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. 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 sodium 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 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 underactive thyroid gland for a long time
• if you suffer from heart problems including angina, coronary artery disease, or high blood pressure
• if you are being treated for diabetes. The dose of your antidiabetic medicine may need to be changed as levothyroxine can raise blood sugar levels
• if you are over 50 years of age.

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.

3. How to take Levothyroxine Tablets

Always take this medicine exactly as your doctor or pharmacist has told you. You may not always use the same dose of medicine. If you are not sure how much you need to take, you should talk to your doctor or pharmacist.

• Do not take this medicine if you are pregnant or breastfeeding. Your doctor will advise you whether you should continue treatment with levothyroxine whilst you are pregnant, particularly in the first three months of your pregnancy.

• If you become pregnant whilst you are taking levothyroxine tablets, you should inform your doctor.

• If you are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

• Levothyroxine tablets should not affect your ability to drive and use machines.

• If you have any doubts about whether you should take this medicine then discuss matters with your doctor before taking it.

4. Possible side effects

The following side effects may occur when you first start taking Levothyroxine tablets. They usually only occur while you are increasing the dose and may include:

• tingling in hands and feet
• nausea
• tiredness
• headache
• loss of appetite

Side effects that may occur while you are on this medicine include:

• loss of weight
• palpitations
• nervousness
• tremor
• anxiety
• depression
• irritability

If any of these side effects become troublesome or persist, tell your doctor.

If you experience any of the following side effects tell your doctor:

• skin rashes
• fits or unconsciousness
• confusion
• blurred vision
• deafness

5. How to store Levothyroxine Tablets

• do not store above 30°C
• keep in the original packaging

6. Contents of the pack and other information

What is in this leaflet:

• information about your medicine
• instructions about how to take your medicine
• warnings about possible side effects

For full details see Summary of Product Characteristics (SMPC).

Package Leaflet: Information for the user

Levothyroxine 25mcg - 28 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 found further questions, please 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.

The name of your medicine is Levothyroxine 25 Micrograms Tablets. In the rest of this leaflet it is called Levothyroxine Tablets.

Neutral code not required on the leaflet artworks.

Package Leaflet: Information for the user

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 further questions, please 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.

The name of your medicine is Levothyroxine Sodium Tablets. In the rest of this leaflet it is called Levothyroxine Tablets.

Neutral code not required on the leaflet artworks.

Package Leaflet: Information for the user

Levothyroxine Sodium 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 further questions, please 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.

The name of your medicine is Levothyroxine Sodium Tablets. In the rest of this leaflet it is called Levothyroxine Tablets.

Neutral code not required on the leaflet artworks.
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:
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 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 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 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 or doctor immediately, or take 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 knows exactly what you have taken.

You should not take more tablets than prescribed, even if you think you need to, unless your doctor tells 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 hypothyroidism (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
• weight loss
• fever, 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 (craniosenosis)
• 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 www.mhra.gov.uk/yellowcard.

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 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 Levothyroxine Tablets contain
The active substance is levothyroxine sodium. Each tablet contains 27.8 micrograms of levothyroxine sodium.

What Levothyroxine Tablets look like and contents of the pack
Levothyroxine 25 micrograms Tablets are white, circular, curved tablets equivalent to 25 micrograms of anhydrous levothyroxine sodium.

The other ingredients are lactose, sucrose (fine powder), maize starch, magnesium stearate.

Levothyroxine 25 micrograms Tablets are available in polypropylene or polyethylene (plastic) containers or blister strip packs of 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.

This is a service provided by the Royal National Institute of Blind People. This leaflet was last revised in 06/2017.

Levothyroxine 25 Micrograms Tablets 29831/0130
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The other ingredients are lactose, sucrose (fine powder), maize starch, magnesium stearate.

Levothyroxine 25 micrograms Tablets are available in polypropylene or polyethylene (plastic) containers or blister strip packs of 28 tablets.

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