

PART III: CONSUMER INFORMATION**Pr** **THYROGEN[®]**

pronounced: THIGH ro jen
(Thyrotropin alfa for injection)

This leaflet is part III of a three-part "Product Monograph" published when THYROGEN[®] was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about THYROGEN[®]. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATIONWhat the medication is 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.

What it does:

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.

When it should not be used:

Before you take this medicine, tell your doctor 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.

What the medicinal ingredient is:

It is called thyrotropin alfa (recombinant human thyroid stimulating hormone)

What the important nonmedicinal ingredients are:

Mannitol, Sodium Chloride, Sodium phosphate monobasic, monohydrate, Sodium phosphate dibasic, heptahydrate.

For a full listing of nonmedicinal ingredients see Part 1 of the product monograph.

What dosage forms it comes in:

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

WARNINGS AND PRECAUTIONS**Serious Warnings and Precautions**

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

BEFORE you use THYROGEN[®] talk to your doctor or pharmacist if:

- 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[®]).

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

INTERACTIONS WITH THIS MEDICATION

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

PROPER USE OF THIS MEDICATION

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

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

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
<i>Monday</i>	<i>Tuesday</i>	<i>Wednesday</i>	<i>Thursday</i>	<i>Friday</i>

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
<i>Monday</i>	<i>Tuesday</i>	<i>Wednesday</i>	<i>Thursday</i>	<i>Friday</i>

Overdose:

In case of overdose, contact your doctor or poison control center

Missed Dose:

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

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medicines, THYROGEN[®] can have side effects. Some of the side effects of THYROGEN[®] can be serious and may require immediate medical treatment and/or stopping THYROGEN[®]. The most common were Hives, Trouble breathing, Tightness in throat, Hoarse voice, Rash, Pain (including pain near the tumour or metastases), Palpitations/irregular heartbeat, Feeling faint or dizzy, and Swelling. Uncommon serious side effects included a sudden onset of redness, pain and/or swelling in the leg (signs of a possible blood clot), and a fast heart rate.

See the following table for a list of *Serious Side Effects, How Often They Happen, and What To Do About Them*.

Other side effects of THYROGEN[®] include:

Very common side effects:

Occurred in more than 10 out of every 100 patients (more than 10%).

- Insomnia, Anxiety
- Fatigue
- Nausea
- 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.

Other side effects include:

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

If any of these symptoms become severe, talk to your doctor immediately.

If you think you have received too much THYROGEN[®], tell your doctor.

HOW TO STORE IT

Keep out of reach and sight of children.

Only a healthcare profession 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 in order to protect from light.

Do not use after expiry date on the label.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect	Talk with your doctor or pharmacist	Stop taking drug and seek immediate medical attention in all cases
	Only if severe	
Very common (more than 10% of patients)		
Nausea	√	
Common (1-10%)		
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		√
Uncommon (less than 1%)		
Fast heart rate; Sudden onset of redness, pain and/or swelling in leg		√

This is not a complete list of side effects. For any unexpected effects while taking THYROGEN[®], contact your doctor or pharmacist.

Overdose

If you receive more THYROGEN[®] than you should Patients who accidentally received too much THYROGEN[®] had nausea, weakness, dizziness, headache, vomiting and hot flushes. Patients who accidentally received THYROGEN[®] in a vein rather than the muscle may also have these symptoms, or feel faint, dizzy, or sweaty or have a fast heartbeat.

MORE INFORMATION

Reporting Suspected Side Effects

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to:
 - Canada Vigilance Program
 - Health Canada
 - Postal Locator 0701D
 - Ottawa, Ontario
 - K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

This document plus the full product monograph, prepared for health professionals can be found at:

<http://www.genzyme.ca>
 or by contacting the sponsor, Genzyme Canada,
 at: 1-877-220-8918

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