

THYROGEN[®]

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Thyrogen?

Thyrogen contains the active ingredient thyrotropin alfa. Thyrogen is used to help in the detection of thyroid cancer cells. Thyrogen is also used in the treatment of thyroid cancer in combination with radioactive iodine. For more information, see Section [1. Why am I using Thyrogen?](#) in the full CMI.

2. What should I know before Thyrogen is given?

Do not use if you have ever had an allergic reaction to thyrotropin alfa or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use Thyrogen?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Thyrogen and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use Thyrogen?

- Your treating physician will decide on the dose that is most suitable.
- Your treating physician will give you two injections of Thyrogen into the muscle of your buttock. The second injection will be given to you a day after the first one.

More instructions can be found in Section [4. How is Thyrogen given?](#) in the full CMI.

5. What should I know while using Thyrogen?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using Thyrogen.• Keep appointments with your treating physician.
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	<ul style="list-style-type: none"> • Have tests when your treating physician says to.
Things you should not do	<ul style="list-style-type: none"> • Do not use Thyrogen if you have a known, severe allergic reaction to Thyrogen or any of its ingredients
Driving or using machines	<ul style="list-style-type: none"> • Be careful driving or operating machinery until you know how Thyrogen affects you.
Looking after your medicine	<ul style="list-style-type: none"> • Thyrogen will be stored in the hospital.

For more information, see Section [5. What should I know while, or after, being given Thyrogen?](#) in the full CMI.

6. Are there any side effects?

Less serious side effects include headache, fatigue, nausea, weakness, vomiting, dizziness, chills, numbness/tingling, fever and diarrhoea. More serious side effects include hoarse voice, difficulty breathing, noisy breathing and itchy rash or hives.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Thyrogen[®]

Active ingredient: *Thyrotropin alfa*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Thyrogen. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Thyrogen.**

Where to find information in this leaflet:

- [1. Why am I using Thyrogen?](#)
- [2. What should I know before Thyrogen is given?](#)
- [3. What if I am taking other medicines?](#)
- [4. How is Thyrogen given?](#)
- [5. What should I know while, or after, being given Thyrogen?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using Thyrogen?

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

Thyrogen is used together with a blood test and/or a whole body scan to help 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.

Thyrogen is also used in the treatment of thyroid cancer in combination with radioactive iodine to kill any remaining thyroid cancer cells or normal thyroid tissue after removal of your thyroid. This also allows the doctors to detect more easily any thyroid cancers that may remain after your treatment.

Thyrogen helps your remaining thyroid cells and the cancer cells take up the radioactive iodine so that they will all be killed by the radiation treatment.

How it works

After you have had your cancer operation, your treating physician will need to test you to make sure that there are no remaining cancer cells in your body or that the cancer has not come back or spread to other parts of your body.

Your treating physician will give you thyroid hormone replacement treatment to replace the hormone that your thyroid gland used to make because you have had all or part of your thyroid gland removed.

Having this replacement treatment will also mean that your pituitary gland will produce less of a hormone called thyroid stimulating hormone (TSH).

TSH sticks to the thyroid cancer cells.

For the cancer cell detection tests to be accurate there needs to be a certain amount of TSH in your body. The thyroid hormone replacement treatment that you are getting means that your body will not be making enough TSH for the tests.

Thyrogen imitates TSH made by your body and makes sure that there is enough TSH in your body for the tests. For detection of thyroid cancer cells, Thyrogen will be given to you about 3 days before your blood test and/or whole body scan so that your doctor can find any thyroid cancer cells that might be in your body. For treatment of thyroid cancer, Thyrogen is given to you one day before your dose of radioiodine and up to several days before your scan.

2. What should I know before Thyrogen is given?

Warnings

Do not use Thyrogen if:

- you are allergic to Thyrogen, or any of the ingredients listed at the end of this leaflet.

Always check the ingredients to make sure you can use this medicine.

