

PATIENT INFORMATION LEAFLET

EUTHYROX TABLETS

SCHEDULING STATUS: S3

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

Euthyrox 25 µg Tablets

Euthyrox 50 µg Tablets

Euthyrox 100 µg Tablets

(Levothyroxine sodium)

Contains sugar (mannitol)

Read all of this leaflet carefully before you start using EUTHYROX

Keep this leaflet. You may need to read it again.

If you have further questions, please ask your doctor or your pharmacist.

EUTHYROX has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

1. What EUTHYROX Contains:

The active substance is levothyroxine sodium.

Each EUTHYROX 25 µg tablet contains 25 µg levothyroxine sodium.

Each EUTHYROX 50 µg tablet contains 50 µg levothyroxine sodium.

Each EUTHYROX 100µg tablet contains 100 µg levothyroxine sodium.

Contains sugar (Mannitol 69,6 mg).

The other ingredients are citric acid anhydrous, croscarmellose sodium, gelatin, magnesium stearate, mannitol.

2. What EUTHYROX 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.

3. 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

Untreated dysfunction of the adrenal gland, pituitary gland or excessive overproduction of thyroid hormones (thyreotoxicosis),

Acute heart disease (myocardial infarction or heart inflammation).

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 heartbeat, high blood pressure, fatty deposits in your arteries (atherosclerosis).

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.

Important information about some of the ingredients of EUTHYROX:

EUTHYROX contains mannitol and may have a laxative effect.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

No studies on the effects on the ability to drive and use machines have been performed. However, since levothyroxine is identical to the naturally occurring thyroid hormone, it is not expected that EUTHYROX has any influence on the ability to drive and use machines, if used as recommended.

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

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.

Warfarins (medicines used to prevent blood clotting):

EUTHYROX may intensify the effect of these medicines, so you may need regular checks of your blood clotting values, especially at the start of EUTHYROX treatment. While you are taking EUTHYROX, adjustment of the dose of your warfarin 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), 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), or proguanil (medicine to prevent malaria), medicines activating certain liver enzymes such as barbiturates (sedatives, sleeping pill), oestrogen-containing medicines used for hormone replacement during and after the menopause or for prevention of pregnancy.

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

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),

phenytoin (anti-epileptic medicine).

Tell your doctor, if you are taking protease inhibitors (medicines to treat HIV infection), because they may influence the effect of EUTHYROX. 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.

4. HOW TO TAKE EUTHYROX:

Always take EUTHYROX exactly as your doctor has told you. Check with your doctor, if you are not sure.

The dose of EUTHYROX for the treatment of any thyroid disorder should be individualised on the basis of clinical response and biochemical tests and should be monitored regularly.

The daily dose can be given in a single administration in the morning on an empty stomach, half an hour before breakfast.

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, tremor or unintended jerky movements. In patients with a disorder affecting the neurological system such as epilepsy, seizures may occur. If any of this happen contact your doctor.

5. POSSIBLE SIDE EFFECTS:

EUTHYROX can cause side effects.

You may experience one or more of the following side effects:

Irregular or rapid heart beat, chest pain, headache, muscle weakness or cramps, flushing (warmth and redness of the face), fever, vomiting, disorders of menstruation, pseudotumour 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 reduce the daily dose until the side effects have disappeared.

Contact your doctor immediately if you have any of these signs of an allergic reaction to EUTHYROX: difficulty breathing, swelling of your face, lips, tongue, or throat.

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

6. STORING AND DISPOSING EUTHYROX:

Keep out of the reach of children.

Store at or below 30 °C

Keep the blisters or the bottle in the outer carton, in order to protect from light.

7. PRESENTATION OF EUTHYROX:

EUTHYROX tablets are available in blisters of aluminium forming foil and aluminium cover foil in packs of 30's, 28's and 100's.

8. IDENTIFICATION OF EUTHYROX:

EUTHYROX 25 µg tablets: off-white, round, dividing score on both sides of tablet with a bevelled edge embossed with "EM 25" on top.

EUTHYROX 50 µg tablets: off-white, round, dividing score on both sides of tablet with a bevelled edge, embossed with "EM 50" on top.

Euthyrox 100 µg tablets: off-white, round, dividing score on both sides of tablet with a bevelled edge, embossed with "EM 100" on top.

9. REGISTRATION NUMBERS:

Euthyrox 25 µg tablets - A39 / 21.3 / 0401

Euthyrox 50 µg tablets - A39 / 21.3 / 0402

Euthyrox 100 µg tablets - A39 / 21.3 / 0403

10. NAME AND ADDRESS OF REGISTRATION HOLDER:

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11. DATE OF PUBLICATION

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