



PACKAGE LEAFLET: INFORMATION FOR THE USER

Thyrogen® 0.9 mg powder for solution for injection
thyrotropin alfa
(Sterile)

sanofi

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- If you experience any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Thyrogen is and what it is used for
2. What you need to know before you use Thyrogen
3. How to use Thyrogen
4. Possible side effects
5. How to store Thyrogen
6. Contents of the pack and other information

1. WHAT THYROGEN IS AND WHAT IT IS USED FOR

Thyrogen contains the active substance thyrotropin alfa. Thyrogen is a human thyroid stimulating hormone (TSH) manufactured using biotechnology processes.

Thyrogen is used to detect certain types of thyroid cancer in patients who have had their thyroid gland removed and who are taking thyroid hormones. One of the effects is that it stimulates any remaining thyroid tissue to take up iodine which is important for radioiodine imaging. It also stimulates the production of thyroglobulin and thyroid hormones if there is any thyroid tissue left. These hormones can be measured in your blood.

Thyrogen is also used with radioiodine treatment to eliminate (ablate) the thyroid tissue left over after surgical removal of the thyroid gland (remnant) in patients who do not have secondary cancer growths (metastases) and who are taking thyroid hormone.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE THYROGEN

Contraindications:

Do not use Thyrogen:

- if you are allergic to bovine or human thyroid stimulating hormone (TSH) or any of the other ingredients of this medicine (listed in section 6).
- If you are pregnant.

Warnings and precautions

- Talk to your doctor or pharmacist before using Thyrogen
- if you have kidney disease that requires dialysis and he will decide how much Thyrogen to give to you as you may have more chance of experiencing headache and nausea.
 - if you have reduced kidney function and he will decide how much radioiodine to give you.
 - if you have reduced liver function; you should still be able to receive Thyrogen.

Effect on tumour growth

In patients with thyroid cancer, tumour growth has been reported during withdrawal of thyroid hormones for diagnostic procedures. This was thought to be related to the elevated thyroid stimulating hormone (TSH) levels over a longer period. It is possible that Thyrogen may also cause tumour growth. In clinical trials this was not seen.

Due to elevation of TSH levels after Thyrogen, patients with secondary cancer growths (metastases) can experience local swelling or bleeding at the site of these metastases which may become bigger. If the metastases are present in narrow spaces e.g. intracerebral (in the brain) or in the spinal cord, patients could experience symptoms which can occur quickly such as partial paralysis affecting one side of the body (hemiparesis), breathing problems or loss of vision.

Your doctor will decide if you belong to a specific group of patients for which pre-treatment with corticosteroids is to be considered (for example, if you have secondary cancer growths in your brain or spinal cord). Please talk to your doctor about this if you have concerns.

Children

Due to a lack of data on the use of Thyrogen in children, Thyrogen should be given to children only in exceptional circumstances.

Elderly

No special precautions for elderly patients are necessary. However, if your thyroid gland has not been removed completely and you are also suffering from heart disease, your doctor will help you decide if Thyrogen should be given to you.

Other medicines and Thyrogen

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

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

Your doctor will determine the exact activity of radioiodine to use for radioiodine imaging, taking into consideration the fact that you continue to take thyroid hormones.

Pregnancy and breast-feeding

Do not take Thyrogen if you are pregnant. If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Thyrogen should not be given to breast-feeding women. Breast-feeding should only be resumed following advice from your doctor.

Driving and using machines

Some patients may feel dizzy or have headaches after administration of Thyrogen which may affect the ability to drive and use machines.

Thyrogen contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per vial, that is to say essentially ‘sodium-free’.

3. HOW TO USE THYROGEN

Your medicine will be injected by a doctor or a nurse.

Your treatment should be supervised by a doctor who has expertise in thyroid cancer. Thyrogen powder must be dissolved in water for injection. Only one vial of Thyrogen is required per injection. Thyrogen should only be administered into the buttock muscle. This solution should never be injected into a vein. Thyrogen must not be mixed with other medicines in the same injection.

The recommended dose of Thyrogen is two doses administered 24 hours apart. Your doctor or nurse will inject 1.0 ml of the Thyrogen solution.

