

Package leaflet: Information for the user

Levothyroxine Teva 25 micrograms Tablets Levothyroxine Teva 50 micrograms Tablets Levothyroxine Teva 100 micrograms Tablets

levothyroxine sodium

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- 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 only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Levothyroxine Teva is and what it is used for
2. What you need to know before you take Levothyroxine Teva
3. How to take Levothyroxine Teva
4. Possible side effects
5. How to store Levothyroxine Teva
6. Contents of the pack and other information

1. What Levothyroxine Teva is and what it is used for

Levothyroxine Teva contains thyroid hormone as its active substance.

The aim of treatment with Levothyroxine Teva is to replace missing thyroid hormone and/or to relieve stress on the thyroid gland.

Levothyroxine Teva is used:

- to replace the missing hormone in all forms of underactive thyroid function,
- to prevent the return of new goitres after goitre surgery in patients with normal thyroid function,
- to treat non malignant goitre (benign struma) in patients with normal thyroid function,

25 micrograms

- as add on therapy in the antithyroid treatment of an overactive thyroid, after normal metabolic status has been reached,
- for malignant thyroid tumours, particularly after surgery to suppress new tumour growth and as a supplement for missing thyroid hormone,

50 micrograms

- as add on therapy in the antithyroid treatment of an overactive thyroid, after normal metabolic status has been reached,
- for malignant thyroid tumours, particularly after surgery to suppress new tumour growth and as a supplement for missing thyroid hormone.

100 micrograms

- as add on therapy in the antithyroid treatment of an overactive thyroid, after normal metabolic status has been reached,
- for malignant thyroid tumours, particularly after surgery to suppress new tumour growth and as a supplement for missing thyroid hormone,
- in the thyroid suppression test.

2. What you need to know before you take Levothyroxine Teva

Do not take Levothyroxine Teva

- if you are allergic to levothyroxine sodium or any of the other ingredients of this medicine (listed in section 6),
- if you have any of the following disorders or conditions:
 - an untreated overactive thyroid,
 - underactive adrenal glands (adrenal insufficiency) and you do not have an adequate replacement treatment,
 - untreated pituitary deficiency (hypopituitarism), if this has resulted in adrenal insufficiency that requires treatment,
 - **an acute myocardial infarction**,
 - acute inflammation of the heart muscle (myocarditis),
 - acute inflammation of all the heart walls (pancarditis).

During pregnancy Levothyroxine Teva must not be used at the same time with medicines against an overactive thyroid gland (antithyroid drugs) (see also under “Pregnancy, breast-feeding and fertility”).

Check for diseases

Before the start of treatment with Levothyroxine Teva, the following disorders or conditions must be ruled out or treated:

- coronary heart disease,
- chest pain with tight chestedness (angina pectoris),
- high blood pressure (hypertension),
- pituitary and/or adrenal cortex deficiency,
- areas in the thyroid that produce uncontrolled amounts of thyroid hormone (thyroid autonomy).

100 micrograms

These disorders and conditions must also be ruled out or treated before performing a thyroid suppression test, with the exception of thyroid autonomy, which may be the reason for carrying out the suppression test.

Warnings and precautions

Talk to your doctor or pharmacist before taking Levothyroxine Teva:

- if you have already suffered a heart attack or if you have coronary heart disease, weak heart muscle, heart rhythm disorders with a rapid heartbeat or a non-acute inflammation of the heart muscle, or if you have a chronic underactive thyroid function. Particular vigilance is required for milder signs of overactive thyroid function caused by the administration of Levothyroxine Teva (see section 4. “Possible side effects”), so as to avoid excessively high hormone levels in the blood. In these cases, more frequent checks on thyroid levels should be made (see section 3. “How to take Levothyroxine Teva”).
- if you have underactive thyroid function caused by a disease of the pituitary gland (see also under “Do not take Levothyroxine Teva”).
- if you are suffering from an underactive adrenal gland (adrenal insufficiency). This condition must be treated (hydrocortisone therapy) before introducing thyroid hormone therapy (see also under “Do not take Levothyroxine Teva”).
- if you are suspected of having areas in the thyroid causing uncontrolled production of the thyroid hormone, further tests are recommended before the start of treatment to check the thyroid regulation system.

