PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

Levothyroxine Sodium 25 microgram Tablets
Levothyroxine Sodium 75 microgram Tablets
Levothyroxine Sodium 100 microgram Tablets

levothyroxine sodium

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Levothyroxine Sodium is and what it is used for
2. What you need to know before you use Levothyroxine Sodium
3. How to use this medicine
4. Possible side effects
5. How to store Levothyroxine Sodium
6. Contents of the pack and other information

1. What Levothyroxine Sodium is and what it is used for

The active ingredient of Levothyroxine Sodium is levothyroxine. Levothyroxine is very similar to the natural hormone produced by the thyroid gland. The thyroid gland is a small organ under the voice box on both sides of the windpipe that produces levothyroxine (thyroid hormone). That thyroid hormone ensures that certain chemical reactions in the body (metabolism) run smoothly. If the thyroid produces too few thyroid hormones, the active ingredient in Levothyroxine Sodium supplements the body's hormone requirements.

Levothyroxine Sodium is used in people who suffer from certain diseases of the thyroid gland, such as:

Goitre
Goitre is a disease in which the thyroid gland is enlarged. The person may see and/or feel a lump at the front of the neck. The enlargement of the thyroid gland occurs because the thyroid gland is stimulated to produce thyroid hormones because of certain causes (for example, because of too little iodine in the food).

Hypothyroidism
In hypothyroidism (for example, after thyroid surgery), the thyroid does not produce enough hormones. If the thyroid gland does not produce enough hormones, the body's various reactions occur more slowly. Levothyroxine Sodium supplements the body's hormone requirements.

Hyperthyroidism

In hyperthyroidism, the thyroid produces too many hormones. If your thyroid produces too many hormones, you should only use Levothyroxine Sodium if you are also taking a medicine that suppresses the function of the thyroid gland (thyreostatic drug). Levothyroxine Sodium then ensures that there is sufficient thyroid hormone in the body.

Furthermore, Levothyroxine Sodium is used in certain tumours of the thyroid gland and in investigations of thyroid function and thyroid hormone production for diagnosis.

2. What you need to know before you use Levothyroxine Sodium

Do not use this medicine
- If you are allergic to levothyroxine sodium or any of the other ingredients of this medicine (listed in section 6).
- If certain conditions are not treated, namely: inadequate functioning of the adrenal gland, inadequate functioning of the pituitary gland (part of the brain related to endocrine function) and a condition caused by too many thyroid hormones (thyreotoxicosis).
- An acute heart attack, acute inflammation of the heart muscle (myocarditis) and/or a certain acute disorder in which both the heart muscle and the surrounding tissue are inflamed (pancarditis).
- Do not take Levothyroxine Sodium with medicines that suppress thyroid function if you are pregnant (see the Pregnancy and Breast-feeding section below).

Warnings and precautions
Talk to your doctor or pharmacist before using Levothyroxine Sodium
- if you suffer from certain heart conditions (recent heart attack, heart weakness and heart rhythm disorders). In these cases, your doctor will check the function of the thyroid gland regularly.
- if you have been through the menopause and your thyroid does not produce enough hormones, your doctor will check the function of the thyroid gland regularly.
- if you have diabetes or are receiving anticoagulation therapy (see also 'Using Levothyroxine Sodium in combination with other medicines').
- if your adrenal glands are not working properly (adrenal insufficiency) and the treatment to replenish your adrenal hormones is insufficient.

Blood pressure should be monitored regularly when levothyroxine treatment is started in premature babies with a very low birth weight, as a rapid drop in blood pressure (known as circulatory collapse) may occur.

If you need to start using another levothyroxine-containing product, your thyroid gland may become imbalanced. Please contact your doctor if you have any questions about changing your medication. During this change, your doctor will monitor you closely (clinically and biologically) for some time. Tell your doctor if you have any undesirable effects as this may indicate that your dose needs to be adjusted up or down.
At the start of treatment, it is important that you have regular contact with the prescribing physician.
Talk to your doctor,
- before you start or stop taking orlistat or adjust treatment with orlistat (medication to treat obesity); you may need more intensive monitoring and dose adjustment.
- if you experience signs of psychotic disorders (you may need more intensive monitoring and dose adjustment).

