

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.

IMPORTANT SAFETY INFORMATION

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.

Do not use ADTHYZA in patients with uncorrected adrenal cortical insufficiency, untreated thyrotoxicosis (high thyroid hormone levels), and apparent hypersensitivity to any component of the product.

The use of thyroid hormones for weight loss, 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 low thyroid levels.

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.

Tell your doctor about any other medical conditions you may have, especially heart disease, diabetes, blood clotting problems, and adrenal or pituitary gland problems. The dose of other drugs you may be taking to control these conditions may have to be changed while you are taking.

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 cancer causing potential, mutagenicity, or impairment of fertility in either males or females.

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 thyroid is administered to a nursing woman. Routine determinations of serum T₄ and/or TSH are strongly advised in neonates in view of the deleterious effects of thyroid deficiency on growth and development.

Tell your doctor immediately if you experience chest pain, increased pulse rate, rapid, strong, irregular heartbeat, excessive sweating, or any other unusual event.

Partial loss of hair may be experienced by children in the first few months of thyroid therapy, but this is usually a transient phenomenon.

Many drugs and some laboratory tests may alter your therapeutic response to ADTHYZA.

Tell your doctor about all medicines you take, including prescription and nonprescription medicines, vitamins, and herbal supplements. Especially tell your doctor if you take medicines to treat and prevent blood clots (anticoagulants), antidiabetic agents, or oral contraceptives.

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

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