

LEVOTHYROXINE 12.5, 25, 50, 75 and 100 microgram TABLETS
levothyroxine sodium

PACKAGE LEAFLET:
INFORMATION FOR THE USER

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 or nurse.
- 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 or nurse. This includes any possible side effects not listed in this leaflet. See section 4.
- Thyroxine is a hormone produced by the thyroid gland. Levothyroxine is used to replace thyroxine in people whose thyroid gland does not work properly. You will usually need to take this medicine for the rest of your life and must not stop taking it, or change the dose, without speaking to your doctor first.
- This medicine can affect the way other medicines work (See Section 2 ‘Other medicines and Levothyroxine’). If you take medicines to control diabetes or warfarin to prevent blood clots, the dose may need to be adjusted by your doctor when you start taking levothyroxine tablets.
- You will start off taking a low dose of this medicine (See Section 3 ‘How to take Levothyroxine’). Your doctor will then increase the dose gradually at 3-4 week intervals until your thyroxine levels are corrected. This will help to reduce the chance of side effects.
- You will need regular blood tests whilst you are taking this medicine.
- These tablets can be taken by both adults and children. If you are giving this medicine to your child make sure you know how many and when to give the tablets (See Section 3 ‘How to take Levothyroxine’) and what side effects to look out for (See Section 4 ‘Possible side effects’).

What is in this leaflet:

- 1. What Levothyroxine is and what it is used for**
- 2. What you need to know before you take Levothyroxine**
- 3. How to take Levothyroxine**
- 4. Possible side effects**
- 5. How to store Levothyroxine**
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1 What Levothyroxine is and what it is used for

Thyroxine is a hormone which is produced naturally in the body by the thyroid gland. Levothyroxine is a synthetic version of this hormone. Thyroxine controls how much energy your body uses. When the thyroid gland does not produce enough thyroxine (a condition known as hypothyroidism), many of the body’s functions slow down. Some of the most common symptoms of hypothyroidism are:

- tiredness
- weight gain
- feeling depressed

Levothyroxine tablets are 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 Levothyroxine

Do not take Levothyroxine if you:

- are allergic to levothyroxine or any of the other ingredients of this medicine (listed in section 6)
- have the following diseases or conditions:
 - suffer from an over-active thyroid gland (thyrotoxicosis)
 - suffer from underactive adrenal glands (adrenal insufficiency) and you do not have an adequate replacement treatment
 - acute myocardial infarction
 - acute inflammation of the heart muscle (myocarditis)
 - acute inflammation of all the heart walls (pancarditis).

During pregnancy Levothyroxine must not be used at the same time with medicines against an overactive thyroid gland (antithyroid drugs).

If any of the above applies to you, do not take this medicine and go back to your doctor to discuss your treatment.

Warnings and precautions

Talk to your doctor or pharmacist or nurse before taking Levothyroxine if you:

- have had a heart attack or any other heart problems, e.g. chest pain (angina), thickening and hardening of artery walls (arteriosclerosis), coronary artery disease, high blood pressure (hypertension), irregular or fast heart rate. The doctor may require ECG before starting treatment with levothyroxine, as changes induced by hyperthyroidism may be confused with evidence of ischaemia (decreased oxygen in a tissue).
- have diabetes as the dose of your insulin or oral anti-diabetic medication, e.g. gliclazide, may need to be altered
- suffer from diabetes insipidus, which is due to a low level of antidiuretic hormone (ADH)
- are suffering from an underactive adrenal gland (adrenal insufficiency), symptoms include swelling of the nose and lips (myxoedema)
- have epilepsy (fits). Fits have been rarely reported when starting the treatment with levothyroxine
- are over 50 years of age

Subclinical hyperthyroidism (where the thyroid gland makes too much thyroxine) may occur if your dose is too high and this could be associated with bone loss (osteoporosis). This will usually disappear after reducing the dose or stopping the tablets. However, you must not change the dose or stop the tablets without talking to your doctor first.

- suffer from an under-active pituitary gland or other causes leading to adrenal insufficiency, as you may need to start corticosteroid therapy before taking levothyroxine
- 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).

Patients occasionally find that they feel less well when changing from one levothyroxine medicine to another. You should tell your doctor if you get any side effects so that your blood can be checked for levels of thyroid hormone. If your symptoms persist you may need a specific brand of levothyroxine to be prescribed.

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.

