

Package leaflet: Information for the patient

Levothyroxine 25micrograms/5ml, 50micrograms /5ml, and 100micrograms /5ml
Oral Solution

Levothyroxine sodium

(referred to as Levothyroxine Oral Solution in the remainder of this leaflet)

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 of the side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

What is in this leaflet:

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

1. What Levothyroxine Oral Solution is and what it is used for

Levothyroxine Oral Solution is used to treat hypothyroidism, a condition in which the thyroid gland is underactive and so does not make enough thyroxine for the body's needs.

Levothyroxine Oral Solution is also used to treat thyroid cancer and diffuse non-toxic goitre or Hashimoto's thyroiditis, conditions in which the thyroid gland becomes enlarged causing a swelling in the front of the neck.

2. What you need to know before you take Levothyroxine Oral Solution

Do not take Levothyroxine Oral Solution:

- if you are allergic to levothyroxine or any of the other ingredients of this medicine (listed in section 6)
- if you suffer from adrenal insufficiency and you do not have adequate corticosteroid cover
- if you have a heart attack (acute myocardial infarction), inflammation of the heart muscle (acute myocarditis) or inflammation of the sac surrounding the heart (acute pancarditis)
- if you are pregnant do not take this medicine in combination with medicines to treat hyperthyroidism (see the section on Pregnancy and breast-feeding).

Warnings and precautions

Talk to your doctor before taking Levothyroxine Oral solution:

- if you have heart disease, problems with your circulation or high blood pressure

- if you are suffering from an overactive thyroid gland (hyperthyroidism), an underactive adrenal gland, diabetes, or have had an underactive thyroid gland for some time.
- if you suffer from a liver or kidney disease, do not take this medicine unless recommended by your doctor. Your doctor may carry out extra checks while you are taking this medicine.

Children

Levothyroxine Oral Solution is not suitable for children under five years of age due to the amount of the ingredient propylene glycol in the medicine (see section 6 and “Levothyroxine Oral Solution contains” in section 2 of this leaflet).

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 Oral Solution

Tell your doctor or pharmacist if you are taking, have recently taken or might use any other medicines.

Levothyroxine can interfere with the action of some other drugs and some drugs can have an effect on Levothyroxine. In particular tell your doctor or pharmacist if you take the following drugs:

- medication to stop your blood clotting (for example warfarin)
- medication for depression (for example sertraline, imipramine, amitriptyline)
- medication for epilepsy (for example phenytoin, phenobarbital, carbamazepine)
- medication for diabetes
- rifampicin (for infections, particularly tuberculosis),
- digoxin or amiodarone (for your heart),
- propranolol (for high blood pressure), lovastatin (for high cholesterol levels) or phenylbutazone or aspirin (anti-inflammatory drugs)
- oestrogen, oestrogen containing products and oral contraceptives, androgens or corticosteroids
- sucralfate, cimetidine or aluminium hydroxide for a stomach ulcer
- colestyramine to lower your cholesterol levels, or calcium carbonate or iron supplements.
- chloroquine or proguanil for the prevention of malaria
- protease inhibitors (for example ritonavir, indinavir and lopinavir) used to treat HIV.
- sevelamer (used to treat high levels of phosphate in the blood in patients with renal failure)
- tyrosine kinase inhibitors (for example imatinib and sunitinib) used to treat cancer
- propylthiouracil (used to treat hyperthyroidism)
- beta-agonists, used to treat cardiac arrest and low blood pressure (for example, dobutamine and isoprenaline)
- glucocorticoids (steroid hormones used to treat adrenal insufficiency and other diseases)
- soy-containing products (these can decrease absorption of levothyroxine)

Let your doctor or pharmacist know. Levothyroxine Oral Solution can be taken with these medicines but not at the same time.

If you go into hospital to have an operation, tell the anaesthetist or the medical staff that you are taking Levothyroxine Oral Solution. It may react with an anaesthetic (ketamine) which you may be given before an operation.

Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Levothyroxine Oral Solution with food, drink and alcohol

You should take your Levothyroxine Oral Solution on an empty stomach, usually before breakfast.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.

