

EUTHYROX[®] TABLET

Levothyroxine Sodium (25mcg, 50mcg, 100mcg)

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What Euthyrox is used for

Euthyrox 25 - 100 microgram is used for:

- Treatment of benign euthyroid goiter (condition present which is causing the thyroid to grow abnormally when there is correct amount of hormone produced), mainly in adults when iodine is not indicated.
- Prophylaxis of relapse after surgery for euthyroid goitre, depending on the post-operative hormone status
- Substitution therapy in underactive thyroid gland
- Suppression therapy in thyroid cancer
- Concomitant supplementation during anti-thyroid medicine treatment of overactive thyroid gland

Euthyrox 100 microgram:

- Diagnostic use for thyroid suppression testing

How Euthyrox works

Euthyrox contains levothyroxine sodium, which is a synthetic thyroid hormone.

The levothyroxine sodium in Euthyrox is intended to replace a hormone that is normally produced by your thyroid gland. Euthyrox, when taken correctly, reverses the symptoms of underactive thyroid gland.

Before you use Euthyrox

- When you must not take it

Do not use this medication if:

you have had an allergic reaction before to any of the ingredients in Euthyrox

- you have had uncorrected adrenal insufficiency (lack of hormone)
- you have had uncorrected pituitary insufficiency
- you have untreated thyrotoxicosis, a disease in which the thyroid gland is overactive and produces too much thyroxine
- you have had an acute myocardial infarction (heart attack)

- Before you start to take it

Tell your doctor before or while you are using Euthyrox if you are allergic to any foods, medicines or are lactose intolerant.

Inform your doctor if you have, either presently or in the past, any other medical problems, whether or not you have received treatment for them:

- a) hardening of the arteries, irregular heartbeat, heart failure, insufficient blood flow in the arteries, heart disease, high blood pressure,
- b) osteoporosis (brittle bone)
- c) blood clotting disorders
- d) history of thyroid, adrenal, or pituitary gland problems

If you are to undergo laboratory testing for monitoring of thyroid hormone levels, inform your doctor/laboratory personnel that you are taking or recently taken biotin (also known as vitamin H, vitamin B7 or vitamin B8). Depending on the test, the result may be falsely high or falsely low due to biotin. Your doctor may ask you stop taking biotin before performing laboratory tests. You should be aware that other products that you may take, such as multivitamins or supplements for hair, skin, and nails could also contain biotin.

Doctor will prepare tests to exclude all these medical conditions before starting Euthyrox treatment.

- Taking other medicines

Euthyrox can interfere with the actions of other medications. When you are taking Euthyrox it is important to let your doctor know if you are taking any other medications, including prescription medications, over-the-counter medications, vitamins and herbal products.

Medicines that may interact with Euthyrox include but are not limited to the following:

- **Antidiabetic agents**
 - Treats diabetes by lowering glucose levels in the blood
- **Anticoagulants** (*Dicoumarol*)
 - Helps to thin the blood
- **Antivirals** (*Protease inhibitors* e.g. *Ritonavir, Indinavir, Lopinavir*)
 - Treats viral infections
- **Anti – epileptics** (*Phenytoin, Carbamazepine*)
 - Treats seizures
- **Antihyperlipidemic** (*Colestyramine, Colestipol, Clofibrate*)
 - Lowers cholesterol
- **Aluminium containing medicines** (*antacids and sucralfate*)
- **Iron containing medicines**
- **Calcium Carbonate**
- **Salicyclates**
 - Treats pain
- **Loop Diuretics** (*Furosemide*)
 - Lowers blood pressure
- **Anti – obesity medicine** (*Orlistat*)
 - Treats obesity
- **Phosphate binding medicine** (*Sevelamer*)
 - Treats high phosphate levels
- **Tyrosine kinase inhibitors** (*Imatinib, Sunitinib*)
 - Anticancer medicines
- **Antihyperthyroid medicine** (*Propylthiouracil*)
 - Treats overactive thyroid
- **Steroids** (*Glucocorticoids*)
 - Reduces inflammation
- **Beta-sympatholytics**
 - Treats high blood pressure or anxiety
- **Antiarrhythmic medicine** (*Amiodarone*)
 - Treats and prevents irregular heartbeats
- **Iodine containing contrast media**
 - Used during radiographic procedures

- **Antidepressants** (*Sertraline*)
 - Treats depression
- **Antimalarials** (*Chloroquine, Proguanil*)
 - Prevents and treats malaria
- **Barbiturates**
 - Treats anxiety
- **Estrogen-containing contraceptives or hormone replacement therapy** – Prevents pregnancy or treats common symptoms of menopause
- **Proton Pump Inhibitors**
 - Medicines that treats stomach and acid reflux such as omeprazole ulcers

Eating certain foods like soybean flour (infant formula) and other soy containing compounds, may decrease the absorption of levothyroxine sodium. You may require a change in your dose.

