**Levothyroxine 50 micrograms and 100 micrograms tablets**

Read all of this leaflet carefully before you start taking this medicine. 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

- Thyroid hormone is produced by the thyroid gland. Levothyroxine is used to replace thyroid hormone 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 ‘Taking other medicines’). 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 must not take levothyroxine if you:
  - are allergic to levothyroxine or to any of the other ingredients (see section 4).
  - suffer from an overactive thyroid gland that produces too much thyroid hormone (thyrotoxicosis).
  - have any condition that affects your adrenal glands (your doctor will be able to advise you if you are not sure).
  - have any disease that affects your blood pressure.
  - have any disease that affects your heart (your doctor will be able to advise you if you are not sure).

- Before you start taking levothyroxine
  - Take levothyroxine in the morning on an empty stomach.
  - Take levothyroxine tablets with water.
  - Take levothyroxine tablets just before you eat breakfast.
  - Take levothyroxine tablets at the same time each day, with food if you find it causes you tummy ache.
  - Keep this leaflet. You may need to read it again.

**Taking other medicines**

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

- Levothyroxine tablets are used to replace the thyroid 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 thyroxine your thyroid gland is making.

**Important information about some of the ingredients**

- amiodarone – used to treat an irregular heart beat.
- ritonavir – used to control HIV and chronic hepatitis C virus.

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 amitryptiline, imipramine and dosulepin.
- medicines that stimulate the sympathetic nervous system such as 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 such as phenylbutazone or aspirin.

**Pregnancy and breast-feeding**

If you have been told by your doctor that you are pregnant or planning to become pregnant or are breast-feeding, tell your doctor or anaesthetist that you are taking levothyroxine.

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  - medicines to treat diabetes such as insulin and metformin.
  - tricyclic antidepressants such as amitryptiline, imipramine and dosulepin.
  - medicines that stimulate the sympathetic nervous system such as adrenaline (epinephrine - used to treat severe allergic reactions) or phenylephrine (a decongestant found in many cold and flu treatments).
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**How to take**

You may be taking this medicine for the rest of your life. Always take Levothyroxine tablets exactly as your doctor has told you. If you are not sure, check with your doctor or pharmacist. 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 usual 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 usual 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 with heart problems:**

The 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.

**Giving these tablets to children:**

The dose for children depends on their age, weight and the condition being treated. Your child will be monitored to make sure he/she gets the right dose. You should give them their medicine at least half an hour before breakfast or their first meal of the day. If necessary, the tablets can be dissolved in 10-15ml of water and given with some more liquid (5-10ml). The dissolved tablets should be taken straight away. Do not keep the solution to give to your child later.

**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 to 50 micrograms a day. The dose should be increased gradually every 2 to 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 thyroxine). The dose will then be reduced slightly. In children over 1 year, initially 2.5-5 micrograms per kg of bodyweight a day should be taken.

If you take more Levothyroxine 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 any contact your nearest hospital casualty department or tell your doctor immediately. Signs of an overdose may include: fever, chest pain (angina), nausea or irregular heartbeat, muscle cramps, headache, restlessness, flushing, sweating and diarrhoea. These signs can take up to 5 days to appear.

If you forget to take Levothyroxine

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. If you forget to give your child their dose, contact your doctor or pharmacist for further advice.

**Stopping the 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.

**Possible side effects**

Some people may have side-effects when taking this medicine.

**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.

- Headache
- Flushing
- High temperature; sweating
- 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 (anginal), 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 (craniosynthesis)
- 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 at: www.mhra.gov.uk/yellowcard or search 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.

**How to store**

- Keep out of the sight and reach of children.
- Do not store above 25ºC. Store in the original package. Keep container in the outer carton.
- Do not use Levothyroxine tablets after the expiry date stated on the label or carton bottle. The expiry date refers to the last day of that month.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

**Further information**

**What Levothyroxine tablets contain**

- The active substance (the ingredient that makes the tablets work) is L-thyroxine 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.

100 microgram tablets are white, circular, shallow convex, uncoated tablets.

Pack size is 28 and 1000 tablets.

**Marketing Authorisation Holder and Manufacturer**

Accord Barnstaple, EX32 8NS, UK.

This leaflet was last revised in August 2019.

If you would like a leaflet with larger text, please contact 01271 385257.

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**Levothyroxine Sodium Tablets PIL - UK**

**Item number:** BBBA5400

**Originator:** G. Worth

**Origination Date:** 04/07/2019

**Revision Date:** 07/08/2019

**Originator:** G. Worth

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**Technical Approval Date:**

**Date sent:** n/a

**Date received:** n/a

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**Supplier:** Accord Barnstaple

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**Pack size:** 28 and 1000 tablets

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**Pharmcode:** 4166

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**Date Sent:** 28/06/19

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**Technically Approved**