Blood tests:

Before you start taking levothyroxine your doctor will do a blood test to see how much thyroxine your thyroid gland is making and what dose of the medicine you will need. Once you start taking the medicine your doctor will want you to have regular blood tests to see how well the medicine is working.

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).

Other medicines and Levothyroxine

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes over the counter medicines, herbal remedies and vitamin supplements. Many medicines affect the way levothyroxine works. The effects of other drugs may also be affected by levothyroxine.

- anticoagulants, used to prevent blood from clotting, such as warfarin, dicoumarol and phenindione
- colestyramine and colestipol used to lower cholesterol levels in the blood
- beta blockers such as atenolol and sotalol – used to treat high blood pressure and heart problems
- medicines used to treat heart problems, such as digoxin, digitoxin, amiodarone or propranolol
- tricyclic antidepressants such as imipramine, amitriptyline and dosulepin
- sertraline – used to treat depression and anxiety disorders
- antacids – used to treat indigestion
- cimetidine and sucralfate, used to treat heartburn and stomach ulcers
- proton pump inhibitors such as omeprazole, lansoprazole and pantoprazole – used to reduce the amount of acid produced by the stomach
- anticonvulsants, used to treat epilepsy, such as phenytoin, primidone, carbamazepine and barbiturates
- barbiturates such as phenobarbital, used as sedatives
- ketamine – used as an anaesthetic. If you need to have an operation, please tell your doctor or anaesthetist that you are taking levothyroxine
- oestrogen containing medicines for hormonal replacement therapy (HRT) and oral contraceptives (“the pill”)
- androgen containing medicines for male hormone replacement therapy
- corticosteroids such as hydrocortisone and prednisolone – used to treat inflammation
- anti-inflammatory medicines such as phenylbutazone or aspirin
- imatinib – used to treat certain types of cancer
- rifampicin, used to treat tuberculosis
- insulin and medicines to treat diabetes
- sodium polystyrene sulphonate (resin) used to treat high levels of potassium
- calcium salt supplements
- iron supplements (see section 3, How to take, Taking Levothyroxine in combination with iron supplements)
- sympathomimetic drugs such as dopamine, terbutaline, salmeterol, salbutamol, ephedrine, adrenaline or phenylpropanolamine. Phenylpropanolamine and ephedrine may be in medicines for colds and nasal stuffiness. Tell your pharmacist you are taking levothyroxine before buying such products.
- colessevelam – used to lower cholesterol
- orlistat – used to treat obesity
- 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).

The effect of Levothyroxine is influenced by other medications as follows:

- ritonavir - used to control HIV and chronic hepatitis C virus
- products containing St. John’s Wort (a herbal medicinal product).

Proton pump inhibitors:

Proton pump inhibitors (such as omeprazole, esomeprazole, pantoprazole, rabeprazole and lanzoprazole) 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.

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. Children receiving thyroid agent may experience partial loss of hair may occur during the first few months of therapy, but this effect is usually temporary and subsequent regrowth usually occurs.

Pregnancy, breast-feeding and fertility

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

Driving and using machines

Levothyroxine is not expected to affect your ability to drive or operate machinery. However, if you are affected by any of the adverse events such as muscle weakness, cramps or shaking, please refrain from driving or using machines and speak to your doctor or pharmacist for further advice.

Information on sodium content

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

3 How to take Levothyroxine

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

The tablets should be swallowed, with a drink of water, in the morning at least 30 minutes and preferably one hour before breakfast.

The usual dosage is:

Adults up to 50 years old

- the usual starting dose for adults is 50 to 100 micrograms daily, preferably taken before breakfast.

Your doctor may gradually increase your dose by 50 micrograms every three to four weeks until thyroid deficiency is corrected, usually at a dosage of 100 - 200 micrograms daily.

Adults over 50 years old, or patients with heart disease

- for patients aged over 50 years, the starting dose should be no more than 50 micrograms per day
- for patients with heart disease, the starting dose should be no more than 25 micrograms per day or 50 micrograms on alternate days.

Your doctor may gradually increase your dose by 25 micrograms every four weeks until thyroid deficiency is corrected.

Use in children:

The dose for children depends on their age, weight and the condition being treated. The child will be monitored to make sure he/she gets the right dose. Give your child this medicine at least half an hour before the first meal of the day.

For young children, your doctor is likely to prescribe a levothyroxine product in a liquid formulation.

Congenital hypothyroidism in infants:

This is a condition where your baby has been born with a thyroid gland that does not produce enough thyroxine.

