

## CLINICAL UPDATE

<b>Brand Name</b>	Thyquidity®
<b>Generic Name</b>	levothyroxine sodium
<b>Drug Manufacturer</b>	Reguliance LLC

### Clinical Update

#### TYPE OF CLINICAL UPDATE

New Brand & Strength

#### FDA APPROVAL DATE

November 30, 2020

#### LAUNCH DATE

January 4, 2021

#### REVIEW DESIGNATION

Standard

#### TYPE OF REVIEW

Type 5 - New Formulation or New Manufacturer

#### DISPENSING RESTRICTIONS

Open

### Overview

#### INDICATION(S) FOR USE

Thyquidity® is levothyroxine sodium (T4) indicated for:

- Hypothyroidism: As replacement therapy in primary (thyroidal), secondary (pituitary), and tertiary (hypothalamic) congenital or acquired hypothyroidism.
- Pituitary Thyrotropin (Thyroid-Stimulating Hormone, TSH) Suppression: As an adjunct to surgery and radioiodine therapy in the management of thyrotropin-dependent well-differentiated thyroid cancer.

#### Limitations of Use:

- Not indicated for suppression of benign thyroid nodules and nontoxic diffuse goiter in iodine-sufficient patients
- Not indicated for treatment of hypothyroidism during the recovery phase of subacute thyroiditis

#### MECHANISMS OF ACTION

Thyroid hormones exert their physiologic actions through control of DNA transcription and protein synthesis. Triiodothyronine (T3) and L-thyroxine (T4) diffuse into the cell nucleus and bind to thyroid receptor proteins attached to DNA. This hormone nuclear receptor complex activates gene transcription and synthesis of messenger RNA and cytoplasmic proteins.

The physiological actions of thyroid hormones are produced predominantly by T3, the majority of which (approximately 80%) is derived from T4 by deiodination in peripheral tissues.

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### DOSAGE FORM(S) AND STRENGTH(S)

Oral Solution: 100 mcg per 5 mL (20 mcg per mL) in 100 mL bottles.

### DOSE & ADMINISTRATION

- Administer once daily, preferably on an empty stomach, one-half to one hour before breakfast.
- Administer at least 4 hours before or after drugs that are known to interfere with absorption.
- Administer orally using syringe provided by the pharmacy.
- Evaluate the need for dose adjustments when regularly administering within one hour of certain foods that may affect Thyquidity® absorption.
- Starting dose depends on a variety of factors, including age, body weight, cardiovascular status, and concomitant medical conditions (including pregnancy), concomitant medications, co-administered food, and the specific nature of the condition being treated. Peak therapeutic effect may not be attained for 4-6 weeks.
- Adequacy of therapy determined with periodic monitoring of TSH and/or T4 as well as clinical status.

### EFFICACY

Thyquidity® was approved via the 505(b)2 pathway based on the safety and efficacy of Synthroid.