Synthroid (levothyroxine sodium) - Drug Summary

Abbott Laboratories

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Synthroid
(levothyroxine sodium)

BOXED WARNING

Do not use for the treatment of obesity or weight loss; doses within range of daily hormonal requirements are ineffective for weight reduction in euthyroid patients. Serious or life-threatening manifestations of toxicity may occur when given in larger doses, particularly when given in association with sympathomimetic amines.

View FDA-Approved Full Prescribing Information for Synthroid

THERAPEUTIC CLASS

Thyroid replacement hormone

DEA CLASS

RX

ADULT DOSAGE & INDICATIONS

Hypothyroidism

Replacement/supplemental therapy in hypothyroidism of any etiology, except transient hypothyroidism during the recovery phase of subacute thyroiditis

Usual: 1.7mcg/kg/day; >200mcg/day seldom required

Severe:
Initial: 12.5-25mcg/day
Titrate: Increase by 25mcg/day every 2-4 weeks until TSH level normalized

Secondary (Pituitary) or Tertiary (Hypothalamic) Hypothyroidism:
Titrate: Increase until clinically euthyroid and serum free-T4 level is restored to the upper half of the normal range

Subclinical Hypothyroidism:
Lower doses (eg, 1mcg/kg/day) may be adequate to normalize serum TSH level

Pituitary TSH Suppressant

Used to treat/prevent various types of euthyroid goiters (eg, thyroid nodules, subacute or chronic lymphocytic thyroiditis, multinodular goiter) and to manage thyroid cancer

Well-Differentiated (Papillary and Follicular) Thyroid Cancer:
Adjunct to Surgery and Radioiodine Therapy:
Usual: >2mcg/kg/day, w/ target TSH level <0.1 mU/L
High-Risk Tumors: Target TSH level <0.01 mU/L

Benign Nodules and Nontoxic Multinodular Goiter:
TSH is suppressed to a higher target (eg, 0.1 to 0.5 or 1.0 mU/L)

PEDIATRIC DOSAGE & INDICATIONS

Hypothyroidism

Usual:
0-3 Months of Age: 10-15mcg/kg/day
3-6 Months of Age: 8-10mcg/kg/day
6-12 Months of Age: 6-8mcg/kg/day

1-5 Years: 5-6mcg/kg/day
6-12 Years: 4-5mcg/kg/day
>12 Years:
Growth/Puberty Incomplete: 2-3mcg/kg/day
Growth/Puberty Complete: 1.7mcg/kg/day

Infants w/ Very Low (<5mcg/dL) or Undetectable Serum T4:
Initial: 50mcg/day

Chronic/Severe Hypothyroidism:
Initial: 25mcg/day
Titrate: Increase by 25mcg every 2-4 weeks

DOSING CONSIDERATIONS

Pregnancy
May increase levothyroxine requirements

Elderly
Hypothyroidism:
>50 Years:
Initial: 25-50mcg/day
Titrate: Increase by 12.5-25mcg increments every 6-8 weeks prn

W/ Underlying Cardiac Disease:
Initial: 12.5-25mcg/day
Titrate: Increase by 12.5-25mg increments every 4-6 weeks

Adverse Reactions
Minimize Hyperactivity in Older Children:
Initial: Give 1/4 of full replacement dose
Titrate: Increase on a weekly basis by 1/4 the full recommended replacement dose until the full recommended replacement dose is reached

Other Important Considerations
Underlying Cardiac Disease:
Hypothyroidism:
Infants (Risk for Cardiac Failure):
Initial: Consider lower dose (eg, 25mcg/day)
Titrate: Increase dose in 4-6 weeks prn

<50 Years:
Initial: 25-50mcg/day
Titrate: Increase by 12.5-25mcg increments every 6-8 weeks prn

ADMINISTRATION

Oral route

Administer as a single daily dose, preferably 30-60 min before breakfast
Take at least 4 hrs apart from drugs that are known to interfere w/ its absorption

