

Talk it Out



Knowing what to talk about can help your treatment be successful

When you visit your doctor, getting and sharing information is key to treating your condition effectively. This guide can help you focus on the right points and ask the right questions about your condition and Tirosint treatment.

Points to share with your doctor:

- Any new symptoms
- Symptoms that have returned or grown worse
- How you're feeling generally, both physically and emotionally
- If you missed any doses of Tirosint
- If you've made changes (even small ones) in the way you take Tirosint
- Other medications or supplements you may be taking
- Any concerns you may have about your condition or treatment

Possible questions for your doctor:

- How am I doing on Tirosint?
- How long will I be taking Tirosint?
- What can I expect during the first several months of treatment?
- If you're adjusting my dose, what's the reason?
- What can I do to keep my treatment consistent?
- How can I keep my symptoms from coming back?

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Important Product Information

Levothyroxine sodium is used for the following indications: Hypothyroidism: As replacement or supplemental therapy in congenital or acquired hypothyroidism of any etiology, except transient hypothyroidism during the recovery phase of subacute thyroiditis. Specific indications include: primary (thyroidal), secondary (pituitary), and tertiary (hypothalamic) hypothyroidism and subclinical hypothyroidism. Primary hypothyroidism may result from functional deficiency, primary atrophy, partial or total congenital absence of the thyroid gland, or from effects of surgery, radiation, or drugs, with or without the presence of goiter.

WARNING: Thyroid hormones, including TIROSINT, either alone or with other therapeutic agents, should not be used for the treatment of obesity or for weight loss. 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.

CONTRAINDICATIONS

Levothyroxine is contraindicated in patients with untreated subclinical (suppressed serum TSH level with normal T3 and T4 levels) or overt thyrotoxicosis of any etiology and in patients with acute myocardial infarction. Levothyroxine is contraindicated in patients with uncorrected adrenal insufficiency since thyroid hormones may precipitate an acute adrenal crisis by increasing the metabolic clearance of glucocorticoids. TIROSINT is contraindicated in patients with hypersensitivity to any of the inactive ingredients in TIROSINT capsules. TIROSINT is also contraindicated for anyone who may be unable to swallow a capsule (eg, infants, small children).

WARNINGS

In patients with nontoxic diffuse goiter or nodular thyroid disease, particularly the elderly or those with underlying cardiovascular disease, levothyroxine sodium therapy is contraindicated if the serum TSH level is already suppressed due to the risk of precipitating overt thyrotoxicosis. If the serum TSH level is not suppressed, TIROSINT should be used with caution in conjunction with careful monitoring of thyroid function for evidence of hyperthyroidism and clinical monitoring for potential associated adverse cardiovascular signs and symptoms of hyperthyroidism.

PRECAUTIONS

Effects on bone mineral density – In women, long-term levothyroxine sodium therapy has been associated with increased bone resorption, thereby decreasing bone mineral density, especially in post-menopausal women on greater than replacement doses or in women who are receiving suppressive doses of levothyroxine sodium. The increased bone resorption may be associated with increased serum levels and urinary excretion of calcium and phosphorous, elevations in bone alkaline phosphatase and suppressed serum parathyroid hormone levels. Therefore, it is recommended that patients receiving levothyroxine sodium be given the minimum dose necessary to achieve the desired clinical and biochemical response.

Patients with underlying cardiovascular disease – Exercise caution when administering levothyroxine to patients with cardiovascular disorders and to the elderly in whom there is an increased risk of occult cardiac disease. In these patients, levothyroxine therapy should be initiated at lower doses than those recommended in younger individuals or in patients without cardiac disease and it should be noted that unlike levothyroxine sodium tablets, TIROSINT capsules cannot be cut in half. If cardiac symptoms develop or worsen, the levothyroxine dose should be reduced or withheld for one week and then cautiously restarted at a lower dose. Overtreatment with levothyroxine sodium may have adverse cardiovascular effects such as an increase in heart rate, cardiac wall thickness, and cardiac contractility and may precipitate angina or arrhythmias. Patients with coronary artery disease who are receiving levothyroxine therapy should be monitored closely during surgical procedures, since the possibility of precipitating cardiac arrhythmias may be greater in those treated with levothyroxine. Concomitant administration of levothyroxine and sympathomimetic agents to patients with coronary artery disease may precipitate coronary insufficiency.

ADVERSE REACTIONS

Adverse reactions associated with levothyroxine therapy are primarily those of hyperthyroidism due to therapeutic overdosage such as fatigue, increased appetite, weight loss, heat intolerance, fever, excessive sweating, and other adverse reactions. This is not an exhaustive list. Please refer to TIROSINT's full Prescribing Information for a more comprehensive list of adverse reactions associated with hyperthyroidism.

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