

Package leaflet: Information for the user
Levothyroxine 25 micrograms / 50 micrograms and
100 micrograms per 5ml Oral Solution
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 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
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1. What levothyroxine oral solution is and what it is used for

Levothyroxine Oral Solution contains the active ingredient levothyroxine sodium. It 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, pharmacist or nurse 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 have epilepsy (fits). Fits have been rarely reported when starting the treatment with levothyroxine
- if you are in elderly age group

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.

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. However, you must not change the dose or stop the dose without talking to your doctor first.

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 Oral Solution)

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.

Other medicines and Levothyroxine Oral Solution

Tell your doctor or pharmacist if you are taking, have recently taken or might take 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-sympatholytics (used to treat cardiac arrest and low blood pressure)
- Glucocorticoids (steroid hormones used to treat adrenal insufficiency and other diseases)
- Soy-containing products (these can decrease absorption of levothyroxine)
- Orlistat (used to treat obesity)
- Ritonavir (used to control HIV and chronic hepatitis C virus)
- products containing St. John's Wort (a herbal medicinal product)
- Proton pump inhibitors:

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 Oral Solution.

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.

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. If you are pregnant while taking this medicine your doctor will monitor you closely.

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 (E219) which may cause allergic reactions (possibly delayed)
- Glycerol which may cause headache, stomach upset and diarrhoea

Information on sodium content:

This medicine contains less than 1 mmol sodium (23 mg) per 5 ml, that is to say essentially ‘sodium-free’.

3. How to take levothyroxine oral solution

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist 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.

The recommended dose is
For hypothyroidism:

Adults and children over 12 years:

The recommended 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.

Older patients (over 50 years of age):

The recommended 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.

Use in children under 12 years:

The dose for children depends on their age or weight. They will be monitored to make sure they get the right dose. The following is a guide:

Age	Micrograms per kg bodyweight
Up to 1 month	5-10 micrograms

Over 1 month	5 micrograms
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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, diarrhoea shaking (tremor), difficulty sleeping (insomnia) and very high temperature (hyperpyrexia). 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 are worried, ask your doctor or pharmacist for advice.

If you stop taking Levothyroxine Oral Solution

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

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. These usually only happens 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

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; yellowing of the skin and eyes also called jaundice; confusion; fits, coma.

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 side effects:

Not known (frequency cannot be estimated from the available data)

- fast or irregular heartbeats
- palpitations
- chest pain
- pain in joint
- muscle cramps or weakness
- headache
- restlessness
- excitability
- flushing
- sweating
- diarrhoea
- vomiting
- fever
- feeling unwell
- menstruation problems
- tremor
- sleeplessness
- weight loss

- rash
- itching
- puffiness
- hair loss.

Additional side effects in children and adolescents

- heat intolerance
- high blood pressure in the cranium
- hair loss at beginning of the treatment (temporary)
- deformity of the skull in infants caused by the early closure of joins in the skull bone (craniosostenosis)
- growth in children may slow or stop due to changes in bone growth

If you feel unwell in any other way, tell your doctor as soon as you can.

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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly. (See details below)

HPRA Pharmacovigilance

Website: www.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 the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label and 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.

Dispose of any remaining medicine 8 weeks after opening.

Levothyroxine Oral Solution is odourless. Do not use this medicine if you notice that the solution has an odour. Talk to your pharmacist.

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 Oral Solution contains

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

- The other ingredients are glycerol, citric acid monohydrate, sodium methyl parahydroxybenzoate (E219), 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 bottle contains 100ml of oral solution. A plastic dosing syringe (pipette) is also included to help measure the dose.

Marketing Authorisation Holder

Amdipharm Limited

Temple Chambers, 3 Burlington Road, Dublin 4, Ireland

Manufacturer

Delpharm Bladel B.V.

Industrieweg 1, BLADEL, 5531 AD,

Netherlands

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