

PACKAGE LEAFLET

Package leaflet: Information for the patient

Levothyroxine sodium Rowex 25 microgram tablets
Levothyroxine sodium Rowex 50 microgram tablets
Levothyroxine sodium Rowex 75 microgram tablets
Levothyroxine sodium Rowex 100 microgram tablets
Levothyroxine sodium Rowex 125 microgram tablets
Levothyroxine sodium Rowex 150 microgram tablets
Levothyroxine sodium Rowex 200 microgram tablets

levothyroxine sodium

Read all of this leaflet carefully before you start taking 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 Rowex is and what it is used for
2. What you need to know before you take Levothyroxine sodium Rowex
3. How to take Levothyroxine sodium Rowex
4. Possible side effects
5. How to store Levothyroxine sodium Rowex
6. Contents of the pack and other information

1. What Levothyroxine sodium Rowex is and what it is used for

Levothyroxine, the active substance in Levothyroxine sodium Rowex, is a synthetic thyroid hormone for the treatment of diseases and dysfunctions of the thyroid gland. It has the same effect as the naturally occurring thyroid hormones.

Levothyroxine sodium Rowex is used

- to treat benign goitre in patients with normal thyroid function
- to prevent recurrence of goitre after surgery
- to replace natural thyroid hormones, when your thyroid gland does not produce enough
- to suppress tumour growth in patients with thyroid cancer.

Levothyroxine sodium Rowex 25 microgram, 50 microgram, 75 microgram and 100 microgram are also used to balance thyroid hormone levels, when overproduction of hormones is treated with antithyroid medicines.

Levothyroxine sodium Rowex 100 microgram, 150 microgram, and 200 microgram may also be used in the testing of your thyroid function.

2. What you need to know before you take Levothyroxine sodium Rowex

Do not take Levothyroxine sodium Rowex

- if you are allergic to levothyroxine or any of the other ingredients of this medicine (listed in section 6)
- if you have untreated dysfunction of the adrenal gland, pituitary gland or excessive overproduction of thyroid hormones (thyrotoxicosis)

- if you have acute heart disease (myocardial infarction or heart inflammation).

Do not take Levothyroxine sodium Rowex together with antithyroid medicines if you are pregnant (see section Pregnancy and breast-feeding below).

Warnings and precautions

Talk to your doctor or pharmacist before taking Levothyroxine sodium Rowex if you have any of the following heart diseases:

- insufficient blood flow in the blood vessels of the heart (angina pectoris)
- heart failure
- rapid and irregular heartbeat
- high blood pressure
- fatty deposits in your arteries (arteriosclerosis).

They must be under medical control before you start taking Levothyroxine sodium Rowex or before a thyroid suppression test is performed. You must have frequent checks of your thyroid hormone levels while you are on Levothyroxine sodium Rowex. If you are not sure whether any of these conditions applies to you, or if you do not receive treatment, contact your doctor.

Your doctor will investigate if you have a dysfunction of the adrenal or pituitary gland or a dysfunction of the thyroid gland with uncontrolled overproduction of thyroid hormones (thyroid autonomy), because this must be medically controlled before you start taking Levothyroxine sodium Rowex or before a thyroid suppression test is performed.

Blood pressure will be regularly monitored when levothyroxine treatment is started in very low birth weight preterm neonates because a rapid fall in blood pressure (known as circulatory collapse) may occur.

Thyroid imbalance may occur if you need to change your medication to another levothyroxine containing product. Talk to your doctor if you have any questions about changing your medication. A close monitoring (clinical and biological) is required during the transition period. You should tell your doctor if you get any side effects as this may indicate that your dose needs to be adjusted up or down.

Speak to your doctor,

- if you are in the menopause or post-menopausal; your doctor may need to check your thyroid function regularly because of the risk of osteoporosis
- before you start or stop taking orlistat, or change the treatment with orlistat (medication to treat obesity; you may need closer monitoring and dose adjustment)
- if you experience signs of psychotic disorders (you may need closer monitoring and dose adjustment).

Thyroid hormones should not be used for weight reduction. Intake of thyroid hormones will not reduce your weight, if your thyroid hormone level is in a normal range. Serious or even life-threatening side 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 medicines for weight reduction, such as amfepramone, cathine and phenylpropanolamine, as the risk of serious or even life-threatening side effects may increase.

