Active substance: Levothyroxine sodium

Composition
1 tablet contains
Medicinally active ingredient:
25 microgram levothyroxine sodium.

Other ingredients:
Corn starch, croscarmellose sodium, gelatin, lactose monohydrate, magnesium stearate.

Presentation and package sizes
Off-white, round, biplanar tablets with a beveled edge, cross score and the following inscription on the top: EM 25.
Packs of 100 tablets

Substance group
Thyroid hormones

Marketing authorisation holder and manufacturer
Merck KGaA
Frankfurter Strasse 250
64293 Darmstadt
Germany

Indications
- Treatment of euthyroid goitre, particularly in adults where iodide therapy is not indicated
- Prophylaxis of goitre relapse after surgery for euthyroid goitre, depending on the postoperative hormonal status
- Thyroid hormone replacement in thyroid underactivity (hypothyroidism)
- In thyroid cancer for suppression of tumour recurrence
- Concomitant therapy during antithyroid drug therapy of hyperthyroidism after normal function has been achieved.

Contraindications
When must you not use Euthyrox 25 μg?
Euthyrox 25 μg must not be used in known intoler-
Drug interactions

What other drugs affect the action of Euthyrox 25 μg?

Cholestyramine (agent lowering blood lipids) inhibits the uptake of levothyroxine in the body. Euthyrox 25 μg should therefore be taken 4-5 hours prior to the intake of cholestyramine.

The same applies to the drug substance colestipol (agent lowering blood lipids).

Aluminium-containing preparations (antacids, sucralfate) are reported in the pertinent literature to potentially attenuate the effect of Euthyrox 25 μg. Euthyrox 25 μg should therefore be taken at least 2 hours before the administration of aluminium-containing preparations.

The same applies to iron-containing preparations and calcium carbonate.

The simultaneous intake of the following drugs may lead to intensification of the effect of Euthyrox: Salicylates (agent for treating pain and fever), dicumarol (agent inhibiting blood clotting), furosemide (diuretic agent), clofibrate (agent lowering blood lipids), phenytoin (agent to treat epileptic seizures).

The simultaneous intake of the following drugs may attenuate the effect of Euthyrox: Propylthiouracil (agent for treating thyroid diseases), glucocorticoids (hormones produced by the adrenal cortex), ß-sympatholytics (agents lowering blood pressure), amiodarone (agent regulating cardiac rhythm).

Due to its high iodine content, amiodarone (agent for regulating the cardiac rhythm) may trigger both hyperthyroidism and hypothyroidism. Particular caution is advised in nodular goitre possibly associated with unknown autonomy.

Sertralin (antidepressive agent) and chloroquine/proguanil (malaria agents) reduce the efficacy of levothyroxine and lead to an increase in TSH.

Barbiturates (hypnotics) and other substances capable of stimulating the hepatic enzyme system may increase levothyroxine excretion via the liver thus reducing efficacy.

ing thyroid hormone therapy. If necessary, in coexisting compensated underactivity of the adrenal cortex the latter must be treated accordingly.

If thyroid autonomy is suspected, a TRH test or a suppression scintigram (radiological examination) must be performed.

In postmenopausal women with hypothyroidism having an increased risk of developing osteoporosis, the thyroid function must be closely monitored in order to prevent increased blood concentrations of Euthyrox.

Levothyroxine must not be given in hyperthyroidism except for concomitant therapy during antithyroid drug therapy of hyperthyroidism.

In ongoing therapy with Euthyrox at adjusted dosage the laboratory values and clinical response of the patient must be monitored upon change of preparation. Dose adjustment may become necessary.

Patients suffering from rare congenital galactose intolerance or lactase deficiency or glucose-galactose malabsorption must not take this drug.

What must you pay attention to if you are driving a vehicle, operating machinery, or working without a firm hold?

Euthyrox 25 μg does not impair the capability to drive a vehicle or to operate machinery.

Special warnings

THIS IS A MEDICAMENT

- Medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor’s prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of the treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.

Keep medicament out of reach of children.

Council of Arab Health Ministers

Union of Arab Pharmacists
What effect does Euthyrox 25μg exert on other drugs?
Levothyroxine may intensify the effect of certain anticoagulant drugs (coumarin derivatives), which inhibit blood clotting, and diminish the effect of hypoglycaemic drugs which lower the blood sugar.
In concomitant therapy with these drugs and levothyroxine your doctor will check your blood clotting parameters and your blood sugar level especially at the start of treatment and, if necessary, will adjust the dosage of the anticoagulant and hypoglycaemic drugs.
Please take into account that this applies also to drugs that you have taken recently.

Dosage instructions, mode and duration of administration

The following dosage instructions apply for Euthyrox 25μg, unless your doctor has prescribed otherwise. Please follow these directions carefully, otherwise Euthyrox 25μg cannot have the proper effect!
Euthyrox 25μg contains 25 microgram of levothyroxine sodium. A range of tablets having contents from 25μg to 150μg of levothyroxine sodium are available for individualised therapy. Thus, most patients need to take only one tablet a day.

