

Consumer Medicine Information

LEVOTHYROXINE

Levothyroxine tablets 50 micrograms and 100 micrograms

What is in this leaflet

Please read this leaflet carefully before you start taking Levothyroxine tablets.

This leaflet answers some common questions about Levothyroxine tablets. It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the expected benefits of you taking Levothyroxine tablets against the risks this medicine could have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with your medicine. You may need to read it again.

What Levothyroxine tablets are used for

Levothyroxine tablets contain the active ingredient levothyroxine. Levothyroxine belongs to a small group of medicines called thyroid hormones, which work by replacing the body's low levels of thyroxine.

Levothyroxine tablets are used to treat hypothyroidism, a disease in which the thyroid gland is underactive and does not produce enough thyroxine, a hormone, which is important for controlling your metabolism. Symptoms of hypothyroidism include tiredness, muscle weakness, cramps, feeling the cold, a slow heart rate, dry and flaky skin, hair loss, a deep husky voice and weight gain.

Levothyroxine tablets are also used to treat children born with hypothyroidism (congenital), those who develop hypothyroidism in the first year of life (neonatal) and children who have hypothyroidism as part of juvenile myxoedema, a condition in which the amount of thyroxine produced by the body is low.

Ask your doctor if you have any questions about why Levothyroxine tablets have been prescribed for you.

Your doctor may have prescribed Levothyroxine tablets for another reason.

This medicine is available only with a doctor's prescription.

Before you take Levothyroxine tablets

When you must not take it

Do not take Levothyroxine tablets if:

- you have had an allergic reaction before to any of the ingredients in Levothyroxine tablets listed at the end of this leaflet
- you have thyrotoxicosis, a disease in which the thyroid gland is overactive and produces too much thyroxine
- the packaging is torn or shows signs of interference, or the tablets look damaged or discoloured.

Do not take it after the expiry date printed on the pack.

If you take it after the expiry date has passed, it may not work as well. If the pharmacist has repacked the medicine for you, there may not be an expiry date on the pack.

If you are not sure whether you should start taking Levothyroxine tablets, talk to your doctor.

Before you start to take it

Tell your doctor if:

- you are allergic to any other medicines, foods, dyes or preservatives
- you have any other health problems, especially:
 - diabetes
 - heart disease
 - high blood pressure
 - osteoporosis
 - underactive adrenal glands.
- 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 *Taking other medicines*).

Tell your doctor if you are pregnant or plan to become pregnant.

Levothyroxine is not thought to be harmful to an unborn baby when taken by a pregnant woman. However, thyroxine levels need to be watched carefully during pregnancy because too much or too little thyroxine in the mother's bloodstream could affect the well-being of an unborn baby.

Also tell your doctor if you are breastfeeding or planning to breastfeed.

Although the active ingredient in Levothyroxine tablets, levothyroxine, passes into breast milk, it is not likely to have a harmful effect on a baby. However, it might interfere with the results of tests to detect congenital hypothyroidism in the baby. You should not breastfeed unless your doctor says you can.

If you have not told your doctor about any of the above, please do so before you start taking Levothyroxine tablets.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from a pharmacy, supermarket or health food shop. You should tell any health professional who is prescribing a new medicine for you that you are taking Levothyroxine tablets.

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 *Before you take Levothyroxine tablets*).

Some medicines may interfere with Levothyroxine tablets. These include:

- anticoagulants, medicines used to thin your blood and treat blood clots
- medicines for epilepsy (e.g. phenytoin, carbamazepine)
- medicines used to treat depression
- cardiac glycosides, for example digoxin (Lanoxin™), used to treat heart problems
- medicines used to lower blood cholesterol levels such as statins (e.g. simvastatin, lovastatin), bile acid sequestrants (e.g. colestipol), cholestyramine (Questran), and clofibrate
- androgens (male hormones) and anabolic steroids (body building hormones)
- antacids such as aluminium hydroxide, magnesium hydroxide and calcium carbonate and proton pump inhibitors used to treat heartburn and indigestion
- cation exchange resins, e.g. Kayexalate
- sucralfate, used to treat ulcers
- calcium carbonate and ferrous sulphate
- tamoxifen, imatinib, sunitinib and 5-fluorouracil, used to treat certain types of cancer
- methadone, used to treat pain
- medicines to treat high blood pressure and heart conditions (e.g. propranolol, amiodarone)
- medicines to relieve asthma attacks
- medicines used for weight reduction

- medicines to treat tuberculosis (e.g. rifampicin) and other infections (ciprofloxacin)
- the oral contraceptive pill
- soyabean flour (e.g. some infant formula and other products)
- medicines used to treat diabetes (e.g. insulin)
- iron, calcium, magnesium and aluminium supplements
- propylthiouracil, a drug used to treat overactive thyroid and Graves disease
- non-steroidal anti-inflammatory drugs (NSAIDs), drugs used to relieve pain and/or inflammatory conditions including arthritis
- oral contrast agents used before X-ray and scans
- antivirals, medicines used to treat HIV/AIDS infection (e.g. ritonavir).
- products containing St. John's Wort (an herbal medicinal product)
- 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 tablets.

These medicines may be affected by Levothyroxine tablets, or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines.

Your doctor or pharmacist has more information on medicines to be careful with or to avoid while taking Levothyroxine tablets.

How to take Levothyroxine tablets

How much to take

Take Levothyroxine tablets exactly as your doctor has prescribed.

Your doctor will tell you how many Levothyroxine tablets to take each day. Your doctor will calculate the dose based on your weight.

Never take more tablets than your doctor has prescribed.

