

THYROSIT TABLET[®]

Thyroxine sodium (100mcg)

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What Thyrosit is used for

Thyrosit is used as replacement therapy to treat thyroid hormone deficiency known as hypothyroidism. Thyrosit is also used in conditions where there is a shortage of thyroid hormones supply in the body. Thyrosit is also used to treat goiter or chronic lymphocytic thyroiditis, conditions in which the thyroid gland becomes enlarged causing a swelling in the front of the neck.

How Thyrosit works

Thyrosit contains the active ingredient thyroxine sodium, which is a thyroid hormone. Thyroxine is an essential hormone produced by thyroid gland in the neck. It controls many bodily functions mainly related to growth and energy.

Before you use Thyrosit

- When you must not use it

- Have ever had allergic reaction to thyroxine sodium, the active ingredient, or to any other ingredients in Thyrosit
- Have overactive thyroid gland
- Subclinical hyperthyroidism (low thyroid stimulating hormone with normal thyroid levels and not being treated)
- Suffer from any conditions that affect your adrenal gland and not being treated
- Suffer from heart attack

If you are not sure whether you should start taking this medicine, consult your doctor.

- Before you start to use it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you:

- Are breast feeding or plan to breast feed
- Suffer from any heart conditions such as high blood pressure, chest pain (angina), heart failure, or heart attack
- Undergoing surgery
- Fasting
- Suffers from any conditions that affects your adrenal gland
- Any abnormalities in thyroid function tests
- Suffer from any kind of illnesses
- Suffer from stress and starvation
- Suffer from bone mineral density problem, especially women after menopause

- Taking other medicines

Tell your doctor if you are taking any other medicine, including any that you buy without a prescription. You may need to use different amounts of these medicines, or you may need to take different medicines. Your doctor will advise you. There may be interactions between Thyrosit and some other medicines including:

- Antacid (e.g. Simethicone), for indigestion.
- Cholestyramine and colestipol, used to reduce cholesterol level in blood
- Calcium supplements (e.g. calcium carbonate)
- Iron preparations (e.g. ferrous sulphate), used to treat anemia
- Medicines for epilepsy treatment (e.g. phenytoin, carbamazepine, phenobarbital, diazepam)
- Rifampin, used to treat infections
- Oral contraceptive pills (OCP) containing estrogens hormone
- Ketamine, used as an anaesthetic
- Medicines to treat diabetes, including insulin, sulphonylureas
- Amiodarone, used for irregular heartbeat
- Sympathomimetic medicines such as dopamine
- Diuretics also known as “water tablets” (e.g. frusemide, hydrochlorothiazide), used for high blood pressure and other heart conditions
- Mefenamic acid, for pain relief
- Salicylates for pain relief or headache
- Phenylbutazone, for arthritis pain
- Anticoagulants (e.g. heparin, warfarin), used to thin the blood and treat blood clots
- Steroids and other hormone treatments such as male hormone replacement therapy

- Sucralfate, used for treatment of intestinal ulcers
- Anticancer medicines (e.g. tamoxifen, 5-fluorouracil, 6-mercaptopurine)
- Iodine-containing medicines including radioiodine contrast
- Levodopa, used for Parkinson’s disease
- Tricyclic antidepressants, used for depression
- Maprotiline, used for depression
- Lithium and Perphenazine, used for mental illness
- Lovastatin, a cholesterol-lowering medicines
- Metoclopramide, used for vomiting
- Foods which may interfere with thyroid functions (e.g. asparagus, cabbage, peas, broccoli, spinach, lettuce, soy beans, turnip greens, brussels sprouts)
- Soybean flour, cottonseed meal, walnut and dietary fibre

Your doctor or pharmacist will have more information on the medicines to be careful with or to avoid while taking Thyrosit.

- Pregnancy and lactation

Tell your doctor if you are pregnant; think you are pregnant or planning to become pregnant. Your doctor will discuss the risks and benefit of taking Thyrosit during pregnancy.

Thyroxine sodium passed into breast milk. Your doctor will discuss the risks and benefits of taking Thyrosit during breast feeding.

How to use Thyrosit

Always take Thyrosit according to the instructions given to you by your doctor or pharmacists. If you are unsure, check with your doctor or pharmacist.

The directions given by your doctor may differ from this leaflet.

It may take a few weeks for Thyrosit to start working. Until it begins working you may not notice any change in your symptoms.

- How much to use

The usual starting dose for adults is 50 micrograms (mcg) daily. The dose may be increased depending on your response to the treatment. The usual adult maintenance dose is 100-200mcg daily.

