

THYROGEN®

Thyrotropin alfa-rch, powder for injection

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Thyrogen.

It does not contain all the available information.

It does not take the place of talking to your treating physician or a trained health care professional.

All medicines have risks and benefits. Your treating physician has weighed the risks of you taking Thyrogen against the benefits they expect it will have.

If you have any concerns about taking this medicine, ask your treating physician or nurse.

Keep this leaflet.

You may need to read it again.

What Thyrogen is used for

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.

Before you are given Thyrogen

When you must not be given it

Do not use Thyrogen if you have a known, severe allergic reaction to:

- Thyrogen
- any of the ingredients listed at the end of this leaflet.

If you are not sure whether you should have Thyrogen, talk to your treating physician.

Before you are given it

Tell your treating physician if you have reacted to previous treatments with any of the following:

- severe allergic reaction
- difficulty breathing

Tell your treating physician if you have allergies to:

- any other medicines
- any other substances, such as foods, preservatives or dyes

Tell your treating physician if you have heart disease.

Tell 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.

Tell your treating physician if you are breastfeeding.

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

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.

Taking other medicines

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

Some medicines and Thyrogen may interfere with each other. No studies have been carried out on drug interactions.

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

How Thyrogen is 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 are given too much (overdose)

There have been no reported overdoses of Thyrogen.

Things you must 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.

After having 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.

Things to be careful of

Be careful driving or operating machinery 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.

Side effects

Tell your treating physician as soon as possible if you do not feel well after having Thyrogen.

Thyrogen may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need urgent medical treatment if you notice some side effects.

Ask your treating physician to answer any questions you may have.

Tell your treating physician if you notice any of the following and they worry you:

- headache
- fatigue
- nausea
- weakness
- vomiting
- dizziness
- chills
- numbness/tingling
- fever
- diarrhoea

If you notice any of the following side effects, tell your treating physician immediately or go to Emergency at your nearest hospital:

- hoarse voice
- difficulty breathing
- noisy breathing
- itchy rash or hives

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything else that is making you feel unwell.

Do not be alarmed by this list of possible side effects. You may not experience any of them. Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Storing Thyrogen

Thyrogen will be stored in the hospital.

Product description

What it 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.

Ingredients

Active ingredient:

thyrotropin alfa-rch

Other ingredients:

sodium chloride, monobasic sodium phosphate monohydrate, dibasic sodium phosphate heptahydrate and mannitol.

Supplied by

Thyrogen® is registered by:

sanofi-aventis australia Pty Ltd
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Australia

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