For the use only of a Registered Medical Practitioner or a Hospital or a Laboratory

Warning: To be sold by retail on the prescription of Oncologist, Nuclear Medicine Physician and Endocrinologist only

Abridged Prescribing Information

THYROGEN®
Thyrotropin alfa Lyophilized powder for solution for injection

COMPOSITION
Each vial contains 1.1 mg thyrotropin alfa. It is available in two–vial kit.
Thyrogen (thyrotropin alfa) injection contains recombinant human thyroid stimulating hormone (TSH) synthesized in a genetically modified Chinese hamster ovary cell line.

THERAPEUTIC INDICATIONS AND USAGE:
Adjunctive Diagnostic Tool for Well Differentiated Thyroid Cancer **-** Thyrogen 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 cancerwho have previously undergone thyroidectomy).
Adjunct for Thyroid Remnant Ablation in Well Differentiated Thyroid Cancer **-**Thyrogen 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 distant metastatic thyroid cancer.

DOSAGE REGIMEN, PREPARATION & ADMINISTRATION: Thyrogen is indicated as a two-injection regimen. The recommended dosage of Thyrogen is a 0.9 mg intramuscular injection to the buttock followed by a second 0.9 mg intramuscular injection to the buttock 24 hours later. The supplied lyophilized powder must be reconstituted with 1.2 ml of Sterile Water for Injection. After reconstitution, 1 mL of the reconstituted Thyrogen solution (0.9 mg of thyrotropin alfa) is withdrawn and injected intramuscularly in the buttocks. Pretreatment with glucocorticoids should be considered for patients in whom tumor expansion may compromise vital anatomic structures.
*Timing of Serum Thyroglobulin Testing Following Thyrogen Administration***:** For serum thyroglobulin testing, the serum sample should be obtained 72 hours after the final injection of Thyrogen.
Timing for Remnant Ablation and Diagnostic Scanning Following Thyrogen Administration: Oral radioiodine should be given 24 hours after the second injection of Thyrogen in both remnant ablation and diagnostic scanning. The activity of ^{131}I is carefully selected at the discretion of the nuclear medicine physician. Diagnostic scanning should be performed 48 hours after the radioiodine administration.

SAFETY RELATED INFORMATION
Contraindications: If THYROGEN is administered with radioiodine, the contraindications to radioiodine also apply to this combination regimen.

Warnings and Precautions:
Thyrogen-induced Hyperthyroidism - When given to patients who have substantial thyroid tissue still *in situ* or functional thyroid cancer metastases, Thyrogen is known to cause a transient (over 7 to 14 days) but significant rise in serum thyroid hormone concentration. There have been reports of death in non-thyroidectomized patients and in patients with distant metastatic thyroid cancer.
Stroke- There are postmarketing reports of radiologically-confirmed stroke and neurological findings suggestive of stroke unconfirmed radiologically (e.g., unilateral weakness) occurring within 72 hours of Thyrogen administration in patients without known central nervous system metastases. The relationship between Thyrogen administration and stroke is unknown. Patients should be well-hydrated prior to treatment with Thyrogen.
Sudden Rapid Tumor Enlargement -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 anatomical location of the tissue.. Pretreatment with glucocorticoids should be considered for patients in whom tumor expansion may compromise vital anatomic structures.
Risks Associated with Radioiodine Treatment-If THYROGEN is administered with radioiodine (RAI), the warnings and precautions for RAI, apply to this combination regimen.
Pregnancy: Available data from case reports and postmarketing experience with THYROGEN use in pregnant women are insufficient to evaluate for a drug-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes
Lactation: There are no available data on the presence of thyrotropin alfa in human milk, the effects on the breastfed infant, or the effects on milk production.
Paediatric use: Safety and effectiveness in pediatric patients have not been established.

ADVERSE REACTIONS: The most common side effect with Thyrogen (seen in more than 1 %) is nausea, headache, fatigue, vomiting, dizziness and asthenia

For full prescribing information, refer to the company website www.sanofi.in

Source: US Prescribing Information of Thyrogen dated March 2020 and CDSCO letter dated 13 Apr 2026 regarding amendment to prescription warning.

Updated: May 2026