

PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

Euthyrox 25/50/75/88/100/112/125/137/150/175/200 microgram, tablets

levothyroxine sodium

Read the entire 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.
- Do you have any questions? Contact your doctor or pharmacist.
- Do not pass this medicine on to others, as it has been prescribed only for you. It may harm them, even if their symptoms are the same as yours.
- Do you experience any side effects listed in section 4? Or do you experience a side effect not listed in this leaflet? Then contact your doctor or pharmacist.

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1. What is Euthyrox and what is it used for?

The active ingredient of Euthyrox is levothyroxine. Levothyroxine closely resembles the natural hormone produced by the thyroid gland. The thyroid gland is a small organ located below the larynx on both sides of the trachea that produces levothyroxine (thyroid hormone). This thyroid hormone ensures that certain chemical reactions in the body (metabolism) proceed properly. If the thyroid gland produces too little thyroid hormone, the active ingredient in Euthyrox supplements the body's hormone needs.

Euthyrox is used in people suffering from certain thyroid diseases, such as:

Goiter

Goiter is a condition where the thyroid gland is enlarged. The patient may then see and/or feel a lump at the front of the neck. The enlargement of the thyroid gland occurs because the thyroid is stimulated to produce thyroid hormones due to certain causes (for example, due to insufficient iodine in the diet).

Hypothyroidism

In hypothyroidism (for example, after thyroid surgery), the thyroid gland produces too few hormones. If the thyroid gland produces too few hormones, various reactions in the body slow down. Euthyrox supplements the body's hormone needs.

Hyperthyroidism

In hyperthyroidism, the thyroid gland produces too many hormones. If your thyroid gland produces too many hormones, you may only use Euthyrox if you are also taking a medication that suppresses the thyroid gland's activity (thyreostatic). Euthyrox then ensures sufficient thyroid hormone in the body.

Furthermore, Euthyrox is used for certain thyroid tumors and in research into the functioning of the thyroid gland and the production of thyroid hormones for diagnostic purposes.

Is your complaint not improving, or is it even getting worse? Then contact your doctor.

2. When should you not take this medicine or be extra careful with it?

When should you not use this medicine?

- If certain conditions are not treated, namely: insufficient adrenal function, insufficient pituitary function (pituitary gland related to hormone regulation), and a condition caused by too much thyroid hormone (thyrotoxicosis).
- In the case of an acute heart attack, acute inflammation of the heart muscle (myocarditis), and/or a certain acute condition where both the heart muscle and the surrounding tissue are inflamed (pancarditis).
- Do not take Euthyrox together with medications that suppress thyroid function if you are pregnant (see the section Pregnancy and breastfeeding below).
- You are allergic to any of the ingredients in this medicine. You can find these ingredients in section 6 of this leaflet.

When should you be extra careful with this medicine?

Contact your doctor or pharmacist before taking this medicine,

- if you suffer from certain heart conditions (angina, heart failure, and arrhythmias). In these cases, your doctor will regularly monitor the thyroid gland's function.
- if you are postmenopausal and your thyroid gland produces insufficient hormones, your doctor will regularly monitor the thyroid gland's function.
- if you have diabetes or are undergoing anticoagulation therapy (see also "Using Euthyrox in combination with other medicines").
- if your adrenal glands do not work properly (adrenal insufficiency) and the treatment to supplement your adrenal hormones is not sufficient.

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

If you need to switch to another levothyroxine-containing product, an imbalance of your thyroid may occur. Contact your doctor if you have questions about changing your medication. During this change, your doctor will closely monitor you for some time (clinically and biologically). Tell your doctor if you experience side effects, as this may indicate that your dose needs to be adjusted up or down.

At the beginning of the treatment, it is important that you have regular contact with the prescribing doctor.

Contact your doctor,

- before you start or stop taking orlistat or adjust the treatment with orlistat (medication to treat obesity); you may need to be monitored more closely and dose adjustment may be necessary.
- if you experience signs of psychotic disorders (you may need to be monitored more closely and dose adjustment may be necessary).

