Tirosint®-Sol (levothyroxine sodium) – New Formulation Approval

- On December 15, 2016, the FDA approved Institut Biochimique SA's Tirosint-Sol (levothyroxine sodium) oral solution, as a replacement therapy in primary (thyroidal), secondary (pituitary), and tertiary (hypothalamic) congenital or acquired hypothyroidism; and as an adjunct to surgery and radioiodine therapy in the management of thyrotropin-dependent well-differentiated thyroid cancer.
    - Tirosint-Sol is not indicated for suppression of benign thyroid nodules and nontoxic diffuse goiter in iodine-sufficient patients.
    - Tirosint-Sol is not indicated for treatment of transient hypothyroidism during the recovery phase of subacute thyroiditis.
- Tirosint-Sol contains levothyroxine (T4), a synthetic thyroid hormone chemically identical to that produced in the human thyroid gland.
    - Levothyroxine is also available as various brand and generic tablets, as an injection, and as capsules (Tirosint®).
- The relative bioavailability of Tirosint-Sol compared to Tirosint capsules is approximately 98%.
- Tirosint-Sol is contraindicated in patients with uncorrected adrenal insufficiency and those with hypersensitivity to glycerol, an inactive ingredient in Tirosint-Sol.
- Tirosint-Sol carries a boxed warning stating that it is not for treatment of obesity or weight loss.
- Warnings and precautions of Tirosint-Sol 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, decreased bone mineral density associated with thyroid hormone over-replacement, and use for the suppression of nontoxic diffuse goiter or nodular thyroid disease.
- The adverse reactions associated with Tirosint-Sol are primarily those of hyperthyroidism due to therapeutic overdosage including: 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.
- Tirosint-Sol is given orally once daily on an empty stomach, one-half to one hour before breakfast. The specific starting dose depends on a variety of factors and is individualized.
    - Tirosint-Sol may be administered in water or directly into the mouth.
    - Tirosint-Sol should be administered at least 4 hours before or after drugs known to interfere with Tirosint-Sol absorption.
    - Peak therapeutic effect may not be attained for 4 – 6 weeks. Adequacy of therapy is determined with periodic monitoring of thyroid stimulating hormone and/or T4 as well as clinical status.

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- Institut Biochimique SA's launch plans for Tirosint-Sol are pending. Tirosint-Sol will be available as an oral solution in unit-dose ampules in the following strengths: 13, 25, 50, 75, 88, 100, 112, 125, 137, 150, 175, and 200 mcg/mL. Each strength is identified on the box and the pouch and is associated with a distinct color, and each ampule bears a colored label with the dosage strength and product name.