Pediatrics
Unable to Swallow Intact Tab:
1. Crush tab and suspend in small amount (5-10mL or 1-2 tsp) of water
2. Administer using a spoon or dropper
3. Do not store sus for later use
4. Do not use foods that decrease absorption of levothyroxine (eg, soybean infant formula) to administer

HOW SUPPLIED

Tab: 25mcg*, 50mcg*, 75mcg*, 88mcg*, 100mcg*, 112mcg*, 125mcg*, 137mcg*, 150mcg*, 175mcg*, 200mcg*, 300mcg* *scored

CONTRAINDICATIONS

Untreated subclinical (suppressed serum TSH level with normal T3 level and T4 levels) or overt thyrotoxicosis of any etiology, acute MI, and uncorrected adrenal insufficiency.

WARNINGS/PRECAUTIONS

Should not be used in the treatment of male or female infertility unless associated with hypothyroidism. Contraindicated in patients with nontoxic diffuse goiter or nodular thyroid disease, particularly in the elderly or with underlying cardiovascular (CV) disease if serum TSH level is already suppressed; use with caution if TSH level is not suppressed and carefully monitor thyroid function. Has narrow therapeutic index; carefully titrate dose to avoid over- or under-treatment. May decrease bone mineral density (BMD) with long-term use; give minimum dose necessary to achieve desired clinical and biochemical response. Caution with CV disorders and the elderly. If cardiac symptoms develop or worsen, reduce or withhold dose for 1 week and then restart at lower dose. Overtreatment may produce CV effects (eg, increase in HR, increase in cardiac wall thickness, increase in cardiac contractility, precipitation of angina or arrhythmias). Monitor patients with CAD closely during surgical procedures; may precipitate cardiac arrhythmias. Caution in patients with diabetes mellitus (DM). Patients with concomitant adrenal insufficiency should be treated with replacement glucocorticoids prior to therapy.

ADVERSE REACTIONS

Fatigue, increased appetite, weight loss, heat intolerance, headache, hyperactivity, irritability, insomnia, palpitations, arrhythmias, dyspnea, hair loss, menstrual irregularities, pseudotumor cerebri (children), slipped capital femoral epiphysis (children).

DRUG INTERACTIONS

Concurrent sympathomimetics may increase effects of sympathomimetics or thyroid hormone; may increase risk of coronary insufficiency with CAD. Upward dose adjustments may be needed for insulin and oral hypoglycemic agents. May decrease absorption with soybean flour, cottonseed meal, walnuts, and dietary fiber. May increase oral anticoagulant activity; adjust dose of anticoagulant and monitor PT. May decrease levels and effects of digitalis glycosides. Transient reduction in TSH secretion with dopamine/dopamine agonists, glucocorticoids, octreotide. Decreased thyroid hormone secretion with aminoglutethimide, amiodarone, iodide (including iodine-containing radiographic contrast agents), lithium, methimazole, propylthiouracil (PTU), sulfonamides, and tolbutamide. May increase thyroid hormone secretion with amiodarone and iodide. May decrease T4 absorption with antacids (aluminum and magnesium hydroxides), simethicone, bile acid sequestrants (cholestyramine, colestipol), calcium carbonate, cation exchange resins (kayexalate), ferrous sulfate, orlistat, and sucralfate; administer at least 4 hrs apart. May increase serum thyroxine-binding globulin (TBG) concentrations with clofibrate, estrogen-containing oral contraceptives, oral estrogens, heroin/methadone, 5-fluorouracil, mitotane, and tamoxifen. May decrease serum TBG concentrations with androgens/anabolic steroids, asparaginase, glucocorticoids, and slow-release nicotinic acid. May cause protein-binding site displacement with furosemide (>80mg IV), heparin, hydantoins, NSAIDs (fenamates, phenylbutazone), and salicylates (>2g/day). May alter T4 and T3 metabolism with carbamazepine, hydantoins, phenobarbital, and rifampin. May decrease T4 5'-deiodinase activity with amiodarone, β-adrenergic antagonists (eg, propranolol >160mg/day), glucocorticoids (eg, dexamethasone >4mg/day), and PTU. Concurrent use with tricyclic (eg, amitriptyline) and tetracyclic (eg, maprotiline) antidepressants may increase the therapeutic and toxic effects of both drugs. Coadministration with sertraline in patients stabilized on levothyroxine may result in increased levothyroxine requirements. Interferon-α may cause development of antithyroid microsomal antibodies and transient hypothyroidism, hyperthyroidism, or both. Interleukin-2 has been associated with transient painless thyroiditis. Excessive use with growth hormones (eg, somatropin, somatrem) may accelerate epiphyseal closure. Ketamine may produce marked HTN and tachycardia. May reduce uptake of radiographic agents. Decreased theophylline clearance may occur in hypothyroid patients. Altered levels of thyroid hormone and/or TSH levels with choral hydrate, diazepam, ethionamide, lovastatin, metoclopramide, 6-mercaptopurine, nitroprusside, para-aminosalicylate sodium, perphenazine, resorcinol (excessive topical use), and thiazide diuretics.

