



**COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE  
POST-AUTHORISATION SUMMARY OF POSITIVE OPINION\***  
**for**  
**THYROGEN**

International Nonproprietary Name (INN): *thyrotropin alfa*

On 19 November 2009 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion\*\* to recommend the variation to the terms of the marketing authorisation for the medicinal product Thyrogen. The Marketing Authorisation Holder for this medicinal product is GENZYME EUROPE B.V.

The CHMP adopted a change to an indication as follows:

“Thyrogen is indicated for pre-therapeutic stimulation in combination with 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.”

Detailed conditions for the use of this product will be described in the updated Summary of Product Characteristics (SPC) which will be published in the revised European Public Assessment Report (EPAR) and will be available in all official European Union languages after the variation to the marketing authorisation has been granted by the European Commission.

For information, the full indication for Thyrogen will be as follows\*\*\*:

“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). Low risk patients with well-differentiated thyroid carcinoma who have undetectable serum Tg levels on THST and no rh (recombinant human) TSH-stimulated increase of Tg levels may be followed-up by assaying rh TSH-stimulated Tg levels.

**Thyrogen is indicated for pre-therapeutic stimulation in combination with 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.”**

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\* Summaries of positive opinion are published without prejudice to the Commission Decision, which will normally be issued within 44 days (Type II variations) and 67 days (Annex II applications) from adoption of the Opinion.

\*\* Marketing Authorisation Holders may request a re-examination of any CHMP opinion, provided they notify the EMEA in writing of their intention to request a re-examination within 15 days of receipt of the opinion.

\*\*\* The text in bold represents the new or the amended indication.