ADTHYZA® (thyroid tablets, USP)

ADTHYZA® (thyroid tablets, USP) Dose Conversions

ADTHYZA® (thyroid tablets, USP)	Desiccated Thyroid Extract (DTE)	Synthetic Levothyroxine (LT_4)
16.25 mg	15 mg	25 mcg
32.5 mg	30 mg	50 mcg
65 mg	60 mg	100 mcg
97.5 mg	90 mg	150 mcg
130 mg	120 mg	200mcg

Note: This conversion chart is only a general guideline. All conversions are approximate and do not negate clinical observations of the signs and symptoms of hypothyroidism. All medication doses derived using the information above and herein should be checked and prescribed by an experienced clinician. The clinician should use this conversion table as a guide only. This conversion chart is offered as a side-by-side comparison based on product labels. Azurity does not confirm other products' mg dosages. ADTHYZA® provides approximately 38 mcg of T_4 and approximately 9 mcg of T_3 per 65 mg. Each ADTHYZA® tablet contains T_4 and T_3 in approximately a 4:1 ratio.

The conversions are from: United States Pharmacopeia Drug Information: Drug Information for the Health Care Professional. Vol. 1. 27th ed. Greenwood Village, CO: 2007. 1 mg of Adthyza = 1.538 mcg L-T_4. Conversion equivalence of 60 mg DTE to 65 mg Adthyza. Conversions were conducted on June 28, 2023.

Reporting of any adverse effects, product quality complaints, or medical information request regarding Desiccated Thyroid Extract and/or synthetic T_4 should be directed to their respective manufacturers.

Adthyza® May Help Patients Focus on Life Instead of Symptoms

Manufactured to ensure quality and consistency
Strict batch-to-batch quality control[1]

Combination T_4 / T_3 natural thyroid extract
Lactose, corn, dye and latex-free[2]

ADTHYZA Cares:
Affordable and accessible medication regardless of insurance

Flexible dosing options
5 dosing strengths for ease of titration to optimal dose

Connect on ADTHYZA.com to Learn More

Please note that Adthyza® has not been reviewed by the FDA for safety or efficacy.

WARNING

DRUGS WITH THYROID HORMONE ACTIVITY, ALONE OR TOGETHER WITH OTHER THERAPEUTIC AGENTS, HAVE BEEN USED FOR THE TREATMENT OF OBESITY. 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.

IMPORTANT SAFETY INFORMATION

INDICATIONS:

- ADTHYZA® (thyroid tablets, USP) is a prescription medicine indicated as replacement or supplemental therapy in patients with hypothyroidism of any etiology, except transient hypothyroidism during the recovery phase of subacute thyroiditis.
- ADTHYZA® is also indicated as a pituitary TSH suppressant in the treatment or prevention of various types of euthyroid goiters, including thyroid nodules, subacute or chronic lymphocytic thyroiditis (Hashimoto's), multinodular goiter, and in the management of thyroid cancer.

Please see the Important Safety Information continued in piece and the accompanying full Prescribing Information for ADTHYZA.

Please note that Adthyza® has not been reviewed by the FDA for safety or efficacy.

ADDITIONAL IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS:

ADTHYZA® is contraindicated in patients with uncorrected adrenal cortical insufficiency, untreated thyrotoxicosis, and apparent hypersensitivity to any component of the product.

The use of thyroid hormones in the therapy of obesity, alone or combined with other drugs, is unjustified and has been shown to be ineffective. Neither is their use justified for the treatment of male or female infertility unless this condition is accompanied by hypothyroidism.

WARNINGS AND PRECAUTIONS:

Thyroid hormones should be used with great caution in circumstances where the integrity of the cardiovascular system is suspected. In the elderly and in patients with cardiovascular disease, ADTHYZA should be used with greater caution. In these patients, therapy should be initiated with low doses of ADTHYZA. When, in such patients, a euthyroid state can only be reached at the expense of an aggravation of the cardiovascular disease, thyroid hormone dosage should be reduced.

Thyroid hormone therapy in patients with concomitant diabetes mellitus or diabetes insipidus, or adrenal cortical insufficiency aggravates the intensity of their symptoms, and appropriate adjustments of the various therapeutic measures directed at these concomitant endocrine diseases are required. The therapy of myxedema coma requires simultaneous administration of glucocorticoids.

Hypothyroidism decreases, and hyperthyroidism increases the sensitivity to oral anticoagulants. Prothrombin time should be closely monitored in thyroid-treated patients on oral anticoagulants, and the dosage of the latter agents should be adjusted on the basis of frequent prothrombin time determinations. In infants, excessive doses of thyroid hormone preparations may produce craniosynostosis.

CARCINOGENESIS/MUTAGENESIS:

A reportedly apparent association between prolonged thyroid therapy and breast cancer has not been confirmed, and patients on thyroid for established indications should not discontinue therapy. No confirmatory long-term studies in animals have been performed to evaluate carcinogenic potential, mutagenicity, or impairment of fertility in either males or females.

PREGNANCY AND LACTATION:

Thyroid replacement therapy for hypothyroid women should not be discontinued during pregnancy, and hypothyroidism diagnosed during pregnancy should be promptly treated.

Minimal amounts of thyroid hormones are excreted in human milk. However, caution should be exercised when the thyroid is administered to a nursing woman. Routine determinations of serum T_4 and/or TSH are strongly advised in neonates in view of the deleterious effects of thyroid deficiency on growth and development.

ADVERSE REACTIONS:

Adverse reactions other than those indicative of hyperthyroidism because of therapeutic overdosage, either initially or during the maintenance period, are rare.

Many drugs and some laboratory tests may alter the therapeutic response to ADTHYZA®. In addition, thyroid hormones and thyroid status have varied effects on the pharmacokinetics and actions of other drugs. Patients on oral anticoagulants, insulin, and oral hypoglycemics should be monitored closely during the initiation of thyroid replacement therapy.

DRUG INTERACTIONS:

- Oral Anticoagulants: Concomitant use of thyroid hormones with oral anticoagulants alters the sensitivity of oral anticoagulants.
- Insulin or Oral Hypoglycemics: Initiating thyroid replacement therapy may cause increases in insulin or oral hypoglycemic requirements. Patients receiving insulin or oral hypoglycemics should be closely watched during initiation of thyroid replacement therapy.
- Cholestyramine or Colestipol—Cholestyramine or colestipol binds both levothyroxine (T_4) and liothyronine (T_3) in the intestine, thus impairing the absorption of these thyroid hormones. Four to five hours should elapse between the administration of cholestyramine or colestipol and thyroid hormones.
- Estrogen, Oral Contraceptives—Estrogens tend to increase serum thyroxine-binding globulin (TBg). In a patient with a nonfunctioning thyroid gland who is receiving thyroid replacement therapy, free levothyroxine (T_4) may be decreased when estrogens are started, thus increasing thyroid requirements. Patients without a functioning thyroid gland who are on thyroid replacement therapy may need to increase their thyroid dose if estrogen or estrogen-containing oral contraceptives are given.

For further information, please see accompanying complete Prescribing Information for ADTHYZA®.

To report SUSPECTED ADVERSE REACTIONS, contact, Azurity Pharmaceuticals, Inc. at 1-800-461-7449, or to the FDA at www.fda.gov/medwatch or call 1-800-FDA-1088.

PP-ADZ-US-0034

References:
1. ADTHYZA. Prescribing information. 2022; Azurity Pharmaceuticals Inc. https://www.adthyza.com/hcp/media/pdf/ADTHYZA-PI.pdf
2. Data on file. Azurity Pharmaceuticals, Inc.

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