PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

Euthyrox 25 µg tablets

Euthyrox 50 µg tablets

Euthyrox 75 µg tablets

Euthyrox 100 µg tablets

Levothyroxine sodium

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, pharmacist, nurse or other health care provider.
- 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.

What is in this leaflet

1. What EUTHYROX is and what it is used for
2. What you need to know before you take EUTHYROX
3. How to take EUTHYROX
4. Possible side effects
5. How to store EUTHYROX
6. Contents of the pack and other 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. When the thyroid gland does not produce enough thyroxine (a condition known as hypothyroidism), many of the body's functions slow down. EUTHYROX is used to replace the thyroxine that your thyroid gland cannot produce and prevent the symptoms of hypothyroidism. Before starting your treatment, your doctor will carry out a blood test to work out how much levothyroxine you need.

2. What you need to know before you take EUTHYROX

Do not use EUTHYROX

If you have any of the following:

- Allergy (hypersensitivity) to the active substance or to any of the other ingredients of EUTHYROX (listed in section 6)
- Untreated dysfunction of the adrenal gland, pituitary gland or excessive overproduction of thyroid hormones (thyrotoxicosis)
- Acute heart disease (myocardial infarction or heart inflammation)

Do not take Euthyrox together with antithyroid medicines if you are pregnant.

Warnings and precautions

Talk to your doctor or pharmacist before taking 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 (arteriosclerosis)

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.

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.

Children and adolescents

Haemodynamic parameters should be monitored when EUTHYROX therapy is initiated in very low birth weight preterm neonates.

Other medicines and EUTHYROX

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional 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.
- Warfarin (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)
- chloroquine, or proguanil (medicine to prevent 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 medicine, 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 (medication to treat obesity)

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

- 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)

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 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 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 EUTHYROX, because you may receive an injection that may influence your thyroid function.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking EUTHYROX.

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

If you are breastfeeding, continue taking EUTHYROX as advised by your doctor.

Driving and using 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.

EUTHYROX contains mannitol

EUTHYROX contains mannitol and may have a laxative effect.

3. How to take EUTHYROX

Do not share medicines prescribed for you with any other person.
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.

If your baby is born with hypothyroidism your doctor may recommend starting 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.

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 may vary depending on the condition for which you use EUTHYROX. Your doctor will tell you how long your treatment with EUTHYROX will last. Most patients need to take EUTHYROX for their lifetime. If you have the impression that the effect of EUTHYROX is too strong or too weak, tell your doctor or pharmacist.

If you take more EUTHYROX than you should

If you have taken a higher dose than prescribed, you may experience symptoms such as rapid heartbeat, 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.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

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.

If you stop taking EUTHYROX

These tablets are for long term use. You may need to take them for the rest of your life. Do not stop taking the tablets unless your doctor has told you to do so. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

EUTHYROX can cause side effects.

Not all side effects reported for EUTHYROX are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking EUTHYROX, please consult your health care provider for advice.

If any of the following happens, stop taking EUTHYROX and tell your doctor immediately or go to the casualty department at your nearest hospital:

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

These are all very serious side effects. If you have them, you may have had a serious reaction to EUTHYROX. You may need urgent medical attention or hospitalisation.

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

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 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.

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

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist.

You can also report side effects to the South African Health Products Regulatory Authority (SAHPRA) via the “6.04 Adverse Drug Reaction Reporting Form”, found online under SAHPRA’s publications:

https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of EUTHYROX.

5. How to store EUTHYROX

Store all medicines out of reach of children.

Store at or below 30 °C.

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

Do not use EUTHYROX after the expiry date, which is stated on the blister and the carton after EXP.

The expiry date refers to the last day of that month.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g., toilets).

6. Contents of the pack and other information

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 75 µg tablet contains 75 µg levothyroxine sodium.

Each EUTHYROX 100 µg tablet contains 100 µg levothyroxine sodium.

The other ingredients are maize starch, citric acid anhydrous, croscarmellose sodium, gelatine, magnesium stearate, mannitol.

What EUTHYROX looks like and contents of the pack

EUTHYROX 25 µg tablets: off-white, round, flat on both sides, with a beveled edge, a dividing score on both sides of tablet, embossed with “EM 25” on one side

EUTHYROX 50 µg tablets: off-white, round, flat on both sides, with a beveled edge, a dividing score on both sides of tablet, embossed with “EM 50” on one side

EUTHYROX 75 µg tablets: off-white, round, flat on both sides, with a beveled edge, a dividing score on both sides of tablet, embossed with “EM 75” on one side

Euthyrox 100 µg tablets: off-white, round, flat on both sides, with a beveled edge, a dividing score on both sides of tablet, embossed with “EM 100” on one side

EUTHYROX tablets are available in blisters of aluminium forming foil and aluminium cover foil in packs of 30’s.

Holder of Certificate of Registration

Merck (Pty) Ltd

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Name and address of the manufacturer

Merck Healthcare KGaA

250 Frankfurterstrasse, 64293 Darmstadt, Germany

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