If you are about to have a laboratory test to check your thyroid hormone levels, you must tell your doctor and/or the laboratory staff that you are taking or have recently taken biotin (also known as vitamin H,

vitamin B7 or vitamin B8). Biotin may affect the results of your laboratory tests. Depending on the study, biotin use may result in erroneously high or low results. Your doctor may ask you to stop taking biotin before the laboratory testing. You should also be aware that other medicines you may be taking, such as multivitamins or supplements for hair, skin and nails, may also contain biotin. This may affect the results of the laboratory tests. Tell your doctor and/or laboratory staff if you are taking any of these medicines (Refer to the information in the section 'Other medicines and Levothyroxine Sodium').

Other medicines and Levothyroxine Sodium
Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines. Levothyroxine Sodium may impact the effect of the following medicines:
- Anti-diabetes medications (blood sugar-lowering medications):
  Levothyroxine Sodium may **reduce** the effect of your antidiabetes medicine, so it may be necessary to do extra checks of your blood sugar levels, especially at the start of the Levothyroxine Sodium treatment. While taking Levothyroxine Sodium, dose adjustment of your antidiabetes medication may be necessary.
- Coumarin derivatives (medicines used to prevent blood clots):
  Levothyroxine Sodium may **increase** the effect of these medicines, which may increase the risk of bleeding, especially in the elderly. Regular checks of your blood clotting levels may be required at the start of and during Levothyroxine Sodium treatment. When using Levothyroxine Sodium, dosage adjustment of your coumarin medicine may be necessary.

Make sure to adhere to the recommended time intervals if you are taking any of the following medications:
- Medications used to bind bile acids and lower high cholesterol (such as cholestyramine or colestipol):
  Make sure you take Levothyroxine Sodium 4 to 5 hours before these medicines, as they block the absorption of Levothyroxine Sodium in the intestines.
- Antacids (for the relief of acid reflux), other aluminium-containing medicines, iron-containing medicines, calcium-containing medicines:
  Make sure you take Levothyroxine Sodium at least 2 hours before these medicines, otherwise they reduce the effect of Levothyroxine Sodium.

Tell your doctor or pharmacist if you are taking or have recently taken any of the following medicines, or if there is a possibility that you will take them in the near future, as they may **reduce** the effect of Levothyroxine Sodium:
- Propylthiouracil (medicine that affects the thyroid gland),
- Glucocorticoids (medicines with anti-allergic and anti-inflammatory effects),
- Beta-blockers (blood pressure-lowering medications also used to treat cardiovascular disease),
- Sertraline (antidepressant medications),
- Chloroquine or proguanil (medicine used to prevent or treat malaria),
- Medicines that activate certain liver enzymes, such as barbiturates (sedativum, sleeping pill), carbamazepine (antiepileptic, also used in some forms of pain and mood disorders), or products containing St John's wort (a herbal medicine),
- Oestrogen-containing drugs for hormone supplementation during and after menopause or in preventing pregnancy,
- Sevelamer (phosphate binding medicine used to treat patients with chronic renal failure),
- Tyrosine kinase inhibitors (anti-cancer and anti-inflammatory drugs),
- Proton pump inhibitors (such as omeprazole, esomeprazole, pantoprazole, rabeprazole, and lansoprazole) are used to reduce the amount of acid produced by the stomach, which may interfere with the absorption of levothyroxine from the intestines and thus reduce the efficacy of levothyroxine. If you are taking levothyroxine while being treated with proton pump inhibitors,

your doctor should check your thyroid function and possibly adjust the dose of Levothyroxine Sodium,
- Orlistat (medicine to treat obesity).

Tell your doctor if you are taking or have recently taken any of the following medicines, or if there is a possibility that you will take them in the near future, as they may **intensify** the effect of Levothyroxine Sodium:
- Salicylates (medicine used to relieve pain and reduce fever),
- Dicoumarol (medicine to prevent blood clots),
- Furosemide at high doses of 250 mg (diuretic),
- Clofibrate (blood lipid lowering medication).

Tell your doctor if you are taking or have recently taken any of the following medicines, or if there is a possibility that you will take them in the near future, as they may impact the effect of Levothyroxine Sodium:
- Ritonavir, indinavir, lopinavir (protease inhibitors, medicines used to treat HIV infection),
- Phenytoin (medicine for epilepsy).