- if you are a woman after the menopause and are at increased risk of brittle bones (osteoporosis). Your thyroid function should be checked more frequently to avoid increased blood levels of levothyroxine and to ensure the lowest required dose.
- if you have diabetes, as the dosage of your diabetic treatment may need to be altered (see also under “Other medicines and Levothyroxine Teva”).
- if you are being treated with certain anti-blood clotting agents or medicines which may affect the thyroid function (e.g. amiodarone, tyrosine kinase inhibitors [for the treatment of cancer], salicylates and furosemide at high doses). Please bear in mind the information given in section “Other medicines and Levothyroxine Teva”.
- if you have epilepsy (fits). Fits have been rarely reported when starting the treatment with levothyroxine.

Talk to your doctor:

- if 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.
- if you experience an allergic reaction (see section 4. “Possible side effects”). Contact a doctor immediately or go to the nearest hospital emergency room right away.
- if you are about to undergo laboratory testing for monitoring your thyroid hormone levels. You must inform your doctor and/or the laboratory personnel that you are taking or have recently taken biotin (also known as vitamin H, vitamin B7 or vitamin B8). Biotin may affect results of your laboratory tests. Depending on the test, the results may be falsely high or falsely low due to biotin. Your doctor may ask you to stop taking biotin before performing laboratory tests. You should also be aware that other products that you may take, such as multivitamins or supplements for hair, skin, and nails could also contain biotin. This could affect the results of laboratory tests. Please inform your doctor and/or the laboratory personnel, if you are taking such products (Please note the information in section “Other medicines and Levothyroxine Teva”).

Inappropriate use

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, especially when taken together with other medicines for weight reduction.

Switching therapy

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.

Children

Blood pressure will be regularly monitored when levothyroxine treatment is started in very low birth weight preterm neonates because rapid fall in blood pressure (known as circulatory collapse) may occur.

If your child is receiving a thyroid replacement therapy, partial loss of hair may occur during the first few months of taking this medicine, but this is usually transient and hair regrowth usually occurs.

Elderly

In the elderly, the dose should be carefully and individually tailored, especially for those with heart problems, and they should be monitored by their doctor more frequently.

Other medicines and Levothyroxine Teva

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Levothyroxine Teva affects the effectiveness of the following medicinal substances and groups of medicines

Anti-diabetic agents (medicines that lower blood sugar)

Levothyroxine (the active substance of Levothyroxine Teva) can reduce the effect of medications that lower blood sugar. Particularly at the start and at the end of thyroid hormone therapy, the blood sugar level of diabetic patients should therefore be regularly monitored and the dosage of the anti-diabetic medicine adjusted if required.

Coumarin derivatives (medicines to prevent the blood from clotting)

Levothyroxine can enhance the effect of anti-blood clotting agents (coumarin derivatives) due to plasma protein binding displacement. In combined treatment, blood clotting must therefore be regularly monitored; if necessary, the dosage of the anti-blood clotting agent must be adjusted (dose reduction).

The way in which Levothyroxine Teva works is affected by other medicines as follows

Ion exchange resins, bile acid sequestrants

Agents used to lower blood fats (e.g. colestyramine, colestipol, colesevelam) or remove high blood potassium or phosphate concentrations (calcium salts and sodium salts of polystyrene sulphonate, sevelamer) block the absorption of levothyroxine from the intestine. For this reason, these should be taken 4 to 5 hours after taking Levothyroxine Teva.

Stomach acid-binding medications containing aluminium, medications containing iron or calcium

Medicines containing aluminium used to bind stomach acid (antacids, sucralfate); iron or calcium containing medications can reduce the absorption of levothyroxine from the intestine. For this reason, Levothyroxine Teva should be taken at least two hours before these medications.