How much Euthyrox 25μg should you take and how often should you take it?
The individually required daily dose should be determined by means of diagnostic laboratory tests and clinical examinations. In elderly patients, patients with coronary heart disease and in patients with severe or long-existing hypothyroidism, special caution is required when initiating therapy with thyroid hormones.
Therapy should be started with a low initial dose (e.g. 12.5μg/day) which is to be slowly increased at lengthy intervals (e.g. gradual dose increase at steps of 12.5μg every 14 days) while frequently monitoring the thyroid hormone levels. Experience has shown that a lower dose is also sufficient in low-weight patients and patients with large nodular goitre. Unless prescribed otherwise, the following dosage instructions apply:

For long-term therapy it is recommended to use higher-strength dosage forms.

How and when should you take Euthyrox 25μg?
The entire daily dose is to be taken in the morning on an empty stomach, at least ½ hour before breakfast. The tablets are to be swallowed whole with some liquid (e.g. half a glass of water).
Infants are given the entire daily dose at least ½ hour before the first meal of the day. For this allow the tablets to disintegrate in some water and give the resultant fine dispersion, which is to be prepared freshly prior to each administration, with some more liquid.

How long should you take Euthyrox 25μg?
Duration of administration: Generally for life in hypothyroidism, after surgery for thyroid cancer and for postoperative prophylaxis of goitre relapse in the
Euthyroid state. Concomitant therapy for the treatment of hyperthyroidism is indicated for the same period as antithyroid drug therapy.

In euthyroid goitre therapy is needed for 6 months up to two years. For the prevention of goitre relapse low-dose iodide prophylaxis (100-200μg/day) is recommended after reduction of goitre volume. The doctor decides on the duration of treatment.

**Overdosage and other incorrect use**

*What must you do if you have taken too much Euthyrox 25μg (intentional or accidental overdosage)?*

In the case of overdosage the following clinical symptoms typical of pronounced metabolic disorder may occur: palpitations, anxiety, excitation and involuntary movements (hyperkinesia). Should these symptoms occur, please consult your doctor.

*What must you pay attention to if you have taken too little Euthyrox 25μg or have forgotten to take it?*

If you have taken too little tablets or if you have forgotten intake completely, do not make up for the forgotten dose but continue with the next dose at the defined intake intervals. By no means must the regimen defined by your doctor be changed or stopped without prior consultation.

*What must you pay attention to if you interrupt treatment or stop it prematurely?*

Regular intake of Euthyrox 25μg at the prescribed dosage is necessary to achieve the desired aim of therapy. Should you interrupt or stop treatment too early, clinical symptoms may occur once again, whose type depends on the respective underlying disease.

**Adverse effects**

*What adverse reactions may occur during use of Euthyrox 25μg?*

If taken according to the directions, adverse reactions are not to be expected during treatment with Euthyrox 25μg.

If in individual cases the respective dosage is not tolerated or in the case of overdosage, symptoms typical of hyperthyroidism may occur, especially if the dose is increased too quickly at the start of treatment. Such symptoms may include: increased heart rate, palpitations, cardiac arrhythmias, angina pectoris, headache, muscle weakness and muscle cramps, sensation of heat, fever, vomiting, menstrual disorders, pseudotumor cerebri, tremor, restlessness, insomnia, hyperhidrosis, weight loss, and diarrhoea.

*What countermeasures are to be taken in the case of adverse reactions?*

After consultation of the treating physician, the daily dosage should be reduced or tablet intake interrupted for several days. As soon as the adverse reaction has disappeared, therapy may be carefully resumed at low dosage.

**Notes and information on the stability of the drug**

The expiry date of this pack is printed on the folding box and on the edge of each blister strip. Do not use this pack once the expiry date has elapsed!

Keep drugs out of reach of children.

*How should you store Euthyrox 25μg?*

Please keep Euthyrox 25μg in the closed folding box and do not store above 25°C. Protect from light.

**Date of issue**

May 2002
in patients with untreated adrenocortical insufficiency, untreated insufficiency of the pituitary gland or untreated hyperthyroidism.

Therapy with Euthyrox 50 μg must not be initiated in acute myocardial infarction, acute myocarditis and acute pancarditis (inflammation involving all layers of the cardiac wall).

What must pregnant women and nursing mothers pay attention to?
Treatment with thyroid hormones is to be carried out consistently during pregnancy and the nursing period in particular. During pregnancy, however, Euthyrox 50 μg must not be taken together with medication for the treatment of hyperthyroidism (antithyroid drugs) as additional intake of Euthyrox 50 μg may make a higher dose of the antithyroid drug necessary.

What must be observed in elderly people?
In elderly patients careful dosing and frequent medical checkups are necessary.

Precautions for use and warnings
What precautions must be observed?
Prior to initiating thyroid hormone therapy, the following diseases are to be excluded: Coronary insufficiency, angina pectoris, arteriosclerosis, hypertension, pituitary or adrenocortical insufficiency, thyroid autonomy.

