

Package leaflet: Information for the user

<Product Name> 25 microgram tablets
<Product Name> 50 microgram tablets
<Product Name> 75 microgram tablets
<Product Name> 100 microgram tablets
<Product Name> 125 microgram tablets
<Product Name> 150 microgram tablets
<Product Name> 175 microgram tablets
<Product Name> 200 microgram tablets

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 <Product Name> is and what it is used for
2. What you need to know before you take <Product Name>
3. How to take <Product Name>
4. Possible side effects
5. How to store <Product Name>
6. Contents of the pack and other information

1. What <product name> is and what it is used for

Levothyroxine, the active substance in <Product Name>, is a synthetic thyroid hormone for the treatment of diseases and dysfunctions of the thyroid gland. It has the same effect as the naturally occurring thyroid hormones.

<Product Name> 25 - 200 microgram is used

- to treat benign goitre in patients with normal thyroid function,
- to prevent recurrence of goitre after surgery,
- to replace natural thyroid hormones, when your thyroid gland does not produce enough,
- to suppress tumour growth in patients with thyroid cancer.

<Product Name> 25 - 100 microgram can also be used to balance thyroid hormone levels, when overproduction of hormones is treated with antithyroid medicines.

<Product Name> 100/150/200 microgram may also be used in the testing of your thyroid function.

2. What you need to know before you take <product name>

DO NOT take <Product Name>

- if you are allergic to levothyroxine sodium or to any of the other ingredients of this medicine (listed in section 6).

- if you have untreated dysfunction of the adrenal gland, pituitary gland or excessive overproduction of thyroid hormones (thyrotoxicosis),
- if you have acute heart disease (myocardial infarction or heart inflammation).

Do not take <Product Name> together with antithyroid medicines if you are pregnant (see section Pregnancy and breast-feeding below).

Warnings and precautions

Talk to your doctor or pharmacist before taking this medicine if you have any of the following heart diseases:

- insufficient blood flow in the blood vessels of the heart (angina pectoris),
- heart failure,
- rapid and irregular heartbeat,
- high blood pressure,
- fatty deposits in your arteries (arteriosclerosis).

You must be under medical care **before** you start taking <Product Name> or before a thyroid suppression test is performed. You **must** have frequent checks of your thyroid hormone levels while you are on <Product Name>. If you are not sure whether any of these conditions applies to you, or if you do not receive treatment, contact your doctor.

Your doctor will investigate if you have a problem with your adrenal or pituitary gland or a problem of the thyroid gland with uncontrolled overproduction of thyroid hormones (thyroid autonomy), because adrenal gland and pituitary problems must be medically controlled before you start taking <Product Name> or before a thyroid suppression test is performed.

Speak to your doctor,

- if you are in the menopause or post-menopausal; your doctor may need to check your thyroid function regularly because of the risk of osteoporosis.
- if you switch from one levothyroxine-containing medicine to another one. The effect may be slightly different and you may need closer monitoring and dose adjustment.
- if you have epilepsy (fits). Fits have been rarely reported when starting the treatment with levothyroxine
- before you take orlistat (medication to treat obesity; you may need closer monitoring and dose adjustment)
- if you experience signs of psychotic disorders (you may need closer monitoring and dose adjustment)

Other medicines and <Product Name>

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

Tell your doctor, if you are taking any of the following medicines, because <Product Name> may influence their effect:

- Anti-diabetic medicines (blood-sugar-lowering medicines):
<Product Name> may reduce the effect of your anti-diabetic medicine, so you may need additional checks of your blood sugar levels, especially at the start of <Product Name> treatment. While you are taking <Product Name>, adjustment of the dose of your anti-diabetic medicine may be necessary.
- Coumarin derivatives e.g. warfarin or phenprocoumon (medicines used to prevent blood clotting):
- <Product Name> may intensify the effect of these medicines, which may increase the risk of bleeding events, especially in elderly people. You may need regular checks of your blood clotting values, at the start of and during <Product Name> treatment. While you are taking <Product Name>, adjustment of the dose of your coumarin medicine may be necessary.

- Drugs used to treat depression and other conditions, including amitriptyline, imipramine and dosulepin.
- Decongestant medicines such as phenylephrine, or adrenaline (for treatment of severe allergies).
- Digoxin, used to treat heart problems including an irregular heart-beat.
- orlistat (medication to treat obesity)

Make sure that you stick to the recommended time intervals, if you need to take any of the following medicines:

- Medicine used to bind bile acids and to lower high cholesterol (such as cholestyramine or colestipol):
Make sure that you take <Product Name> 4 - 5 hours before these medicines, because they may block the uptake of <Product Name> from the intestine.
- Antacids (for the relief of acid indigestion), sucralfate (for ulcers of the stomach or intestine), other aluminium-containing medicines, iron-containing medicines, calcium carbonate:
Make sure that you take <Product Name> at least 2 hours before these medicines, because otherwise they may reduce the effect of <Product Name>.

