Levothyroxine Sodium Is Listed on Florida's Negative Formulary

Important News for Florida Pharmacists

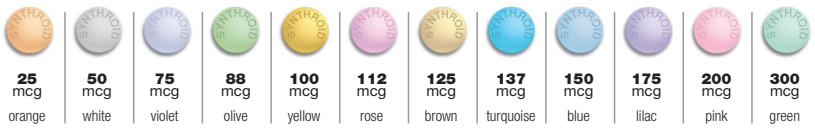
Effective August 11, 2009, the Florida Board of Pharmacy has recognized the Florida judicial decision that levothyroxine sodium be listed on Florida's negative formulary. This decision effectively revokes a 2008 Board of Pharmacy notice announcing that levothyroxine sodium was being removed from the list, and that pharmacists could legally start substituting generic levothyroxine products for Synthroid.

It is now clear that, under Florida state law, pharmacists may not substitute a generic or other brand of levothyroxine for prescriptions written for Synthroid.

Substitution by a dispensing pharmacist on a prescription written for any brand name equivalent of a generic named drug product listed on the negative formulary or for a drug within the class of certain dosage forms as listed, is strictly prohibited.[1]

Florida Administrative Code Rule 64B16-27.500 Negative Drug Formulary

Synthroid®
(levothyroxine sodium tablets, USP)



SYNTHROID® (levothyroxine sodium tablets, USP) is indicated as replacement or supplemental therapy in congenital or acquired hypothyroidism of any etiology, except transient hypothyroidism during the recovery phase of subacute thyroiditis. Specific indications include: primary (thyroidal), secondary (pituitary), and tertiary (hypothalamic) hypothyroidism and subclinical hypothyroidism. Primary hypothyroidism may result from functional deficiency, primary atrophy, partial or total congenital absence of the thyroid gland, or from the effects of surgery, radiation, or drugs, with or without the presence of goiter.[2]

SYNTHROID should not be used for the treatment of obesity or for weight loss. SYNTHROID is contraindicated in the following: patients with untreated subclinical or overt thyrotoxicosis, acute myocardial infarction, uncorrected adrenal insufficiency, and hypersensitivity to inactive tablet ingredients. SYNTHROID is contraindicated in patients with nontoxic diffuse goiter or nodular thyroid disease, if the serum TSH level is already suppressed. If TSH is not suppressed, use in conjunction with careful clinical and TSH monitoring. SYNTHROID is a narrow therapeutic index drug requiring careful titration.[2]

Please see additional Important Safety Information, including boxed warning regarding inappropriate treatment for obesity, on page 2.

For Synthroid full Prescribing Information, visit www.rxabbott.com/pdf/synthroid.pdf

Abbott
A Promise for Life

Indication[2]

- SYNTHROID® (levothyroxine sodium tablets, USP) is indicated as replacement or supplemental therapy in congenital or acquired hypothyroidism of any etiology, except transient hypothyroidism during the recovery phase of subacute thyroiditis. Specific indications include: primary (thyroidal), secondary (pituitary), and tertiary (hypothalamic) hypothyroidism and subclinical hypothyroidism. Primary hypothyroidism may result from functional deficiency, primary atrophy, partial or total congenital absence of the thyroid gland, or from the effects of surgery, radiation, or drugs, with or without the presence of goiter.

Important Safety Information[2]

WARNING:

Thyroid hormones, including Synthroid, either alone or with other therapeutic agents, should not be used for the treatment of obesity or for weight loss. In euthyroid patients, doses within the range of daily hormonal requirements are ineffective for weight reduction. Larger doses may produce serious or even life-threatening manifestations of toxicity, particularly when given in association with sympathomimetic amines such as those used for their anorectic effects.

- Levothyroxine is **contraindicated** in patients with untreated subclinical or overt thyrotoxicosis, acute myocardial infarction, uncorrected adrenal insufficiency, or with hypersensitivity to any of the inactive tablet ingredients.
- In patients with nontoxic diffuse goiter or nodular thyroid disease, particularly the elderly or those with underlying cardiovascular disease, levothyroxine sodium therapy is **contraindicated** if the serum TSH level is already suppressed due to the risk of precipitating overt thyrotoxicosis. If the serum TSH level is not suppressed, levothyroxine should be **used with caution** in conjunction with careful monitoring of thyroid function for evidence of hyperthyroidism and clinical monitoring for adverse cardiovascular signs and symptoms of hyperthyroidism.
- Levothyroxine **should not be used** in the treatment of **male or female infertility** unless this condition is associated with hypothyroidism.
- Levothyroxine has a **narrow therapeutic index**. Regardless of the indication for use, careful dosage titration is necessary to avoid the consequences of over- or under-treatment.
- In women, long-term levothyroxine sodium therapy has been associated with increased bone resorption, thereby **decreasing bone mineral density**, especially in post-menopausal women on greater than replacement doses or in women who are receiving suppressive doses of levothyroxine sodium.
- Patients receiving levothyroxine sodium should be given the minimum dose necessary to achieve the desired response.
- Patients with coronary artery disease who are receiving levothyroxine therapy should be monitored closely during surgical procedures, since the possibility of precipitating cardiac arrhythmias may be greater in those treated with levothyroxine.
- In patients with secondary or tertiary hypothyroidism, additional hypothalamic/pituitary hormone deficiencies should be considered, and, if diagnosed, treated.
- Patients with **concomitant adrenal insufficiency** should be treated with replacement glucocorticoids prior to initiation of treatment with levothyroxine sodium. Failure to do so may precipitate an acute adrenal crisis when thyroid hormone therapy is initiated. Patients with diabetes mellitus may require upward adjustments of their antidiabetic therapeutic regimens when treated with levothyroxine.
- **Adverse reactions** associated with levothyroxine therapy are primarily those of hyperthyroidism due to therapeutic overdosage.
- Levothyroxine should not be discontinued during **pregnancy** and hypothyroidism diagnosed during pregnancy should be promptly treated.
- **Drug Interactions:** Many drugs affect thyroid hormone pharmacokinetics and metabolism, and thyroid hormones and thyroid status have varied effects on the pharmacokinetics and actions of other drugs. Levothyroxine increases the response to oral anticoagulant therapy and may reduce the therapeutic effects of digitalis glycosides. Prescribers should consult appropriate reference sources for drug-thyroidal axis interactions.

References: 1. Florida Department of State Notice 2470801. Department of Health, Board of Pharmacy, RULE: 64B16-27.500 Negative Drug Formulary. Available at https://www.flrules.org/Gateway/View_notice.asp?id=2470801. Accessed July 1, 2009. **2.** Synthroid [package insert]. North Chicago, IL: Abbott Laboratories.

For Synthroid full Prescribing Information, visit www.rxabbott.com/pdf/synthroid.pdf

Synthroid®
(levothyroxine sodium tablets, USP)

Abbott
A Promise for Life