If you are pregnant or breast-feeding, do not take this medicine unless recommended by your doctor. Your doctor may carry out extra checks while you are taking this medicine.

Driving and using machines

Your medicine is unlikely to affect your ability to drive or to operate machinery.

Levothyroxine Oral Solution contains sodium methyl parahydroxybenzoate, sodium propyl parahydroxybenzoate, propylene glycol and maltitol

- Levothyroxine Oral Solution contains maltitol. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.
- Levothyroxine Oral Solution contains sodium methyl parahydroxybenzoate (E219) and sodium propyl parahydroxybenzoate (E217) which may cause allergic reactions (possibly delayed).
- Levothyroxine 25micrograms/5ml and 50micrograms/5ml Oral Solution contains 100mg propylene glycol in each 5ml of oral solution, which is equivalent to 20mg/ml.
- Levothyroxine 100micrograms/5ml Oral Solution contains 150mg propylene glycol in each 5ml of oral solution, which is equivalent to 30mg/ml.

3. How to take Levothyroxine Oral solution

Always take this medicine exactly as your doctor has told you. Check with your doctor if you are not sure. Levothyroxine Oral Solution should be swallowed. Your doctor will have decided what dose you should take each day depending on your condition. Your doctor will take blood samples at regular intervals to monitor your response to treatment. If you are switching from the oral solution to the tablet version of levothyroxine or from the tablet version to the oral solution of levothyroxine your doctor will monitor you more closely.

Administration

You should take your Levothyroxine Oral Solution on an empty stomach, usually before breakfast.

For hypothyroidism the recommended daily dosages are:

Adults and children over 12 years:

The starting dose is 50 to 100 micrograms a day, increasing by 25 to 50 micrograms every 3-4 weeks, until you are taking the right amount for your condition. The usual maintenance dose is 100 to 200 micrograms daily.

For diffuse non toxic goitre or Hashimoto's thyroiditis the recommended dose is 50-200 micrograms per day.

For the treatment of thyroid cancer the recommended dose is 150-300 micrograms per day.

Children between five and 12 years:

The dose for children depends on their age or weight. They will be monitored to make sure they get the right dose. 5 micrograms per kg bodyweight may be used as a guide.

Children under five years:

Levothyroxine Oral Solution is not suitable for children under five years of age due to the amount of the ingredient propylene glycol in the medicine (see section 6 and "Levothyroxine Oral Solution contains" in section 2 of this leaflet).

Older patients (over 50 years of age):

The starting dose is 12.5 micrograms a day, increasing by 12.5 micrograms every 2 weeks until the correct dose is obtained. The usual final dose is between 50 and 200 micrograms daily. This dose also applies to patients with severe hypothyroidism, and to those with heart disease.

The duration of treatment is usually for life if you are being treated for hypothyroidism, non toxic diffuse goitre or Hashimoto's thyroiditis.

Please use the oral syringe provided to deliver your specific dose (see instructions below). The syringe can be used to measure your dose by drawing the liquid to the correct mark on the syringe. For example if your dose is 50 micrograms daily then the corresponding volume would be:

For the 25 microgram/5ml strength – 2 x 5ml (10ml in total)

For the 50 microgram/5ml strength – 5ml

For the 100 microgram/5ml strength – 2.5 ml

How to use the oral syringe:

1. Shake the bottle well, making sure the cap is firmly on the bottle.
2. Remove the cap. Note : Keep the cap nearby to close the bottle after each use.
3. Push the plastic adapter into the neck of the bottle. Note: The adapter must always stay in the bottle.
4. Take the syringe and check the plunger is fully down.
5. Keep the bottle upright and insert the oral syringe firmly into the plastic adapter
6. Turn the whole bottle with the syringe upside down.
7. Slowly pull the plunger down fully so that the syringe fills with medicine. Push the plunger back up completely to expel any large air bubbles that may be trapped inside the oral syringe.
8. Then pull the plunger slowly back to the volume you need for your dose.
9. Turn the whole bottle with the syringe the right way up and take the syringe out of the bottle.
10. The dose of medicine can now be swallowed directly from the oral syringe. Please ensure that you are sitting upright and the plunger must be pushed slowly to allow you to swallow the dose.
11. Replace the child resistant cap after use, leaving the adapter in place.
12. Cleaning: After use, wipe the outside of the syringe with a dry, clean tissue.

