

INDICATION

THYQUIDITY™ is levothyroxine sodium (T4) indicated for:

- Hypothyroidism: As a 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.

IMPORTANT SAFETY INFORMATION

WARNING: NOT FOR TREATMENT OF OBESITY OR FOR WEIGHT LOSS

See full prescribing information for complete boxed warning

- **Thyroid hormones, including THYQUIDITY, should not be used for the treatment of obesity or for weight loss.**
- **Doses beyond the range of daily hormonal requirements may produce serious or even life-threatening manifestations of toxicity. (6, 10).**

Do not use THYQUIDITY if you have uncorrected adrenal problems.

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, THYQUIDITY 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 THYQUIDITY. If you have diabetes, check your blood sugar levels and/or the glucose in your urine, as ordered by your doctor, and immediately tell your doctor if there are any changes. If you are taking blood thinners, your blood clotting status should be checked often.

Taking too much levothyroxine has been associated with increased bone loss, especially in women after menopause.

Once your doctor has found your specific THYQUIDITY dose, it is important to have lab tests done, as ordered by your doctor, at least once a year.

Foods like soybean flour, cottonseed meal, walnuts, and dietary fiber may cause your body to absorb less THYQUIDITY from the gastrointestinal tract. Grapefruit juice may cause your body to absorb less

levothyroxine and may reduce its effect. Let your doctor know if you eat these foods, as your dose of THYQUIDITY may need to be adjusted.

Use THYQUIDITY only as ordered by your doctor. Take THYQUIDITY as a single dose, preferably on an empty stomach, one-half to one hour before breakfast.

Products such as iron and calcium supplements and antacids can lower your body's ability to absorb levothyroxine, so THYQUIDITY should be taken 4 hours before or after taking these products.

Tell your doctor if you are pregnant or breastfeeding or are thinking of becoming pregnant while taking THYQUIDITY. Your dose of THYQUIDITY may need to be increased during your pregnancy.

Monitor your baby from birth to 3 months of age for vomiting and/or diarrhea as THYQUIDITY can cause gastrointestinal irritation due to the glycerol component.

It may take several weeks before you notice an improvement in your symptoms.

Tell your doctor about all medicines you take, including prescription and nonprescription medicines, vitamins, and herbal supplements.

Tell your doctor or dentist that you are taking THYQUIDITY before any surgery.

Adverse reactions associated with THYQUIDITY therapy are primarily those of hyperthyroidism due to therapeutic overdose: rapid or abnormal heartbeat, chest pain, difficulty catching your breath, leg cramps, headache, nervousness, irritability, sleeplessness, shaking, change in appetite, weight gain or loss, vomiting, diarrhea, increased sweating, difficulty tolerating heat, fever, changes in menstrual periods, swollen red bumps on the skin (hives) or skin rash, or any other unusual medical event. Tell your doctor if you develop any of these symptoms.

Partial hair loss may occur during the first few months you are taking THYQUIDITY.

The Important Safety Information does not include all the information needed to use THYQUIDITY safely and effectively. Visit THYQUIDITY.com for Full Prescribing Information.

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

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