

### Read this entire leaflet carefully before you start taking the medication.

- Keep this leaflet. You may need to read again.
- Ask your doctor or pharmacist if you need more information or advice.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

### WHAT IS IN THIS LEAFLET?

1. What Thyrosit is used for
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### 1. 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.

### 2. HOW THYROSIT WORKS

Thyrosit contains the active ingredient *L-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.

### 3. BEFORE YOU TAKE THYROSIT

#### When you must not take it

Do not take Thyrosit if you:

- Have ever had allergic reaction to L-thyroxine sodium, the active ingredient, or to any other ingredients in Thyrosit,
- Have overactive thyroid gland (thyroid gland produces too much thyroid hormone),
- Suffer from any conditions that affects 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 take it:

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

Tell your doctor if you:

- Are pregnant; think you are pregnant or planning to become pregnant,
- 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,
- Are taking medicines to treat diabetes,
- 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

### Taking / using other medicines

Inform your doctor or pharmacist if you are taking or if you have recently taken any other medicines, including medicines obtained without a prescription.

There may be interference between Thyrosit and some other medicines including:

- Antacid, for indigestion,
- Simethicone, for bloating,
- 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,
- Amiodarone, used for irregular heartbeat,
- Sympathomimetic medicines such as adrenaline and dopamine,
- Diuretics also known as “water tablets” (e.g. frusemide, hydrochlorothiazide), used for high blood pressure and other heart conditions,
- Non-steroidal anti-inflammatory drugs (NSAIDs) such as mefenamic acid, for pain relief,

- Aspirin 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 (e.g. imipramine, amitriptyline), used for depression,
- Maprotiline, used for depression,
- Lithium and Perphenazine, used for mental illness,
- Lovastatin, an cholesterol-lowering medicines,
- Metoclopramide, used for vomiting,
- Foods which may interfere with thyroid functions (e.g. asparagus, cabbage, peas, broccoli, spinach, lettuce, soy beans),
- Soybean flour (e.g. infant formula), cottonseed meal, walnut and dietary fibre.

These medicines or food may be affected by Thyrosit or may affect how well it works. You may need different amounts of your medicines or take different medicines. Your doctor or pharmacist will have more information on the medicines to be careful with or to avoid while taking Thyrosit.

### Pregnancy and breast-feeding

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

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

### 4. HOW TO TAKE 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 take

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 patients and patients 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 take it

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

### How long to take 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 suddenly stop taking Thyrosit. If you are to stop taking Thyrosit, your doctor will advise you to reduce the dose slowly.

### If you forget to take it

Take the dose as soon as you remember and continue taking as normal. If it is almost time for your next dose, skip the dose you missed and take your next dose at the normal time it is due. Do not take a double dose to make up for the dose you missed or taking more than one dose at a time. This may cause unwanted side effects.

### If you take too much (overdose)

If you or anyone else takes too many tablets, you should immediately go to your nearest hospital emergency department or tell your doctor. Do this even if there are no signs of discomfort or poisoning. Take the carton or any remaining tablets you have with you.

Symptoms of overdose may include fast pounding heartbeat, chest pain, headache, nervousness, excitability, sweating, flushing,

fever, muscle weakness and cramps, diarrhea and vomiting.

*If you have any further questions on the use of this product, ask your doctor or pharmacist.*

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## 5. WHILE YOU ARE USING THYROSIT

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### Things you must do

- Always follow your doctor's instruction carefully.
- Tell your doctor immediately if you notice any unusual symptoms or discomfort.
- 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, or plan on becoming pregnant while taking Thyrosit, tell your doctor immediately.
- Inform any other doctors, dentists and pharmacists who treat you that you are taking Thyrosit.
- If you plan to have surgery, tell your doctor or dentist 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.

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## 6. POSSIBLE SIDE EFFECTS

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Do not be alarmed by this list of possible side effects.

All medicines can have side effects. Thyrosit may cause unwanted side effects although not everybody gets them.

Tell your doctor or pharmacist if you notice the following side effects and they worry 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 diarrhea,
- Abdominal cramps,
- Hair loss; partial hair loss may occur in children during first few months of therapy but this is usually mild and subsequent re-growth usually occurs,
- Menstrual irregularities,
- Decreased libido,

*The above list is the more common side effects of the medicine.*

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 (e.g. rash)

*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 make you feel unwell. Other side effects not listed above may also occur in some people.**

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## 7. AFTER USING THYROSIT

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### 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.

# THYROSIT 50/100 MCG TABLET

L-Thyroxine sodium

Patient Information Leaflet

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.

## 8. PRODUCT DESCRIPTION

### What Thyrosit looks like and contents of the pack.

*Thyrosit 50mcg Tablet:* White, round, biconvex tablet embossed with “SPS” on one side and “T05” with a bisect line on the other side.

*Thyrosit 100mcg Tablet:* White, round, biconvex tablet with bisect line and embossed with “THYROSIT” and “SPS” on one side and plain on the other side.

## Packing

*Thyrosit 50mcg Tablet* comes in blister strip of 10 tablets pack in a box of 20 and 50 strips and bottle pack of 200 tablets.

*Thyrosit 100mcg Tablet* comes in blister strip of 10 tablets pack in a box of 10, 20 and 50 strips and bottle pack of 500 and 1000 tablets.

## Ingredients

Active ingredient:

*Thyrosit 50mcg Tablet:*

Contains 50mcg L-thyroxine sodium.

*Thyrosit 100mcg Tablet:*

Contains 100mcg L-thyroxine sodium.

Other ingredients:

Rice starch, magnesium stearate, croscarmellose sodium, sodium starch glycolate,

*Thyrosit 50mcg Tablet also contains:*

Talc, microcrystalline cellulose.

*Thyrosit 100mcg Tablet also contains:*

Sodium lauryl sulphate, dicalcium phosphate.

## Registration Number

Thyrosit 50mcg Tablet: MAL20040628A

Thyrosit 100mcg Tablet: MAL19963154A

## 9. MARKETING AUTHORISATION HOLDER AND MANUFACTURER

### Manufactured by:

Sriprasit Pharma Co. Ltd.,  
619 Charoenrath Road, Klongsarn,  
Bangkok 10600, Thailand.

### Marketing Authorisation Holder:

*Thyrosit 50mcg Tablet:*

IMEKS Pharma Sdn. Bhd.  
No. 1 & 2, Jalan 6/33B,  
MWE Commercial Park,  
52000 Kuala Lumpur. Malaysia

*Thyrosit 100mcg Tablet:*

Idaman Pharma Sdn. Bhd.  
No. 15 & 17, Jalan Wangsa Delima 1A,  
Seksyen 5, Pusat Bandar Wangsa Maju,  
53300 Kuala Lumpur. Malaysia

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