Even mild levothyroxine-induced hyperthyroidism must be avoided by all means especially in patients with coronary insufficiency, heart failure or tachycardiac arrhythmias (heart rhythm disturbances of the rapid type).

In patients with thyroid underactivity due to a disease of the pituitary gland (secondary hypothyroidism) the actual cause must be clarified before initiating thyroid hormone therapy. If necessary, coexisting compensated underactivity of the adrenal cortex the latter must be treated accordingly.
If thyroid autonomy is suspected, a TRH test or a suppression scintigram (radiological examination) must be performed.

In postmenopausal women with hypothyroidism having an increased risk of developing osteoporosis, the thyroid function must be closely monitored in order to prevent increased blood concentrations of Euthyrox. Levothyroxine must not be given in hyperthyroidism except for concomitant therapy during antithyroid drug therapy of hyperthyroidism.

In ongoing therapy with Euthyrox at adjusted dosage the laboratory values and clinical response of the patient must be monitored upon change of preparation. Dose adjustment may become necessary.

Patients suffering from rare congenital galactose intolerance or lactase deficiency or glucose-galactose malabsorption must not take this drug.

**What must you pay attention to if you are driving a vehicle, operating machinery, or working without a firm hold?**

Euthyrox 50 μg does not impair the capability to drive a vehicle or to operate machinery.

**Special warnings**

**THIS IS A MEDICAMENT**

- Medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor’s prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of the treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.

*Keep medicament out of reach of children.*

Council of Arab Health Ministers

Union of Arab Pharmacists

**Drug interactions**

**What other drugs affect the action of Euthyrox 50 μg?**

Cholestyramine (agent lowering blood lipids) inhibits the uptake of levothyroxine in the body. Euthyrox 50 μg should therefore be taken 4-5 hours prior to the intake of cholestyramine. The same applies to the drug substance colestipol (agent lowering blood lipids).

Aluminium-containing preparations (antacids, sucralfate) are reported in the pertinent literature to potentially attenuate the effect of Euthyrox 50 μg. Euthyrox 50 μg should therefore be taken at least 2 hours before the administration of aluminium-containing preparations.

The same applies to iron-containing preparations and calcium carbonate.

The simultaneous intake of the following drugs may lead to intensification of the effect of Euthyrox: Salicylates (agent for treating pain and fever), dicumarol (agent inhibiting blood clotting), furosemide (diuretic agent), clofibrate (agent lowering blood lipids), phenytoin (agent to treat epileptic seizures).

The simultaneous intake of the following drugs may attenuate the effect of Euthyrox: Propylthiouracil (agent for treating thyroid diseases), glucocorticoids (hormones produced by the adrenal cortex), β-sympatholytics (agents lowering blood pressure), amiodarone (agent regulating cardiac rhythm).

Due to its high iodine content, amiodarone (agent for regulating the cardiac rhythm) may trigger both hyperthyroidism and hypothyroidism. Particular caution is advised in nodular goitre possibly associated with unknown autonomy.

Sertralin (antidepressive agent) and chloroquine/proguanil (malaria agents) reduce the efficacy of levothyroxine and lead to an increase in TSH. Barbiturates (hypnotics) and other substances capable of stimulating the hepatic enzyme system may increase levothyroxine excretion via the liver thus reducing efficacy.

**What effect does Euthyrox 50 μg exert on other drugs?**

Levothyroxine may intensify the effect of certain anticoagulant drugs (coumarin derivatives), which inhibit blood clotting, and diminish the effect of hypoglycaemic drugs which lower the blood sugar.
In concomitant therapy with these drugs and levothyroxine your doctor will check your blood clotting parameters and your blood sugar level especially at the start of treatment and, if necessary, will adjust the dosage of the anticoagulant and hypoglycaemic drugs. Please take into account that this applies also to drugs that you have taken recently.

**Dosage instructions, mode and duration of administration**

The following dosage instructions apply for Euthyrox 50 μg, unless your doctor has prescribed otherwise. Please follow these directions carefully, otherwise Euthyrox 50 μg cannot have the proper effect!

Euthyrox 50 μg contains 50 microgram of levothyroxine sodium. A range of tablets having contents from 25 μg to 150 μg of levothyroxine sodium are available for individualised therapy. Thus, most patients need to take only one tablet a day.

**How much Euthyrox 50 μg should you take and how often should you take it?**

The individually required daily dose should be determined by means of diagnostic laboratory tests and clinical examinations. In elderly patients, patients with coronary heart disease and in patients with severe or long-existing hypothyroidism, special caution is required when initiating therapy with thyroid hormones.

Therapy should be started with a low initial dose (e.g. 12.5 μg/day) which is to be slowly increased at lengthy intervals (e.g. gradual dose increase at steps of 12.5 μg every 14 days) while frequently monitoring the thyroid hormone levels.

