Introduction:

Thyrogen® (thyrotropin alfa for injection) is indicated for use as an adjunctive diagnostic tool for serum thyroglobulin (Tg) testing with or without radioiodine imaging in the follow-up of patients with well-differentiated thyroid cancer.

Thyrogen® (thyrotropin alfa for injection) is indicated for use as an adjunctive treatment for radioiodine ablation of thyroid tissue remnants in patients who have undergone a near-total or total thyroidectomy for well-differentiated thyroid cancer and who do not have evidence of metastatic thyroid cancer.

DOSAGE AND ADMINISTRATION

• A two-injection regimen is recommended for Thyrogen® administration.

• The two-injection regimen is Thyrogen® 0.9 mg intramuscularly (IM), followed by a second 0.9 mg IM injection 24 hours later.

• After reconstitution with 1.2 mL Sterile Water for Injection, a 1.0 mL solution (0.9 mg thyrotropin alfa) is administered by intramuscular injection to the buttock.

• For radioiodine imaging or remnant ablation, radioiodine administration should be given 24 hours following the final Thyrogen® injection. Diagnostic scanning should be performed 48 hours after the radioiodine administration, whereas post-therapy scanning may be delayed additional days to allow background activity to decline.

• The following parameters are recommended for diagnostic radioiodine scanning with Thyrogen®:

1. A diagnostic activity of 4mCi (148 MBq) $^{131}$I should be used.
2. Whole images should be acquired for a minimum of 30 minutes and/or should contain a minimum of 140,000 counts.
3. Scanning times for single (spot) images of body regions should be 10-15 minutes or less of the minimum number of counts is reached sooner (i.e. 60,000 for a large field of view camera, 35,000 counts for a small field of view).

• For radioiodine ablation of thyroid tissue remnants, the activity of $^{131}$I (Dose) is carefully selected at the discretion of the nuclear medicine physician.

• For serum Tg testing, the serum sample should be obtained 72 hours after the final injection of Thyrogen®.
SAFETY:

1. When Thyrogen®-stimulated serum, thyroglobulin (Tg) testing is performed in combination with radioiodine imaging, there remains a meaningful risk of missing a diagnosis of thyroid cancer or of underestimating the extent of disease.

2. Although Thyrogen® appeared non-inferior to thyroid hormone withdrawal in a study of postsurgical thyroid remnant ablation, long-term clinical outcome data are limited. Due to relatively small clinical experience with Thyrogen® in remnant ablation, it is not possible to conclude whether long-term thyroid cancer outcomes would be equivalent after use of Thyrogen® or hormone withdrawal for TSH elevation prior to remnant ablation.

3. Caution should be exercised in patients with a known history of heart disease and with significant residual thyroid tissue. Careful evaluation of benefit risk should be assessed for high risk elderly patients with functioning thyroid tumors undergoing Thyrogen® administration, to avoid palpitations or cardiac rhythm disorder.

SIDE EFFECTS AND RECAUTIONS:

- It is recommended that pretreatment with glucocorticoids be considered for patients in whom local tumor expansion may comprise vital anatomic structures (such as trachea, central nervous system, or extensive macroscopic lung metastases).

- In clinical studies, the most common side effects reported were nausea, headache, fatigue, vomiting, dizziness, paraesthesia, asthenia, insomnia, and diarrhea.

**Diagnostic Testing Schedule**

<table>
<thead>
<tr>
<th>Day 1</th>
<th>Day 2</th>
<th>Day 3</th>
<th>Day 4</th>
<th>Day 5</th>
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</thead>
<tbody>
<tr>
<td>First Thyrogen® injection</td>
<td>Second Thyrogen® injection</td>
<td>Radioactive iodine dose</td>
<td></td>
<td>Serum Thyroglobulin with or without Whole Body Scan</td>
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</tbody>
</table>

**Ablation Schedule**

<table>
<thead>
<tr>
<th>Day 1</th>
<th>Day 2</th>
<th>Day 3</th>
<th>A post-ablation scan should be performed 3-5 days after the administration of ¹³¹I</th>
</tr>
</thead>
<tbody>
<tr>
<td>First Thyrogen® Injection</td>
<td>Second Thyrogen® injection</td>
<td>Radioactive iodine dose</td>
<td></td>
</tr>
</tbody>
</table>