

Package Leaflet: Information for the user
Levothyroxine Abdi 25 microgram tabletten
Levothyroxine Abdi 50 microgram tabletten
Levothyroxine Abdi 75 microgram tabletten
Levothyroxine Abdi 100 microgram tabletten
Levothyroxine Abdi 125 microgram tabletten
Levothyroxine Abdi 150 microgram tabletten
Levothyroxine Abdi 175 microgram tabletten
Levothyroxine Abdi 200 microgram tabletten
levothyroxine sodium

Read all of this leaflet carefully before you start taking this medicine because it contains important information.

- Keep this leaflet. You might need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you personally. Do not give it on to others. It can harm other people, even if they have the same complaints/symptoms as you.
- If you notice any adverse effects, consult your doctor or pharmacist. This also applies to adverse effects not listed in this leaflet. See Section 4.

What is in this leaflet

1. What is Levothyroxine Abdi and what is it used for
2. What you need to know before you take Levothyroxine Abdi
3. How to take Levothyroxine Abdi
4. Possible side effects
5. How to store Levothyroxine Abdi
6. Content of the pack and other information

1. What is Levothyroxine Abdi and what is it used for

Levothyroxine, the active substance in Levothyroxine Abdi, is a synthetically produced thyroid hormone used to treat thyroid gland disorders and dysfunction. It has the same effect as the naturally occurring thyroid hormones.

Levothyroxine Abdi is used:

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

Levothyroxine Abdi is also used to balance thyroid hormone levels, when overproduction of hormones is treated with antithyroid medicines.

Levothyroxine Abdi 100 microgram, 150 microgram, and 200 microgram may also be used in the testing of your thyroid function.

2. What you need to know before you take Levothyroxine Abdi

Do not take Levothyroxine Abdi

if you have any of the following:

- allergy (hypersensitivity) to the active substance or to any of the other ingredients of Levothyroxine Abdi (see section 6),
- untreated dysfunction of, pituitary gland or excessive overproduction of thyroid hormones (thyreotoxicosis),
- underactive adrenal glands (adrenal insufficiency) and you do not have an adequate replacement treatment,
- acute heart disease (myocardial infarction or heart inflammation).

During pregnancy Levothyroxine Abdi must not be used at the same time with medicines against an overactive thyroid gland (antithyroid drugs) (see section Pregnancy and breast-feeding).

Warnings and Precautions

Please talk to your doctor or pharmacist before taking Levothyroxine Abdi 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).

These disorders must be treated with medication prior to taking Levothyroxine Abdi or performing a thyroid suppression test. While taking Levothyroxine Abdi, your thyroid hormone levels must be checked frequently. If you are not sure any of these conditions apply to you or if you have these conditions but are not yet treated, please consult your doctor.

Talk to your doctor before taking Levothyroxine Abdi if you are suffering from an underactive adrenal gland (adrenal insufficiency). Your doctor will investigate if you have an adrenal gland, pituitary or thyroid dysfunction with uncontrolled overproduction of thyroid hormone (thyroid autonomy) because you need to be treated with medication before taking Levothyroxine Abdi or performing a thyroid suppression test.

Please talk 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 your previous levothyroxine supplement to another. The effect may be slightly different, i.e. you may need to be monitored more often and your dose may need to be adjusted.
- before you start or stop taking orlistat (drugs used for the treatment of obesity) or change your treatment with orlistat. In these cases, closer monitoring and, if necessary, dose adjustment may be necessary.
- if you experience any signs of psychotic disorders, in these cases, closer monitoring and, if necessary, dose adjustment may be necessary.
- 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 Abdi).

Other medicines and Levothyroxine Abdi

If you are taking or have recently taken any of the following medicines, talk to your doctor or pharmacist, as Levothyroxine Abdi may affect the following drugs' effects:

- Antidiabetic agents (blood-sugar-lowering drugs):

Levothyroxine Abdi may reduce the effect of the blood sugar lowering agent, this case may require additional blood glucose testing, especially at the beginning of Levothyroxine Abdi treatment. During Levothyroxine Abdi treatment, a dose adjustment of your antidiabetic medicine may need to be adjusted.