When you undergo radioiodine imaging or elimination (ablation), 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). Post-treatment scanning may be delayed a few days to allow background radioactivity to decline.

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

Use in children

Your child’s doctor will help you decide if Thyrogen should be given to your child.

If you are given more Thyrogen than you should receive
Patients who accidentally received too much Thyrogen have reported nausea, weakness, dizziness, headache, vomiting and hot flashes.
A suggested treatment in case of overdose would be the reestablishment of fluid balance and administration of an antiemetic may also be considered.

If you have any further questions on the use of this medicine, ask your doctor.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The following effects have been reported with Thyrogen:

Very common (may affect more than 1 in 10 people):

- nausea

Common (may affect up to 1 in 10 people):

- vomiting
- fatigue
- dizziness
- headache
- weakness

Uncommon (may affect up to 1 in 100 people):

- feeling hot
- hives (urticaria)
- rash
- flu symptoms
- fever
- chills
- back pain
- diarrhoea
- prickling or tingling sensation (paraesthesia),
- neck pain
- inability to taste (ageusia)
- impaired sense of taste (dysgeusia)
- influenza

Not known (frequency cannot be estimated from the available data):

- swelling of the tumour
- pain (including pain at the site of metastases (secondary cancer growths))
- tremor
- stroke
- palpitations
- flushing
- shortness of breath
- itching (pruritus)
- excessive sweating
- muscle or joint pain
- injection site reactions (including redness, discomfort, itching, local pain or stinging, and an itchy rash)
- low TSH
- hypersensitivity (allergic reactions), these reactions include hives (urticaria), itching, flushing, difficulty in breathing and rash.

Very rare cases of **hyperthyroidism** (increased activity of the thyroid gland) or **atrial fibrillation** have been reported when Thyrogen was administered to patients who had not undergone total or partial removal of the thyroid gland.

The following information is intended for healthcare professionals only:

The recommended dose regimen of Thyrogen is two intramuscular injections of 0.9 mg thyrotropin alfa administered at a 24-hour interval.

Traceability

In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.

Use aseptic technique.

Add 1.2 ml water for injection to the Thyrogen powder in the vial. Swirl the contents of the vial gently until all material is dissolved. Do not shake the solution. When the powder is dissolved the total volume in the vial is 1.2 ml. The pH of the Thyrogen solution is approximately 7.0. Visually inspect the Thyrogen solution in the vial for foreign particles and discoloration. The Thyrogen solution should be a clear, colourless solution. Do not use vials exhibiting foreign particles, cloudiness or discoloration.

Withdraw 1.0 ml of the Thyrogen solution from the product vial. This equals 0.9 mg thyrotropin alfa to be injected.

Thyrogen does not contain preservatives. Dispose of any unused solution immediately. No special requirements for disposal.

After reconstitution, the solution should be injected within three hours. The reconstituted solution can be stored for up to 24 hours in a refrigerator (2°C - 8°C) under protection from light, while avoiding microbial contamination. It is important to note that the microbiological safety depends on the aseptic conditions during the preparation of the solution.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE THYROGEN

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label after “EXP”. The expiry date refers to the last day of that month.

Store in a refrigerator (2°C - 8°C).

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

It is recommended that the Thyrogen solution be injected within three hours after reconstitution. The reconstituted solution can be stored for up to 24 hours in a refrigerator (2°C - 8°C) under protection from light, while avoiding microbial contamination.

Do not use this medicine if you notice foreign particles, cloudiness or discoloration.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Thyrogen contains

- The active substance is thyrotropin alfa. Each vial contains 0.9 mg/ml of thyrotropin alfa when reconstituted with 1.2 ml water for injection. Only 1 ml should be withdrawn equal to 0.9 mg of thyrotropin alfa.
- The other ingredients are:
Mannitol
Sodium phosphate monobasic, monohydrate
Sodium phosphate dibasic, heptahydrate
Sodium chloride.

Thyrogen contains sodium, see section 2.

What Thyrogen looks like and contents of the pack

Powder for solution for injection. White to off-white lyophilised powder.

Pack sizes: one or two vials of Thyrogen per carton. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Sanofi B.V.
Paasheuvelweg 25
1105 BP Amsterdam
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Manufacturer

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