Thyrogen® (thyrotropin alfa) Administration Schedule

Thyrogen is given as an injection into the muscle of the buttock for two days in a row. These injections are given by a health care provider. If you are receiving Thyrogen for ablation or diagnostic testing the following schedule may be used:

Your Thyrogen ablation checklist and schedule (to be filled out by your doctor or nurse)

Follow a low-iodine diet before ablation therapy

☐ Start low-iodine diet on _____ ☐ End low-iodine diet on _____

☐ You will receive two Thyrogen injections. The dates, times and location for your appointments are listed on the schedule below.☐

Ask your HCP about obtaining a pregnancy test before starting this protocol.

☐ Discuss radiation precautions with your health care providers to be started right after you receive radioactive iodine ablation on day

WHEN		WHAT	WHERE
Day	Date/Time	Schedule	Write in location
1		Thyrogen 0.9 mg IM injection #1	
2		Thyrogen 0.9 mg IM injection #2 This injection should follow 24 hours after the 1st Thyrogen injection	
3		Radioactive iodine ablation I-131 dose administered orally Radioiodine should follow 24 hours after the 2nd Thyrogen injection	
4			
5			
6,7 , or 8+		Post-therapy whole body scan (Your physician may decide that post-therapy scanning may be delayed additional days)	

Your Thyrogen Diagnostic Testing Schedule and Checklist for Whole Body Scan and Thyroglobulin Testing (to be filled out by your doctor or nurse)

☐ You are having both a stimulated thyroglobulin (Tg) blood test and a whole body scan (WBS) with Thyrogen

☐ Follow a low-iodine diet before the whole body scan
Start low-iodine diet on_____☐ End low-iodine diet on_____

☐ You will receive two Thyrogen injections. The dates, times and location for your appointments are listed on the schedule below.

☐ Ask your HCP about obtaining a pregnancy test

WHEN		WHAT	WHERE
Day	Date/Time	Schedule	Write in location
1		Thyrogen 0.9 mg IM injection #1	
2		Thyrogen 0.9 mg IM injection #2 This injection should follow 24 hours after the 1st Thyrogen injection	
3		☐Radioactive iodine I-131 Scanning dose administered orally. Radioiodine should follow 24 hours after the 2nd Thyrogen injection	
4			
5		☐I-131 whole body scan ☐Thyroglobulin (Tg) blood test	

Your Thyrogen Diagnostic Testing Schedule and Checklist for Stimulated Thyroglobulin Testing Only (to be filled out by your nurse or doctor)

☐ You are having only a stimulated thyroglobulin (Tg) blood test with Thyrogen

☐ You will receive two Thyrogen injections. The dates, times and location for your appointments are listed on the schedule below.

WHEN		WHAT	WHERE
Day	Date/Time	Schedule	Write in location
1		Thyrogen 0.9 mg IM injection #1	
2		Thyrogen 0.9 mg IM injection #2 This injection should follow 24 hours after the 1st Thyrogen injection	
3			
4			
5		☐Thyroglobulin (Tg) blood test	

Thyrogen® (thyrotropin alfa) Administration Schedule

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.

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

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