Your doctor may vary your dose depending on how you respond to Levothyroxine tablets.

In adults, the usual dose is 50 microgram to 100 microgram daily, increased every 4 to 6 weeks as needed. The maximum dose is 200 microgram daily.

The dose in children is reduced according to other pre-existing conditions, weight and age.

Elderly people or people with pre-existing health conditions usually need a smaller dose because they are more sensitive to the effects of levothyroxine.

Your doctor will do regular blood tests to make sure levothyroxine is working for you.

How to take it

Swallow tablets whole with a glass of water.

Tablets should be taken on an empty stomach, preferably at least 30 minutes before breakfast.

How long to take it

Many people need treatment with Levothyroxine tablets long term.

If you forget to take it

Do not take an extra dose. Wait until the next dose and take your normal dose then.

Do not try to make up for the dose that you missed by taking more than one dose at a time.

If you are not sure what to do, ask your doctor or pharmacist.

While you are taking Levothyroxine tablets

Things you must do

Tell all doctors and pharmacists involved in your healthcare that you are taking Levothyroxine tablets.

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking Levothyroxine tablets.

Tell your doctor if you are pregnant or planning to become pregnant or are breastfeeding while taking Levothyroxine tablets.

Tell your doctor if, for any reason, you have not taken Levothyroxine tablets exactly as prescribed.

Otherwise, your doctor may think it is not working for you and change your Levothyroxine tablets dose unnecessarily.

Tell your doctor if you feel that Levothyroxine tablets are not helping your condition.

Things you must not do

Do not stop taking Levothyroxine tablets or change the dose without first checking with your doctor, or your symptoms could return.

Do not let yourself run out of medicine over the weekend or on holidays.

Do not give Levothyroxine tablets to anyone else, even if they have the same condition as you.

Do not take any other medicines, whether they require a prescription or not, without first asking your doctor or a pharmacist.

Things to be careful of

Do not drive or operate machinery until you know how your Levothyroxine tablets dose is affecting you.

In case of overdose

If you take too much (overdose)

Immediately telephone your doctor, or the National Poisons Centre [telephone 0800 POISON or 0800 764 766], or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have taken too much Levothyroxine tablets.

Do this even if there are no signs of discomfort or poisoning.
You may need urgent medical attention.

Keep phone numbers for these places handy.

An overdose of Levothyroxine tablets can cause agitation, confusion, irritability, hyperactivity, sweating, headaches, fever, widened pupils, fits, palpitations and diarrhoea.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Levothyroxine tablets.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

TELL YOUR DOCTOR IMMEDIATELY if you think you are having an allergic (hypersensitivity) reaction to Levothyroxine tablets.

Symptoms include:

- severe skin rash, itching or hives
- swelling of the face, lips, mouth or throat
- difficulty breathing or swallowing
- fever
- low blood pressure (feeling faint or dizzy).

However, these symptoms do not necessarily mean that you are allergic to Levothyroxine tablets.

Tell your doctor if you notice any of the following:

- diarrhoea
- nausea
- vomiting
- irregular or fast heart beat
- chest pain
- sweating, flushing
- weight loss
- muscle weakness/cramps, tremors
- rapid breathing
- fever
- constantly feeling hungry
- abdominal pain
- headache
- inability to sleep
- feeling restless/excited/nervous
- hair loss
- irregular period in women
- Intolerance to heat
- difficulty in conceiving (carrying a child)
- anxiety
- depression
- shortness of breath.

The above side effects are rare and usually mean that your daily Levothyroxine tablets dose is too high.

Children taking Levothyroxine tablets may experience partial loss of hair during the first few months of therapy, but this effect is usually temporary and subsequent regrowth usually occurs.

Tell your doctor if you notice any other effects.

Other adverse effects not listed above may also occur in some patients.

Do not be alarmed by this list of possible adverse effects.

You may not experience any of them.

After taking Levothyroxine tablets

Storage

Keep your tablets in the blisters until it is time to take them.

If you take the tablets out of the blisters they may not keep well.

Keep Levothyroxine tablets in a cool dry place away from light where the temperature stays below 25°C.

Do not store Levothyroxine tablets or any other medicine in a bathroom or near a sink.

Do not leave it in a car or on a window sill.

Heat and dampness can destroy some medicines.

Keep Levothyroxine tablets where young children cannot reach it.

A locked cupboard at least one and a half meters above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking Levothyroxine tablets, or the medicine has passed its expiry date, **ask your pharmacist what to do with any tablets that are left.**

Product description

What it looks like

- Levothyroxine **50** microgram tablets are white, uncoated, biconvex tablets, engraved on one face with “LT” and “50” on the other.
- Levothyroxine **100** microgram tablets are white, uncoated, biconvex tablets, engraved on one face with “LT” and “100” on the other.

Ingredients

50 microgram tablets

Active ingredient:

Levothyroxine sodium

Inactive ingredients:

- sodium citrate
- lactose
- maize starch

- acacia powdered
- purified water
- magnesium stearate.

100 microgram tablets

Active ingredient:

Levothyroxine sodium

Inactive ingredients:

- sodium citrate
- lactose
- maize starch
- acacia powdered
- purified water
- magnesium stearate.

Further information

Your doctor is the best person to give you advice on the treatment of your illness. You may also be able to find general information about hypothyroidism and its treatment from other sources, for example, books in public libraries and on the Internet.

Sponsor Details

Levothyroxine tablets are supplied in New Zealand by:

Boucher & Muir (NZ) t/a Mercury Pharma (NZ)
39 Anzac Road
Browns Bay
Auckland 0753

Date of Preparation

This leaflet was prepared in October 2024.