If you are about to undergo a laboratory test to check your thyroid hormone levels, you should inform your doctor and/or the laboratory staff that you are using or have recently used biotin (also known as vitamin H, vitamin B7, or vitamin B8). Biotin can affect the results of your laboratory test. Depending on the test, the results may be falsely high or low due to the use of biotin. Your doctor may ask you to stop using biotin prior to the laboratory test. You should also be aware that other products you may be using, such as multivitamins or supplements for hair, skin, and nails, may also contain biotin. This can affect the results of the laboratory test. Inform your doctor and/or the laboratory staff if you are using such products (Refer to the information in the section 'Are you using any other medicines?').

Are you using any other medicines?

Are you using any other medicines besides Euthyrox, have you done so recently, or are you planning to do so soon? Then tell your doctor or pharmacist. Euthyrox can affect the effect of the following medicines:

- Antidiabetic medicines (blood sugar-lowering medicines):
Euthyrox can reduce the effect of your antidiabetic medicine, so it may be necessary to perform extra checks on your blood sugar levels, especially at the start of Euthyrox treatment. During the use of Euthyrox, adjustment of the dose of your antidiabetic medicine may be necessary.
- Coumarin derivatives (medicines used to prevent blood clots):
Euthyrox can enhance the effect of these medicines, which increases the risk of bleeding, especially in the elderly. Regular checks of your blood clotting values may be necessary at the start of and during Euthyrox treatment. When using Euthyrox, adjustment of the dosage of your coumarin medicine may be necessary.

Make sure to adhere to the recommended time intervals if you are using any of the following medicines:

- Medicines used to bind bile acids and lower high cholesterol (such as cholestyramine or cholestipol):
Make sure to take Euthyrox 4 to 5 hours before these medicines, as they block the absorption of Euthyrox in the intestines.
- Antacids (for the relief of acid reflux), other aluminum-containing medicines, iron-containing medicines, calcium-containing medicines:
Make sure to take Euthyrox at least 2 hours before these medications, as they otherwise reduce the effect of Euthyrox.

Tell your doctor or pharmacist if you are using any of the following medications or have recently done so, or if there is a possibility that you will use them in the near future, as they can reduce the effect of Euthyrox:

- Propylthiouracil (medicine that affects the thyroid),
- Glucocorticoids (medicines with anti-allergic and anti-inflammatory effects),
- Beta-blockers (blood pressure-lowering medicines also used to treat cardiovascular diseases),
- Sertraline (antidepressant medicines),
- Chloroquine or proguanil (medicine for the prevention or treatment of malaria),
- Medicines that activate certain liver enzymes, such as barbiturates (sedative, sleeping pill), carbamazepine (anti-epileptic, also used for some forms of pain and mood disorders), or products containing St. John's wort (an herbal remedy),
- Estrogen-containing medicines for hormone replacement during and after menopause or for preventing pregnancy,
- Sevelamer (phosphate-binding medicine, used to treat patients with chronic kidney failure),
- Tyrosine kinase inhibitors (anti-cancer and anti-inflammatory medicines),
- Proton pump inhibitors (such as omeprazole, esomeprazole, pantoprazole, rabeprazole, and lansoprazole) are used to reduce the amount of acid produced by the stomach which can hinder the absorption of levothyroxine from the intestines and thus reduce the efficacy of levothyroxine. If you are using levothyroxine while being treated with proton pump inhibitors, your doctor should monitor your thyroid function and possibly adjust the dose of Euthyrox,
- Orlistat (medicine to treat obesity).

Tell your doctor if you are using any of the following medications or have recently done so, or if there is a possibility that you will use them in the near future, as they can intensify the effect of Euthyrox:

- Salicylates (medicine used to relieve pain and reduce fever),
- Dicoumarol (medicine to prevent blood clots),
- Furosemide in high doses of 250 mg (diuretic),
- Clofibrate (blood lipid-lowering medication).

