What is L-Thyroxin Berlin-Chemie 50 mcg tablets and what they are used for

L-Thyroxin Berlin-Chemie 50 mcg tablets are a medicine that contains a thyroid hormone called levothyroxine as the active ingredient. Its effects are the same as that of the naturally produced hormone.

You have been prescribed L-Thyroxin Berlin-Chemie 50 mcg tablets to replace deficient thyroid hormone and/or to relieve stress on the thyroid.

L-Thyroxin Berlin-Chemie 50 mcg tablets are used

- to provide hormone replacement as part of the treatment of any form of hypothyroidism.
- to treat the benign enlargement of the thyroid (benign struma) in patients with normal thyroid function.
- to prevent thyroid enlargement (struma) from recurring after an operation in patients with normal thyroid function.
- to treat overactive thyroid with thyrostatic medicines (medicines used to inhibit overactive thyroid function) after the metabolism has normalised.
- to treat malignant tumours of the thyroid, primarily following an operation, to suppress the formation of a new tumour and replace a deficient thyroid hormone.

L-Thyroxin Berlin-Chemie 50 mcg tablets are used in all age groups.

2. What you need to know before you take L-Thyroxin Berlin-Chemie 50 mcg tablets

Do not take L-Thyroxin Berlin-Chemie 50 mcg tablets:

- If you are allergic to levothyroxine sodium or any other ingredient(s) of this medicine (listed in section 6).
- If you suffer from any of the diseases or conditions listed below:
  - untreated overactive thyroid disorder (hyperthyroidism).
  - untreated adrenocortical insufficiency.
- untreated pituitary gland insufficiency, which necessitates the treatment of adrenocortical insufficiency.
- recent myocardial infarction
- acute inflammation of the heart muscle (myocarditis).
- acute inflammation of all layers of the heart wall (pancarditis).

If you are pregnant, you must not take L-Thyroxin Berlin-Chemie 50 mcg tablets concurrently with medicines that inhibit overactive thyroid function (thyreostatic medicines) (also see section ‘Pregnancy, breast-feeding, and fertility’).

The following diseases or conditions must be ruled out or treated before starting treatment with L-Thyroxin Berlin-Chemie 50 mcg tablets:
- Coronary heart disease
- Pain or feeling of tightness in the chest (stenocardia)
- High blood pressure
- Pituitary or adrenocortical insufficiency
- Presence of areas in the thyroid gland which produce thyroid hormone uncontrollably (thyroid autonomy)

**Warnings and precautions**

Talk to your doctor before taking L-Thyroxin Berlin-Chemie 50 mcg tablets.

Take special care when using L-Thyroxin Berlin-Chemie 50 mcg tablets:
- If you have any previous history of infarction or coronary artery disease, weak heart muscle, heart rhythm disorders (tachycardias) or non-acute myocarditis, or if you suffer from long-term hypothyroidism. In these cases, excessive levels of thyroid hormone in the blood must be avoided. Your thyroid hormone levels must be monitored more frequently. Tell your doctor if you notice any mild symptoms of overly active thyroid function when taking L-Thyroxin Berlin-Chemie 50 mcg (see paragraph 4, ‘Possible side effects’).
- If you have adrenal insufficiency and you do not receive adequate replacement therapy.
- If your hypothyroidism is caused by a pituitary gland disorder. Concurrent adrenal insufficiency needs to be treated before starting treatment with L-Thyroxin Berlin-Chemie 50 mcg tablets (hydrocortisone treatment). Lack of adequate treatment may lead to the development of acute adrenal insufficiency (Addisonian crisis).
- If your doctor suspects that you may have areas in your thyroid that are uncontrollably producing thyroid hormone (thyroid autonomy), additional tests must be carried out before starting treatment.
- In postmenopausal women with an increased risk of osteoporosis, thyroid function must be monitored more frequently to avoid increased thyroid hormone levels in the blood and the dosages of medication used should be as small as possible.
- If you have diabetes, please refer to the section ‘Other medicines and L-Thyroxin Berlin-Chemie 50 mcg tablets’ for details.
- If you are being treated with certain types of anticoagulant medications (e.g. dicumarol) or medications which affect the thyroid gland (e.g. amiodarone, thyroxine kinase inhibitors (anti-cancer medications), salicylates, or large doses of furosemide), please refer to the section ‘Other medicines and L-Thyroxin Berlin-Chemie 50 mcg tablets’ for details.
- If you are a patient receiving dialysis who is being treated with sevelamer (due to excessive phosphate content in the blood), your doctor will probably consider running certain blood tests to determine the effectiveness of levothyroxine (see section ‘Other medicines and L-Thyroxin Berlin-Chemie 50 mcg tablets’).
- If you have a history of epilepsy, there is an increased risk of seizures.