Proton pump inhibitors

Proton pump inhibitors (such as omeprazole, esomeprazole, pantoprazole, rabeprazole and lansoprazole) are used to reduce the amount of acid produced by the stomach, which may reduce the absorption of levothyroxine from the intestine and thereby make it less effective. If you are taking levothyroxine while receiving treatment with proton pump inhibitors, your doctor should monitor your thyroid function and may have to adjust the dose of Levothyroxine Teva.

Propylthiouracil (medicine used for overactive thyroid function), glucocorticoids (adrenal cortex hormones) and beta-blockers (medicines that reduce the heart rate and lower blood pressure)

These substances block the conversion of levothyroxine to liothyronine, the more active form, and may thereby make Levothyroxine Teva less effective.

Amiodarone (medicine used to treat heart rhythm disorders) and iodine-containing contrast media (certain agents used in X-ray diagnosis)

can due to their high iodine content trigger both overactive and underactive thyroid function. Particular caution should be exercised in patients with a nodular goitre (struma) with possibly undetected areas of uncontrolled hormone production (autonomies). Amiodarone blocks the conversion of levothyroxine to liothyronine, the more active form, and may thereby affect the effect of Levothyroxine Teva. The dose of Levothyroxine Teva may need to be adjusted.

Salicylates, dicumarol, furosemide, clofibrate

Levothyroxine may be displaced from its plasma protein binding by salicylates (fever reducing medications and painkillers), specifically at doses greater than 2.0 g/day, dicumarol (an anti blood

clotting agent), high doses (250 mg) of furosemide (a water tablet), clofibrate (medicine used to reduce high blood fat levels) and other substances. This may lead to an increase in the concentration of free thyroxine in the blood.

Oestrogen-based contraceptives or medications used in hormone replacement therapy after the menopause

The need for levothyroxine may increase in patients taking hormonal contraceptives (the “Pill”) or hormone replacement therapy after the menopause.

Sertraline (an antidepressant), chloroquine/proguanil (medicines used in malaria and rheumatic diseases)

These substances reduce the effectiveness of levothyroxine and increase the serum TSH level.

Tricyclic antidepressants (e.g. amitriptyline, imipramine)

Your response to tricyclic antidepressant therapy may be accelerated if you take levothyroxine as well, as it increases receptor sensitivity to catecholamines.

Tyrosine kinase inhibitors (anti-cancer and anti-inflammatory medicines)

These drugs (e.g. imatinib, sunitinib, sorafenib, motesanib) could reduce concentration of levothyroxine (thyroxine) in your blood. Your doctor may adjust the dose of Levothyroxine Teva.

Digitalis preparations (digoxin, used to treat heart problems)

If you start with levothyroxine therapy while using digitalis preparations, your doctor may have to adjust your digitalis dose. Hyperthyroid patients may need their digoxin dosage gradually increased as treatment proceeds because initially patients are relatively sensitive to digoxin.

Sympathomimetic agents (e.g. adrenaline)

When sympathomimetic agents are used together with levothyroxine, their effect is enhanced.

Enzyme inducing medications

Rifampicin (an antibiotic), carbamazepine (medicine used to treat seizures), phenytoin (medicine used to treat seizures and heart rhythm disorders), barbiturates (used in seizures, for anaesthesia; certain sleeping pills) and products containing St John’s Wort (an herbal medicinal product used to treat depression, anxiety, sleep disorders) can weaken the effect of levothyroxine.

Protease inhibitors (medicines used to treat HIV infections and chronic hepatitis C virus infections)

Levothyroxine has been reported to lose its therapeutic effect when used together with lopinavir/ritonavir. For this reason, clinical symptoms and thyroid function should be carefully monitored in patients using both levothyroxine and protease inhibitors.

Orlistat (medicine used to treat obesity)

An underactive thyroid gland (hypothyroidism and/or reduced control of hypothyroidism) may occur when levothyroxine is taken concomitantly with orlistat.

