1. What Levothyroxine Tablets are and what they are used for

The active ingredient in Levothyroxine Tablets is levothyroxine sodium which is the same as thyroxine, a hormone produced by the thyroid gland.

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, and when the thyroid gland does not produce enough thyroxine (a condition known as hypothyroidism), many of the body’s functions may be affected.

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

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.

If you start taking the medicine your doctor will want you to have regular blood tests to see how well the medicine is working.

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 (linked to circumcisional 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 any other medicines. This includes over the counter medicines, herbal remedies and vitamin supplements. Many medicines affect levothyroxine gland functions. The effects of other drugs may also be affected by levothyroxine.

If you are taking or have recently taken any of the following medicines, you must inform your doctor and/or the laboratory personnel when you are about to undergo laboratory testing to monitor your thyroid hormone levels. Blood tests may affect your laboratory tests (see warnings and precautions).

- corticosteroids such as hydrocortisone and prednisolone – used to treat inflammation
- amiodarone – used to treat an irregular heart beat
- ritonavir – used to control HIV and chronic hepatitis C virus
- estilbestrol – used to treat obesity
- products containing St. John’s Wort (a herbal medicinal product)
- products that stimulate the sympathetic nervous system such as adrenaline (used to treat severe allergic reactions) or phentermine (is a decongestant found in many cold and flu treatments)
- medicines that stimulate the sympathetic nervous system such as phentolamine or aspirin
- products containing St. John’s Wort (a herbal medicinal product)

These medicines affect the way levothyroxine works. The effects of other drugs may also be affected by levothyroxine.

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 blood can be checked for levels of thyroid hormones. 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 take more or less than the dose without special advice from your doctor, especially when taken together with other medicines for weight reduction.

Blood tests

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Changes in detail:

- Text update to sections 4.3, 4.4 and 4.6

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- Text update to sections 4.3, 4.4 and 4.6

Before you take Levothyroxine Tablets

Before you start taking Levothyroxine Tablets you should tell your doctor if you:

- have a particular hormonal disorder called panhypopituitarism
- have diabetes. The dose of your antidiabetic medicines may need to be changed as levothyroxine can raise blood sugar levels.
- have an overactive thyroid gland that produces too much thyroxine (thyrotoxicosis)
- suffer from an overactive thyroid gland that produces too much thyroxine (thyrotoxicosis)
- are taking or have recently taken medicines against an overactive thyroid gland (antithyroid drugs).
- have heart disease (for example, angina, ischaemia (decreased oxygen in a tissue), heart failure, or heart valve disease)
- have high blood pressure or if you have diabetes. The doctor may require blood pressure to be regularly monitored when levothyroxine treatment is started in very low birth weight preterm neonates because rapid fall in blood pressure (linked to circumcisional collapse) may occur.

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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.

Leflothyroxine Tablets contain lactose and sucrose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product, as it contains lactose and sucrose. You should not take Leflothyroxine Tablets if you have hereditary problems such as galactose-intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption.

3. How to take Leflothyroxine 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 daily. Your doctor may increase the dose you take every 1 – 4 weeks. 50 micrograms until your thyroid 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 thyroid 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 then be increased by 25 micrograms every 4 weeks until your thyroid levels are correct. Your final daily dose will usually be between 50 – 200 micrograms daily.

Use in children:

For children, your doctor is likely to prescribe Leflothyroxine Oral Solution instead of tablets.

Congenital hypothyroidism in infants:

This is a condition where your baby’s thyroid gland does not produce enough thyroid hormone. The starting dose is 10 – 15 micrograms/kg body weight 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 hypothyroidism (a condition where the thyroid gland produces too much thyroid hormone). The dose will then be reduced slightly.

If you take more Leflothyroxine Tablets than you should

If you take more tablets than you should or if you take 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, nausea, vomiting, 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 doctor can check exactly what you have taken.

If you forget to take Leflothyroxine Tablets

If you forget to take a dose, take another as soon as you remember unless it is almost 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 Leflothyroxine 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 severe 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:

- Raised levels of thyroid hormones:
  - growth in children may delay 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 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 Leflothyroxine 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 label. The expiry date refers to the last day of that month. Do not use this medicine if you notice signs of deterioration such as discolouration.

Do not store above 25°C.

Store in the original container or package in order to protect from light and moisture. Do not transfer the tablets to another container. 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 Leflothyroxine Tablets contain

The active substance is levothyroxine sodium. Each tablet contains 27.8 micrograms of levothyroxine sodium equivalent to 25 micrograms of endogenous levothyroxine. The other ingredients are lactose, sucrose (fine powder), maize starch, magnesium stearate.

What Leflothyroxine Tablets look like and contents of the pack

Leflothyroxine 25 micrograms Tablets are white, circular, curved tablets marked ‘25’ on one face and ‘5’ on the other face. Leflothyroxine 25 micrograms Tablets are available in polyporous or polyeutathane plastic container and blister strip contains 28 tablets.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder: Wockhardt UK Ltd, Ash Road North, Wrexham, LL13 9UF, UK.

Manufacturer: CP Pharmaceuticals Ltd, Ash Road North, Wrexham, LL13 9UF, UK.

Other formats:

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge: 0800 198 5005 (UK Only) or email: hq.webhelp@wckard.co.uk Please be ready to give the following information:

Product name Reference number

Leflothyroxine 25 Micrograms Tablets 29853/0130

This is a service provided by the Royal National Institute of Blind People.

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