**Misuse of the medicine**

You must not take L-Thyroxin Berlin-Chemie 50 mcg tablets for weight loss. If your thyroid hormone levels are within the normal range, supplementing with thyroid hormones will not cause weight loss.
Overdosing without a doctor's recommendation may cause serious or even life-threatening side effects, especially if taken with certain weight loss medicines.

**Switching treatment**
If you need to change your medicine to another medicine containing levothyroxine, you may develop thyroid hormone imbalance. Talk to your doctor if you have any questions about changing your medicine. Close monitoring (both clinical and biological) is required during the transition period. Tell your doctor if you experience side effects, as your dose may need to be adjusted higher or lower.

**Elderly patients**
In elderly patients, the dose will be adjusted carefully (especially in the case of heart problems) and the doctor will run regular tests.

**Children and adolescents**
When very low birth weight preterm infants are started on levothyroxine, their blood pressure is monitored regularly as a rapid fall in blood pressure may occur (so-called circulatory collapse) (see section 4, ‘Possible side effects’).

**Other medicines and L-Thyroxin Berlin-Chemie 50 mcg tablets**
Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines.

**L-Thyroxin Berlin-Chemie 50 mcg tablets influence the therapeutic effect of the following active ingredients and groups of medications:**

- **Diabetes medications** (medications which lower blood sugar levels, e.g. metformin, glimepiride, glibenclamide, and insulin)
  If you have diabetes, you must have your blood sugar levels checked regularly, especially at the beginning and end of your thyroid hormone treatment. Your doctor should adjust the dosages of your hypoglycaemic medications if necessary, as levothyroxine may lessen their therapeutic effect.

- **Coumarin derivatives** (anticoagulant medications):
  If you are receiving concurrent treatment with L-Thyroxin Berlin-Chemie 50 mcg tablets and coumarin derivatives (e.g. dicoumarol), your blood clotting factors should be monitored regularly. Your doctor must reduce the dose of anticoagulant medications if necessary, as levothyroxine may increase their therapeutic effect.

**The therapeutic effect of the L-Thyroxin Berlin-Chemie 50 mcg tablets may be affected by other medications in the following ways:**

- **Ion-exchange resins:**
  Take medications for lowering lipid levels in the blood (e.g. cholestyramine, colestipol) or medications which lower elevated blood potassium levels (calcium and sodium salts of polystyrene sulfonic acid) 4 to 5 hours after taking the L-Thyroxin Berlin-Chemie 50 mcg tablets. Otherwise, these medications will inhibit the absorption of levothyroxine from the gut, reducing its efficacy.

- **Sevelamer and lanthanum carbonate:**
  Sevelamer and lanthanum carbonate (medications used to lower elevated blood phosphate levels in dialysis patients) may affect the efficacy of levothyroxine. Your doctor will monitor your thyroid function more frequently (also see the paragraph ‘Warnings and precautions’).

- **Bile acid-binding substances:**
  Colesevelam (a medication that lowers elevated blood cholesterol levels) binds levothyroxine, thus decreasing its absorption from the gut. Therefore, you should take levothyroxine 4 hours before colesevelam.

- **Stomach acid-binding medications** that contain aluminium, medications which contain iron or calcium:
Take L-Thyroxin Berlin-Chemie 50 mcg tablets at least 2 hours before taking stomach acid-binding medicines that contain aluminium (e.g. antacids, sucralfate) or medications that contain iron or calcium. Otherwise, these medications may decrease the absorption of levothyroxine from the gut and thus lessen its efficacy.

- Propylthiouracil, glucocorticoids, beta-blockers (especially propranolol):
  Propylthiouracil (thyroid function suppressant), glucocorticoids (adrenal hormones, ‘cortisone’), and beta-blockers (medications which lower heart rate and blood pressure) inhibit the conversion of levothyroxine into its more active form, liothyronine, thus decreasing the efficacy of L-Thyroxin Berlin-Chemie 50 mcg tablets.

