

PACKAGE LEAFLET

PACKAGE LEAFLET: INFORMATION FOR THE USER

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

Levothyroxine sodium

Read all of this leaflet carefully before you start taking this medicine.

- 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. 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.

In this leaflet:

1. What Euthyrox is and what it is used for
2. Before you take Euthyrox
3. How to take Euthyrox
4. Possible side effects
5. How to store Euthyrox
6. Further information

1. WHAT EUTHYROX IS AND WHAT IT IS USED FOR

Levothyroxine, the active substance in Euthyrox, 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.

Euthyrox 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.

Euthyrox 25 microgram, 50 microgram, 75 microgram, 88 microgram and 100 microgram are also used to balance thyroid hormone levels, when overproduction of hormones is treated with antithyroid medicines.

Euthyrox 100 microgram, 150 microgram, and 200 microgram may also be used in the testing of your thyroid function. **

**** the respective information will only be included in the package leaflets of Euthyrox 100 microgram, 150 microgram or 200 microgram.**

2. BEFORE YOU TAKE EUTHYROX

Do not take Euthyrox

if you have any of the following:

- allergy (hypersensitivity) to the active substance or to any of the other ingredients of Euthyrox (see section 6.),
- untreated dysfunction of the adrenal gland, pituitary gland or excessive overproduction of thyroid hormones (thyreotoxicosis),
- acute heart disease (myocardial infarction or heart inflammation).

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

Take special care with Euthyrox

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 heart beat,
- high blood pressure,
- fatty deposits in your arteries (arteriosclerosis).

They must be under medical control **before** you start taking Euthyrox or before a thyroid suppression test is performed. You **must** have frequent checks of your thyroid hormone levels while you are on Euthyrox. 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 Euthyrox or before a thyroid suppression test is performed.

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.
- if you switch from one levothyroxine-containing medicine to another one. The effect may be slightly different and you may need closer monitoring and dose adjustment.

Taking other medicines

Tell your doctor, if you are taking any of the following medicines, because Euthyrox may influence their effect:

- Anti-diabetic medicines (blood-sugar-lowering medicines):
Euthyrox 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 Euthyrox treatment. While you are taking Euthyrox, adjustment of the dose of your anti-diabetic medicine may be necessary.
- Coumarin derivatives (medicines used to prevent blood clotting):
Euthyrox 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 Euthyrox treatment. While you are taking Euthyrox, 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 Euthyrox 4 - 5 hours **before** these medicines, because they may block the uptake of Euthyrox 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 carbonate:
Make sure that you take Euthyrox at least 2 hours **before** these medicines, because otherwise they may reduce the effect of Euthyrox.

Tell your doctor, if you are taking any of the following medicines, because they may **reduce** the effect of Euthyrox:

- propylthiouracil (antithyroid medicine),
- glucocorticoids (anti-allergic and anti-inflammatory medicines),
- beta-blockers (blood-pressure-lowering medicines also used to treat heart diseases),
- sertraline (antidepressive 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).

Tell your doctor, if you are taking any of the following medicines, because they may **intensify** the effect of Euthyrox:

- salicylates (medicine used to relief 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).
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Tell your doctor, if you are taking any of the following medicines, because they may influence the effect of Euthyrox:

- 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 Euthyrox may be necessary.

Tell your doctor, if you are taking amiodarone (medicine used to treat irregular heart beat), 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 Euthyrox, 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.

Thyroid hormones are not suitable 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.

Taking Euthyrox 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 Euthyrox from the intestine and therefore, an adjustment of your Euthyrox dose may be necessary.

Pregnancy and breast-feeding

If you are pregnant continue taking Euthyrox. Speak to your doctor, because the dose may need to be changed.

If you have taken Euthyrox together with an antithyroid medicine to treat an overproduction of thyroid hormones, your doctor will advise you to stop Euthyrox treatment when you become pregnant.

If you are breast-feeding, continue taking Euthyrox 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 Euthyrox has any influence on the ability to drive and use machines, because levothyroxine is identical to the naturally occurring thyroid hormone.

Important information about some of the ingredients of Euthyrox

Tell your doctor, if you have an intolerance to certain sugars, because Euthyrox contains lactose.

3. HOW TO TAKE EUTHYROX

Always take Euthyrox exactly as your doctor has told you. Check with your doctor, 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.

