



## CONSUMER INFORMATION

# **Thyrogen**<sup>®</sup> thyrotropin alfa for injection

*This leaflet is part III of a three-part "Product Monograph" published when THYROGEN<sup>®</sup> 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<sup>®</sup>. Contact your doctor or pharmacist if you have any questions about the drug.*

## ABOUT THIS MEDICATION

What 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 will want to test you to see if the cancer has come back or spread to other parts of your body. 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<sup>®</sup> allows you to be tested accurately without having to stop taking your thyroid medication.

THYROGEN<sup>®</sup> may be used for testing in patients who are:

- Unwilling to undergo thyroid hormone withdrawal/hypothyroid testing
- Unable to tolerate withdrawal/hypothyroidism (medically contraindicated)
- Unable to mount an adequate endogenous TSH response to thyroid hormone withdrawal

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

What it does:

THYROGEN<sup>®</sup> is recombinant human thyroid stimulating hormone (rhTSH) manufactured in a laboratory. Because it's just like the TSH that the body normally produces it causes thyroid cells to do two things on a short-term basis:

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

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

When it should not be used:

You should tell your doctor, if you have ever had an allergic reaction (for example, rash, or itchiness) to bovine or human

thyroid stimulating hormone (TSH) or any ingredient in this medicine, before you take this medicine.

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<sup>®</sup> 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<sup>®</sup> should only be injected into a muscle; it should not be infused into a vein.

BEFORE you use THYROGEN<sup>®</sup> talk to your doctor or pharmacist if:

- Your doctor decides that you belong to a specific group of patients for which pre-treatment with corticosteroids is to be considered (for example, patients with intracerebral or spinal cord metastases).
- You are pregnant or plan to 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.

THYROGEN<sup>®</sup> 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:

The recommended dose of THYROGEN<sup>®</sup> is two doses of 0.9 mg thyrotropin alfa administered intramuscularly at 24 hour intervals. Your doctor or nurse will inject 1.0 ml of the THYROGEN<sup>®</sup> solution (0.9 mg thyrotropin alfa).

THYROGEN<sup>®</sup> 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
<b>Monday</b>	<b>Tuesday</b>	<b>Wednesday</b>	<b>Thursday</b>	<b>Friday</b>

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

**Overdose:**

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

**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.

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

Symptom / effect		Talk with your doctor or pharmacist
<b>Most common</b> (≥10%)	Nausea	T
<b>Common</b> (≥1% and ≤10%)	Headache, weakness, vomiting, dizziness, tingling sensation, pain (including pain at site of metastases), chills, fever, flu symptoms	T
<b>Uncommon</b> (≤ 1%)	Hypersensitivity (allergic reactions): urticaria, rash, pruritis, flushing, respiratory signs & symptoms	T

This is not a complete list of side effects.

For any unexpected effects while taking THYROGEN®, contact your doctor or pharmacist.

**REPORTING SUSPECTED SIDE EFFECTS**

To monitor drug safety, Health Canada collects information on serious and unexpected effects of drugs. If you suspect you have had a serious or unexpected reaction to this drug you may notify Health Canada by:

toll-free telephone: 866-234-2345  
 toll-free fax: 866-678-6789  
 By email: cadmp@hc-sc.gc.ca

By regular mail:

National AR Centre  
 Marketed Health Products Safety and Effectiveness  
 Information Division  
 Marketed Health Products Directorate  
 Tunney's Pasture, AL 0701C  
 Ottawa ON K1A 0K9

*NOTE: Before contacting Health Canada, you should contact your physician or pharmacist.*

**HOW TO STORE IT**

Keep out of reach and sight of children.

Store at 2 to 8°C (in a refrigerator). Although not recommended, the reconstituted solution can be stored for up to 24 hours at a temperature between 2 to 8°C, while avoiding microbial contamination.

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

Do not use after expiry date on the label.

**MORE INFORMATION**

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 Inc.,  
 at: 1-877-220-8918

This leaflet was prepared by Genzyme Canada Inc.  
 Last revised: May 17, 2007.

THYROGEN is a registered trademark of Genzyme Corporation.



CANADA INC

20-07-17E