- Amiodarone, iodine-containing contrast media:
  Due to their high iodine content, amiodarone (heart dysrhythmia medication) and iodine-containing contrast media (certain medications used in X-ray diagnostics) may cause both hyperactivity and hypofunction of the thyroid gland. Special care must be taken in nodular struma, when there are unidentified areas in the thyroid gland that uncontrollably produce the thyroid hormone (autonomies). Amiodarone inhibits the conversion of levothyroxine into its more active form, liothyronine, thus lessening the efficacy of L-Thyroxin Berlin-Chemie 50 mcg tablets. Your doctor will adjust the dose of L-Thyroxin Berlin-Chemie 50 mcg tablets as necessary.

The following medicines may influence the therapeutic effect of L-Thyroxin Berlin-Chemie 50 mcg tablets:
- Salicylates, especially in daily doses of over 2 g (anti-pyretics, analgesics)
- Dicoumarol (anticoagulant medication)
- Large doses (205 mg) of furosemide (diuretic)
- Clofibrate (a medication which reduces elevated blood lipid levels)
- Contraceptives or hormonal replacement therapy:
  Your levothyroxine requirement may be increased if you are taking oestrogen-containing medications to avoid pregnancy (“the pill”) or postmenopausal hormonal replacement therapy
- Setraline, chloroquine/proguanil:
  Setraline (antidepressant) and chloroquine/proguanil (medications used to treat malaria and rheumatic disorders) lessen the efficacy of levothyroxine.
- Barbiturates, rifampicin, carbamazepine, and phenytoin:
  Barbiturates (anticonvulsants, anaesthetics, certain soporifics), rifampicin (antibiotic), carbamazepine (anticonvulsant), and phenytoin (anticonvulsant and antiarrhythmic drug) may decrease the efficacy of levothyroxine.
- Protease inhibitors (medications used to treat the HIV infection and/or chronic hepatitis C):
  If you are taking levothyroxine and protease inhibitors (lopinavir, ritonavir) concurrently, your doctor must monitor you carefully for signs of illness, as well as monitoring your thyroid function. Concurrent use of lopinavir/ritonavir may decrease the efficacy of levothyroxine.
- Tyrosine kinase inhibitors (cancer medications):
  If you are taking levothyroxine and tyrosine kinase inhibitors (e.g. imatinib, sunitinib, sorafenib, motesanib) concurrently, your doctor must monitor you carefully for signs of illness, as well as monitoring your thyroid function. The efficacy of levothyroxine may be decreased and your doctor may adjust the dose if necessary.

L-Thyroxin Berlin-Chemie 50 mcg tablets with food and drink
You must not take L-Thyroxin Berlin-Chemie 50 mcg tablets with food, especially with food rich in calcium (e.g. milk and dairy), as this may significantly lower the intestinal absorption of levothyroxine.

If your diet contains soy, your doctor will monitor your thyroid hormone levels more frequently. Your doctor may adjust the dose of L-Thyroxin Berlin-Chemie 50 mcg tablets during or after such a diet, if necessary (large doses may also be needed on rare occasions), because products containing soy may inhibit the absorption of levothyroxine from the gut, thus decreasing its efficacy.
Pregnancy, breast-feeding, and fertility
If you are pregnant or breast-feeding, think you may be pregnant, or are planning to have a baby, ask your doctor for advice before taking this medicine.

It is vital to the health of the mother and the unborn baby that appropriate treatment with thyroid hormones be continued throughout pregnancy and breast-feeding. The treatment must be consistent and supervised by your doctor. Despite the widespread use of levothyroxine during pregnancy, no adverse effects of levothyroxine on the pregnancy or the unborn baby have been reported so far.

Have your thyroid function checked before and after pregnancy. Your doctor may need to adjust the dose, as the thyroid hormone requirement may be increased due to increased blood oestrogen (female sex hormone) levels. You must not take the L-Thyroxin Berlin-Chemie 50 mcg tablets concurrently with medications that suppress overactive thyroid function (thyreostatics) during pregnancy, as that may require larger doses of thyreostatics. Thyreostatics (unlike levothyroxine) are able to pass the placental barrier and enter the baby’s blood stream, causing thyroid hypofunction in the unborn baby. If you have an overactive thyroid, your doctor will only use low doses of thyreostatics to treat it during pregnancy.

The amount of thyroid hormone excreted into breast milk during breast-feeding is very low even when taking larger doses of levothyroxine and is therefore harmless.

