Adequacy of therapy determined with periodic monitoring of TSH and/or serum T4.

TIROSINT is L-thyroxine (T4) indicated for adults and pediatric patients 6-17 years of age for hypothyroidism. Titrate TIROSINT dosing per above instructions.

- Use the serum free-T4 level to monitor adequacy of therapy in this patient population.  Titrate TIROSINT dosing per above instructions.
- Hormone over-replacement and hormone insufficiency are associated with different serum TSH levels in the trimester-specific reference range.  For patients with hypothyroidism during the recovery phase of subacute thyroiditis: start at one-fourth the recommended full dose of TIROSINT by 12.5 to 25 mcg per day and measure TSH every four weeks until a stable TIROSINT dose is reached and serum TSH is within the trimester-specific reference range.
- Use the serum free-T4 level to monitor adequacy of therapy in this patient population.  Titrate TIROSINT dosing per above instructions.
- Hormone insufficiency is associated with low serum TSH levels in the trimester-specific reference range.

Pregnancy
- The dose of TIROSINT for hypothyroidism or pituitary TSH suppression is calculated as 1.6 mcg/kg/day. See full prescribing information for complete boxed warning and for use in specific populations.

DRUG INTERACTIONS
- Many drugs can exert effects on thyroid hormone pharmacokinetics and may worsen glycemic control and result in increased antidiabetic medication requirements.
- Use the serum free-T4 level to monitor adequacy of therapy in this patient population.  Titrate TIROSINT dosing per above instructions.
- Hormone over-replacement and hormone insufficiency are associated with different serum TSH levels in the trimester-specific reference range.
- Hormone insufficiency is associated with low serum TSH levels in the trimester-specific reference range.

Drug-Laboratory Test Interactions
- Use the serum free-T4 level to monitor adequacy of therapy in this patient population.  Titrate TIROSINT dosing per above instructions.
- Hormone over-replacement and hormone insufficiency are associated with different serum TSH levels in the trimester-specific reference range.
- Hormone insufficiency is associated with low serum TSH levels in the trimester-specific reference range.

7.6 Ketamine
- Use the serum free-T4 level to monitor adequacy of therapy in this patient population.  Titrate TIROSINT dosing per above instructions.
- Hormone over-replacement and hormone insufficiency are associated with different serum TSH levels in the trimester-specific reference range.
- Hormone insufficiency is associated with low serum TSH levels in the trimester-specific reference range.

5.4 Prevention of Hyperthyroidism or Incomplete Treatment of Hypothyroidism
- Use the serum free-T4 level to monitor adequacy of therapy in this patient population.  Titrate TIROSINT dosing per above instructions.
- Hormone over-replacement and hormone insufficiency are associated with different serum TSH levels in the trimester-specific reference range.
- Hormone insufficiency is associated with low serum TSH levels in the trimester-specific reference range.

12.2 Pharmacodynamics
- Use the serum free-T4 level to monitor adequacy of therapy in this patient population.  Titrate TIROSINT dosing per above instructions.
- Hormone over-replacement and hormone insufficiency are associated with different serum TSH levels in the trimester-specific reference range.
- Hormone insufficiency is associated with low serum TSH levels in the trimester-specific reference range.

Form and Strengths
- 6-12 years 4-5 mcg/kg/day
- Greater than 12 years 6-7.5 mcg/kg/day
- 175 mcg
- 25 mcg

Precautions
- Use the serum free-T4 level to monitor adequacy of therapy in this patient population.  Titrate TIROSINT dosing per above instructions.
- Hormone over-replacement and hormone insufficiency are associated with different serum TSH levels in the trimester-specific reference range.
- Hormone insufficiency is associated with low serum TSH levels in the trimester-specific reference range.

5 WARNINGS AND PRECAUTIONS
- Use the serum free-T4 level to monitor adequacy of therapy in this patient population.  Titrate TIROSINT dosing per above instructions.
- Hormone over-replacement and hormone insufficiency are associated with different serum TSH levels in the trimester-specific reference range.
- Hormone insufficiency is associated with low serum TSH levels in the trimester-specific reference range.

Acute adrenal crisis in patients with concomitant adrenal insufficiency: start with replacement glucocorticoids prior to initiation of TIROSINT treatment. Myxedema coma: administer emergency treatment and assist the patient as necessary. Pregnancy may require the use of higher doses of TIROSINT. See full prescribing information for complete boxed warning and for use in specific populations.

3 DOSAGE FORMS AND STRENGTHS
- Strength (mcg) Imprint Code
- 175 mcg FI/164  (USA) 9004  Ed.V/04.17
- 25 mcg FI/164  (USA) 9004  Ed.V/04.17

CONTRAINDICATIONS
- Use the serum free-T4 level to monitor adequacy of therapy in this patient population.  Titrate TIROSINT dosing per above instructions.
- Hormone over-replacement and hormone insufficiency are associated with different serum TSH levels in the trimester-specific reference range.
- Hormone insufficiency is associated with low serum TSH levels in the trimester-specific reference range.

HYPERSensitivity Reactions
- Use the serum free-T4 level to monitor adequacy of therapy in this patient population.  Titrate TIROSINT dosing per above instructions.
- Hormone over-replacement and hormone insufficiency are associated with different serum TSH levels in the trimester-specific reference range.
- Hormone insufficiency is associated with low serum TSH levels in the trimester-specific reference range.

Table 3: Drugs That May Alter T4 and Triiodothyronine (T3) Serum Levels

<table>
<thead>
<tr>
<th>Drug or Drug Class</th>
<th>Effect</th>
</tr>
</thead>
<tbody>
<tr>
<td>Simethicone</td>
<td>Decrease levothyroxine absorption.</td>
</tr>
<tr>
<td>Aluminum &amp; Magnesium</td>
<td>Increase TSH.</td>
</tr>
<tr>
<td>Proton Pump Inhibitors</td>
<td>Decrease TSH.</td>
</tr>
<tr>
<td>Kayexalate</td>
<td>Increase TSH.</td>
</tr>
</tbody>
</table>

If you have any questions about this content, feel free to ask! I'm here to help with any further details or questions you might have. How can I assist you further today?
have not reported increased rates of fetal malformations, miscarriages, or spontaneous abortions in pregnant women, including data from post-marketing studies that have been available for the past 2 decades. [see Dosage and Administration (2.3)].

7.8 Tyrosine-Kinase Inhibitors

Thyroid hormones may affect the efficacy of tyrosine-kinase inhibitors. These drugs may accelerate the onset of action of tricyclic antidepressants and decrease the time to peak serum levels of digitalis glycosides. TIROSINT may accelerate the onset of action of tricyclic antidepressants.

7.7 Sympathomimetics

Thyroid hormones may affect the efficacy of sympathomimetics. TIROSINT may accelerate the onset of action of tricyclic antidepressants and decrease the time to peak serum levels of digitalis glycosides.