The starting dose is 10 to 15 micrograms/kg body weight a day for the first 3 months. The dose will then be adjusted depending on response to treatment.

Acquired hypothyroidism in children:

This is a condition where your child’s thyroid gland stops working properly because it has been attacked by their immune system, e.g. in children with an autoimmune disease or following a viral infection. The starting dose is 12.5 to 50 micrograms a day. The dose will then be increased gradually every 2 to 4 weeks depending on response to treatment.

Juvenile myxoedema:

This is a condition where children and adolescents develop severe hypothyroidism (produce very low levels of thyroid hormones).

The starting dose is 25 micrograms every day. The dose will then be increased by 25 micrograms every 2-4 weeks until your child shows mild symptoms of hyperthyroidism (a condition where the thyroid gland produces too much thyroxine). The dose will then be reduced slightly.

Taking Levothyroxine in combination with iron supplements:

- if you take iron supplements, you should take levothyroxine and your iron supplement at least 4-5 hours apart.

If you take more Levothyroxine than you should

If you (or someone else) swallow a lot of the tablets all together, or if you think a child has accidentally swallowed any of the tablets, contact your nearest hospital casualty department or your doctor immediately. An overdose is likely to cause agitation, confusion, hyperactivity, irritability, sweating, very dilated pupils, fast or irregular heart beat, muscle cramps, headache, rapid breathing, fever, fits, difficulty sleeping (insomnia), very high temperature (hyperpyrexia) and increased bowel movements. These can take up to 5 days to appear. Please take this leaflet, any remaining tablets and the container with you to the hospital or doctor so that they know which tablets were consumed.

If you forget to take Levothyroxine

If you forget to take a dose take one as soon as you remember, unless it is nearly time to take the next one. Do not take a double dose to make up for a forgotten dose.

If you stop taking Levothyroxine

Do not stop taking your medicine without talking to your doctor first even if you feel better.

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

4 Possible side effects

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

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

- an allergic reaction (swelling of the lips, face, tongue and throat leading to severe difficulty in breathing; skin rash or hives and general feeling of being unwell).

This is a very serious but rare side effect. You may need urgent medical attention or hospitalisation.

Some patients may experience a severe reaction to high levels of thyroid hormone. This is called a “thyroid crisis” and you should contact your doctor immediately if you have any of the following symptoms:

- very high temperature; fast heart rate; irregular heartbeat; low blood pressure; heart failure; jaundice; confusion; fits and coma.

Tell your doctor as soon as possible if you suffer from any of the following side effects, as they are usually due to your dose being too high:

- fast heart beat, palpitations, irregular heart beat, chest pain (angina), pounding, heart attack
- headache, tremor, excitability, restlessness, difficulty in sleeping (insomnia)
- increased pressure around the brain in children that is not caused by a tumour or other disease, with symptoms such as nausea, vomiting, increased blood pressure, decreased mental abilities, confusion, double vision, pupils that don’t respond to changes in light, shallow breathing, seizures, loss of consciousness, coma (benign intracranial hypertension)
- muscle spasms or weakness, shaking
- deformity of the skull in infants caused by the early closure of joins in the skull bone (carniostenosis)
- growth in children may slow or stop due to changes in bone growth

- irregular periods
- high temperature, flushing, intolerance to heat
- shortness of breath
- vomiting, diarrhoea
- weight loss
- hair loss and temporary hair loss in children.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Levothyroxine

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

Do not store above 25°C. Store in the original package.

Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month. 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 tablets contain:

- The active ingredient is levothyroxine sodium, 12.5, 25, 50, 75 or 100 micrograms.
- The other ingredients are maize starch, mannitol (E421), microcrystalline cellulose, sodium citrate, acacia and magnesium stearate.

What Levothyroxine tablets look like and contents of the pack:

- The 12.5 microgram tablets are white, round, biconvex tablets with marking 12.5 on one side of the tablet.
- The 25 microgram tablets are white, round biconvex tablets with score-line on one side and marking 25 on the other side of the tablet.
- The 50 microgram tablets are white, round biconvex tablets with score-line on one side and marking 50 on the other side of the tablet.
- The 75 microgram tablets are white, round biconvex tablets with score-line on one side and marking 75 on the other side of the tablet.
- The 100 microgram tablets are white, round biconvex tablets with score-line on one side and marking 100 on the other side of the tablet.

The product is available in packs of 28, 56 and 112 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder: Teva UK Limited, Ridings Point, Whistler Drive, Castleford, WF10 5HX, United Kingdom

Manufacturer

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