Negative effects on neither male nor female fertility have been reported. There are no suspicions or references regarding this.

Driving and using machines
The effect of L-Thyroxin Berlin-Chemie 50 mcg tablets on driving and using machines has not been studied.

L-Thyroxin Berlin-Chemie 50 mcg tablets contain sodium
This medicinal product contains less than 1 mmol (23 mg) of sodium per tablet, rendering it practically ‘sodium free’.

3. How to take L-Thyroxin Berlin-Chemie 50 mcg tablets
Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The required daily dose will be determined by your doctor based on your blood test results.

Dosing
Sodium levothyroxine tablets are available in several strengths (50–150 mcg) to facilitate individualised treatment. The normal dose is one tablet per day. To start the treatment, or to increase the dose in adults as well as children, the doctor may prescribe tablets that contain less of the active ingredient if necessary.

Depending on the symptoms, the doctor may refer to the following guidelines:
- To treat hypothyroidism in adults, the initial daily dose is 25...50 mcg of levothyroxine sodium (corresponding to ½...1 L-Thyroxin Berlin-Chemie 50 mcg tablet). The doctor may increase the dose in increments of 25...50 mcg of levothyroxine sodium with 2...4-week intervals up to 100...200 mcg of sodium levothyroxine daily (corresponding to 2...4 tablets of L-Thyroxin Berlin-Chemie 50 mcg).
- To prevent the recurrence of thyroid enlargement (struma) after struma removal and to treat benign struma: 75...200 mcg of levothyroxine daily (corresponding to 1.5 to 4 tablets of L-Thyroxin Berlin-Chemie 50 mcg).
- To treat hyperthyroidism in combination with thyreostatics: 50...100 mcg of levothyroxine daily (corresponding to 1...2 tablets of L-Thyroxine Berlin-Chemie 50 mcg).
To treat malignant thyroid tumours after surgery, the daily dose is 150...300 mcg of levothyroxine sodium (corresponding to 3...6 tablets of L-Thyroxin Berlin-Chemie 50 mcg). Smaller doses of thyroid hormone may also be adequate.

Use in children
The maintenance dose for long-term treatment of an underactive thyroid (congenital or acquired hypothyroidism) is usually 100...150 mcg of levothyroxine per m² of body surface per day. Early hormone replacement therapy is especially important in new-borns and infants with congenital hypothyroidism to ensure normal cognitive and physical development. The recommended starting dose is 10...15 mcg of levothyroxine per kg of body weight per day for the first 3 months. After that, the doctor will adjust the dose individually based on clinical indicators (primarily content of thyroid hormone in the blood). The recommended starting dose in children with acquired hypothyroidism is 12.5...50 mcg of levothyroxine per day. The doctor will incrementally increase the daily dose every 2...4 weeks until reaching the complete replacement dose. Your doctor will measure the thyroid hormone content in the blood to determine this.

Elderly patients, patients with coronary heart disease, patients with hypothyroidism
In elderly patients, patients with coronary heart disease, or patients with severe or prolonged hypothyroidism, the treatment with thyroid hormones is started with particular caution (a small starting dose that is increased gradually over long periods, accompanied with frequent tests on thyroid hormone levels).

Patients with low body weight and patients with a large struma
Experience has shown that a smaller dose is also suitable for patients with a low body weight or a large struma.

Splitting the tablets: The tablet can be divided into equal doses. Place the tablet on a hard, flat surface with the score line facing up. By pressing the tablet with your finger, it is now divided into two halves.

Method of administration
Please take the whole daily dose in the morning with an adequate amount of liquid, for example, a glass of water. Take the dose in the morning on an empty stomach at least half an hour before breakfast. The active substance is absorbed better when taken on an empty stomach than when taken immediately before or after a meal.

Children receive the whole daily dose at least half an hour before the first meal of the day. You may also dissolve the tablets in a small amount of water (10...15 ml) and administer the resultant solution (must be prepared separately every time!) with a small amount of extra liquid (5...10 ml).

Duration of treatment
Treatment with L-Thyroxin Berlin-Chemie 50 mcg tablets is lifelong in the case of hypothyroidism and after malignant thyroid tumour removal. For the treatment of benign thyroid enlargement (struma)
and the prevention of the recurrence of struma, duration of treatment may be from a few months or a year to lifelong. The duration of treatment for hyperthyroidism when used in combination with thyreostatics (medications that suppress overactive thyroid function), the duration of treatment is the same as for the thyreostatics. For benign thyroid enlargement with normal thyroid function, the duration of treatment is 6 months to 2 years. If treatment with L-Thyroxin Berlin-Chemie 50 mcg has not had the desired effect, your doctor will consider other treatment options.