You may need to check your thyroid hormone levels regularly. Adjustment of your dose of Levothyroxine Sodium may be necessary.

Tell your doctor if you are taking amiodarone (a medicine used to treat irregular heartbeats), as this medicine may impact the function and the way the thyroid gland works.

If you need to have a diagnostic test or scan with iodine-containing contrast agents, tell your doctor that you are taking Levothyroxine Sodium, as you may receive an injection that may affect your thyroid function.

If you are taking or have recently taken biotin, you should inform your doctor and/or the laboratory staff when you are about to have a laboratory test to check your thyroid hormone levels. Biotin may affect the results of the laboratory tests (see section 'Warnings and precautions').

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medications you can get without a prescription.

Thyroid hormones should not be used for weight loss. Taking thyroid hormones will not reduce your weight if your thyroid hormone level is within normal range. Serious or even life-threatening undesirable effects may occur if you increase the dose without special advice from your doctor. High doses of thyroid hormones should not be taken together with certain weight loss medications, such as amfepramone, cathine, and phenylpropanolamine, as the risk of serious or even life-threatening undesirable effects may increase.

Soy-containing products may reduce the body's absorption of levothyroxine. Therefore, the dosage of Levothyroxine Sodium may need to be adjusted, especially at the start or after discontinuation of a soy supplement diet.

Levothyroxine Sodium with food and drink
Talk to your doctor if you are using soy-containing products.
Soy-containing products may reduce the absorption of levothyroxine. Therefore, the dosage of Levothyroxine Sodium may need to be adjusted, especially at the start or after discontinuation of a soy supplemented diet.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

A sufficient amount of thyroid hormone is necessary for the good course of a pregnancy. Therefore, you should continue to take Levothyroxine Sodium if you are pregnant. During pregnancy, you should not take Levothyroxine Sodium if you are also taking so-called thyreostatics (medicines used to treat too much thyroid hormone). Your doctor may adjust the dosage if necessary. If you become pregnant, you should contact your doctor.

There is no evidence that the use of Levothyroxine Sodium in breast-feeding women is harmful to the infant with a normally functioning thyroid gland. If you are breastfeeding, you should not use Levothyroxine Sodium if you are also taking so-called thyreostatics (drugs to treat excess thyroid hormone).

Driving and using machines
Levothyroxine Sodium has no influence on the ability to drive or use machines.

Levothyroxine Sodium contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to use this medicine

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Your doctor will prescribe the dose. You must follow this carefully. In general, your doctor will first prescribe you a low dose and increase it if necessary.

In elderly patients, in patients with coronary artery disease of the heart, and in patients with severe or long-standing hypothyroidism, a low starting dose should be given.

In low-weight patients and those with a severely enlarged thyroid gland, a lower maintenance dose is usually sufficient.

If your child suffers from congenital hypothyroidism, the doctor may recommend a higher starting dose, as prompt substitution is important.

The usual dosing schedule is shown in the table below.

Indication	**Recommended dose (sodium levothyroxine/day)**
Treatment of euthyroid goitre	75 – 200 micrograms
Recurrent prophylaxis after goitre resection	75 – 200 micrograms

Substitution in hypothyroidism in adults, when the thyroid does not produce enough - starting dose - maintenance dose	Adults 25 – 50 micrograms 100 – 200 micrograms		Children 12.5 – 50 micrograms 100 – 150 micrograms per	
Substitution during concomitant treatment with thyreostatic agents in hyperthyroidism	50 – 100 micrograms			
Suppression treatment in thyroid cancer	150 – 300 micrograms			
Diagnostic use in thyroid suppression study	Week 4 before the test	Week 3 before the test	Week 2 before the test	Week 1 before the test
Levothyroxine Sodium 100 microgram	---	---	2 tab/day	2 tab/day

You should take Levothyroxine Sodium once a day, half an hour before breakfast. Levothyroxine Sodium should be taken with some liquid (for example, half a glass of water).

If you notice that Levothyroxine Sodium is too strong or not strong enough, consult your doctor or pharmacist.

Levothyroxine Sodium should usually be used for a long time.

The tablet can be divided into equal doses.

Use in children
Children should take Levothyroxine Sodium once a day, at least half an hour before the first meal of the day. You should dissolve the tablets in some water. The suspension should be taken with more liquid. You should only prepare the suspension just before you are ready to give it to your child.

