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## EPAR summary for the public

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# Thyrogen

## thyrotropin alfa

This is a summary of the European public assessment report (EPAR) for Thyrogen. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Thyrogen.

### What is Thyrogen?

Thyrogen is a powder that is made up into a solution for injection. It contains the active substance thyrotropin alfa.

### What is Thyrogen used for?

Thyrogen is used in patients who have had thyroidectomy (thyroid surgery) because of cancer, to detect any thyroid tissue that might have been left over after the surgery.

Thyrogen can also be used in combination with radioactive iodine to ablate (eliminate) any remaining thyroid tissue in patients who have had all or almost all of their thyroid gland removed and whose cancer has not spread to other parts of the body.

The medicine can only be obtained with a prescription.

### How is Thyrogen used?

The use of Thyrogen should be supervised by a doctor with expertise in thyroid cancer.

It is given as two injections into the buttock muscle, 24 hours apart. Seventy-two hours after the last injection, a blood test is carried out to check for the presence of a thyroid protein called thyroglobulin, which indicates the presence of thyroid tissue. Another way to check for left-over tissue is to give the patient a dose of radioactive iodine that will show up in the thyroid tissue on a scan. The iodine is given 24 hours after the last Thyrogen injection and scan is performed 48 to 72 hours later.



When Thyrogen is used to eliminate left-over thyroid tissue, radioactive iodine is also given 24 hours after the last Thyrogen injection. In these cases, a scan will be carried out a few days later to see if there is any more thyroid tissue left.

## **How does Thyrogen work?**

For thyroid tissue to be detected, it needs to be active, and this requires the presence of a hormone called thyroid stimulating hormone (TSH). However, patients who have had their thyroid gland removed receive medication (thyroid hormone replacement therapy) that stops their production of TSH.

The active substance in Thyrogen, thyrotropin alfa, is a copy of TSH and is used to stimulate any remaining thyroid tissue in the body, including cancerous tissue. The presence of thyroid tissue can be checked by a blood test (showing that the thyroid protein thyroglobulin is being produced by any remaining thyroid tissue) or, if the patient has been given radioactive iodine, by a scan (showing that the remaining thyroid tissue is actively taking up the iodine).

Thyrogen can be used to eliminate remaining thyroid tissue when the patient is given higher doses of radioactive iodine. This is because Thyrogen will stimulate the cells in the tissue to take up the radioactive iodine, which then eliminates them.

Thyrotropin alfa is produced by a method known as 'recombinant DNA technology': it is made by a cell that has received a gene (DNA), which makes the cell able to produce the hormone.

## **How has Thyrogen been studied?**

Thyrogen was used in two studies to detect any remaining thyroid tissue in 381 patients who had had thyroidectomy (thyroid surgery). In these studies the ability of Thyrogen to stimulate left-over thyroid tissue was compared with the patients' own TSH. To do this, measurements of thyroid stimulation (production of thyroglobulin and uptake of radioactive iodine) were taken twice: once after treatment with Thyrogen and once after the patients had stopped taking the replacement therapy that inhibits their natural TSH production.

The results of the two measurements were compared to see if they were in agreement. The company also presented the results of studies from the published literature looking at Thyrogen's effect when it was used with a thyroglobulin test, but without a radioactive iodine scan. The thyroglobulin test is an alternative to the radioactive iodine scan for detecting remaining thyroid tissue which involves measuring thyroglobulin produced by the thyroid tissue in the blood.

Thyrogen was used to eliminate any left-over thyroid tissue in a study involving 63 patients with thyroid cancer who were given higher doses of radioactive iodine. This study also compared Thyrogen with the patients' own TSH. The main measure of effectiveness was based on a test to see if the patient had any thyroid tissue remaining at eight months after treatment. Following this, 51 of the patients went on to be followed up for an average of three and a half more years. The company also presented the results of 13 studies from the published literature, including one key study that compared the effect of Thyrogen and the effect of stopping replacement therapy in 394 patients who were followed up for around two and a half years. Two further published studies involving 1,190 patients were carried out with Thyrogen using lower doses of radioactive iodine.

## **What benefit has Thyrogen shown during the studies?**

Using Thyrogen to detect left over thyroid tissue following surgery was comparable with using the patients' own TSH after their replacement therapy was stopped. However, Thyrogen has the advantage

of allowing patients to remain on their replacement therapy before the test is carried out, resulting in a better quality of life, as the temporary withdrawal of the replacement therapy has transient side-effects which cannot always be tolerated easily. The published studies showed that using Thyrogen was also effective in low-risk patients when leftover tissue was detected only by measuring thyroglobulin levels and that it was not always necessary to do a radioactive iodine scan.

For eliminating remaining thyroid tissue following thyroid cancer surgery, both treatments were 100% successful after eight months. This finding was confirmed in the follow-up study: all 43 patients whose results could be evaluated after a further three and a half years had successful treatment. This included 25 patients using Thyrogen and 18 whose replacement therapy was stopped. The larger published studies confirmed that Thyrogen had a similar effect to stopping replacement therapy in patients whose cancer had not spread to other parts of the body. Thyrogen used with lower doses of radioactive iodine was also shown to be effective.

### **What is the risk associated with Thyrogen?**

The most common side effect with Thyrogen (seen in more than 1 patient in 10) is nausea (feeling sick). For the full list of all side effects reported with Thyrogen, see the package leaflet.

Thyrogen should not be used in people who may be hypersensitive (allergic) to bovine (cow) or human TSH or to any of the other ingredients. Thyrogen must not be used during pregnancy.

### **Why has Thyrogen been approved?**

The CHMP decided that Thyrogen's benefits are greater than its risks and recommended that it be given marketing authorisation.

### **Other information about Thyrogen**

The European Commission granted a marketing authorisation valid throughout the European Union for Thyrogen on 9 March 2000.

The full EPAR for Thyrogen can be found on the Agency's website: [ema.europa.eu/Find/medicine/Human\\_medicines/European\\_public\\_assessment\\_reports](http://ema.europa.eu/Find/medicine/Human_medicines/European_public_assessment_reports). For more information about treatment with Thyrogen, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 11-2012.