Tell your doctor, if you are taking any of the following medicines, because they may reduce the effect of <Product Name>:

- propylthiouracil (antithyroid medicine),
- glucocorticoids (anti-allergic and anti-inflammatory medicines),
- beta-blockers (blood-pressure-lowering medicines also used to treat heart diseases),
- sertraline (antidepressive medicine),
- chloroquine, or proguanil (medicine to prevent or treat malaria),
- medicines activating certain liver enzymes such as barbiturates (sedatives, sleeping pill) or carbamazepine (anti-epileptic medicine, also used to modify some types of pain and to control mood disorders),
- oestrogen-containing medicines used for hormone replacement during and after the menopause or for prevention of pregnancy,
- sevelamer (phosphate binding drug, used to treat patients with chronic renal failure),
- tyrosine kinase inhibitors (anti-cancer and anti-inflammatory medicines).

Tell your doctor, if you are taking any of the following medicines, because they may intensify the effect of <Product Name>:

- salicylates (medicine used to relieve pain and to reduce fever),
- dicoumarol (medicine to prevent blood clotting),
- furosemide in high doses of 250 mg (diuretic medicine),
- clofibrate (blood-lipid-lowering medicine).

Tell your doctor, if you are taking any of the following medicines, because they may influence the effect of <Product Name>:

- ritonavir, indinavir, lopinavir (protease inhibitors, medicines to treat HIV infection),
- phenytoin (anti-epileptic medicine).

You may need regular checks of your thyroid hormone parameters. An adjustment of your dose of <Product Name> may be necessary.

Tell your doctor, if you are taking amiodarone (medicine used to treat irregular heart beat), because this medicine may influence the function and activity of your thyroid gland.

If you need to have a diagnostic test or scan with iodine-containing contrast media, tell your doctor that you take <Product Name>, because you may receive an injection that may influence your thyroid function.

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.

<Product Name> with food and drink

Tell your doctor, if you eat soy products, especially if you change the amount you eat. Soy-products may lower the uptake of <Product Name> from the intestine and therefore, an adjustment of your <Product Name> dose may be necessary.

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 continue taking <Product Name>. Speak to your doctor, because the dose may need to be changed.

If you have taken <Product Name> together with an antithyroid medicine to treat an overproduction of thyroid hormones, your doctor will advise you to stop <Product Name> treatment when you become pregnant.

If you are breast-feeding, continue taking <Product Name> as advised by your doctor. The amount of drug that is excreted into the breast milk is so small that it will not affect the child.

Driving and using machines

No studies on the effects on the ability to drive and use machines have been performed.

It is not expected that <Product Name> has any influence on the ability to drive and use machines, because, levothyroxine is identical to the naturally occurring thyroid hormone.

3. How to take <product name>

Always take this medicine exactly as your doctor has told you. Check with your doctor, if you are not sure.

Your doctor will determine your individual dose based on examinations and as well as on laboratory tests. In general, you start with a low dose, which is increased every 2 - 4 weeks, until your full individual dose is reached. During the initial weeks of treatment you will have appointments for laboratory tests in order to adjust the dose.

If your baby is born with hypothyroidism your doctor may recommend to start with a higher dose because a rapid replacement is important. The initial recommended dosage is 10 to 15 micrograms per kg body weight for the first 3 months. Thereafter, your doctor will adjust the dose individually.

The usual dose range is shown in the table below. A lower individualised dose may be sufficient,

- if you are an elderly patient,
- if you have heart problems,
- if you have severe or long-standing thyroid sub-function,
- if you have low weight or a large goitre.

<i>Use of <Product Name></i>	<i>Recommended daily dose of <Product Name></i>
- to treat benign goitre in patients with normal thyroid function	75 - 200 microgram
- to prevent recurrence of goitre after surgery	75 - 200 microgram

- to replace natural thyroid hormones, when your thyroid gland does not produce enough – initial dose – maintenance dose	adults 25 - 50 microgram 100 - 200 microgram	children 12.5 - 50 microgram 100 - 150 microgram per m ² of body surface
- to suppress tumour growth in patients with thyroid cancer	150 - 300 microgram	
- to balance thyroid hormone levels, when overproduction of hormones is treated with anti-thyroid medicines	50 - 100 microgram	
- to test thyroid function	75 - 200 microgram starting 2 or 4 weeks before the test	

Administration

<Product Name> is meant for oral use. Take a single daily dose on an empty stomach in the morning (at least half an hour before breakfast), preferably with a little liquid, for example with half a glass of water. The tablet can be divided into equal doses.

Infants may receive the entire daily dose of <Product Name> at least half an hour before the first meal of the day. Immediately before use, crush the tablet and mix it with some water and give it to the child with some more liquid. Always prepare the mixture freshly.

Duration of treatment

Duration of treatment may vary depending on the condition for which you use <Product Name>. Your doctor will therefore discuss with you how long you need to take it. Most patients need to take <Product Name> for their lifetime.

If you take more <Product Name> than you should

If you have taken a higher dose than prescribed, you may experience symptoms such as rapid heart beat, anxiety, agitation or unintended movements. In patients with a disorder affecting the neurological system such as epilepsy, seizures may occur in isolated cases. In patients at risk of psychotic disorders, symptoms of acute psychosis may occur. If any of this happens, contact your doctor.