Interferences with laboratory test

Biotin

If you are taking or have recently taken biotin, you must inform your doctor and/or the laboratory personnel when you are about to undergo laboratory testing for monitoring your thyroid hormone levels. Biotin may affect results of your laboratory tests (see “Warnings and precautions”).

Levothyroxine Teva with food and drink

Products containing soya may impair the absorption of levothyroxine from the intestine. In children, there have been reports of a rise in the serum level of TSH (thyroid stimulating hormone) when they were given a diet containing soya and treatment with levothyroxine for congenital under-active thyroid function. Unusually high doses of Levothyroxine Teva may be required to achieve normal serum

levels of levothyroxine and TSH. During and upon termination of a diet containing soya, the serum levels of levothyroxine and TSH need to be closely monitored; the dose of Levothyroxine Teva may have to be adjusted.

Do not take Levothyroxine Teva together with coffee as this may reduce the absorption of levothyroxine from the intestine and thus reduce its effectiveness. After taking Levothyroxine Teva you should wait at least half an hour to an hour before drinking coffee. Patients who are already being treated with levothyroxine are advised not to change their coffee drinking habit without the levothyroxine levels being checked and monitored by their treating physician.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Consistent treatment with thyroid hormones is particularly important during pregnancy and breast-feeding and must therefore be continued under the supervision of the treating doctor. Despite extensive use during pregnancy, no undesirable effects on pregnancy or the health of the unborn or newborn infant have yet been reported for levothyroxine.

The need for levothyroxine may increase during pregnancy due to increased blood levels of oestrogen (female sex hormone). Thyroid function should therefore be monitored both during and after pregnancy and the thyroid hormone dose adjusted as appropriate.

During pregnancy, you must not take Levothyroxine Teva at the same time as antithyroid medications (so-called thyrostatic agents), as this will result in the need for a higher thyrostatic dosage. Thyrostatic agents (unlike levothyroxine) can enter the child's blood circulation via the placenta and are capable of causing underactive thyroid function in the unborn child. If you suffer from an overactive thyroid, your doctor should treat this during pregnancy only with low-dose thyrostatic agents.

If you are breast-feeding, continue taking levothyroxine as advised by your doctor. Even during high dose levothyroxine therapy, the amount of levothyroxine passing into breast milk during lactation is very low and therefore harmless.

100 micrograms

Suppression tests must not be performed during pregnancy and breast-feeding.

Hypothyroidism or hyperthyroidism are likely to have an effect on fertility. When treating patients with hypothyroidism the Levothyroxine Teva dose must be adjusted based on laboratory test results because an insufficient dose may not improve the hypothyroidism and an overdose can cause hyperthyroidism.

Driving and using machines

There are no available studies on the effects on the ability to drive and use machines. As levothyroxine is identical to the naturally occurring thyroid hormone, Levothyroxine Teva is not expected to have any influence on the ability to drive and use machines.

Levothyroxine Teva contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Levothyroxine Teva

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

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

If any residual thyroid function remains, a lower dose of thyroid hormone may be sufficient.

In elderly patients, patients with coronary heart disease and patients with severe or chronic underactive thyroid function, particular caution is required when starting treatment with thyroid hormones. This means that a lower starting dose must be selected, which is then increased slowly and at longer intervals, with frequent thyroid hormone monitoring. Experience has shown that a lower dose is also sufficient in patients with a low body weight and in patients with large goitres.

Dosage

For individual treatment, tablets are available with graduated levels ranging from 25-200 micrograms of levothyroxine sodium, which means that only one tablet daily needs to be taken in most cases.

For the treatment of underactive thyroid function, adults initially take 25-50 micrograms of levothyroxine sodium daily. If instructed by the doctor, this dose can be increased by 25-50 micrograms of levothyroxine sodium at two to four week intervals, up to a daily dose of 100-200 micrograms of levothyroxine sodium.

To prevent the formation of new goitres after goitre removal and for the treatment of benign goitres, 75-200 micrograms of levothyroxine sodium are taken daily.