If you take more Levothyroxine Sodium than you should
If you have taken too much Levothyroxine Sodium, contact your doctor or pharmacist immediately.

The following symptoms may indicate an overdose: accelerated metabolism, palpitations, anxiety, irritability, seizures, excessive mobility. Symptoms of acute psychosis may occur in people who are at risk of psychotic disorders.

If you forget to take Levothyroxine Sodium
Do not take a double dose to make up for a forgotten tablet. Take the next dose with the next breakfast.

If you stop taking Levothyroxine Sodium
If treatment with Levothyroxine Sodium is stopped, the symptoms associated with an underactive thyroid gland may recur.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

You may experience one or more of the following side effects if you take more Levothyroxine Sodium than prescribed or if you do not tolerate the prescribed dose (e.g., when the dose is increased quickly):

Allergic reactions to the active substance or to any of the ingredients of Levothyroxine Sodium Sodium are possible (see section 6. 'What Levothyroxine Sodium contains'). Allergic reactions may include swelling of the face or throat (angioedema), rash, rash on the skin with pink bumps and severe itching (hives or nettle rash). If this happens, **contact your doctor immediately**.

Other side effects:
- Irregular or rapid heartbeat
- chest pain
- headache
- muscle weakness or cramps
- flushing (warmth and redness of the face)
- fever
- vomiting
- menstrual disorders
- pseudotumor cerebri (increased pressure in the head)
- shaking
- restlessness
- sleep disturbances
- sweating
- weight loss
- diarrhoea

If you experience any of these side effects, contact your doctor. Your doctor may decide to interrupt the therapy for several days or to reduce the daily dose until the side effects have disappeared.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:

Malta
ADR Reporting
Website: www.medicinesauthority.gov.mt/adrportal

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Levothyroxine Sodium

Keep this medicine out of the sight and reach of children. Do no store above 25°C.

Do not use this medicine after the expiry date which is stated on the label/carton after "EXP". The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Levothyroxine Sodium contains
- The active substance in this medicine is levothyroxine sodium. Each tablet contains 25, 75 or 100 micrograms of levothyroxine sodium, respectively.
- The other ingredients of this medicine are microcrystalline cellulose, povidone, sodium starch glycolate and magnesium stearate.

What Levothyroxine Sodium looks like and contents of the pack

Levothyroxine Sodium 25 microgram Tablets are 6.0 mm, white to off-white, round tablets with '25' inscription on one side and deep bisect on other side.

Levothyroxine Sodium 75 microgram Tablets are 6.0 mm, white to off-white, round tablets with '75' inscription on one side and deep bisect on other side.

Levothyroxine Sodium 100 microgram Tablets are 6.0 mm, white to off-white, round tablets with '100' inscription on one side and deep bisect on other side.

Levothyroxine Sodium Tablets are available in high density polyethylene (HDPE) bottles with a polypropylene child-resistant closure. Each bottle contains 100 tablets.

Marketing Authorisation Holder and Manufacturer
Renata Pharmaceuticals (Ireland) Limited, 12 Crowe Street, Dundalk, Co. Louth, Ireland, A91 NN29

Manufacturer
Alterno Labs d.o.o., Brnčićeva ulica 29, Ljubljana-Črnuče, 1231, Slovenia

This medicine is authorised in the Member States of the European Economic Area under the following names:

Ireland	Levothyroxine Sodium 25 microgram Tablets
	Levothyroxine Sodium 75 microgram Tablets
	Levothyroxine Sodium 100 microgram Tablets
Germany	Levothyrox Renata 25 Mikrogramm Tabletten
	Levothyrox Renata 75 Mikrogramm Tabletten
	Levothyrox Renata 100 Mikrogramm Tabletten
Italy	Levotiroxina Renata
Malta	Levothyroxine Sodium 25 microgram Tablets
	Levothyroxine Sodium 75 microgram Tablets
	Levothyroxine Sodium 100 microgram Tablets
Poland	Levothyroxine Renata
Portugal	Levotiroxina Renata 0,025 mg comprimidos
	Levotiroxina Renata 0,075 mg comprimidos
	Levotiroxina Renata 0,1 mg comprimidos

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