PREGNANCY AND LACTATION

Category A, caution in nursing.

MECHANISM OF ACTION

Thyroid replacement hormone; mechanism not established. Suspected that principal effects are exerted through control of DNA transcription and protein synthesis.

PHARMACOKINETICS

Absorption: Majority absorbed from jejunum and upper ileum. **Distribution:** Plasma protein binding (>99%); found in breast milk. **Metabolism:** Sequential deiodination and conjugation in the liver (mainly), kidneys, and other tissues. **Elimination:** Urine; feces (approximately 20% unchanged). $T_{1/2}$=6-7 days (T4), ≤2 days (T3).

ASSESSMENT

Assess for untreated subclinical or overt thyrotoxicosis, acute MI, uncorrected adrenal insufficiency, CAD, CV disorders, nontoxic diffuse goiter, nodular thyroid disease, DM, hypersensitivity, pregnancy/nursing status, and for possible drug interactions. In patients with secondary or tertiary hypothyroidism, assess for additional hypothalamic/pituitary hormone deficiencies. Assess TSH levels. In infants with congenital hypothyroidism, assess for other congenital anomalies.

MONITORING

Monitor for CV effects. In patients on long-term therapy, monitor for signs/symptoms of decreased BMD. In patients with nontoxic diffuse goiter or nodular thyroid disease, monitor for precipitation of thyrotoxicosis. In adults with primary hypothyroidism, perform periodic monitoring of serum TSH levels. In pediatric patients with congenital hypothyroidism, perform periodic monitoring of serum TSH levels and total or free T4 levels. In patients with secondary and tertiary hypothyroidism, perform periodic monitoring of serum free-T4 levels. Refer to PI for TSH and T4 monitoring parameters. Closely monitor PT if coadministered with an oral anticoagulant.

PATIENT COUNSELING

Instruct to notify physician if allergic to any foods or medicines, pregnant/planning to become pregnant, breastfeeding, or taking any other drugs, including prescriptions and OTC preparations. Instruct to notify physician of any other medical conditions, particularly heart disease, diabetes, clotting disorders, and adrenal or pituitary gland problems. Instruct not to stop or change dose unless directed by physician. Instruct to take on empty stomach, at least 30-60 min before eating breakfast. Advise that partial hair loss may occur during the 1st few months of therapy, but is usually temporary. Instruct to notify physician or dentist prior to surgery about levothyroxine therapy. Inform that drug should not be used for weight control. Instruct to notify physician if rapid or irregular heartbeat, chest pain, SOB, leg cramps, headache, or any other unusual medical event occurs. Inform that dose may be increased during pregnancy. Inform that drug should not be administered within 4 hrs of agents such as iron/calcium supplements and antacids.

STORAGE

25°C (77°F); excursions permitted to 15-30°C (59-86°F). Protect from light and moisture.

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