

Package leaflet: Information for the patient

Levothyroxine 50 micrograms and 100 micrograms tablets

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.
- 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 tablets'). 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 tablets'). 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 tablets') and what side effects to look out for (See Section 4 'Possible side effects').

What is in this leaflet

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2. **What you need to know before you take Levothyroxine tablets**
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1. What Levothyroxine tablets are and what they are used for

Thyroxine is a hormone produced by the thyroid gland. Levothyroxine is a synthetic version of thyroxine. Thyroxine controls how much energy your body uses. When the thyroid gland produces too little thyroxine (hypothyroidism), many of the body's functions slow down. Some of the most common symptoms of hypothyroidism are tiredness, weight gain and feeling depressed.

Levothyroxine tablets replace the thyroxine that your thyroid gland cannot produce and prevents the symptoms of hypothyroidism.

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

Do not take Levothyroxine tablets if you:

- are **allergic** to levothyroxine or any of the other ingredients of this medicine (listed in section 6)
- suffer from an overactive thyroid gland that produces too much thyroid hormone (**thyrotoxicosis**)
- have any condition that affects your **adrenal glands** (ask your doctor if you are not sure)

- have the following diseases or conditions:
 - an acute **myocardial infarction**
 - acute inflammation of the heart muscle (**myocarditis**)
 - acute inflammation of all the heart walls (**pancarditis**)
- are **pregnant**, Levothyroxine tablets must not be used together with medicines for an overactive thyroid gland (antithyroid drugs).

If any of these apply to you, do not take this medicine and discuss your treatment with your doctor.

Warnings and precautions

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

- suffer from an underactive adrenal gland (adrenal insufficiency)
- suffer from heart problems including angina, coronary artery disease or high blood pressure
- are being treated for diabetes, the dose of your anti-diabetic medicine may need to be changed
- have epilepsy (fits). Fits have been rarely reported when starting the treatment with levothyroxine
- have suffered with an under active thyroid gland for a long time
- are over 50 years of age.

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 they can check your thyroid hormone levels. If your symptoms persist you may need a specific brand of levothyroxine to be prescribed.

Thyroid hormones are not suitable for weight reduction. Taking thyroid hormones will not reduce your weight, if your thyroid hormone level is in a normal range. Serious or 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 starting levothyroxine your doctor will do a blood test to see how much thyroxine your thyroid gland is making and what dose you will need. Once you start taking levothyroxine your doctor will request regular blood tests to see how well it 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 tablets').

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.

Other medicines and Levothyroxine tablets

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

The following may affect the way levothyroxine works:

- medicines for epilepsy, e.g. carbamazepine, phenytoin, primidone and barbiturates
- sertraline – used to treat depression and anxiety disorders
- antacids – used to treat indigestion
- medicines containing calcium salts
- cimetidine – used to reduce excess stomach acid
- proton pump inhibitors, (e.g. 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
- sucralfate – used to treat and prevent stomach and duodenal ulcers
- colestyramine and colestipol – used to treat high blood fat levels
- polystyrene sulphone resin – used to reduce high blood potassium levels
- oral medicines containing iron
- rifampicin – used to treat infections
- imatinib – used to treat certain types of cancer
- beta blockers, e.g. atenolol and sotalol – used to treat high blood pressure and heart problems
- oestrogen containing medicines for hormone replacement therapy (HRT) and the contraceptive pill
- androgen containing medicines for male hormone replacement therapy
- corticosteroids, e.g. hydrocortisone and prednisolone – used to treat inflammation
- amiodarone – used to treat an irregular heartbeat
- orlistat – used to treat obesity
- ritonavir – used to control HIV and chronic hepatitis C virus
- products containing St. John's Wort (a herbal medicine)
- 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).

The following may be affected by levothyroxine:

- anticoagulant medicines, e.g. warfarin, to prevent blood clots
- medicines to treat diabetes, e.g. insulin and metformin
- tricyclic antidepressants, e.g. amitriptyline, imipramine and dosulepin
- medicines that stimulate the sympathetic nervous system, e.g. adrenaline (epinephrine – used to treat severe allergic reactions) or phenylephrine (a decongestant found in many cold and flu treatments)
- digoxin – used to treat heart problems
- anti-inflammatory medicines, e.g. phenylbutazone or aspirin
- propranolol – used to treat high blood pressure and heart problems
- ketamine – used as an anaesthetic. If you need to have an operation, please tell your doctor or anaesthetist that you are taking levothyroxine.

Pregnancy and breast-feeding

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. Your doctor will decide if you should continue treatment with levothyroxine whilst you are pregnant, particularly in the first three months of your pregnancy.