Tell your doctor if you are using any of the following medications or have recently done so, or if there is a possibility that you will use them in the near future, as they can affect the effect of Euthyrox:

- Ritonavir, indinavir, lopinavir (protease inhibitors, medications for the treatment of HIV-infection),
- Phenytoin (medication for epilepsy).

It may be necessary to regularly monitor your thyroid hormone levels. An adjustment of your Euthyrox dose may be necessary.

Tell your doctor if you are using amiodarone (a medication for the treatment of irregular heartbeat), as this medication can affect the function and operation of the thyroid.

If you need to undergo a diagnostic test or scan with iodine-containing contrast agents, tell your doctor that you are using Euthyrox, as you may receive an injection that can affect your thyroid function.

If you are using biotin or have recently used it, you must inform your doctor and/or laboratory personnel when you are about to undergo a laboratory test to check your thyroid hormone levels. Biotin can affect the results of the laboratory test (see the section 'When should you be extra careful with this medicine?').

Tell your doctor or pharmacist if you are using other medications or have recently used other medications. This also applies to medications that you can obtain without a prescription.

Thyroid hormones should not be used for weight loss. Use of thyroid hormones will not reduce your weight if your thyroid hormone levels are within normal values. Severe or even life-threatening side effects can 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 severe or even life-threatening side effects may increase.

Soy-containing products can reduce the absorption of levothyroxine in the body. Therefore, the dosage of Euthyrox may need to be adjusted, especially at the start or after the end of a diet with soy supplements.

What should you pay attention to with food and drink?

Consult your doctor if you use soy-containing products.

Soy-containing products can reduce the absorption of levothyroxine. Therefore, the dosage of Euthyrox may need to be adjusted, especially at the start or after the end of a diet with soy additives.

Pregnancy and breastfeeding

Are you pregnant, do you think you might be pregnant, do you want to become pregnant, or are you breastfeeding? Then contact your doctor or pharmacist before using this medication.

For the proper course of a pregnancy, a sufficient amount of thyroid hormone is necessary. Therefore, you should continue to use Euthyrox if you are pregnant. During pregnancy, you should not use Euthyrox if you are also using so-called thionamides (medications for the treatment of an excess of thyroid hormone). Your doctor can adjust the dosage if necessary. If you become pregnant, you should contact your doctor.

There is no evidence that the use of Euthyrox by breastfeeding women is harmful to the infant with a normally functioning thyroid. If you are breastfeeding, you should not use Euthyrox if you are also using so-called thionamides (medications for the treatment of an excess of thyroid hormone).

Driving and using machines

Euthyrox does not affect the ability to drive and use machines.

Euthyrox contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, which means it is essentially 'sodium-free'.

3. How to take this medicine?

Always take this medicine exactly as your doctor or pharmacist has told you. Are you unsure about the correct use? Then contact your doctor or pharmacist.

Your doctor will prescribe the dosage for you. You must adhere to this precisely. In general, your doctor will first prescribe a low dosage and increase it if necessary.

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

In patients with low body weight and in patients with a significantly 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 rapid substitution is important.

The usual dosage schedule is shown in the table below.

Indication	Recommended dose (sodium levothyroxine/day)			
	adults	children	body surface area	
Treatment of euthyroid goiter	75 – 200 micrograms			
Recurrence prophylaxis after goiter resection	75 – 200 micrograms			
Substitution in hypothyroidism in	adults	children		
adults, when thyroid does not produce enough				
- starting dose	25 – 50 micrograms	12.5 – 50 micrograms		
- maintenance dose	100 – 200 micrograms	100 – 150 micrograms per		
			m ²	
Substitution during concurrent treatment with antithyroid drugs in hyperthyroidism	50 – 100 micrograms			
Suppression treatment in Thyroid carcinoma	150 – 300 micrograms			
Diagnostic use in thyroid suppression test	Week 4 before the test	Week 3 before the test	Week 2 before the test	Week 1 before the test
Euthyrox 200 µg	---	---	1 tabl/day	1 tabl/day
Euthyrox 100 µg	---	---	2 tabl/day	2 tabl/day
Euthyrox 150 µg	½ tabl/day	½ tabl/day	1 tabl/day	1 tabl/day

You should take Euthyrox once a day, half an hour before breakfast. It is best to take Euthyrox with some liquid (for example, half a glass of water).