In severe hypothyroidism, elderly and person suffering from heart problems, the starting dose will be lower than 50mcg daily. Your doctor will advise you further on the dosage for such situations.

Children: The body weight and conditions of your children will be taken into account by your doctor before deciding on the dose.

- When to use it

Take Thyrosit on empty stomach, preferably in the morning before breakfast. Swallow the tablets with a glass of water.

If you are on any calcium supplements, you should only take Thyrosit four hours before or after you take your supplement. This is because calcium can prevent Thyrosit from being absorbed into your body properly.

- How long to use it

Continue to take your medicines as long as your doctor tells you. The medicine helps to control your condition but not to cure it. It is important that you continue to take the medicine even if you feel healthy.

Do not stop taking Thyrosit abruptly. If you are to stop taking Thyrosit, your doctor will advise you to reduce the dose slowly.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Symptoms of thyroxine overdosage include rapid or pounding heartbeat, chest pain, headache, nervousness, excitability, sweating, flushing, fever, weight loss, muscle weakness and cramps, menstrual irregularities, diarrhoea and vomiting.

While you are using it

- Things you must do

- Always follow your doctor's instruction carefully
- If you are about to be started on a new medicine, remind your doctor and pharmacist that you are taking Thyrosit.
- If you become pregnant, while taking Thyrosit, tell your doctor immediately.
- Inform any other doctors, dentists and pharmacist who treat you that you are taking Thyrosit.
- Visit your doctor regularly so that they can check on your progress.

- Things you must not do

- Do not stop taking Thyrosit or change the dose without first checking with your doctor.
- Do not take Thyrosit to treat any other complaint unless your doctor tells you to.
- Do not give Thyrosit to anyone else, even if they have the same condition as you.

- Things to be careful of

- Be careful while driving or operating machinery until you know how Thyrosit affects you.

Side effects

Like many medicines, Thyrosit may cause side effects in some people, but not everyone will get it.

Tell your doctor or pharmacist if you notice the following side effects and it worries you:

- Fatigue
- Increased appetite
- Weight loss
- Heat intolerance
- Fever
- Excessive sweating
- Headache
- Hyperactivity
- Nervousness
- Anxiety, irritability
- Frequent mood changes
- Inability to sleep
- Tremors
- Muscle weakness, cramps
- Flushing

- Rapid or pounding heartbeat
- Increased pulse rate and blood pressure
- Chest pain
- Irregular heartbeats
- Shortness of breath
- Vomiting and diarrhoea
- Abdominal cramps
- Hair loss; partial hair loss may occur in children during first few months of therapy but this is usually mild and subsequent regrowth usually occurs
- Menstrual irregularities
- Infertility
- Pseudotumor cerebri (condition in which the pressure inside the skull is increased) has been reported in children

Tell your doctor immediately or go to nearest hospital if you notice any of the following:

- Increase in liver function test
- Heart failure
- Heart attack
- Cardiac arrest (cessation of normal blood circulation due to failure of heart to pump effectively)
- Seizure
- Skin reactions

The above list is the rare side effects of the medicine. You may need medical attention or hospitalization.

Tell your doctor or pharmacist if you notice anything else that makes you feel unwell. Other side effects not listed above may also occur in some people.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website nppra.moh.gov.my (Public -> Reporting Medicinal Problems / Side Effects / AEFI / Vaccine Safety)

Storage and Disposal of Thyrosit

Storage

Store in a cool, dry place below 30°C. Keep in original package to protect from light.

Do not store Thyrosit or any other medicines in the bathroom, near a sink or leave it at the window sill or in the car.

Keep out of the reach and sight of children

- Disposal

Do not use Thyrosit after the expiry date which is stated on the carton and blister. If your doctors tell you to stop taking Thyrosit or the expiry date has passed, ask your pharmacist what to do with the remaining medicines.

Product Description

- What it looks like

Thyrosit 100mcg Tablet is a white, round, biconvex tablet with a bisect and embossed with “THYROSIT” and “SPS” on one side and plain on the other side.

- Ingredients

- Active ingredient

Each tablet contains 100mcg thyroxine sodium.

- Inactive ingredients

Rice starch, magnesium stearate, croscarmellose sodium, sodium starch glycolate, sodium lauryl sulphate and dicalcium phosphate.

- Packing

It comes in blister strip of 10 tablets pack in a box of 10, 20, and 50 strips.

- MAL Number

MAL19963154AZ

Manufacturer

Sriprasit Pharma Co. Ltd.,
216 Moo 6 Suanluang, Krathum Baen,
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Product Registration Holder

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