If you forget to take <Product Name>

Do not take a double dose to make up for a forgotten dose, but take the normal dose the following day.

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.

All medicines can cause allergic reactions although serious allergic reactions are rare. Any sudden wheeziness, difficulty in breathing, swelling of the eyelids, face or lips, rash or itching (especially affecting your whole body) or joint pain should be reported to a doctor immediately.

The following effects can occur especially if your initial dose of the medicine is too high.

- fever
- intolerance to heat
- loose stools

- tremor (shaking), restlessness, excitability
- difficulty sleeping
- rapid heart-beat or angina (pain in the chest on exercise)
- heart failure
- yellowing of the skin and eyes (jaundice)
- confusion, seizures and coma

Children

- Rarely there have been reports of build-up of fluid around the brain (benign intracranial hypertension). Symptoms include headache, nausea, vomiting, and/or visual or hearing disturbances.
- Developmental abnormality of the skull bone (Cranioostenosis).
- Bone deformities (Premature closure of epiphysis).
- Mild hair-loss

You should consult your doctor if any of the above effects occur. The effects usually go away when the dose has been changed.

Other side effects you could experience are:

- irregular heart-beats, palpitations (thumping heart beats)
- muscle cramps or weakness
- low blood pressure
- vomiting
- headaches, flushing, sweating
- loss of weight
- in women - changes to your periods

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 {to be completed nationally: the national reporting system listed in Appendix V}. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store <product name>

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

Do not store above 25° C. Keep the blisters in the outer carton, in order to protect from light.

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 <Product Name> contains

- The active substance is levothyroxine sodium.

Each 25 microgram tablet contains 25 microgram levothyroxine sodium.

Each 50 microgram tablet contains 50 microgram levothyroxine sodium.

Each 75 microgram tablet contains 75 microgram levothyroxine sodium.

Each 100 microgram tablet contains 100 microgram levothyroxine sodium.

Each 125 microgram tablet contains 125 microgram levothyroxine sodium.

Each 150 microgram tablet contains 150 microgram levothyroxine sodium.

Each 175 microgram tablet contains 175 microgram levothyroxine sodium.

Each 200 microgram tablet contains 200 microgram levothyroxine sodium.

- The other ingredients are mannitol, microcrystalline cellulose, hypromellose and magnesium stearate.

What <Product Name> looks like and contents of the pack

<Product Name> 25 microgram Tablet

White or almost white, round biconvex tablet with a score line on one side and “25” engraved on the other side and with a diameter of 7 mm.

<Product Name> 50 microgram Tablet

White or almost white, round biconvex tablet with a score line on one side and “50” engraved on the other side and with a diameter of 7 mm.

<Product Name> 75 microgram Tablet

White or almost white, round biconvex tablet with a score line on one side and “75” engraved on the other side and with a diameter of 7 mm.

<Product Name> 100 microgram Tablet

White or almost white, round biconvex tablet with a score line on one side and “100” engraved on the other side and with a diameter of 7 mm.

<Product Name> 125 microgram Tablet

White or almost white, round biconvex tablet with a score line on one side and “125” engraved on the other side and with a diameter of 7 mm.

<Product Name> 150 microgram Tablet

White or almost white, round biconvex tablet with a score line on one side and “150” engraved on the other side and with a diameter of 7 mm.

<Product Name> 175 microgram Tablet

White or almost white, round biconvex tablet with a score line on one side and “175” engraved on the other side and with a diameter of 7 mm.

<Product Name> 200 microgram Tablet

White or almost white, round biconvex tablet with a score line on one side and “200” engraved on the other side and with a diameter of 7 mm.

The tablet can be divided into equal doses.

<Product Name> tablets are supplied in PVC/PVDC/aluminium blisters

Package size(s):

25 micrograms 28, 30, 50, 90, 100

50 micrograms	28, 30, 50, 90, 100
75 micrograms	30, 50, 90, 100
100 micrograms	28, 30, 50, 90, 100
125 micrograms	30, 50, 90, 100
150 micrograms	30, 50, 90, 100
175 micrograms	30, 50, 90, 100
200 micrograms	30, 50, 90, 100

tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

[To be completed nationally]

This medicinal product is authorised in the Member States of the EEA under the following names:

AT Thyrostat 25 / 50 / 75 / 100 / 125 / 150 / 175/ 200 Mikrogramm Tabletten
DE L-Thyroxin AL 25 µg / 50 µg / 75 µg / 100 µg / 125 µg / 150 µg / 175 µg / 200 µg Tabletten
DK Levothyroxin STADA
IE Levothyroxine Clonmel 25, 50, 100 µg tablets
NL Levothyroxine CF 0,025/0,05/0,075/0,100/0,125/0,150/0,175/0,200 mg, tabletten
SE Levothyroxin STADA 25 / 50 / 75 / 100 / 125 / 150 / 175/ 200 mikrogramm tabletter
IT LEVOTIROXINA EG 25 µg / 50 µg / 75 µg / 100 µg / 125 µg / 150 µg / 175 µg / 200 µg
comprese

This leaflet was last revised in June 2015.