Other medicines and Levothyroxine sodium Rowex

Tell your doctor or pharmacist if you are taking, have recently taken or might take any of the following medicines, because Levothyroxine sodium Rowex may influence their effect:

- Anti-diabetic medicines (blood-sugar-lowering medicines):
Levothyroxine sodium Rowex may **reduce** the effect of your anti-diabetic medicine, so you may need additional checks of your blood sugar levels, especially at the start of Levothyroxine sodium Rowex treatment. While you are taking this medicine, adjustment of the dose of your anti-diabetic medicine may be necessary.
- Coumarin derivatives (medicines used to prevent blood clotting):

Levothyroxine sodium Rowex may **intensify** the effect of these medicines, which may increase the risk of bleeding events, especially in elderly people. You may need regular checks of your blood clotting values, at the start of and during Levothyroxine sodium Rowex treatment. While you are taking this medicine, adjustment of the dose of your coumarin medicine may be necessary.

Make sure that you stick to the recommended time intervals, if you need to take any of the following medicines:

- Medicine used to bind bile acids and to lower high cholesterol (such as cholestyramine or cholestipol):
Make sure that you take Levothyroxine sodium Rowex 4 - 5 hours **before** these medicines, because they may block the uptake of Levothyroxine sodium Rowex from the intestine.
- Antacids (for the relief of acid indigestion), sucralfate (for ulcers of the stomach or intestine), other aluminium-containing medicines, iron-containing medicines, calcium-containing medicines:
Make sure that you take Levothyroxine sodium Rowex at least 2 hours before these medicines, because otherwise they may reduce the effect of Levothyroxine sodium Rowex.

Tell your doctor or pharmacist if you are taking, have recently taken or might take any of the following medicines, because they may reduce the effect of Levothyroxine sodium Rowex:

- propylthiouracil (antithyroid medicine)
- glucocorticoids (anti-allergic and anti-inflammatory medicines)
- beta-blockers (blood-pressure-lowering medicines also used to treat heart diseases)
- sertraline (anti-depressive medicine)
- chloroquine, or proguanil (medicine to prevent or treat malaria)
- medicines activating certain liver enzymes such as barbiturates (sedatives, sleeping pill) or carbamazepine (anti-epileptic medicine, also used to modify some types of pain and to control mood disorders)
- oestrogen-containing medicines used for hormone replacement during and after the menopause or for prevention of pregnancy
- sevelamer (phosphate binding drug, used to treat patients with chronic renal failure)
- tyrosine kinase inhibitors (anti-cancer and anti-inflammatory medicines)
- proton pump inhibitors (medicines to treat stomach ulcers and acid reflux such as omeprazole)
- orlistat (medicine to treat obesity).

Tell your doctor or pharmacist if you are taking, have recently taken or might take any of the following medicines, because they may intensify the effect of Levothyroxine sodium Rowex:

- salicylates (medicine used to relieve pain and to reduce fever)
- dicumarol (medicine to prevent blood clotting)
- furosemide in high doses of 250 mg (diuretic medicine)
- clofibrate (blood-lipid-lowering medicine).

Tell your doctor or pharmacist if you are taking, have recently taken or might take any of the following medicines, because they may influence the effect of Levothyroxine sodium Rowex:

- ritonavir, indinavir, lopinavir (protease inhibitors, medicines to treat HIV infection)
- phenytoin (anti-epileptic medicine).

You may need regular checks of your thyroid hormone parameters. An adjustment of your dose of Levothyroxine sodium Rowex may be necessary.

Tell your doctor, if you are taking amiodarone (medicine used to treat irregular heartbeat), because this medicine may influence the function and activity of your thyroid gland.

If you need to have a diagnostic test or scan with iodine-containing contrast media, tell your doctor that you take Levothyroxine sodium Rowex, because you may receive an injection that may influence your thyroid function.

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

Levothyroxine sodium Rowex with food and drink

Tell your doctor, if you eat soy products, especially if you change the amount you eat. Soy-products may lower the uptake of Levothyroxine sodium Rowex from the intestine and therefore, an adjustment of your Levothyroxine sodium Rowex dose may be necessary.

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.

If you are pregnant continue taking Levothyroxine sodium Rowex. Speak to your doctor because the dose may need to be changed.