Levothyroxine tablets contain lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Information on sodium content

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

3. How to take Levothyroxine tablets

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. You may be taking this medicine for the rest of your life. Your dose will be decided by your doctor and will depend on the results of your blood tests. The dose you should take will be on the label attached by your pharmacist. Swallow the tablets with plenty of water. You should take your tablets preferably 30-60 minutes before breakfast, caffeine-containing liquids (e.g. coffee, tea), or other medication.

Adults

The recommended starting dose is 50 - 100 micrograms every day. The dose may be increased every 3 - 4 weeks by 50 micrograms until your thyroxine levels are correct. Your final daily dose may be up to 100 - 200 micrograms daily.

Patients over 50 years of age without heart problems

The recommended starting dose will be no more than 50 micrograms every day. The dose may be increased by 50 micrograms every 3 - 4 weeks until your thyroxine levels are correct. Your final daily dose will be between 50 - 200 micrograms daily.

Patients over 50 years with heart problems

The recommended starting dose will be 25 micrograms every day or 50 micrograms every other day. The dose may be increased by 25 micrograms every 4 weeks until your thyroxine levels are correct. Your final daily dose will usually be between 50 - 200 micrograms daily.

Use in children and adolescents

For young children, your doctor is likely to prescribe Levothyroxine Oral Solution.

Congenital hypothyroidism in infants

A condition where your baby has been born with a thyroid gland that does not produce enough thyroxine. The starting dose is 10 - 15 micrograms/kg bodyweight per day for the first three months. The dose will then be adjusted depending on how your baby responds to the treatment.

Acquired hypothyroidism in children

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 - 50 micrograms per day. The dose should be increased gradually every 2 - 4 weeks depending on how your child responds to the medicine.

Juvenile myxoedema

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.

If you take more Levothyroxine tablets than you should

If you (or someone else) have taken too many tablets, or you think a child may have swallowed any, contact your nearest hospital A&E department or tell your doctor immediately. Signs of an overdose may include: fever, chest pain (angina), racing or irregular heartbeat, muscle cramps, headache, restlessness, flushing, sweating and diarrhoea. These signs can take up to 5 days to appear. Take any remaining tablets and this leaflet with you so that the medical staff know exactly what you have taken.

If you forget to take Levothyroxine tablets

If you forget to take a dose, take it as soon as you remember unless it is nearly time for your next dose. Do not take a double dose to make up for a forgotten dose. If you forget to give your child their dose, contact your doctor or pharmacist for further advice.

If you stop taking Levothyroxine tablets

These tablets are for long term use. You may need to take them for the rest of your life. Do not stop taking the tablets unless your doctor has told you to.

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.

Stop taking the tablets and go to hospital at once if you have:

- a rare **allergic reaction** such as swelling of the face, tongue, lips and throat, difficulty breathing, skin rash, severe itching of your skin with raised lumps, joint pain, sensitivity to the sun, general feeling of being unwell. You may need urgent medical attention.

Some patients may experience a severe reaction to high levels of thyroid hormone. This is called a "thyroid crisis", 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 or pharmacist if any of the following side effects continue, get worse or if you notice any other side effects not listed.

Most of the side effects are similar to the symptoms of hyperthyroidism (where the thyroid gland makes too much thyroxine) and are due to your dose of the medicine being too high. They 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.**

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

- headache
- flushing
- high temperature, sweating
- hair loss
- weight loss
- tremor, restlessness, excitability, difficulty sleeping (insomnia)
- increased pressure around the brain in children that is not caused by a tumour or other diseases (benign intracranial hypertension)
- chest pain (angina), pounding, irregular or fast heartbeat
- diarrhoea, vomiting
- muscle cramps, muscle weakness
- deformity of the skull in infants caused by the early closure of joins in the skull bone (craniostenosis)
- growth in children may slow or stop due to changes in bone growth
- irregular periods
- intolerance to heat
- 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 Website: 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 tablets

- Keep this medicine out of the sight and reach of children.
- Do not store above 25°C. Store in the original package. Keep container in the outer carton.
- Do not use this medicine after the expiry date which is stated on the label/carton/bottle. 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 to protect the environment.

6. Contents of the pack and other information

What Levothyroxine tablets contain

- The active substance (the ingredient that makes the tablets work) is anhydrous levothyroxine sodium. Each tablet contains either 50 micrograms or 100 micrograms of the active substance.
- The other ingredients are lactose, magnesium stearate, maize starch, stearic acid and pregelatinised maize starch.

What Levothyroxine tablets look like and contents of the pack

50 microgram tablets are white, circular, biconvex, uncoated tablets impressed "C" on one face and the identifying letters "T" and "A" on either side of a central division line on the reverse.

100 microgram tablets are white, circular, shallow convex, uncoated tablets impressed "C" on one face and the identifying letters "TC" on the reverse.

Pack size: 28 and 1000 tablets.

Marketing Authorisation Holder and Manufacturer

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