Experience has shown that a lower dose is also sufficient in low-weight patients and patients with large nodular goitre. Unless prescribed otherwise, the following dosage instructions apply:

<table>
<thead>
<tr>
<th>Indications</th>
<th>recommended dosage (μg levothyroxine sodium/day)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Euthyroid goitre</td>
<td>75-200 (equiv. to 1½-4 tabl. Euthyrox 50 μg/day)</td>
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<td>Prophylaxis of goitre relapse after surgery for euthyroid goitre</td>
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</tr>
<tr>
<td>Thyroid hormone replacement in thyroid underactivity (hypothyroidism)</td>
<td></td>
</tr>
<tr>
<td><strong>In adults:</strong></td>
<td></td>
</tr>
<tr>
<td>- initial dose</td>
<td>25-50 (equiv. to ½-1 tabl. Euthyrox 50 μg/day)</td>
</tr>
<tr>
<td>- maintenance dose</td>
<td>100-200 (equiv. to 2-4 tabl. Euthyrox 50 μg/day)</td>
</tr>
<tr>
<td>Thyroid hormone replacement in thyroid underactivity (hypothyroidism)</td>
<td></td>
</tr>
<tr>
<td><strong>In children:</strong></td>
<td></td>
</tr>
<tr>
<td>- initial dose</td>
<td>12.550 (equiv. to ¼-1 tabl. Euthyrox 50 μg/day)</td>
</tr>
<tr>
<td>- maintenance dose</td>
<td>100-150 μg/m² body surface area</td>
</tr>
<tr>
<td>In thyroid cancer</td>
<td></td>
</tr>
<tr>
<td>for suppression of tumour recurrence</td>
<td>150-300 (equiv. to 3-6 tabl. Euthyrox 50 μg/day)</td>
</tr>
<tr>
<td>Concomitant therapy</td>
<td></td>
</tr>
<tr>
<td>in antithyroid therapy</td>
<td></td>
</tr>
<tr>
<td>of hyperthyroidism</td>
<td>50-100 (equiv. to daily 1-2 tabl. Euthyrox 50 μg)</td>
</tr>
</tbody>
</table>

For long-term therapy it is recommended to use higher-strength dosage forms.

**How and when should you take Euthyrox 50 μg?**

The entire daily dose is to be taken in the morning on an empty stomach, at least ½ hour before breakfast. The tablets are to be swallowed whole with some liquid (e.g. half a glass of water).

Infants are given the entire daily dose at least ½ hour before the first meal of the day. For this allow the tablets to disintegrate in some water and give the resultant fine dispersion, which is to be prepared freshly prior to each administration, with some more liquid.

**How long should you take Euthyrox 50 μg?**

Duration of administration: Generally for life in hypothyroidism, after surgery for thyroid cancer and for postoperative prophylaxis of goitre relapse in the euthyroid state. Concomitant therapy for the treatment of hyperthyroidism is indicated for the same period as antithyroid drug therapy.

In euthyroid goitre therapy is needed for 6 months up to two years. For the prevention of goitre relapse low-dose iodide prophylaxis (100-200 μg/day) is recommended after reduction of goitre volume.

The doctor decides on the duration of treatment.
Overdosage and other incorrect use

What must you do if you have taken too much Euthyrox 50 μg (intentional or accidental overdosage)?
In the case of overdosage the following clinical symptoms typical of pronounced metabolic disorder may occur: palpitations, anxiety, excitation and involuntary movements (hyperkinesia). Should these symptoms occur, please consult your doctor.

What must you pay attention to if you have taken too little Euthyrox 50 μg or have forgotten to take it?
If you have taken too little tablets or if you have forgotten intake completely, do not make up for the forgotten dose but continue with the next dose at the defined intake intervals. By no means must the regimen defined by your doctor be changed or stopped without prior consultation.

What must you pay attention to if you interrupt treatment or stop it prematurely?
Regular intake of Euthyrox 50 μg at the prescribed dosage is necessary to achieve the desired aim of therapy. Should you interrupt or stop treatment too early, clinical symptoms may occur once again, whose type depends on the respective underlying disease.

Adverse effects

What adverse reactions may occur during use of Euthyrox 50 μg?
If taken according to the directions, adverse reactions are not to be expected during treatment with Euthyrox 50 μg.
If in individual cases the respective dosage is not tolerated or in the case of overdosage, symptoms typical of hyperthyroidism may occur, especially if the dose is increased too quickly at the start of treatment. Such symptoms may include: increased heart rate, palpitations, cardiac arrhythmias, angina pectoris, headache, muscle weakness and muscle cramps, sensation of heat, fever, vomiting, menstrual disorders, pseudotumor cerebri, tremor, restlessness, insomnia, hyperhidrosis, weight loss, and diarrhoea.

What countermeasures are to be taken in the case of adverse reactions?
After consultation of the treating physician, the daily dosage should be reduced or tablet intake interrupted for several days. As soon as the adverse reaction has disappeared, therapy may be carefully resumed at low dosage.

Notes and information on the stability of the drug
The expiry date of this pack is printed on the folding box and on the edge of each blister strip.
Do not use this pack once the expiry date has elapsed!
Keep drugs out of reach of children.