25 micrograms

As add on therapy in the antithyroid treatment of an overactive thyroid, 50-100 micrograms of levothyroxine sodium are taken daily.

After thyroid surgery due to a malignant thyroid tumour, the daily dose is 150-300 micrograms of levothyroxine sodium.

50 micrograms

As add on therapy in the antithyroid treatment of an overactive thyroid, 50-100 micrograms of levothyroxine sodium are taken daily.

After thyroid surgery due to a malignant thyroid tumour, the daily dose is 150-300 micrograms of levothyroxine sodium.

100 micrograms

As add on therapy in the antithyroid treatment of an overactive thyroid, 50-100 micrograms of levothyroxine sodium are taken daily.

After thyroid surgery due to a malignant thyroid tumour, the daily dose is 150-300 micrograms of levothyroxine sodium.

For a thyroid suppression test, 200 micrograms of levothyroxine sodium are taken daily for 14 days until scanning of administered radio nuclides in the body is performed.

If appropriate, the use of a medicinal product with a lower active substance content is recommended for starting treatment and increasing the dose in adults and for the treatment of children.

The tablet can be divided into equal doses.

Use in children

For newborns and infants with inborn thyroid hormone deficiency, where it is particularly important to start treatment as soon as possible, in order to achieve normal mental and physical development, the initial recommended dosage is 10-15 micrograms per kg body weight per day for the first 3 months. Thereafter, the dose would be adjusted individually according to the clinical findings and thyroid hormone and TSH values measured in blood.

Children with acquired hypothyroidism start on 12.5-50 micrograms of levothyroxine sodium daily. The dose should be increased gradually every 2 to 4 weeks according to the clinical findings and thyroid hormone and TSH values measured in blood until the full replacement dose is reached. As well as other values, the dosage in long term treatment will depend on the age and body weight of the individual child.

Method of administration

Take the total daily dose in the morning on an empty stomach, at least half an hour before breakfast, as the active substance is better absorbed on an empty stomach than before or after a meal. Swallow the tablets whole without chewing, with plenty of liquid (e.g. a glass of water).

Infants are given the total daily dose at least half an hour before their first meal of the day. For this, the tablet is allowed to dissolve in some water (10-15 ml) and the resulting fine dispersion (note: to be freshly prepared for each dose) is administered with some more liquid (5-10 ml).

Duration of treatment

You should take this medicine for as long as your doctor tells you.

- If you have an underactive thyroid gland or have had thyroid surgery for a malignant tumour of the thyroid, you will usually take Levothyroxine Teva for life.
- For benign goitre and for prevention of recurrent goitre growth, you must take Levothyroxine Teva for anything between several months or years to the rest of your life.
- In supportive therapy for the treatment of an overactive thyroid, you must take Levothyroxine Teva as long as you take a thyreostatic medicine.
- For the treatment of benign goitre with normal thyroid function, a treatment period of 6 months to 2 years is necessary. If the treatment with Levothyroxine Teva has not produced the desired result within this period, other treatment options should be considered.

If you take more Levothyroxine Teva than you should

Symptoms of an overactive thyroid may occur in the event of an overdose (see section 4. "Possible side effects"). Please consult your doctor if such symptoms occur.

If you forget to take Levothyroxine Teva

Do not take a double dose to make up for a forgotten tablet.
Continue to take your tablets regularly as prescribed.

If you stop taking Levothyroxine Teva

For your treatment to be successful, you must take Levothyroxine Teva regularly at the dosage prescribed by your doctor. On no account should you change, suspend or stop the prescribed treatment without talking to your doctor. Symptoms of disease may return if you suspend or stop treatment before you should. The nature of these symptoms depends on the underlying disease.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

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

Hypersensitivity to the active substance or the other ingredients of Levothyroxine Teva

In the case of hypersensitivity to levothyroxine sodium or any of the other ingredients of Levothyroxine Teva, allergic reactions of the skin and respiratory tract region may occur (either immediately or within several days of drug administration), that may be life-threatening. Symptoms may include difficulty in breathing, shortness of breath, swelling of the eyelids, face, lips, throat or tongue (angioedema), rash, urticaria or itching. **Contact a doctor immediately or go to the nearest hospital emergency room right away.**

Intolerance to the dosage strength, overdose

If the dosage strength is not tolerated in individual cases or in the case of an overdose, symptoms typical of an overactive thyroid (hyperthyroidism) may occur, particularly if the dose is increased too rapidly at the start of treatment.