If you have taken this medicine together with an anti-thyroid medicine to treat an over-production of thyroid hormones, your doctor will advise you to stop Levothyroxine sodium Rowex treatment when you become pregnant.

If you are breast-feeding, continue taking Levothyroxine sodium Rowex as advised by your doctor. The amount of drug that is excreted into the breast milk is so small that it will not affect the child.

Driving and using machines

No studies on the effects on the ability to drive and use machines have been performed.

It is not expected that Levothyroxine sodium Rowex has any influence on the ability to drive and use machines, because levothyroxine is identical to the naturally occurring thyroid hormone.

Levothyroxine sodium Rowex contains sodium

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

3. How to take Levothyroxine sodium Rowex

Always take 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 determine your individual dose based on examinations and as well as on laboratory tests. In general, you start with a low dose, which is increased every 2 - 4 weeks, until your full individual dose is reached. During the initial weeks of treatment, you will have appointments for laboratory tests in order to adjust the dose.

If your baby is born with hypothyroidism your doctor may recommend to start with a higher dose because a rapid replacement is important. The initial recommended dosage is 10 to 15 micrograms per kg body weight for the first 3 months. Thereafter, your doctor will adjust the dose individually.

The usual dose range is shown in the table below. A lower individualised dose may be sufficient,

- if you are an elderly patient
- if you have heart problems
- if you have severe or long-standing thyroid sub-function
- if you have low weight or a large goitre.

Use of Levothyroxine sodium Rowex	Recommended daily dose of Levothyroxine sodium Rowex
- to treat benign goitre in patients with normal thyroid function	75 - 200 microgram
- to prevent recurrence of goitre after surgery	75 - 200 microgram

<ul style="list-style-type: none"> - to replace natural thyroid hormones, when your thyroid gland does not produce enough • initial dose • maintenance dose 	<p>Adults</p> <p>25 - 50 microgram</p> <p>100 - 200 microgram</p>	<p>Children</p> <p>12.5 – 50 microgram</p> <p>100 – 150 microgram per m² of body surface</p>
<ul style="list-style-type: none"> - to suppress tumour growth in patients with thyroid cancer 	<p>150 - 300 microgram</p>	
<ul style="list-style-type: none"> - to balance thyroid hormone levels, when overproduction of hormones is treated with anti-thyroid medicines 	<p>50 - 100 microgram</p>	
<ul style="list-style-type: none"> - to test thyroid function 	<p>100 microgram: 200 microgram (2 tablets) starting 2 weeks before the test</p> <p>150 microgram: Starting 4 weeks before the test 75 microgram (½ tablet) for two weeks, then 150 microgram (1 tablet) until the test</p> <p>200 microgram: 200 microgram (1 tablet) starting 2 weeks before the test</p>	

Administration

Levothyroxine sodium Rowex is meant for oral use. Take a single daily dose on an empty stomach in the morning (at least half an hour before breakfast), preferably with a little liquid, for example with half a glass of water.

Infants may receive the entire daily dose of Levothyroxine sodium Rowex at least half an hour before the first meal of the day. Immediately before use, crush the tablet and mix it with some water and give it to the child with some more liquid. Always prepare the mixture freshly.

The tablet can be divided into equal doses.

Duration of treatment

Duration of treatment may vary depending on the condition for which you use Levothyroxine sodium Rowex. Your doctor will therefore discuss with you how long you need to take it. Most patients need to take Levothyroxine sodium Rowex for their lifetime.

If you take more Levothyroxine sodium Rowex than you should

If you have taken a higher dose than prescribed, you may experience symptoms such as rapid heartbeat, anxiety, agitation or unintended movements. In patients with a disorder affecting the neurological system such as epilepsy, seizures may occur in isolated cases. In patients at risk of psychotic disorders, symptoms of acute psychosis may occur. If any of this happens, contact your doctor.

If you forget to take Levothyroxine sodium Rowex

Do not take a double dose to make up for a forgotten tablet but take the normal dose the following day.

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

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 Rowex than prescribed, or if you do not tolerate your prescribed dose (e.g. when the dose is increased quickly):

Irregular or rapid heartbeat, chest pain, headache, muscle weakness or cramps, flushing (warmth and redness of the face), fever, vomiting, disorders of menstruation, pseudotumor cerebri (increased pressure in the head), trembling, 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.

