Please note:
Patient – Red Text
Physician – Black Text
Safety – Blue Text

I. Opening Safety Information

INDICATIONS AND USAGE with voiceover

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.

II. Video Introduction

My name is Amy. I live in Salem, New Hampshire.

I recently got married last year and I'm a trainer for a biotech company in Cambridge, Massachusetts.

So I found out that I had thyroid cancer. I was told it's a good cancer to have. You know, you're going to have your thyroid removed. You're going to be on medication for the rest of your life. Well, I knew I had to have my thyroid removed. I mean that is standard of care. It is a pretty routine procedure.

I met Amy because she was being prepared for her first one year follow-up stimulated whole body scan and she was not able to get Thyrogen from the academic center that she was being seen at and wanted a second opinion about how to manage her thyroid cancer.

She was very educated and she knew that she could have used the Thyrogen for her initial ablation. Her physician that was managing her disease did not prefer to use it so she actually went through the hypothyroidism.

III. 1st Ablation/Hypothyroidism

I was preparing for the ablation. So now they have to give me an artificial medication. Just act like I have a thyroid. Synthroid is because I don't have a thyroid. They told me I had to go through withdrawal so I said, okay, tell me a little bit about this. What's going to happen when I go hypothyroid? You'll be uncomfortable. You can still work, and you have to go on this low iodine diet. I said, okay.

So I started going to work, and after about maybe a week, I went on medical leave. I couldn't focus on anything. I typed emails. There were some mistakes on every page. I felt like I was walking in peanut butter. I think I gained 22 pounds, eating nothing—really, eating next to nothing. I used to describe it as like being, now that I have a 13-year-old stepdaughter, being hyper-emotional. I mean once I said it's like having an out of body experience and watching yourself do things, and you can't control it or being hyper-emotional because you would start to cry. But you know that it's happening, and you can't control yourself. You also feel like you're constantly in a brain fog and everything's an effort. Like there's just such a disconnect between what you're doing.

Remember what you do, you stop the medication for three to four weeks. You do the therapy and then when you restart the thyroid hormone, it takes another four to eight weeks to recover so you end up being hypothyroid for a total of three months.

IV. 2nd Ablation/Thyrogen

So when I was talking to other people, very knowledgeable about thyroid cancer or what I was going through, they said, I think you have an obligation to talk to somebody else. At least go get a second opinion. So that's when I was given the name of Dr. Lee, and I reached out to Dr. Lee.

And I went in there explaining what I had been through and when she said what she thought, you know, what she wanted to do, which was a second ablation. I said, first of all, I've been through hypothyroidism. I really don't want to go through that again. And I'm very familiar with thyrogen. And she said, well, of course, I would use thyrogen.

She really did not want to become hypothyroid again; and actually, came to me requesting whether a recombinant human TSH or Thyrogen would be useful in her particular case? I said yes.

Her post-therapy scan showed iodine uptake into local nodes. But after that, her thyroglobulin in her blood did not fall. That told me that she had significant residual disease.

And her original institution was going to make her hypothyroid again to do a whole body scan for localization. And she came to me saying, "Is this the best way to manage that?"

So, for Thyrogen, I had to come into the office, I think, a total of three days. I had to come in and get the injection and had to come in to the office for follow-up.

So now experiencing thyrogen, it's a little injection in your butt. So maybe people don't like that. I didn't have to miss work, I felt no different.

It was simple. I would say, if there was an option provided, patients should definitely look into Thyrogen.

V. Scrolling ISI/with Professional Voiceover

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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This patient story reflects the real-life experience of a person diagnosed with thyroid cancer who has been prescribed Thyrogen. However, individual experiences may vary. Patient stories are not necessarily representative of what another person using Thyrogen may experience.

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Please visit www.thyrogen.com for full prescribing information

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