How should you store Euthyrox 50 μg?
Please keep Euthyrox 50 μg in the closed folding box and do not store above 25°C. Protect from light.

Date of issue
May 2002
EUTHYROX 100μg
Merck Serono

Active substance: Levothyroxine sodium

Composition
1 tablet contains
Medicinally active ingredient: 100 microgram levothyroxine sodium.
Other ingredients: Corn starch, croscarmellose sodium, gelatin, lactose monohydrate, magnesium stearate.

Presentation and package sizes
Off-white, round, biplanar tablets with a beveled edge, cross score and the following inscription on the top: EM 100.
Packs of 100 tablets

Substance group
Thyroid hormones

Marketing authorisation holder and manufacturer
Merck KGaA
Frankfurter Strasse 250
64293 Darmstadt
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Indications
- Treatment of euthyroid goitre, particularly in adults where iodide therapy is not indicated
- Prophylaxis of goitre relapse after surgery for euthyroid goitre, depending on the postoperative hormonal status
- Thyroid hormone replacement in thyroid underactivity (hypothyroidism)
- In thyroid cancer for suppression of tumour recurrence
- Concomitant therapy during antithyroid drug therapy of hyperthyroidism after normal function has been achieved.
- For diagnosis within the scope of the thyroid suppression test

Contraindications
When must you not use Euthyrox 100μg?
Euthyrox 100μg must not be used in known intol-
Drug interactions

What other drugs affect the action of Euthyrox 100 μg?

Cholestyramine (agent lowering blood lipids) inhibits the uptake of levothyroxine in the body. Euthyrox 100 μg should therefore be taken 4-5 hours prior to the intake of cholestyramine. The same applies to the drug substance colestipol (agent lowering blood lipids).

Aluminium-containing preparations (antacids, sucralfate) are reported in the pertinent literature to potentially attenuate the effect of Euthyrox 100 μg. Euthyrox 100 μg should therefore be taken at least 2 hours before the administration of aluminium-containing preparations.

The same applies to iron-containing preparations and calcium carbonate.

The simultaneous intake of the following drugs may lead to intensification of the effect of Euthyrox: Salicylates (agent for treating pain and fever), dicumarol (agent inhibiting blood clotting), furosemide (diuretic agent), clofibrate (agent lowering blood lipids), phenytoin (agent to treat epileptic seizures).

The simultaneous intake of the following drugs may attenuate the effect of Euthyrox: Propylthiouracil (agent for treating thyroid diseases), glucocorticoids (hormones produced by the adrenal cortex), β-sympatholytics (agents lowering blood pressure), amiodarone (agent regulating cardiac rhythm).

Due to its high iodine content, amiodarone (agent for regulating the cardiac rhythm) may trigger both hyperthyroidism and hypothyroidism. Particular caution is advised in nodular goitre possibly associated with unknown autonomy.

Sertralin (antidepressive agent) and chloroquine/proguanil (malaria agents) reduce the efficacy of levothyroxine and lead to an increase in TSH.

Barbiturates (hypnotics) and other substances capable of stimulating the hepatic enzyme system may increase levothyroxine excretion via the liver thus reducing efficacy.

What effect does Euthyrox 100 μg exert on other drugs?

Levothyroxine may intensify the effect of certain thyroid hormone therapy. If necessary, in coexisting compensated underactivity of the adrenal cortex the latter must be treated accordingly.

If thyroid autonomy is suspected, a TRH test or a suppression scintigram (radiological examination) must be performed.

In postmenopausal women with hypothyroidism having an increased risk of developing osteoporosis, the thyroid function must be closely monitored in order to prevent increased blood concentrations of Euthyrox.

Levothyroxine must not be given in hyperthyroidism except for concomitant therapy during antithyroid drug therapy of hyperthyroidism.

In ongoing therapy with Euthyrox at adjusted dosage the laboratory values and clinical response of the patient must be monitored upon change of preparation. Dose adjustment may become necessary.

Patients suffering from rare congenital galactose intolerance or lactase deficiency or glucose-galactose malabsorption must not take this drug.

What must you pay attention to if you are driving a vehicle, operating machinery, or working without a firm hold?

Euthyrox 100 μg does not impair the capability to drive a vehicle or to operate machinery.

Special warnings
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Keep medicament out of reach of children.

Council of Arab Health Ministers
Union of Arab Pharmacists
anticoagulant drugs (coumarin derivatives), which inhibit blood clotting, and diminish the effect of hypoglycaemic drugs which lower the blood sugar. In concomitant therapy with these drugs and levothyroxine your doctor will check your blood clotting parameters and your blood sugar level especially at the start of treatment and, if necessary, will adjust the dosage of the anticoagulant and hypoglycaemic drugs. 

Please take into account that this applies also to drugs that you have taken recently.