If you take more Levothyroxine Oral Solution than you should

If you accidentally take an overdose of your medicine, either call your doctor straight away, or go to your nearest hospital casualty department. Symptoms of overdose include fever, irregular heart beat, muscle cramps, headache, restlessness, flushing, sweating or diarrhoea. Always take any remaining medicine, the container and the label with you, so that the medicine can be identified.

If you forget to take Levothyroxine Oral Solution

If you forget to take your medicine, take your dose when you remember and then take your next dose at the usual time. Do not take a double dose to make up for a forgotten dose. If you have forgotten several doses tell your doctor when you have your next check-up or blood test.

If you stop taking Levothyroxine Oral Solution

It can be dangerous to stop taking your medicine without your doctor's advice.

If you are worried, ask your doctor or pharmacist for advice.

If you have any further questions on the use of this medicine, ask your doctor

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. These usually only happen if the dose you are taking is too high.

If any of the following happen, stop taking Levothyroxine Oral Solution and tell your doctor immediately or go to the casualty department at your nearest hospital

- Swelling of the hands, feet, ankles, face, lips, mouth, or throat which may cause difficulty in swallowing or breathing
- Hives
- Fainting
- Yellowing of the skin and eyes also called jaundice

These are all very serious side effects. If you have them, you may have a serious allergic reaction to Levothyroxine Oral Solution. You may need urgent medical attention or hospitalisation. All of these very serious side effects are very rare.

Tell your doctor if you notice any of the following:

Fast or irregular heart beats, palpitations, chest pain, muscle cramps or weakness, headache, restlessness, excitability, flushing, sweating, diarrhoea, vomiting, fever, menstruation problems, tremor, sleeplessness, heat intolerance and excessive weight loss. Rash, itching and puffiness may also occur.

Very rarely, if far too much Levothyroxine Oral Solution has been taken in one go or over many years, the heart may fail and coma and death have been reported. If you feel unwell in any other way, tell your doctor as soon as you can.

Children may have some hair loss at the beginning of treatment, however this is usually temporary and the hair returns.

Do not be alarmed by this list of possible events. You may not have any of them.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRAs Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517; Website: www.hpra.ie; e-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Levothyroxine Oral Solution

Keep this medicine out of sight and reach of children.

Do not use this medicine after the expiry date, which is stated on the carton. The expiry date refers to the last day of that month. The solution should not be used for longer than three months after the bottle has been opened.

Do not store above 25°C

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 Oral Solution contains:

The active substance is levothyroxine sodium. Each 5ml of oral solution contains 25micrograms, 50micrograms or 100micrograms of levothyroxine sodium.

It also contains the following inactive ingredients:

citric acid monohydrate, sodium methyl parahydroxybenzoate (E219), sodium propyl parahydroxybenzoate, propylene glycol, maltitol liquid, sodium hydroxide, hydrochloric acid, sodium hydroxide and purified water.

What Levothyroxine Oral Solution looks like and contents of the pack

Levothyroxine Oral Solution is a clear colourless liquid. Each amber glass bottle contains either 100ml or 150ml of oral solution. A plastic dosing syringe (pipette) is also included to help measure the dose.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing authorisation holder: Wockhardt UK Ltd, Ash Road North, Wrexham, LL13 9UF.

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

This Medicinal Product is authorised in the Member States under the following names:

UK and Ireland:

Levothyroxine 25 micrograms/5ml Oral Solution

Levothyroxine 50 micrograms/5ml Oral Solution

Levothyroxine 100 micrograms/5ml Oral Solution

Other sources of information:

To listen to or request a copy of this leaflet in Braille, large print or audio, please call: +44 1978 661 261. Please be ready to give the following information:

Product name	Reference number
Levothyroxine 25 micrograms/5ml Oral Solution	1339/44/2
Levothyroxine 50 micrograms/5ml Oral Solution	1339/44/3
Levothyroxine 100 micrograms/5ml Oral Solution	1339/44/4

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