- Coumarin derivatives (medicines used to prevent blood clotting drugs):
Levothyroxine Abdi may increase the effect of these drugs, which may increase the risk of bleeding, especially in the elderly. For this reason, periodic blood coagulation monitoring may be required at baseline and during Levothyroxine Abdi treatment. During Levothyroxine Abdi treatment, your coumarin preparation dosage may need to be adjusted.

Be sure to follow the recommended intervals if you are taking any of the following medicines:

- Medicinal products for binding bile acids and lowering high cholesterol levels (such as cholestyramine or cholestipol):

Make sure to take Levothyroxine Abdi for 4 to 5 hours before taking these medicines, as they may inhibit the absorption of Levothyroxine Abdi from the intestine.

- Antacids (gastric and heartburn relievers), sucralfate (used to treat gastric or duodenal ulcers), other aluminum-containing medicines, iron-containing medicines, calcium-containing medicines:

Make sure to take Levothyroxine Abdi for at least 2 hours before taking these medicines, as they may reduce the effectiveness of Levothyroxine Abdi.

Talk to your doctor or pharmacist if you are taking or have recently taken any of the following medicines, as they may reduce the effects of Levothyroxine Abdi:

- Propylthiouracil (medicine used for hyperthyroidism),
- Glucocorticoids (anti-allergic and anti-inflammatory drugs),
- Beta-blockers (antihypertensive medicines, with which also be used to treat heart diseases),
- Sertraline (medicines used for depression),
- Chloroquine or proguanil (medicines used for the prevention or treatment of malaria),
- Medicines that activate certain liver enzymes, e.g. barbiturates (tranquilizers, sleeping pills), carbamazepine (anticonvulsant medicines, also used to modify certain forms

of pain and to control certain depressive disorders), or products containing St. John's Wort (an herbal medicinal product),

- estrogen-containing medicines for hormone replacement treatment during and after menopause or for contraception,
- Sevelamer (phosphate-binding medicine used to treat patients with chronic kidney failure),
- Tyrosine kinase inhibitors (anti-cancer and anti-inflammatory drugs),
- Orlistat (medicine used to treat obesity).
- 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 Abdi.

Talk to your doctor or pharmacist if you are taking or have recently taken any of the following medicines, as they may increase the effects of Levothyroxine Abdi:

- Salicylates (analgesic and antipyretic drugs),
- Dicumarol (medicine to inhibit blood coagulation),
- Furosemide in high dosage from 250 mg (diuretic drug),
- Clofibrate (medicine for lowering blood lipids).

Talk to your doctor or pharmacist if you are taking or have recently taken any of the following medicines, as they may influence the efficacy of Levothyroxine Abdi.

- Protease inhibitors (ritonavir, indinavir, lopinavir) used to treat HIV and chronic hepatitis C virus, phenytoin (anti-epileptic medicines),
- 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).

Your thyroid hormone levels may need to be regularly checked. Your Levothyroxine Abdi dose may need to be adjusted.

Thyroid imbalance may occur if you need to change your medication to another levothyroxine

containing product. Talk to your doctor if you have any questions about changing your medication. A close monitoring (clinical and biological) is required during the transition period. You should tell your doctor if you get any side effects as this may indicate that your dose needs to be adjusted up or down.

Talk to your doctor if you are taking amiodarone (a medicine to treat irregular heart beat) as this medicine may affect the function and activity of your thyroid gland.

If you need to undergo an X-ray or other diagnostic test with an iodine-based contrast agent, tell your doctor that you are taking Levothyroxine Abdi, as you may be injected with an agent that may affect your thyroid function.

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

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.

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.

Levothyroxine Abdi with food and drink

Tell your doctor if you eat soy products, especially if you make any change in the proportion of soy products in your diet. Soya products may reduce the absorption of Levothyroxine Abdi from the intestine, so your dose of Levothyroxine Abdi may need to be adjusted.

Pregnancy and breast-feeding

If you are pregnant, continue to take Levothyroxine Abdi. Talk to your doctor as your dose may need to be adjusted.