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

Euthyrox usually needs to be used long-term.

Use in children

Children should take Euthyrox 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 giving it to your child.

Have you taken too much of this medicine?

If you have taken too much Euthyrox, contact your doctor or pharmacist immediately.

The following symptoms may indicate an overdose: accelerated metabolism, palpitations, anxiety, irritability, seizures, excessive mobility. In patients at risk of psychotic disorders, symptoms of acute psychosis may occur.

Have you forgotten to take this medicine?

Do not take a double dose to make up for a forgotten tablet. Take the next dose at the next breakfast.

If you stop taking this medicine

If the treatment with Euthyrox is stopped, the symptoms associated with an underactive thyroid may return.

Do you have any other questions about the use of this medicine? Then contact your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects. Not everyone will experience them.

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

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), tremors, restlessness, sleep disturbances, sweating, weight loss, diarrhea.

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

Allergic reactions to any of the ingredients of Euthyrox are possible (see section 6. "What substances are in this medicine?"). Allergic reactions may include swelling of the face or throat (angioedema), skin rash, rash with pink bumps and severe itching (hives or urticaria). If this occurs, contact your doctor immediately.

Reporting side effects

If you experience side effects, contact your doctor or pharmacist. This also applies to side effects not listed in this leaflet. You can also report side effects via the Netherlands Pharmacovigilance Centre Lareb, website: www.lareb.nl. By reporting side effects, you help us obtain more information about the safety of this medicine.

5. How to store this medicine?

Keep out of the sight and reach of children.

Store below 25°C in the original packaging to protect from light.

Do not use this medicine after the expiry date. You will find this on the blister and the box after "EXP". It includes a month and a year. The last day of that month is the expiry date.

Do not flush medicines down the sink or toilet and do not throw them in the trash. Ask your pharmacist what to do with medicines you no longer use. Proper disposal of medicines ensures they are destroyed correctly and do not enter the environment.

6. Contents of the packaging and other information

What substances are in this medicine?

- The active substance in this medicine is levothyroxine sodium, each tablet contains 25, 50, 75, 88, 100, 112, 125, 137, 150, 175, and 200 micrograms of levothyroxine sodium respectively.
- The other substances in this medicine are corn starch, citric acid, croscarmellose sodium, gelatin, magnesium stearate, and mannitol (E421).

What does Euthyrox look like and what is in a package?

Euthyrox is a white, round, flat tablet on both sides with a rounded edge, a score line, and an inscription on one side:

Euthyrox 25	: EM 25
Euthyrox 50	: EM 50
Euthyrox 75	: EM 75
Euthyrox 88	: EM 88

Euthyrox 100	: EM 100
Euthyrox 112	: EM 112
Euthyrox 125	: EM 125
Euthyrox 137	: EM 137
Euthyrox 150	: EM 150
Euthyrox 175	: EM 175
Euthyrox 200	: EM 200

Euthyrox is packaged in a calendar pack. Each box contains 3 calendar packs of 30 tablets.

Marketing authorization holder and manufacturer

Marketing authorization holder Merck BV
Tupolevlaan 41-61
1119 NW Schiphol-Rijk

Manufacturer
Merck Healthcare KGaA
Frankfurter Str. 250
Darmstadt
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Alcorcón, 28923 Madrid
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Registered under:

Euthyrox 25: RVG 11718
Euthyrox 50: RVG 11344
Euthyrox 75: RVG 21494
Euthyrox 88: RVG 101391
Euthyrox 100: RVG 09009
Euthyrox 112: RVG 101393
Euthyrox 125: RVG 15468
Euthyrox 137: RVG 101394
Euthyrox 150: RVG 11345
Euthyrox 175: RVG 26173
Euthyrox 200: RVG 26174.

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