

Package leaflet: Information for the user

Levothyroxine 25 micrograms /5ml Oral Solution

Levothyroxine 50 microgram/5ml Oral Solution

Levothyroxine 100 micrograms/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 or pharmacist.
- 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 or pharmacist. 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
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 (hypersensitive) to levothyroxine or any of the other ingredients of this medicine (listed in section 6)
- you suffer from adrenal insufficiency and you do not have adequate corticosteroid cover
- you have a heart attack (acute myocardial infarction), inflammation of the heart muscle (acute myocarditis) or acute inflammation of all layers of the heart (acute pancarditis)
- 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
- you are suffering from an overactive thyroid gland (hyperthyroidism), an underactive adrenal gland, diabetes, or have had an underactive thyroid gland for some time.

Other medicines and Levothyroxine Oral Solution

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

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).

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

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

If you are due to have surgery

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.

Levothyroxine Oral Solution with food, drink and alcohol

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

Children and adolescents

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.

Pregnancy and breast-feeding

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

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, sodium propyl parahydroxybenzoate, glycerol and sodium.

This medicine contains sodium propyl parahydroxybenzoate (E217) and sodium methyl parahydroxybenzoate (E219), ("parabens"). May cause allergic reactions (possibly delayed).

Also contains Glycerol which may cause headache, stomach upset and diarrhoea.

This medicine contains 21.7 mg sodium (main component of cooking/table salt) in each 5 ml. This is equivalent to 1.1% of the recommended maximum daily dietary intake of sodium for an adult.

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 usual 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. This dose also applies to patients with severe hypothyroidism and to those with heart disease.

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

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.

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

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

Method of administration:

Your doctor, pharmacist or nurse will show you how to administer this medicine. The box containing this medicine will contain a 10 ml graduated dosing pipette and a dosing adaptor.



10 ml pipette, each numbered section is 1 ml and the smaller increments are 0.25 ml.

Levothyroxine 25 micrograms/5ml Oral Solution: 1 ml is equivalent to 5 micrograms and 0.25 ml is equivalent to 1.25 micrograms

Levothyroxine 50 micrograms/5ml Oral Solution: 1 ml is equivalent to 10 micrograms and 0.25 ml is equivalent to 2.5 micrograms

Levothyroxine 100 micrograms/5ml Oral Solution: 1 ml is equivalent to 20 micrograms and 0.25 ml is equivalent to 5 micrograms

Instructions are provided below for using the dosing pipette. If you have any questions about the dose you should use or how to use the pipette, you should ask your doctor or pharmacist.

Instructions for use:

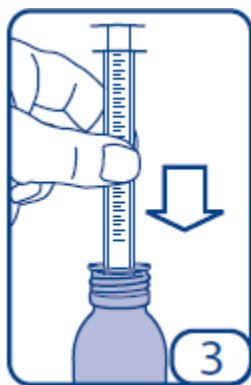
- Open the bottle: press the cap and turn it anticlockwise (figure 1)



- On using the bottle for the first time, the pipette adaptor must be fitted. It will then stay in place for future doses. Holding the bottle, take the plastic pipette adaptor from the box and insert the adaptor into the bottle neck (figure 2). Ensure it is well fixed.



- Take the pipette and put it in the adaptor opening (figure 3).



- Hold the pipette in place and turn the bottle upside down. Fill the pipette with a small amount of the suspension by pulling the piston down (figure 4), then push the piston up in order to remove any possible air.
- Still holding the pipette in place, pull the piston down to the graduation mark corresponding to the quantity in millilitres (ml) prescribed by your doctor (figure 4).



- Turn the bottle the right way up. Remove the pipette from the adaptor (figure 5).



- Administer the contents of the pipette into the mouth by pushing the piston to the bottom of the pipette and ensure the medicine is swallowed.

Do not remove the adaptor from the bottle neck, it is intended to stay in place. Close the bottle with the plastic screw cap.

Wash the pipette with warm water. Dry it with a clean paper towel and replace into the box with your medicine.

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 heartbeat, 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, pharmacist or nurse.

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.

This medicine contains parahydroxybenzoates (“parabens”). These may cause allergic reactions (possibly delayed).

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 heartbeat
- palpitations
- chest pain
- muscle cramps or weakness
- headache
- restlessness
- excitability
- flushing
- sweating
- diarrhoea
- vomiting
- fever
- menstruation (period) problems
- shaking known as tremors
- sleeplessness
- excessive weight loss
- rash
- itching
- puffiness.

The frequency of these possible side-effects is not known (frequency cannot be estimated from the available data).

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.

Additional side effects in children and adolescents

High blood pressure in your head, heat intolerance, hair loss at the beginning of the treatment (this is usually temporary and the hair returns).

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 or your child gets 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 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 store above 25 °C.

Do not freeze.

Dispose of any remaining medicine 28 days after first opening.

Do not use this medicine after the expiry date which is stated on the label and carton after EXP (month, year). The expiry date refers to the last day of that month.

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 to 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 25 micrograms.
- Each 5 ml of oral solution contains levothyroxine equivalent to levothyroxine sodium 50 micrograms .
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- Each 5 ml of oral solution contains levothyroxine equivalent to levothyroxine sodium 100 micrograms.
- The other ingredients are glycerol, citric acid monohydrate, Sodium methyl parahydroxybenzoate (E219), Sodium propyl parahydroxybenzoate (E217), and purified water.

What Levothyroxine Oral Solution looks like and contents of the pack

Levothyroxine Oral Solution is a clear, colourless solution supplied in 100 ml amber glass bottles. Each pack contains one bottle of solution, a 10 ml dosing pipette and a bottle/pipette adaptor to fit onto the bottle when measuring the dose.

Marketing Authorisation Holder and Manufacturer:

Marketing Authorisation Holder

JensonR+ (Ireland) Limited,
104, Lower Baggot Street,
Dublin 2
Ireland

Manufacturer

BCM Limited
1 Thane Road West,

Nottingham
NG2 3AA,
United Kingdom

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