<i>Use of Euthyrox</i>	<i>Recommended daily dose of Euthyrox</i>	
- to treat benign goitre in patients with normal thyroid function	75 - 200 microgram	
- to prevent recurrence of goitre after surgery	75 - 200 microgram	
- to replace natural thyroid hormones, when your thyroid gland does not produce enough - initial dose - maintenance dose	adults 25 - 50 microgram * 100 - 200 microgram	children 12.5 – 50 microgram * 100 – 150 microgram per m ² of body surface
- to suppress tumour growth in patients with thyroid cancer	150 - 300 microgram	
- to balance thyroid hormone levels, when overproduction of hormones is treated with anti-thyroid medicines	50 - 100 microgram	
- to test thyroid function**	100 microgram: *** 200 microgram (2 tablets) starting 2 weeks before the test 150 microgram: **** Starting 4 weeks before the test 75 microgram (½ tablet) for two weeks, then 150 microgram (1 tablet) until the test	

	200 microgram: ***** 200 microgram (1 tablet) starting 2 weeks before the test
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** the following information will only be included in the package leaflets of Euthyrox 112 microgram, 125 microgram, 137 microgram, 150 microgram, 175 microgram or 200 microgram:*

Euthyrox 112 microgram, 125 microgram, 137 microgram, 150 microgram, 175 microgram or 200 microgram tablets are not suitable for the lower dose range listed here, but your doctor may prescribe a lower strength of Euthyrox tablets.

*** only applicable for the package leaflets of Euthyrox 100 microgram, 150 microgram or 200 microgram.*

**** the respective information will only be included in the package leaflet of Euthyrox 100 microgram.*

***** the respective information will only be included in the package leaflet of Euthyrox 150 microgram.*

****** the respective information will only be included in the package leaflet of Euthyrox 200 microgram.*

Administration

Euthyrox 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 Euthyrox 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.

Duration of treatment

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

If you take more Euthyrox than you should

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

If you forget to take Euthyrox

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 Euthyrox, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

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

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

Irregular or rapid heart beat, 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 with eye swelling), 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 Euthyrox are possible (see section 6. 'What Euthyrox contains'). Allergic reactions may include swelling of the face or throat (angio-oedema). If this happens, contact your doctor immediately.

If you notice any side effects not listed in this leaflet, tell your doctor or pharmacist.

5. HOW TO STORE EUTHYROX

Keep out of the reach and sight of children.

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

Do not store above 25° C. Keep the blisters or the bottle in the outer carton, in order to protect from light.

After first opening of the bottle, the tablets can be used for a maximum of 3 months.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Euthyrox <strength> microgram contains

- The active substance is levothyroxine. Each tablet contains 25 microgram, 50 microgram, 75 microgram, 88 microgram, 100 microgram, 112 microgram, 125 microgram, 137 microgram, 150 microgram, 175 microgram, or 200 microgram levothyroxine sodium.
- The other ingredients are maize starch, croscarmellose sodium, gelatine, lactose monohydrate, and magnesium stearate (Ph.Eur.).

What Euthyrox <strength> microgram looks like and contents of the pack

Euthyrox <strength> microgram tablets are white, round, flat on both sides, with a bevelled edge, a dividing score and an inscription EM 25, EM 50, EM 75, EM 88, EM 100, EM 112, EM 125, EM 137, EM 150, EM 175 or EM 200 on top:

Euthyrox is available in packs of 50 and 100 tablets.

Euthyrox is available in bottles with 100 and und 500 tablets.*

** only applicable for the package leaflets of container with Euthyrox 25 microgram, 50 microgram or 100 microgram.*

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Merck Serono GmbH

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64289 Darmstadt

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Servicenummer (6 Cent pro Gespräch aus dem Netz der Telekom, ggf. abweichende Preise aus dem Mobilfunknetz):

Tel.: (0180) 222 76 00

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Manufacturer

Merck KGaA
Frankfurter Strasse 250
64293 Darmstadt, Germany

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria: Euthyrox
Belgium: Supratirox
Denmark: Euthyrox
Germany: Euthyrox
Greece: Euthyrox
Iceland: Euthyrox
Italy: Supratirox
Norway: Euthyrox
Portugal: Eutirox
Spain: Eutirox
Sweden: Euthyrox

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