

## Thyquidity<sup>™</sup> (levothyroxine sodium) – New drug approval

- On November 30, 2020, the <u>FDA approved</u> Reguliance/Vertice Specialty Group's <u>Thyquidity</u> (<u>levothyroxine sodium</u>), for:
  - Replacement therapy in primary (thyroidal), secondary (pituitary), and tertiary (hypothalamic) congenital or acquired hypothyroidism
  - Adjunct to surgery and radioiodine therapy in the management of thyrotropin-dependent well-differentiated thyroid cancer.
- Limitations of use for Thyquidity include:
  - Not indicated for suppression of benign thyroid nodules and nontoxic diffuse goiter in iodinesufficient patients as there are no clinical benefits and overtreatment with Thyquidity may induce hyperthyroidism
  - Not indicated for treatment of hypothyroidism during the recovery phase of subacute thyroiditis.
- Levothyroxine sodium is already available in several other formulations, including generic <u>tablets</u>. In addition, another brand oral solution formulation, <u>Tirosint®-SOL</u>, is available.
  - Tirosint-SOL and generic tablets of levothyroxine sodium share the same indications as Thyquidity.
- Thyquidity carries a boxed warning stating that it is not for treatment of obesity or for weight loss.
- Thyquidity is contraindicated in patients with uncorrected adrenal insufficiency.
- Warnings and precautions for Thyquidity include cardiac adverse reactions in the elderly and in
  patients with underlying cardiovascular disease; myxedema coma; acute adrenal crisis in patients
  with concomitant adrenal insufficiency; prevention of hyperthyroidism or incomplete treatment of
  hypothyroidism; worsening of diabetic control; and decreased bone mineral density associated with
  thyroid hormone over replacement.
- Adverse reactions associated with Thyquidity therapy are primarily those of hyperthyroidism due to therapeutic overdosage: arrhythmias, myocardial infarction, dyspnea, muscle spasm, headache, nervousness, irritability, insomnia, tremors, muscle weakness, increased appetite, weight loss, diarrhea, heat intolerance, menstrual irregularities, and skin rash.
- Thyquidity should be administered as a single daily oral dose, on an empty stomach, one-half to one
  hour before breakfast. The dose of Thyquidity for hypothyroidism or pituitary thyroid-stimulating
  hormone (TSH) suppression depends on a variety of factors including: the patient's age, body
  weight, cardiovascular status, concomitant medical conditions (including pregnancy), concomitant
  medications, co-administered food and the specific nature of the condition being treated.
  - Refer to the Thyquidity drug label for additional dosing and administration recommendations.

•	Reguliance available a	e/Vertice Specialty Group's launch plans for Thyquidity are pending. Thyquidity will be as a 100 mcg/5 mL oral solution (in 100 mL bottles).	
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