

MY DOCTOR DISCUSSION GUIDE

Use this resource to help make the most of your next appointment with your endocrinologist

Thyrogen®
(thyrotropin alfa) for injection

Thyrogen® (thyrotropin alfa), for intramuscular use

INDICATIONS AND USAGE

Thyrogen (thyrotropin alfa) is used to help identify thyroid disease by testing the blood for a hormone called thyroglobulin in the follow up of patients with a certain type of thyroid cancer known as well differentiated thyroid cancer. It is used with or without a radiology test using a form of iodine.

Limitations of Use:

- The effect of Thyrogen on long term thyroid cancer outcomes has not been determined.
- When Thyrogen is used to help detect thyroid cancer, there is still a chance all or parts of the cancer could be missed.

Thyrogen is also used to help patients prepare for treatment with a form of iodine, called radioiodine, to remove leftover thyroid tissue in patients who have had surgery to take out the entire thyroid gland for patients with well differentiated thyroid cancer who do not have signs of thyroid cancer which has spread to other parts of the body.

Limitations of Use:

- In a study of people being prepared for treatment with a form of iodine after thyroid surgery, results were similar between those who received Thyrogen and those who stopped taking their thyroid hormone for up to 5 years after treatment. Researchers do not know if results would be similar over a longer period of time.

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After you've received a diagnosis for thyroid cancer, it may be helpful to take a family member or a friend with you on your appointment to help you remember all the information and help you ask all the important questions.

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START A CONVERSATION with questions to help you talk to your doctor about your diagnosis, care, and treatment plan. Make sure you check off each question you ask your doctor and write down notes on their responses.

Questions about your initial treatment

- What is the type and risk level of my cancer?
- What kind of initial treatment do you recommend for me - total thyroidectomy, lobectomy, "watch and wait"? What are the pros and cons of each procedure?
- What are the chances my cancer will reoccur after my thyroid surgery?
- Shall I start taking levothyroxine immediately after my thyroid surgery?
- What are the signs and symptoms of hypothyroidism? How long will it take post-surgery for the thyroid hormone medication to be effective?

Questions about post-operative diagnostic testing

- How often do I need to come back to your office after thyroid surgery?
- How will you determine if I need radioactive iodine (RAI)?
- What is the difference between stimulated and non-stimulated thyroglobulin blood testing?
- Which tests will you order to ensure my cancer has not spread and did not recur?

Questions about radioactive iodine (RAI) ablation

- If I do need RAI ablation, what steps do I need to take to prepare for RAI?
- When should I start the diet and for how long should I follow the diet?
- After I receive radioactive iodine, what do I need to do to avoid radiation exposure to other people around me?

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Questions about Thyrogen and Hypothyroidism

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- How can Thyrogen help me avoid the symptoms of acute hypothyroidism?
- How is Thyrogen administered?
- What are the side effects of Thyrogen?
- What is acute hypothyroidism?
- Can I continue on my thyroid hormone medication while preparing for Whole Body Scans and RAI?
- In case I have to hold thyroid hormone to prepare for RAI or diagnostic tests, how long do I need to be off the medication and how long will it be before I can feel "normal" again?

IMPORTANT SAFETY INFORMATION

Patients should not use Thyrogen with radioiodine if they have a contraindication to the use of radioiodine. Please consult with your doctor for a list of contraindications for radioiodine.

Thyrogen can cause serious side effects, including:

Thyrogen-Induced Hyperthyroidism:

- There have been reports of events that led to death in patients who not had surgery to have their thyroid gland removed, and in patients with thyroid cancer cells that have spread to other parts of the body.
- Patients over 65 years old with large amounts of leftover thyroid tissue after surgery, or with a history of heart disease, should discuss with their physicians the risks and benefits of Thyrogen.
- Thyrogen can be administered in the hospital for patients at risk for complications from Thyrogen administration.

Stroke:

- Since Thyrogen was first approved for use, there have been reports of central nervous system problems such as stroke in young women who have a higher chance of having a stroke, and weakness on one side of the body. The relationship between THYROGEN administration and stroke is unknown. Patients should remain hydrated prior to treatment with Thyrogen.

Sudden Rapid Tumor Enlargement:

- Leftover thyroid tissue after surgery and cancer cells that have spread to other parts of the body can quickly grow and become painful after Thyrogen administration. Patients with cancer cells near their windpipe, in their central nervous system, or in their lungs may need treatment with a glucocorticoid (a medication to help prevent an increase in the size of the cancer cells before using Thyrogen.)

Risks Associated with Radioiodine Treatment:

- If THYROGEN is administered with radioiodine (RAI), the serious side effects for RAI apply to this combination regimen. Please consult with your doctor for a list of contraindications for radioiodine.

ADVERSE REACTIONS

In clinical studies, the most common side effects reported were nausea and headache.

USE IN SPECIFIC PATIENT POPULATIONS

Pregnant patients: Notify your healthcare provider immediately in the event of a pregnancy. If THYROGEN is administered with radioiodine, the combination regimen should not be used in pregnant women. Thyrogen should be given to a pregnant woman only if the doctor thinks there is a clear need for it.

Breastfeeding patients: If THYROGEN is administered with radioiodine, the combination regimen should not be used in breastfeeding women. It is not known whether Thyrogen can appear in human milk. Breastfeeding women should discuss the benefits and risks of Thyrogen with their physician.

Children: Safety and effectiveness in young patients (under the age of 18) have not been established.

Elderly: Studies do not show a difference in the safety and effectiveness of Thyrogen between adult patients less than 65 years and those over 65 years of age.

Patients with kidney disease: Thyrogen exits the body much slower in dialysis patients and can lead to longer high TSH levels.

Please see Important Safety Information on page 3 and
full Prescribing Information at https://products.sanofi.us/Thyrogen/Thyrogen.pdf

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