

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr**THYROGEN**[®]

Thyrotropin alfa for injection

Read this carefully before you start taking **THYROGEN**[®] and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **THYROGEN**[®].

Serious Warnings and Precautions

- Thyrogen[®] should only be injected into a muscle; it should not be infused into a vein.

What is Thyrogen[®] used for?

If you have had surgery to remove your thyroid gland because of thyroid cancer, it's important to get regular checkups to make sure that you remain cancer-free. Your doctor may want to treat you or test you to see if the cancer has come back or spread to other parts of your body or give you more treatment. Usually two types of tests are used, one is a blood test called thyroglobulin or Tg test and the other is a scan called a Whole Body Scan (WBS).

Thyrogen[®] allows you to be tested without having to stop taking your thyroid medication.

Thyrogen[®] may be used for testing in patients:

- who can't tolerate stopping their thyroid medication due to withdrawal symptoms of hypothyroidism (medically contraindicated)
- who don't want to stop their thyroid medication for the test
- whose bodies don't produce enough of TSH (thyroid stimulating hormone) after stopping thyroid medications

Your treatment should be supervised by a healthcare professional knowledgeable in the management of thyroid cancer.

How does Thyrogen[®] work?

Thyrogen[®] is recombinant human thyroid stimulating hormone (rhTSH) manufactured in a laboratory. Because it's similar to the TSH that the body normally produces, it causes thyroid cells to do three things for a short time:

- Make thyroglobulin and release it into your blood stream, and
- Absorb radioactive iodine

- To remove (ablate) thyroid tissue left over after surgery to remove the thyroid gland (remnant) in low risk patients, Thyrogen® (thyrotropin alfa) plus radioiodine treatment may be used while you continue taking your thyroid hormone.

Only thyroid cells or well-differentiated thyroid cancer cells that have spread to other parts of your body can do these three things.

What are the ingredients in Thyrogen®?

Medicinal Ingredients: Thyrotropin alfa (recombinant human thyroid stimulating hormone)

Non-medicinal ingredients: Mannitol, Sodium phosphate monobasic monohydrate, Sodium phosphate dibasic heptahydrate, Sodium chloride, Nitrogen, Sterile water for injection

Thyrogen® comes in the following dosage forms:

Thyrogen® is supplied as a sterile powder that when mixed with sterile water forms a solution for intramuscular injection in the gluteal muscle (buttocks).

Do not use Thyrogen® if:

You have ever had an allergic reaction (for example, hives, rash, itchiness, trouble breathing) to bovine [from cows] or human thyroid stimulating hormone (TSH) or any ingredient in this medicine, or if you have ever had heart disease or kidney disease.

You should not use Thyrogen® if you are pregnant. You should not breastfeed after treatment with Thyrogen® until your doctor tells you it is safe.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Thyrogen®. Talk about any health conditions or problems you may have, including if you:

- You have distant metastases [thyroid cancer anywhere outside of the neck]
- You have kidney disease, especially if you are on dialysis
- Your doctor decides that you might need pre-treatment with corticosteroids
- You are pregnant or could become pregnant, or are breast-feeding.
- You have any allergies to this drug or its ingredients or components of the container.
- You have a history of heart disease.
- You are taking any other medicines or treatments, including any products you buy, such as over-the-counter medicines and herbal or home remedies.

A 'Whole Body Scan' should be performed 48 to 72 hours after the radioiodine administration (72 to 96 hours after the final injection of Thyrogen®).

Other warnings you should know about:

Thyrogen® injections should be supervised by a healthcare professional knowledgeable in the management of thyroid cancer.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

There are no known drug interactions with the thyroid hormones you may be taking.

How to take Thyrogen®:

Thyrogen® injections should be supervised by a healthcare professional knowledgeable in the management of thyroid cancer.

Thyrogen® should only be administered into the gluteal muscle (buttocks). Thyrogen® solution should never be injected into a vein.

Thyrogen® has to be reconstituted with 1.2 mL Sterile Water for Injection, USP. Only one vial of Thyrogen® is required per injection.

Reconstituted Thyrogen® solution should be a clear, colourless solution. Do not use vials exhibiting foreign particles, cloudiness or discoloration.

1.0 mL of the Thyrogen® solution from the product vial equals 0.9 mg thyrotropin alfa to be injected.

Usual dose:

A two-injection regimen is recommended for Thyrogen® administration, Thyrogen® 0.9 mg intramuscularly (IM) followed by a second 0.9 mg IM injection 24 hours later.