**If you take more L-Thyroxin Berlin-Chemie 50 mcg tablets than you should**
The symptoms of overdose are described in paragraph 4, ‘Possible side effects’. If you experience any of these symptoms, please consult your doctor immediately.

**If you forget to take L-Thyroxin Berlin-Chemie 50 mcg tablets**
Do not take a double dose to make up for a forgotten dose if you have taken too little of the medication or forgotten your dose. Continue taking the medication as prescribed.

**If you stop taking L-Thyroxin Berlin-Chemie 50 mcg tablets**
You have to take this medicine regularly at the prescribed doses for the treatment to be effective. You must under no circumstances change the dose or discontinue or stop taking L-Thyroxin Berlin-Chemie 50 mcg tablets earlier than prescribed, because your symptoms may recur.
If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. **Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

**Dose intolerance, overdosing**
If you cannot tolerate your dose or have overdosed, especially if your dose has been increased too rapidly at the beginning of the treatment, you may experience the typical signs of hyperthyroidism.

Very common: may affect more than 1 user in 10:
- palpitations
- insomnia
- headaches

Common: may affect up to 1 user in 10:
- very rapid heart rate (tachycardia)
- nervousness

Rare: may affect up to 1 user in 1,000:
- increase in intracranial pressure (especially in children), which may manifest as strong headaches, nausea, double vision (diplopia), and amplification of heart beats in the ears (pulsing tinnitus)

Unknown: frequency cannot be estimated based on available data
- hypersensitivity
- heart dysrhythmia
- pain and feeling of tightness in the chest (stenocardia)
- allergic skin reactions (e.g. angioedema, pruritus, urticaria)
- restlessness
- muscle weakness, muscle cramping
- osteoporosis, especially in postmenopausal women who are receiving prolonged treatment with large doses of levothyroxine
- hot flashes, heat intolerance, circulatory collapse in premature infants with low birth weights (see paragraph 2, ‘Warnings and precautions')
- menstrual cycle disturbances
- diarrhoea
- vomiting
- weight loss
- tremor
- excessive sweating
- fever

**Hypersensitivity to the active ingredient or any of the other excipients of L-Thyroxin Berlin-Chemie 50 mcg tablets.**

Hypersensitivity to the active ingredient or any of the other excipients of L-Thyroxin Berlin-Chemie 50 mcg tablets may cause allergic reactions in the skin (e.g. rash, urticaria) and respiratory tract. If you experience any hypersensitivity reactions, stop using the medication and consult your doctor immediately.

Inform your doctor of any side effects that you experience. Your doctor will decrease your daily dose or stop treatment for several days. As soon as the side effects have subsided, the treatment may be continued with cautiously measured dose.

**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 [www.ravimiamet.ee](http://www.ravimiamet.ee). By reporting side effects, you can help provide more information on the safety of this medicine.

5. **How to store L-Thyroxin Berlin-Chemie 50 mcg tablets**

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 carton and blister. The expiry date refers to the last day of that month.

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 protect the environment.

6. **Contents of the pack and other information**

**What L-Thyroxin Berlin-Chemie 50 mcg tablets contain**

The active substance is levothyroxine sodium. One tablet contains 53.2...56.8 mcg of levothyroxine sodium hydrate, which corresponds to 50 mcg of levothyroxine sodium. The other ingredients are calcium hydrogen phosphate dihydrate, microcrystalline cellulose, sodium starch glycolate (type A), dextrin (from cornstarch), partially substituted long-chain glycerides.

**What L-Thyroxin Berlin-Chemie 50 mcg tablets look like and the contents of the pack**

L-Thyroxin Berlin-Chemie 50 mcg tablets are almost white to light beige, round, slightly convex tablets, with a score line on one side and ‘50’ debossed on the other side.

The tablet can be divided into equal doses.
The original packs of L-Thyroxin Berlin-Chemic 50 mcg tablets contain 25, 50, or 100 tablets.

Not all pack sizes may be marketed.

**Marketing Authorisation Holder and Manufacturer**
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For further information about this medicine, please contact the local representative of the Marketing Authorisation Holder.
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