If you have diabetes, your dose of insulin or oral antidiabetic agent may need to be changed after starting Euthyrox. You should monitor your blood and urinary glucose levels as directed by your doctor and report any changes to your doctor immediately. If you are taking an oral anticoagulant drug (blood thinner) such as warfarin, your dose may need to be changed after starting Euthyrox. Your coagulation status should be checked often to determine if a change in dose is required. Inform your doctor if your brand of levothyroxine sodium has changed.

How to take Euthyrox

- How much to take

Your doctor will decide and adjust your dosage depending upon your response to the medication.

Thyroid hormone therapy should be started at low dose and increased gradually every 2 to 4 weeks

For neonates and infants with congenital hypothyroidism, the initial recommended dosage is 10 to 15 micrograms per kg body weight per day for the first 3 months.

General range of dose:

Children: 12.5-50mcg

Adults: 25-300mcg

- When to take it

Take Euthyrox as a single dose, preferably on an empty stomach, half an hour before breakfast. Euthyrox should be taken with half a glass of water and swallowed whole. As food and drink can significantly change the absorption of Euthyrox, you are advised to take Euthyrox at the same time every day and be consistent in how you take it with regard to meals (i.e. always take it on an empty stomach (preferred method)).

Infants receive the entire dose at once at least 30 minutes before the first meal of the day. Tablets are to be disintegrated in some water and the resultant suspension must be prepared freshly as required.

- How long to take it

Use Euthyrox only as prescribed by your doctor. Do not change the amount you take or how often you take it, unless directed to do so by your doctor. Like all medicines obtained from your doctor, Euthyrox must be used only by you and for the condition determined appropriate by your doctor. Thyroid hormone replacement therapy is usually taken lifelong.

- If you forget to take it

If you miss a dose of Euthyrox take the missed dose as soon as possible. If it is almost time for your next dose, skip the missed dose and take only the next regularly scheduled dose. Do not take more than one dose at a time (as prescribed by your doctor). If you miss two or more doses in a row, please contact your physician.

- If you take too much (overdose)

If you take too much Euthyrox, contact your doctor as soon as possible.

Symptoms of overdose include: heart rate increased, anxiety, agitation, uncontrolled movement, fits, sudden heart death

While you are using Euthyrox

- Things you must do

Treatment with levothyroxine should be given consistently during pregnancy and breast-feeding in particular. Dosage requirements may even increase during pregnancy. If you become pregnant or are planning to get pregnant tell your doctor immediately. Consult your doctor before taking Euthyrox if you are breast feeding or about to start breast-feeding. Combination levothyroxine and anti-thyroid agents is not indicated in pregnancy.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor or pharmacist.

- Things to be careful of

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

Side effects

Adverse reactions associated with Euthyrox are primarily due to overdose.

Call your doctor immediately if you experience any of these symptoms, or if you experience any other unusual medical event:

- chest pain, rapid or irregular heartbeat
- muscle weakness & cramps
- fever, flushing
- vomiting
- menstruation disorders,
- tremors
- insomnia (sleeping disorder), restlessness
- excessive sweating
- weight loss
- diarrhoea
- hypersensitivity, hives or skin rash, angioedema (swelling under the skin)

This is not a complete list of side effects. For any unexpected effects while taking Euthyrox, contact your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835490, or visiting the website npra.gov.my (Consumer → Reporting Side Effects to Medicines (ConSERF or Vaccines (AEFI))

Storage and Disposal of Euthyrox

- *Storage*

Keep out of the reach and sight of children.

Do not store above 30°C. Protected from light.

Do not use Euthyrox after the expiry date which is stated on the box

- *Disposal*

If your doctor tells you to stop taking Euthyrox, or the medicine have passed their expiry date ask your pharmacist how to dispose of medicines that no longer required. Medicines should not be disposed of via wastewater or household waste. These measures will help to protect the environment.

Product Description

- *What it looks like*

Off white, round, flat on both sides, with a bevelled edge, a dividing score and an inscription on top:

Euthyrox 25 microgram: EM 25

Euthyrox 50 microgram: EM 50

Euthyrox 100 microgram: EM 100.

Pack size: Cartons of 100 tablets.

- *Ingredients*

- Active ingredient:

Levothyroxine sodium

- Inactive ingredients: Maize

starch, Citricacid, anhydrous,

Croscarmellose sodium,

Gelatin, Magnesium stearate,

Mannitol (E421).

- *MAL Number:*

Euthyrox 100mcg tablet:

MAL19985514AZ

Euthyrox 25mcg tablet:

MAL20032259AZ

Euthyrox 50mcg tablet:

MAL20032260AZ

Manufacturer

Merck Healthcare KGaA,
Frankfurter Strasse 250,
64293 Darmstadt, Germany

Product Registration Holder

Merck Sdn Bhd (178145-V)
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