Very common (may affect more than 1 in 10 people)

- palpitations (thumping heart beats),
- difficulty sleeping,
- headache.

Common (may affect up to 1 in 10 people)

- rapid heartbeat (tachycardia),
- nervousness.

Rare (may affect up to 1 in 1,000 people)

- increased brain pressure (especially in children).

Not known (frequency cannot be estimated from the available data)

- flushing, excessive sweating,
- loss of weight,
- tremor (shaking), restlessness, excitability,
- angina (chest pain with tightchestedness),
- irregular heartbeats
- high blood pressure (hypertension), heart failure, heart attack,
- circulatory collapse in very low birth weight preterm neonates (see section 2. “What you need to know before you take Levothyroxine Teva”),
- shortness of breath (dyspnoea),
- increased appetite, feeling sick (nausea), being sick (vomiting), loose stools (diarrhoea), abdominal pain,
- muscle weakness and muscle cramps,
- brittle bones (osteoporosis) at high doses of levothyroxine, especially in postmenopausal women, mainly when treated for a long period,
- fever,
- intolerance to heat,
- mild hair-loss is seen in children,
- in women – changes to your periods.

You should consult your doctor if any of the above effects occur. The effects usually go away when the dose has been changed.

In children, overdosing with levothyroxine may cause too early fusion of skull bones and premature stopping of the growth.

Measures to treat an overdose

Tell your doctor if side effects occur. He/she will decide whether the daily dose should be reduced or whether you should stop taking your tablets for a few days. As soon as the side effect has disappeared, treatment can be started again at a cautious dosage.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRC Pharmacovigilance, Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Levothyroxine Teva

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C.

Do not use this medicine if you notice any visible signs of deterioration.

Do not throw away any medicines via wastewater <or household waste>. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Levothyroxine Teva contains

- The active substance is levothyroxine sodium.
Each tablet contains 25 micrograms levothyroxine sodium.
Each tablet contains 50 micrograms levothyroxine sodium.
Each tablet contains 100 micrograms levothyroxine sodium.
- The other ingredients are maize starch, maize starch pregelatinised, microcrystalline cellulose, silica, colloidal anhydrous, magnesium stearate.

What Levothyroxine Teva looks like and contents of the pack

Levothyroxine Teva 25 micrograms tablets are white to off-white, round, 8 mm in diameter, plain tablets with a cross break-line on one side and debossing L1 on the other side.

Levothyroxine Teva 50 micrograms tablets are white to off-white, round, 8 mm in diameter, plain tablets with a cross break-line on one side and debossing L2 on the other side.

Levothyroxine Teva 100 micrograms tablets are white to off-white, round, 8 mm in diameter, plain tablets with a cross break-line on one side and debossing L4 on the other side.

Levothyroxine Teva is available in the following pack sizes: 20, 28, 30, 50, 56, 60, 84, 90, 100, 112 and 250 (blisters), 50 x 1 (unit dose blisters), 98 (calendar packs).

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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This medicine is authorised in the Member States of the European Economic Area under the following names:

Bulgaria: Teva Thyrox

Germany: Levothyroxine Teva

Italy: Levotiroxina Teva

Czech Republic, Ireland: Levothyroxine Teva

Spain: Levotiroxina Sódica Teva

The Netherlands: Levothyroxinenatrium Teva

Poland: Wolarex

Portugal: Levotiroxina sódica Ratiopharm

Slovenia: Dicitirox

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