MercuryPharma

Package leaflet: Information for the user

Levothyroxine 25 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, 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. WHAT LEVOTHYROXINE TABLETS ARE AND WHAT THEY ARE 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 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)
- if you suffer from an overactive thyroid gland that produces too much thyroid hormone (thyrotoxicosis)
- if you have any condition that affects your adrenal glands (your doctor will be able to advise you if you are not sure).
- if you have the following diseases or conditions:
  - o an acute myocardial infarction,
  - o acute inflammation of the heart muscle (myocarditis),
  - o 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 these apply to you, do not take this medicine and go back to your doctor to discuss your treatment.

Warnings and precautions
Talk to your doctor, pharmacist or nurse before taking Levothyroxine Tablets
- if you have suffered with an under active thyroid gland for a long time
- if you suffer from heart problems including angina, coronary artery disease or high blood pressure. The doctor may require ECG before starting treatment with levothyroxine, as changes induced by hypothyroidism may be confused with evidence of ischaemia (decreased oxygen in a tissue)
- if you have epilepsy (fits). Fits have been rarely reported when starting the treatment with levothyroxine
- if you have a particular hormonal disorder called panhypopituitarism
- if you are being treated for diabetes. The dose of your anti-diabetic medicine may need to be changed as levothyroxine can raise blood sugar levels
- if you 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.

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 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.
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.

Other medicines and Levothyroxine Tablets:
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.

The following may affect the way that levothyroxine works:
- medicines for epilepsy such as **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** (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 Tablets
- **sucralfate** – used to treat and prevent stomach and duodenal ulcers
- **cholestyramine** and **colestipol** – used to treat high level of fat in the blood
- **polystyrene sulphone resin** – used to reduce high levels of potassium in the blood
- medicines containing **iron** that are taken by mouth
- **fibre supplements or medicines containing fibre such as isphagula husk** – these may reduce absorption of levothyroxine; your doctor may need to monitor your thyroid function or adjust your levothyroxine dose
- **rifampicin** – used to treat infections
- **imatinib** – used to treat certain types of cancer
- **beta blockers** such as **atenolol** and **sotalol** – used to treat high blood pressure and heart problems
- **oestrogen containing medicines** for hormone replacement therapy (HRT) and contraception (the 'pill')
- **androgen containing medicines** for male hormone replacement therapy
- **corticosteroids** such as **hydrocortisone** and **prednisolone** – used to treat inflammation
- **amiodarone** – used to treat an irregular heart beat
- **orlistat** – used to treat obesity
- **ritonavir** – used to control HIV and chronic hepatitis C virus
- products containing St. John's Wort (an herbal medicinal product).

The following may be affected by levothyroxine:
- **anticoagulant medicines** to prevent blood clots such as **warfarin**
- medicines to treat diabetes such as **insulin** and **metformin**
- **tricyclic antidepressants** such as **amitriptyline, imipramine** and **dosulepin**
- medicines that stimulate the sympathetic nervous system such as **adrenaline** (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 such as **phenylbutazone** or **aspirin**
- **propanolol** – 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.

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).

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.

Driving and using machines
This medicine should not affect your ability to drive and use machines.

Levothyroxine Tablets contain lactose
This medicine also contains lactose, a sugar. 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 or pharmacist 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 usually take your tablets before breakfast or your first meal of the day.

Adults:
The recommended starting dose is 50 – 100 micrograms every day. Your doctor may increase the dose you take 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:
The recommended starting dose will be no more than 50 micrograms every day. The dose may then 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 of age 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 instead of tablets.

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 -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:
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 – 50 micrograms per day. The dose will then be increased every 2 - 4 weeks depending on how your child responds to the medicine.

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.

If you take more Levothyroxine Tablets than you should:
If you (or someone else) swallow a lot of the tablets at the same time, or you think a child may have swallowed some, contact your nearest hospital casualty 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, diarrhoea, shaking (tremor), difficulty sleeping (insomnia) and very high temperature (hyperpyrexia). These signs can take up to 5 days to appear. Take any remaining tablets and this leaflet with you so that the medical staff knows 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 do so.

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. **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, 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" 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 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 joints in the skull bone (craniostenosis)
- growth in children may slow or stop due to changes in bone growth
- irregular periods
- intolerance to heat 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 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 use this medicine after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.
Do not store above 25°C. Store in the original package in order to protect from light and moisture.
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 substance is anhydrous levothyroxine sodium. Each tablet contains 25 micrograms of anhydrous levothyroxine sodium.
- The other ingredients are sodium citrate, lactose, maize starch, acacia powder and magnesium stearate.

What Levothyroxine Tablets look like and contents of the pack:
Each tablet is engraved on one side with LT and engraved on the other with 25.
They are packed in a blister pack of 28, 56 or 112 tablets and polypropylene containers of 28, 56, 100, 112, 500 or 1000 tablets.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
Marketing Authorisation Holder:
Mercury Pharmaceuticals Ltd., Dashwood House, 69 Old Broad Street, London, EC2M 1QS, United Kingdom

Manufacturer:
Custom Pharmaceuticals Ltd., Tecore House, Conway Street, Hove, East Sussex, BN3 3LW, UK

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AW-LF-0000517 (v0.6)
LFLT00014

MercuryPharma

AMS Component No.:	**AW-LF-0000517 (v0.6)**
Product Description:	**Levothyroxine 25 mcg Tab UK 28 Tab,Levothyroxine 25 mcg Tab UK 500 Tab**
Component:	Leaflet
Product Code:	100071,100057
Country:	UK
Vendor Name:	Custom Pharma Services
Proof Number:	**0.6**

Dimension:	297 x 190 mm
Commodity No.:	LFLT00014
Pharma Code:	1295
Print Colours:	Black
Non-Print Colours:	Cutter
Min. Font Size:	8.5 pt