsants: such as carbamazepine, primidone and phenytoin, enhance the metabolism of thyroid hormones and increase requirement for thyroid hormones in hypothyroidism.

Antiarrhythmics: Amiodarone may inhibit the deiodination of thyroxine to triiodothyronine resulting in a decreased concentration of triiodothyronine, thereby reducing the effects of thyroid hormones.

Antidiabetics: Blood sugar levels are raised and dosage of antidiabetic agents may require adjustment.

Beta Blockers: Levothyroxine Sodium accelerates metabolism of propranolol.

Antidepressant: Levothyroxine Sodium increases receptor

sensitivity to catecholamines thus accelerating the response to tricyclic antidepressants (e.g. amitriptyline, imipramine).

Sympathomimetics: The effects of sympathomimetic agents (e.g. adrenaline) are also enhanced.

Cardiac glycosides: Hyperthyroid patients may need their digoxin dosage gradually increased as treatment proceeds because initially patients are relatively sensitive to digoxin.

Sex Hormones: Oestrogen, oestrogen containing product (including hormone replacement therapy) and oral contraceptives may increase the requirement of thyroid therapy dosage.

Metabolism of Levothyroxine Sodium accelerated by rifampicin, barbiturates (may increase requirements for Levothyroxine Sodium in hypothyroidism).

Absorption of Levothyroxine Sodium possibly reduced by antacids, calcium salts, cimetidine, oral iron, sucralfate, colestipol, polystyrene sulphonate resin and cholestyramine (administration should be separated by 4-5 hours).

Overdosage

Hyperthyroidism, cerebral embolism, shock, coma, and death have been reported. Symptoms may not necessarily be evident or may not appear until several days after ingestion of Levothyroxine Sodium.

Dose of Levothyroxine Sodium should be reduced or temporarily discontinued if signs or symptoms of overdosage occur.

Use in Pregnancy and Lactation

Pregnancy Category A. Studies in women taking Levothyroxine Sodium during pregnancy have not shown an increased risk of congenital abnormalities. Therefore, the possibility of fetal harm appears remote. Levothyroxine Sodium should not be discontinued during pregnancy and hypothyroidism diagnosed during pregnancy should be promptly treated.

Nursing Mothers

Although thyroid hormones are excreted only minimally in human milk, caution should be exercised when Levothyroxine Sodium is administered to a nursing woman. However, adequate replacement doses of levothyroxine are generally needed to maintain normal lactation.

Side Effects

Side effects are usually indicative of excessive dosage and usually disappear on reduction of dosage or withdrawal of treatment for a few days. Such effects include:

General: headache, flushing, fever and sweating

Immune system disorders: hypersensitivity reactions including rash, pruritus and oedema

Metabolic: weight loss

Nervous system: tremor, restlessness, excitability, insomnia. Rarely, benign intracranial hypertension in children.

Rarely, seizures can occur in patients with a known history of epilepsy.

Cardiac: anginal pain, cardiac arrhythmias, palpitations, tachycardia

Gastrointestinal: diarrhoea, vomiting

Musculoskeletal and connective tissue: muscle cramps, muscle weakness, craniostenosis in infants and premature closure of epiphysis in children.

Reproductive: menstrual irregularities

Fever, heat intolerance, transient hair loss in children, hypersensitivity reactions including rash, pruritus and oedema also reported.

Storage

Keep out of the reach of children. Keep in a cool & dry place. Protect from light.

Commercial Pack

Synroid® Tablet: Each container contains 100 tablets. Each tablet contains Levothyroxine Sodium USP 50 µg.



Manufactured by

BEXIMCO PHARMACEUTICALS LTD.

TONGI, BANGLADESH BL 9552 090614

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