Lyophilized powder containing 1.1 mg of thyrotropin alfa for single use after reconstitution with Sterile Water for Injection.

INDICATIONS AND USAGE:

THYROGEN® is a pituitary-stimulating hormone that stimulates the thyroid to produce thyroid hormone.

Limitations of Use:

The most common adverse reactions reported in clinical trials were nausea and headache. (6.1)

Sudden, rapid and painful enlargement of residual thyroid tissue or distant metastases can occur following treatment with THYROGEN. This may lead to acute symptoms, which depend on the anatomic location of enlargement. For example, local symptoms may include moderate to severe pain, swelling, and tenderness in the area. The swelling may lead to a loss of vision or difficulty breathing if untreated for 3 to 4 days after THYROGEN administration.

Adrenal crisis, pain at the site of distant metastases, and respiratory distress should be anticipated and prepared for after THYROGEN administration. If these symptoms persist or worsen, these patients should be managed using standard medical therapies.

Adverse reactions of THYROGEN are to be considered for patients in tumor vascularity expansion may compromise regional structures.

DOSAGE AND ADMINISTRATION

1. Advise patients to take the injection at the same time each day and to avoid missing or skipping doses.

2. If a dose is missed or not tolerated, instruct patients to resume treatment as soon as possible.

3. For patients not responding to treatment, consider the need for additional treatment or adjusting the dose.

4. Monitor patients closely for evidence of toxicity and adjust the dose accordingly.

CONTRAINdications

None

WARNINGS AND PRECAUTIONS

1. Risk of thyroid hyperfunction and thyrotoxicosis: Patients with pre-existing thyroid disease are at increased risk.

2. Risk of radiation exposure: Patients with active thyroiditis, thyroid cancer, or large goiters are at increased risk.

3. Risk of hypothyroidism: Patients with hypothyroidism may require higher doses or longer treatment periods.

4. Risk of thyroid surgery: Patients undergoing thyroid surgery may require additional treatment to achieve a euthyroid state.

5. Risk of pregnancy: Patients who are pregnant or may become pregnant should not receive THYROGEN.

DOSAGE FORMS AND STRENGTHS

- Thyrotropin alfa as a white or off-white, crystalline powder
- Thyrotropin alfa as a 0.9 mg/mL solution for injection

ADVERSE REACTIONS

The adverse reactions reported in clinical trials were primarily related to the injection site and included:

1. Pain at the injection site
2. Nausea and vomiting
3. Hot flashes
4. Transient hypothyroidism

Safety of the drug is not affected by impaired renal function, and the dosage is not modified.

ADVERSE REACTIONS

1. Pain at the injection site
2. Nausea and vomiting
3. Hot flashes
4. Transient hypothyroidism

Table 1: Summary of Adverse Reactions by THYROGEN and Thyroid Hormone

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<tr>
<th>Adverse Reaction</th>
<th>THYROGEN (n=227)</th>
<th>Thyroid Hormone Withdrawal (n=97)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain at the injection site</td>
<td>20 (9)</td>
<td>12 (12)</td>
</tr>
<tr>
<td>Nausea and vomiting</td>
<td>11 (5)</td>
<td>13 (14)</td>
</tr>
<tr>
<td>Hot flashes</td>
<td>11 (5)</td>
<td>15 (16)</td>
</tr>
<tr>
<td>Transient hypothyroidism</td>
<td>11 (5)</td>
<td>15 (16)</td>
</tr>
</tbody>
</table>

Postmarketing Experience

A detailed account of postmarketing experience is not possible. However, the reported reactions are consistent with the expected adverse reactions.

1. Pain at the injection site
2. Nausea and vomiting
3. Hot flashes
4. Transient hypothyroidism

Table 2: Table of Adverse Reactions by THYROGEN and Thyroid Hormone

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Clinical Studies

1. Clinical Trials of THYROGEN as an Adjunctive Diagnostic Test

Two open-label, randomized, controlled studies were conducted in patients with well-differentiated thyroid cancer to compare THYROGEN to the standard of care. In both studies, THYROGEN was administered in a two-injection regimen.

2. Clinical Trials of THYROGEN as an Adjunctive Treatment for Radioiodine Ablation

Two randomized, controlled studies were conducted in patients with well-differentiated thyroid cancer. In both studies, THYROGEN was administered in a two-injection regimen.

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11. Clinical Trials of THYROID as an Adjunctive Treatment for Radioiodine Ablation

Two randomized, controlled studies were conducted in patients with well-differentiated thyroid cancer. In both studies, THYROGEN was administered in a two-injection regimen.
In the anti-Tg antibody negative patients with thyroid remnant or cancer (as defined by a withdrawal Tg ≥ 2.5 ng/mL), the Thyroglobulin (Tg) Results in these same patients, adding the whole body scan increased the detection rate of thyroid remnant or cancer to positive (≥ 2.5 ng/mL) in 69% (40/58) of patients after 2 doses of THYROGEN.

Among patients with metastatic disease confirmed by a post-treatment scan or by lymph node biopsy (35/84, 42%), therapy was positive (≥ 2.5 ng/mL) in 79% of these patients.

In the diagnostic study and in the remnant ablation study, following THYROGEN administration, little change from baseline was observed in any of the eight QOL domains of the SF-36. Following thyroid hormone withdrawal, the difference between treatment groups was statistically significant (p<0.0001) for eight QOL domains, including Thyroid hormone withdrawal (Figure 2). In the remnant ablation study, following thyroid hormone withdrawal, statistically significant negative changes were noted in five of the eight QOL domains (physical function, role emotional, social function, role physical, physical health).