Abbreviated Prescribing Information

Abridged Prescribing Information
THYROGEN 0.9 mg powder for solution for injection.
Thyrotropin (alfa thyrotropin)

COMPOSITION: Each vial of Thyrogen contains a nominal value of 0.9 mg thyrotropin alfa. Following reconstitution, each vial of Thyrogen contains 0.9 mg of thyrotropin alfa in 1.0 ml**.**

Therapeutic indications:-Thyrogen is indicated for use with serum thyroglobulin (Tg) testing with or without radioiodine imaging for the detection of thyroid remnants and well-differentiated thyroid cancer in post-thyroidectomy patients maintained on hormone suppression therapy (THST).
-Thyrogen is indicated for pre-therapeutic stimulation in combination with a range of 30 mCi (1.1 GBq) to 100 mCi (3.7 GBq) radioiodine for 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.
Posology and method of administration: The recommended dose regimen is two doses of 0.9 mg thyrotropin alfa administered at a 24-hour interval by intramuscular injection only. After reconstitution with water for injection, 1.0 ml solution (0.9 mg thyrotropin alfa) is administered by intramuscular injection to the buttock.
For radioiodine imaging or ablation, radioiodine administration should be given 24 hours following the final Thyrogen injection. Diagnostic scintigraphy should be performed 48 to 72 hours following radioiodine administration, whereas post-ablation scintigraphy may be delayed additional days to allow background activity to decline.
For diagnostic follow-up serum thyroglobulin (Tg) testing, the serum sample should be obtained 72 hours after the final injection of Thyrogen. Use of Thyrogen with Tg testing in follow up of post-thyroidectomy well differentiated thyroid cancer patients should be in accordance with official guidelines. **Contraindications:**-Hypersensitivity to bovine or human thyroid stimulating hormone or to any of the excipients.-Pregnancy. **Special Warnings and Precautions:**-Thyrogen should not be administered intravenously. -When used as an alternative to thyroid hormone withdrawal, the combination of the whole body scintigraphy (WBS) and Tg testing after Thyrogen administration assures the highest sensitivity for detection of thyroid remnants or cancer. False negative results may occur with Thyrogen. -Careful evaluation of benefit-risk relationships should be assessed for Thyrogen administration in high risk elderly patients who have heart disease (e.g. valvular heart disease, cardiomyopathy, coronary artery disease, and prior or current tachyarrhythmia including atrial fibrillation) and have not undergone thyroidectomy. -Thyrogen is known to cause a transient but significant rise in serum thyroid hormone concentration when given to patients who have substantial thyroid tissue still in situ. Therefore, careful evaluation of individual risk-benefit is necessary for patients with significant residual thyroid tissue.- There is a theoretical possibility that Thyrogen, like thyroid hormone withdrawal, may lead to stimulated tumour growth. In clinical trials with thyrotropin alfa, which produces a short-term increase in serum TSH levels, no case of tumour growth has been reported. -Due to elevation of TSH levels after Thyrogen administration patients with metastatic thyroid cancer particularly in confined spaces such as the brain, spinal cord and orbit or disease infiltrating the neck, may experience local oedema or focal haemorrhage at the site of these metastases resulting in increased tumour size.-This medicinal product contains less than 1 mmol sodium (23 mg) per injection, i.e. essentially 'sodium free'. **Interaction with other medicinal products and other forms of interaction:** Formal interaction studies between Thyrogen and other medicinal products have not been performed. In clinical trials, no interactions were observed between Thyrogen and the thyroid hormones triiodothyronine (T3) and thyroxine (T4) when administered concurrently.-The use of Thyrogen allows for radioiodine imaging while patients are euthyroid on thyroid hormone suppression treatment. Data on radioiodine kinetics indicate that the clearance of radioiodine is approximately 50% greater while euthyroid than during the hypothyroid state when renal function is decreased, thus resulting in less radioiodine retention in the body at the time of imaging.
Pregnancy: Animal reproduction studies have not been conducted with Thyrogen. It is not known whether Thyrogen can cause foetal harm when administered to a pregnant woman or whether Thyrogen can affect reproductive capacity. Thyrogen in combination with diagnostic radioiodine whole body scintigraphy is contra-indicated in pregnancy because of the consequent exposure of the foetus to a high dose of radioactive material. **Breast Feeding:** It is unknown whether thyrotropin alfa /metabolites are excreted in human milk. A risk to the suckling child cannot be excluded. Thyrogen should not be used during breast-feeding. **Fertility:** It is not known whether Thyrogen can affect fertility in humans. **Effects on ability to drive and use machines**:Thyrogen may reduce the ability to drive or use machines, since dizziness and headaches have been reported. **Undesirable Effects:** The most commonly reported adverse reactions are nausea and headache, occurring in approximately 11%, and 6% of patients, respectively. **Overdose:** In clinical trials of THYROGEN, three patients experienced symptoms after receiving THYROGEN doses higher than those recommended. Two patients had nausea after a 2.7 mg IM dose (3 times the recommended dose), and in one of these patients, the event was accompanied by weakness, dizziness and headache. Another patient experienced nausea, vomiting and hot flashes after a 3.6 mg IM dose (4 times the recommended dose). One additional patient enrolled in a clinical trial experienced symptoms after receiving Thyrogen intravenously. This patient received 0.3 mg of Thyrogen as a single intravenous (IV) bolus and, 15 minutes later experienced severe nausea, vomiting, diaphoresis, hypotension and tachycardia. A suggested treatment in case of overdose would be the reestablishment of fluid balance and administration of an antiemetic may also be considered. Revision date: April 2023

To report an adverse event or if you have any medical enquiry, please call +964 751 740 2599 or email us at:

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