**Dosage instructions, mode and duration of administration**

The following dosage instructions apply for Euthyrox 100 μg, unless your doctor has prescribed otherwise. Please follow these directions carefully, otherwise Euthyrox 100 μg cannot have the proper effect! Euthyrox 100 μg contains 100 microgram of levothyroxine sodium. A range of tablets having contents from 25 μg to 150 μg of levothyroxine sodium are available for individualised therapy. Thus, most patients need to take only one tablet a day.

How much Euthyrox 100 μg should you take and how often should you take it?
The individually required daily dose should be determined by means of diagnostic laboratory tests and clinical examinations.

In elderly patients, patients with coronary heart disease and in patients with severe or long-existing hypothyroidism, special caution is required when initiating therapy with thyroid hormones. Therapy should be started with a low initial dose (e.g. 12.5 μg/day) which is to be slowly increased at lengthy intervals (e.g. gradual dose increase at steps of 12.5 μg every 14 days) while frequently monitoring the thyroid hormone levels. Experience has shown that a lower dose is also sufficient in low-weight patients and patients with large nodular goitre. Unless prescribed otherwise, the following dosage instructions apply:

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<td>100-150 μg/m² body surface area</td>
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<td>In thyroid cancer for suppression of tumour recurrence</td>
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</tr>
<tr>
<td>Concomitant therapy in antithyroid therapy of hyperthyroidism</td>
<td>50-100 (equiv. to daily ½-1 tabl. Euthyrox 100 μg)</td>
</tr>
<tr>
<td>Diagnosis within the scope of the thyroid suppression test:</td>
<td></td>
</tr>
<tr>
<td>- week prior to test week</td>
<td>2 tabl. Euthyrox 100 μg/day</td>
</tr>
<tr>
<td>- test week</td>
<td>2 tabl. Euthyrox 100 μg/day</td>
</tr>
</tbody>
</table>

For initiation of therapy it is recommended, where applicable, to use lower-strength dosage forms. This applies also to the treatment of children.

For long-term therapy it is recommended, where applicable, to use higher-strength dosage forms.

**How and when should you take Euthyrox 100 μg?**
The entire daily dose is to be taken in the morning on an empty stomach, at least ½ hour before breakfast. The tablets are to be swallowed whole with some liquid (e.g. half a glass of water).

Infants are given the entire daily dose at least ½ hour before the first meal of the day. For this allow the tablets to disintegrate in some water and give the resultant fine dispersion, which is to be prepared freshly prior to each administration, with some more liquid.
How long should you take Euthyrox 100 μg?
Duration of administration: Generally for life in hypothyroidism, after surgery for thyroid cancer and for postoperative prophylaxis of goitre relapse in the euthyroid state. Concomitant therapy for the treatment of hyperthyroidism is indicated for the same period as antithyroid drug therapy.
In euthyroid goitre therapy is needed for 6 months up to two years. For the prevention of goitre relapse low-dose iodide prophylaxis (100-200 μg/day) is recommended after reduction of goitre volume.
The doctor decides on the duration of treatment.

Overdosage and other incorrect use
What must you do if you have taken too much Euthyrox 100 μg (intentional or accidental overdosage)?
In the case of overdosage the following clinical symptoms typical of pronounced metabolic disorder may occur: palpitations, anxiety, excitation and involuntary movements (hyperkinesia). Should these symptoms occur, please consult your doctor.

What must you pay attention to if you have taken too little Euthyrox 100 μg or have forgotten to take it?
If you have taken too little tablets or if you have forgotten intake completely, do not make up for the forgotten dose but continue with the next dose at the defined intake intervals. By no means must the regimen defined by your doctor be changed or stopped without prior consultation.

What must you pay attention to if you interrupt treatment or stop it prematurely?
Regular intake of Euthyrox 100 μg at the prescribed dosage is necessary to achieve the desired aim of therapy. Should you interrupt or stop treatment too early, clinical symptoms may occur once again, whose type depends on the respective underlying disease.

Adverse effects
What adverse reactions may occur during use of Euthyrox 100 μg?
If taken according to the directions, adverse reactions are not to be expected during treatment with Euthyrox 100 μg.
If in individual cases the respective dosage is not tolerated or in the case of overdosage, symptoms typical of hyperthyroidism may occur, especially if the dose is increased too quickly at the start of treatment. Such symptoms may include: increased heart rate, palpitations, cardiac arrhythmias, angina pectoris, headache, muscle weakness and muscle cramps, sensation of heat, fever, vomiting, menstrual disorders, pseudotumor cerebri, tremor, restlessness, insomnia, hyperhidrosis, weight loss, and diarrhea.

What countermeasures are to be taken in the case of adverse reactions?
After consultation of the treating physician, the daily dosage should be reduced or tablet intake interrupted for several days. As soon as the adverse reaction has disappeared, therapy may be carefully resumed at low dosage.

Notes and information on the stability of the drug
The expiry date of this pack is printed on the folding box and on the edge of each blister strip.
Do not use this pack once the expiry date has elapsed!
Keep drugs out of reach of children.

How should you store Euthyrox 100 μg?
Please keep Euthyrox 100 μg in the closed folding box and do not store above 25°C. Protect from light.