Check with your doctor or pharmacist if you:

- have reacted to previous treatments with any of the following: severe allergic reaction; difficulty breathing

- take any medicines for any other condition
- have allergies to: any other medicines; any other substances, such as foods, preservatives or dyes

Tell your treating physician if you have heart disease.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your treating physician if you are pregnant or intend to become pregnant.

Thyrogen may cause harm to your unborn baby. Your treating physician will discuss the possible risks and benefits of having Thyrogen during pregnancy.

Talk to your treating physician if you are breastfeeding or intend to breastfeed.

It is not known whether Thyrogen passes into breast milk. Your doctor will discuss the possible risks and benefits of having Thyrogen during breastfeeding.

Children

The safety of Thyrogen in children has not been studied.

If your child has been prescribed Thyrogen, you may wish to discuss this with your child's treating physician.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with Thyrogen and affect how it works.

No studies have been carried out on drug interactions.

Your treating physician will decide whether or not to give you Thyrogen.

Check with treating physician if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Thyrogen.

4. How is Thyrogen given?

Your treating physician will give you two injections of Thyrogen into the muscle of your buttock. The second injection will be given to you a day after the first one.

Your treating physician will decide on the dose that is most suitable.

If you use too much Thyrogen (overdose)

There have been no reported overdoses of Thyrogen.

5. What should I know while, or after, being given Thyrogen?

Things you should do

- **Keep appointments with your treating physician.**

It is important to have your Thyrogen injections at the times your treating physician has told you. This will make sure that there is the right amount of Thyrogen in your body for the cancer cell detection tests to be accurate. It is also important so that the right amount of Thyrogen is present when you have your radioactive iodine treatment after your thyroid surgery.

Remind any doctor, dentist or pharmacist you visit that you have been given Thyrogen.

- **Have tests when your treating physician says to.**

You are being given Thyrogen to make sure that the tests you will be having can detect any thyroid cancer cells in your body so it is important to have the tests when your doctor tells you to.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Thyrogen affects you.

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, light-headed, tired or drowsy.

Thyrogen may cause dizziness in some people.

Looking after your medicine

- Thyrogen will be stored in the hospital.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your treating physician, doctor or pharmacist if you have any further questions.

Less serious side effects

Less serious side effects	What to do
<p>Gastrointestinal related:</p> <ul style="list-style-type: none">• nausea• vomiting• diarrhoea <p>Head and neurology related:</p> <ul style="list-style-type: none">• Headache• fatigue• dizziness	<p>Speak to your treating physician if you have any of these less serious side effects and they worry you.</p>

Less serious side effects	What to do
<ul style="list-style-type: none"> • numbness/tingling <p>General</p> <ul style="list-style-type: none"> • weakness • chills • fever 	

Serious side effects

Serious side effects	What to do
<p>Respiratory</p> <ul style="list-style-type: none"> • difficulty breathing • noisy breathing <p>Voice-related</p> <ul style="list-style-type: none"> • hoarse voice <p>Skin-related</p> <ul style="list-style-type: none"> • itchy rash or hives 	<p>Tell your treating physician immediately, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

7. Product details

This medicine is only available with a doctor's prescription.

What Thyrogen contains

Active ingredient (main ingredient)	thyrotropin alfa
Other ingredients (inactive ingredients)	sodium chloride monobasic sodium phosphate monohydrate dibasic sodium phosphate heptahydrate mannitol

Do not take this medicine if you are allergic to any of these ingredients.

What Thyrogen looks like

Thyrogen is a white to off-white powder before it is prepared for injection and a clear, colourless solution after it has been prepared for injection. (Aust R 79777).

Who distributes Thyrogen

Thyrogen® is registered by:

sanofi-aventis australia pty ltd

12-24 Talavera Road

Macquarie Park NSW 2113 Australia

Toll Free Number (medical information): 1800 818 806

Email: medinfo.australia@sanofi.com

This leaflet was prepared in April 2021.

thyr-ccds2-cmiv3-12apr21