Allergic reactions to any of the ingredients of Levothyroxine sodium Rowex are possible (see section 6. 'What Levothyroxine sodium Rowex contains'). Allergic reactions may include rash, urticaria and swelling of the face or throat (angio-oedema). If this happens, contact your doctor immediately.

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 the national reporting system: HPRA Pharmacovigilance; website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Levothyroxine sodium Rowex

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the blister and bottle after EXP. The expiry date refers to the last day of that month.

Blister pack:

Store below 25°C.

HDPE bottle pack:

No special storage conditions.

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 Rowex contains

- The active substance is levothyroxine. Each tablet contains 25 microgram, 50 microgram, 75 microgram, 100 microgram, 125 microgram, 150 microgram or 200 microgram levothyroxine sodium.
- The other ingredients are microcrystalline cellulose (E460(i)), pregelatinized starch (E1422)), silica, colloidal anhydrous (E551), talc (E553b), magnesium stearate (E572), sunset yellow FCF lake (E110) for strengths 25, 100 and 125 microgram), allura red lake (E129) (for strengths 75, 125 and 200 microgram), indigo carmine lake (E132) (for strengths 75 and 150 microgram), brilliant blue FCF lake (E133) (for strengths 125 microgram), quinoline yellow lake (E104) (for strengths 100 microgram).

What Levothyroxine sodium Rowex looks like and contents of the pack

Levothyroxine sodium Rowex 25 microgram tablets

Round orange colour tablets with score line on one side and "25" debossed on other side of the tablet.
Diameter: 7 mm.

Levothyroxine sodium Rowex 50 microgram tablets

Round white colour tablets with score line on one side and "50" debossed on other side of the tablet.
Diameter: 7 mm.

Levothyroxine sodium Rowex 75 microgram tablets

Round violet colour tablets with score line on one side and “75” debossed on other side of the tablet.
Diameter: 7 mm.

Levothyroxine sodium Rowex 100 microgram tablets

Round yellow colour tablets with score line on one side and “100” debossed on other side of the tablet.
Diameter: 7 mm.

Levothyroxine sodium Rowex 125 microgram tablets

Round brown colour tablets with score line on one side and “125” debossed on other side of the tablet.
Diameter: 7 mm.

Levothyroxine sodium Rowex 150 microgram tablets

Round blue colour tablets with score line on one side and “150” debossed on other side of the tablet.
Diameter: 7 mm.

Levothyroxine sodium Rowex 200 microgram tablets

Round pink colour tablets with score line on one side and “200” debossed on other side of the tablet.
Diameter: 7 mm.

Levothyroxine sodium Rowex is proposed in two pack style i.e., blister pack and HDPE bottle pack.

Blister pack

oPA/Alu/PVC//Alu blisters containing 30, 50 and 100 tablets.

Levothyroxine sodium Rowex is available in aluminium blisters containing 14 tablets. Packs with 28 (2x14), 56 (4x14) and 98 (7x14) tablets.

HDPE bottle pack

100 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Rowex Ltd., Bantry, Co. Cork, Ireland.

Manufacturer

Lek Pharmaceuticals d.d., Verovškova Ulica 57, Ljubljana, 1526, Slovenia.

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

NO	Levotyroksinnatrium Sandoz
AT	Thyrex Sandoz 25 Mikrogramm –Tabletten Thyrex Sandoz 50 Mikrogramm –Tabletten Thyrex Sandoz 75 Mikrogramm –Tabletten Thyrex Sandoz 100 Mikrogramm -Tabletten Thyrex Sandoz 125 Mikrogramm –Tabletten Thyrex Sandoz 150 Mikrogramm –Tabletten Thyrex Sandoz 200 Mikrogramm -Tabletten
FI	Levothyroxine Sandoz 25 mikrog tabletti Levothyroxine Sandoz 100 mikrog tabletti

DE
Levothyroxin - 1 A Pharma 25 Mikrogramm Tabletten
Levothyroxin - 1 A Pharma 50 Mikrogramm Tabletten
Levothyroxin - 1 A Pharma 75 Mikrogramm Tabletten
Levothyroxin - 1 A Pharma 100 Mikrogramm Tabletten
Levothyroxin - 1 A Pharma 125 Mikrogramm Tabletten
Levothyroxin - 1 A Pharma 150 Mikrogramm Tabletten
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IE
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This leaflet was last revised in 02/2026.