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in patients with untreated adrenocortical insufficiency, untreated insufficiency of the pituitary gland or untreated hyperthyroidism.

Therapy with Euthyrox 150 μg must not be initiated in acute myocardial infarction, acute myocarditis and acute pancarditis (inflammation involving all layers of the cardiac wall).

What must pregnant women and nursing mothers pay attention to?

Treatment with thyroid hormones is to be carried out consistently during pregnancy and the nursing period in particular.

During pregnancy, however, Euthyrox 150 μg must not be taken together with medication for the treatment of hyperthyroidism (antithyroid drugs) as additional intake of Euthyrox 150 μg may make a higher dose of the antithyroid drug necessary.

What must be observed in elderly people?

In elderly patients careful dosing and frequent medical checkups are necessary.

Precautions for use and warnings

What precautions must be observed?

Prior to initiating thyroid hormone therapy, the following diseases are to be excluded: Coronary insufficiency, angina pectoris, arteriosclerosis, hypertension, pituitary or adrenocortical insufficiency, thyroid autonomy.

Even mild levothyroxine-induced hyperthyroidism must be avoided by all means especially in patients with coronary insufficiency, heart failure or tachycardiac arrhythmias (heart rhythm disturbances of the rapid type).

In patients with thyroid underactivity due to a disease of the pituitary gland (secondary hypothyroidism) the actual cause must be clarified before initiating thyroid hormone therapy. If necessary, coexisting compensated underactivity of the adrenal cortex the latter must be treated accordingly.
If thyroid autonomy is suspected, a TRH test or a suppression scintigram (radiological examination) must be performed.

In postmenopausal women with hypothyroidism having an increased risk of developing osteoporosis, the thyroid function must be closely monitored in order to prevent increased blood concentrations of Euthyrox. Levothyroxine must not be given in hyperthyroidism except for concomitant therapy during antithyroid drug therapy of hyperthyroidism.

In ongoing therapy with Euthyrox at adjusted dosage the laboratory values and clinical response of the patient must be monitored upon change of preparation. Dose adjustment may become necessary.

Patients suffering from rare congenital galactose intolerance or lactase deficiency or glucose-galactose malabsorption must not take this drug.

**What must you pay attention to if you are driving a vehicle, operating machinery, or working without a firm hold?**

Euthyrox 150 μg does not impair the capability to drive a vehicle or to operate machinery.

**Special warnings**

THIS IS A MEDICAMENT
- Medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor’s prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of the treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.

*Keep medicament out of reach of children.*

Council of Arab Health Ministers
Union of Arab Pharmacists

**Drug interactions**

*What other drugs affect the action of Euthyrox 150 μg?*

Cholesteryramine (agent lowering blood lipids) inhibits the uptake of levothyroxine in the body. Euthyrox 150 μg should therefore be taken 4-5 hours prior to the intake of cholesteryramine.

The same applies to the drug substance colestipol (agent lowering blood lipids).

Aluminium-containing preparations (antacids, sucralfate) are reported in the pertinent literature to potentially attenuate the effect of Euthyrox 150 μg. Euthyrox 150 μg should therefore be taken at least 2 hours before the administration of aluminium-containing preparations.

The same applies to iron-containing preparations and calcium carbonate.

The simultaneous intake of the following drugs may lead to intensification of the effect of Euthyrox: Salicylates (agent for treating pain and fever), dicumarol (agent inhibiting blood clotting), furosemide (diuretic agent), clofibrate (agent lowering blood lipids), phenytoin (agent to treat epileptic seizures).

The simultaneous intake of the following drugs may attenuate the effect of Euthyrox: Propylthiouracil (agent for treating thyroid diseases), glucocorticoids (hormones produced by the adrenal cortex), β-sympatholytics (agents lowering blood pressure), amiodarone (agent regulating cardiac rhythm).

Due to its high iodine content, amiodarone (agent for regulating the cardiac rhythm) may trigger both hyperthyroidism and hypothyroidism. Particular caution is advised in nodular goitre possibly associated with unknown autonomy.

Sertralin (antidepressive agent) and chloroquine/proguanil (malaria agents) reduce the efficacy of levothyroxine and lead to an increase in TSH.

Barbiturates (hypnotics) and other substances capable of stimulating the hepatic enzyme system may increase levothyroxine excretion via the liver thus reducing efficacy.

*What effect does Euthyrox 150 μg exert on other drugs?*

Levothyroxine may intensify the effect of certain anticoagulant drugs (coumarin derivatives), which
inhibit blood clotting, and diminish the effect of hypoglycaemic drugs which lower the blood sugar.

In concomitant therapy with these drugs and levothyroxine your doctor will check your blood clotting parameters and your blood sugar level especially at the start of treatment and, if necessary, will adjust the dosage of the anticoagulant and hypoglycaemic drugs.

Please take into account that this applies also to drugs that you have taken recently.