When you undergo radioiodine imaging, your doctor will give you radioiodine 24 hours after your final Thyrogen® injection. Diagnostic scanning should be performed 48 to 72 hours after the radioiodine administration (72 to 96 hours after the final injection of Thyrogen®).

Day 1	Day 2	Day 3	Day 4	Day 5
Thyrogen®	Thyrogen®	Radioiodine		WBS +/- Tg testing
Monday	Tuesday	Wednesday	Thursday	Friday

For serum thyroglobulin (Tg) testing, your doctor or nurse will take a blood sample 72 hours after the final injection of Thyrogen®.

Day 1	Day 2	Day 3	Day 4	Day 5
Thyrogen®	Thyrogen®			Serum Tg testing
Monday	Tuesday	Wednesday	Thursday	Friday

Overdose:

If you think you, or a person you are caring for, have taken too much Thyrogen[®], contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

You may experience nausea, weakness, dizziness, headache, vomiting and hot flushes.

If you accidentally receive Thyrogen[®] in a vein rather than the muscle you may also experience these symptoms, or feel faint, dizzy, or sweaty or have a fast heartbeat.

Missed Dose:

If you have missed a Thyrogen[®] injection, please contact your doctor.

What are possible side effects from using Thyrogen[®]?

These are not all the possible side effects you may have when taking Thyrogen[®]. If you experience any side effects not listed here, tell your healthcare professional. Please also see Warnings and Precautions.

Very common side effects:

- Insomnia, Anxiety
- Fatigue
- Runny nose, Sore throat

Common side effects:

Occurred in 1 to 10 out of every 100 patients (between 1% and 10% of patients).

- Diarrhoea, Vomiting, Dry lips or mouth, Constipation, Haemorrhoids, Pain with eating, Salivary gland (saliva glands in the cheeks and mouth or under the jaw) enlargement
- Sweating, Dry skin, Blister, Easy bruising, Cough, Hair loss, Change in the colour of skin
- Flu symptoms, Sinus inflamed or congested (stuffed up)
- Muscle stiffness, spasms or tightness
- Headache, Tingling sensation, Tremor/Shaking, Migraine, Trouble with attention span or memory, Abnormal sense in taste or touch
- Feeling unwell, Weakness, Swelling, Injection site warmth, Feeling cold, Feeling hot, Irritability, Fever, Chills
- Depression, Restlessness
- Painful or enlarged lymph nodes
- Ringing in the ears

Uncommon side effects:

These side effects may affect up to 1 in every 100 people (less than 1%).

- Decreased appetite, Dehydration
- Yeast infection
- Nervousness, Agitation, Mood swings, Sleep Disorder
- Injection site discomfort, Injection site itchiness, Inflammation (Eye, Finger), Thirst
- Menstrual spotting
- Nosebleed

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
VERY COMMON			
Nausea	X		
COMMON			
Breathing problems and hypersensitivity (allergic reactions) which may include: trouble breathing, tightness in throat or hoarse voice; Hives, rash, itching, flushing, swelling in face; Pain in your body or near the tumour; Dizziness or feeling faint; Palpitations/irregular heartbeat			X
RARE			
Fast heart rate; Sudden onset of redness, pain and/or swelling in leg			X
FREQUENCY NOT KNOW			
Stroke (with symptoms such as: weakness/numbness to body, severe headaches, speech disturbance)			X

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

<p>Reporting Side Effects</p> <p>You can report any suspected side effects associated with the use of health products to Health Canada by:</p> <ul style="list-style-type: none"> • Visiting the Web page on Adverse Reaction Reporting (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html) for information on how to report online, by mail or by fax; or • Calling toll-free at 1-866-234-2345. <p><i>NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.</i></p>
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Storage:

Keep out of reach and sight of children.

Only a healthcare professional should prepare the medicine and administer it to you.

Store at 2 to 8°C (in a refrigerator). The reconstituted solution should be injected within three hours; however, the solution will be stable for up to 24 hours when mixed and stored properly at 2 to 8°C to avoid contamination.

Keep the vial in the outer carton to protect from light.

Do not use after expiry date on the label.

If you want more information about Thyrogen®:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website www.sanofi.ca, or by contacting the sponsor, Sanofi Genzyme, at: 1-800-265-7927.

This leaflet was prepared by Sanofi Genzyme.

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