PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S4

THYROGEN® 0,9 mg powder for solution for injection

Thyrotropin alfa

Contains sugar: 29 mg/mL mannitol (following reconstitution).

Please read this leaflet carefully before you receive THYROGEN.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or other health care provider.

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 which is a recombinant human thyroid stimulating hormone (rhTSH).

THYROGEN is used:

- In combination with a blood test and/or a whole-body scan to assist in the detection of thyroid cancer cells in patients who have had all or part of their thyroid gland removed (as a result) of thyroid cancer.
- In the treatment of thyroid cancer in combination with radioactive iodine (radioiodine) to eliminate any remaining thyroid cancer cells or normal thyroid tissue after removal of your thyroid gland. This also allows the doctors to detect any thyroid cancer that may remain after your treatment more easily.

2. What you need to know before you use THYROGEN

Do not use THYROGEN:

- If you are allergic (hypersensitive) to thyrotropin alfa or any of the other ingredients in THYROGEN (listed in section 6 of this leaflet).

Warnings and precautions:

Take special care with THYROGEN:

- Even when THYROGEN-stimulated thyroglobulin testing is done with radioiodine imaging, there is a meaningful risk of missing the existence of thyroid cancer or of underestimating the disease. Thyroid hormone withdrawal testing with radioiodine imaging remains the standard diagnostic test to assess the presence, location and extent of thyroid cancer.
- Tell your doctor if you have been treated with bovine TSH in the past and if you experienced an allergic reaction to bovine TSH.
- THYROGEN can cause a temporary but significant increase in the level of thyroid hormone in your blood. Therefore, your doctor will monitor you more closely if you have a history of heart problems and if you have cancerous thyroid tissue remaining in your body.
- Injection with THYROGEN should never be into a vein.

- Tell your doctor if you have a kidney disease that requires dialysis. He/she will decide how much THYROGEN to give to you as you may have a greater chance of experiencing headache and nausea.
- If you have reduced kidney function your doctor will decide how much radioiodine to give you.

Children and adolescents:

As safety and effectiveness are not proven in children, your child's doctor will decide if THYROGEN should be given to your child.

Other medicines and THYROGEN:

Always tell your health care provider if you are taking any other medicine. (This includes complementary or traditional medicines.)

- Some medicines and THYROGEN may interfere with each other. No studies have been carried out on interactions with other medicines.
- Your doctor will decide whether or not to give you THYROGEN.

THYROGEN and food:

There are no known interactions between THYROGEN and food.

Pregnancy and breastfeeding:

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider before you receive THYROGEN.

Driving and using machinery:

The effect of THYROGEN on your ability to drive a car or operate machinery has not been studied. Make sure that you know how you react to THYROGEN before you drive a car or operate

machinery or do anything else that may be dangerous if you are dizzy, lightheaded, tired or drowsy.

THYROGEN contains sodium:

THYROGEN contains less than 1 mmol sodium (23 mg) per vial and is essentially sodium free.

3. How to use THYROGEN

Always use THYROGEN exactly as your doctor has told you. Check with your doctor if you are not sure.

Your doctor or health care provider has experience in the treatment of thyroid cancer and should always supervise your treatment. You will not be expected to give yourself THYROGEN. It will be given to you by a person who is qualified to do so.

The THYROGEN powder must be dissolved in water for injection. Only one vial of THYROGEN is required per injection. The injection must be given intramuscularly. Your doctor, nurse or pharmacist will prepare the injection for you.

The recommended treatment with THYROGEN is two doses of 0,9 mg thyrotropin alfa given intramuscularly 24 hours apart. Your doctor or nurse will inject 1,0 mL of the THYROGEN solution (0,9 mg thyrotropin alfa). If you have any questions about the proper dose of THYROGEN, ask your doctor.

If you have reduced liver function you should still be able to receive THYROGEN.

If you have reduced kidney function your doctor will decide how much radioiodine to give you.

When you undergo radioiodine imaging or ablation, your doctor will give you radioiodine 24 hours after your final THYROGEN injection.

Diagnostic scans should be performed 48 to 72 hours after the radioiodine administration (72 to 96 hours after the final injection of THYROGEN), whereas post-therapy scans may be delayed additional days to allow background activity to decline.

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

If you have the impression that the effect of THYROGEN is too strong or too weak, tell your doctor or pharmacist.

If you receive more THYROGEN than you should:

Since your doctor will administer THYROGEN, he/she will control the dosage. However, in the event of overdosage, your doctor will treat the side effects symptomatically.

If you forget to use THYROGEN:

Your doctor will make sure you receive THYROGEN at the right time.

4. Possible side effects

THYROGEN can have side effects.

Not all side effects reported for THYROGEN are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving THYROGEN, please consult your doctor, pharmacist or other health care provider for advice.

If any of the following happens, stop receiving THYROGEN and tell your doctor immediately:

- swelling of your hands, feet, ankles, face, lips, tongue, mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching
- fainting.

These are all very serious side effects. You may have had a serious allergic reaction to THYROGEN. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately if you notice any of the following:

- very rare cases of stroke (sudden headache, weakness in your arm or leg (only on one side of your body), difficulty speaking, loss of vision) have been reported.
- swelling of the tumour, including pain (at the tumour site) and cancer growths
- difficulty breathing, shortness of breath.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- headache, dizziness
- nausea, vomiting, diarrhoea
- weakness, tiredness
- numbness or tingling sensation.

Less frequent side effects:

- flu-like symptoms (headache, sore throat, body aches, coughing, congestion)
- loss of or change in taste
- feeling hot, chills, fever

- back pain, neck pain
- hives (urticaria), rash.

The following side effects may occur, but the frequency is unknown:

- tremor
- a sensation that your heart is racing or skipping a beat
- flushing
- itching
- excessive sweating
- muscle or joint pain
- pain or discomfort (including redness, itching or stinging) at the site of the injection
- blood results showing low thyroid stimulating hormone (TSH) levels.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects:

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to:

- The Pharmacovigilance Unit at Sanofi: za.drugsafety@sanofi.com (email) or 011 256 3700 (tel), or
- SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8

By reporting side effects, you can help provide more information on the safety of THYROGEN.

5. How to store THYROGEN

- Store in a refrigerator (2 °C – 8 °C).
- Keep the vial in the outer carton in order to protect from light.
- Do not freeze or shake the reconstituted solution.
- The reconstituted solution can be stored for up to 24 hours at a temperature of 2 °C – 8 °C under protection from light, while avoiding microbial contamination. It is recommended that the THYROGEN solution be injected within three hours.
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

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 sterile water for injection. Only 1 mL should be withdrawn equal to 0,9 mg of thyrotropin alfa.

The other ingredients are: Mannitol, sodium chloride, sodium phosphate dibasic heptahydrate and sodium phosphate monobasic monohydrate.

What THYROGEN looks like and contents of the pack:

A sterile, non-pyrogenic, white to off-white lyophilised cake or powder. The reconstituted solution is a clear, colourless solution, free from any visible particles.

THYROGEN is packed into a 5 mL Type I flint glass vial with a grey rubber stopper and sealed with an aluminium seal with a dark blue polypropylene flip-off cap.

Two vials of THYROGEN packed in an outer container with the professional information.

Holder of the certificate of registration:

sanofi-aventis south africa (pty) ltd

Hertford Office Park, Building I, 5th Floor

90 Bekker Road, Vorna Valley

Midrand 2196

South Africa

Tel. no.: 011 256 3700

This leaflet was last revised:

14 February 2022

Registration number:

43/21.3/0869

Date of registration:

26 October 2012