**Dosage instructions, mode and duration of administration**

The following dosage instructions apply for Euthyrox 150μg, unless your doctor has prescribed otherwise. Please follow these directions carefully, otherwise Euthyrox 150μg cannot have the proper effect!

Euthyrox 150μg contains 150 microgram of levothyroxine sodium. A range of tablets having contents from 25μg to 150μg of levothyroxine sodium are available for individualised therapy. Thus, most patients need to take only one tablet a day.

**How much Euthyrox 150μg should you take and how often should you take it?**

The individually required daily dose should be determined by means of diagnostic laboratory tests and clinical examinations.

In elderly patients, patients with coronary heart disease and in patients with severe or long-existing hypothyroidism, special caution is required when initiating therapy with thyroid hormones.

Therapy should be started with a low initial dose (e.g. 12.5μg/day) which is to be slowly increased at lengthy intervals (e.g. gradual dose increase at steps of 12.5μg every 14 days) while frequently monitoring the thyroid hormone levels.

Experience has shown that a lower dose is also sufficient in low-weight patients and patients with large nodular goitre.

Unless prescribed otherwise, the following dosage instructions apply:

<table>
<thead>
<tr>
<th>Indications</th>
<th>recommended dosage (μg levothyroxine sodium/day)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Euthyroid goitre</td>
<td>75-200 (equiv. to ½-1 tabl. Euthyrox 150μg/day)</td>
</tr>
<tr>
<td>Prophylaxis of goitre relapse after surgery for euthyroid goitre</td>
<td>75-200 (equiv. to ½-1 tabl. Euthyrox 150μg/day)</td>
</tr>
<tr>
<td>Thyroid hormone replacement in thyroid underactivity (hypothyroidism)</td>
<td></td>
</tr>
</tbody>
</table>

**In adults:**

- **Initial dose**
  - 25-50 (equiv. to ¼ tabl. Euthyrox 150μg/day)

- **Maintenance dose**
  - 100-200 (equiv. to 1 tabl. Euthyrox 150μg/day)

**In children:**

- **Initial dose**
  - 12.5-50 (equiv. to ¼ tabl. Euthyrox 150μg/day)

- **Maintenance dose**
  - 100-150 μg/m² body surface area

**In thyroid cancer for suppression of tumour recurrence**

- 150-300 (equiv. to 1-2 tabl. Euthyrox 150μg/day)

**Concomitant therapy in antithyroid therapy of hyperthyroidism**

- 50-100 (equiv. to daily ½ tabl. Euthyrox 150μg)

**Diagnosis within the scope of the thyroid suppression test**

- 3 weeks prior to test week
- 2 weeks prior to test week
- week prior to test week
- test week

- ½ tabl. Euthyrox 150μg/day
- 1 tabl. Euthyrox 150μg/day
- 1 tabl. Euthyrox 150μg/day

For initiation of therapy it is recommended, where applicable, to use lower-strength dosage forms. This applies also to the treatment of children.

**How and when should you take Euthyrox 150μg?**

The entire daily dose is to be taken in the morning on an empty stomach, at least ½ hour before breakfast. The tablets are to be swallowed whole with some liquid (e.g. half a glass of water).

Infants are given the entire daily dose at least ½ hour before the first meal of the day. For this allow the tablets to disintegrate in some water and give the resultant fine dispersion, which is to be prepared freshly prior to each administration, with some more liquid.

**How long should you take Euthyrox 150μg?**

Duration of administration: Generally for life in hypo-
thyroidism, after surgery for thyroid cancer and for postoperative prophylaxis of goitre relapse in the euthyroid state. Concomitant therapy for the treatment of hyperthyroidism is indicated for the same period as antithyroid drug therapy.

In euthyroid goitre therapy is needed for 6 months up to two years. For the prevention of goitre relapse low-dose iodide prophylaxis (100-200 μg/day) is recommended after reduction of goitre volume. The doctor decides on the duration of treatment.

**Overdosage and other incorrect use**

**What must you do if you have taken too much Euthyrox 150 μg (intentional or accidental overdosage)?**

In the case of overdosage the following clinical symptoms typical of pronounced metabolic disorder may occur: palpitations, anxiety, excitation and involuntary movements (hyperkinesia).

Should these symptoms occur, please consult your doctor.

**What must you pay attention to if you have taken too little Euthyrox 150 μg or have forgotten to take it?**

If you have taken too little tablets or if you have forgotten intake completely, do not make up for the forgotten dose but continue with the next dose at the defined intake intervals. By no means must the regimen defined by your doctor be changed or stopped without prior consultation.

**What must you pay attention to if you interrupt treatment or stop it prematurely?**

Regular intake of Euthyrox 150 μg at the prescribed dosage is necessary to achieve the desired aim of therapy. Should you interrupt or stop treatment too early, clinical symptoms may occur once again, whose type depends on the respective underlying disease.

**Adverse effects**

**What adverse reactions may occur during use of Euthyrox 150 μg?**

If taken according to the directions, adverse reactions are not to be expected during treatment with Euthyrox 150 μg.