If you are taking Levothyroxine Abdi with an anti-thyroid medicine for the treatment of

hyperthyroidism, your doctor will tell you to stop Levothyroxine Abdi treatment at the beginning of pregnancy.

If you are breast-feeding, continue to take Levothyroxine Abdi as directed by your doctor. The amount of drug that is secreted into breast milk is so low that it does not affect the baby.

Driving and using machines

There have been no studies conducted on the impact on the ability to drive and the operate machinery. Since levothyroxine is identical to the naturally occurring thyroid hormone, Levothyroxine Abdi is not expected to affect the ability to drive and operate machinery.

Levothyroxine Abdi contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Levothyroxine Abdi contains sodium

This medicinal product contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Levothyroxine Abdi

Always take this medicine exactly as your doctor or pharmacist has recommended to you. Ask your doctor or pharmacist 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 a low body weight or a large goiter.

<i>Use of Levothyroxine Abdi</i>	<i>Recommended daily dose of Levothyroxine Abdi</i>	
<ul style="list-style-type: none"> • to treat benign goiter in patients with normal thyroid function 	75 - 200 microgram	
<ul style="list-style-type: none"> • to prevent recurrence of goiter after surgery 	75 - 200 microgram	
<ul style="list-style-type: none"> • to replace natural thyroid hormones, when your thyroid gland does not produce enough - initial dose - maintenance dose 	adults	children
	<ul style="list-style-type: none"> - initial dose 	25 - 50 microgram*
<ul style="list-style-type: none"> - maintenance dose 	100 - 200 microgram	100 – 150 microgram per m ² of body surface
<ul style="list-style-type: none"> • to suppress tumour growth in patients with thyroid cancer 	150 - 300 microgram	
<ul style="list-style-type: none"> • to balance thyroid hormone levels, when overproduction of hormones is treated with anti-thyroid medicines 	50 -100 microgram	
<ul style="list-style-type: none"> • to test thyroid function 	100 microgram: 200 microgram (2 tablets) starting 2 weeks before the test 150 microgram: Starting 4 weeks before the test 75 microgram (½ tablet) for two weeks, then 150 microgram (1 tablet) until the test 200 microgram: 200 microgram (1 tablet) starting 2 weeks before the test	

* Levothyroxine Abdi 125 microgram, 150 microgram, 175 microgram or 200 microgram tablets are not suitable for the lower dose range listed here, but your doctor may prescribe a lower strength of Levothyroxine Abdi tablets.

Administration

Levothyroxine Abdi is intended for oral use.

Take the entire daily dose in the morning on an empty stomach (at least half an hour before breakfast), preferably with a little liquid, for example with half a glass of water.

Infants receive the entire daily Levothyroxine Abdi dose at least half an hour before the first meal of the day. For that, crush the tablet immediately before taking it and mix it with a little water, then give this mixture to the child with a little more fluid. Always prepare the mixture freshly.

Duration of treatment

The duration of treatment depends on the condition of which you are taking Levothyroxine Abdi. Therefore, your doctor will discuss with you on how long you will take. Most patients require to use Levothyroxine Abdi for lifelong.

If you have used more Levothyroxine Abdi than you should

If you take a higher dose than prescribed, you may experience symptoms such as palpitations, anxiety, restlessness or involuntary movements. In patients with neurological disorders, e.g. Epilepsy, seizures may occasionally occur in individual cases. Patients at risk for psychotic disorders may experience acute psychosis symptoms. Please contact your doctor in such cases.

If you forget to take Levothyroxine Abdi

Do not take a double dose if you forget to take the previous dose, but return to the normal dose range in the next 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, Levothyroxine Abdi can have side effects, although not everybody gets them.

If you take more Levothyroxine Abdi than prescribed or you can't tolerate the dose (for example, if the dose increase is too rapid), the following adverse effects may occur:

Rapid or irregular heartbeat, chest pain, headache, muscle weakness or spasms, flushing (warmth feeling and redness of the face), fever, vomiting, menstrual disorders, pseudo-tumor cerebri (increased pressure in the head with eye swelling), tremors, inner restlessness, sleep disturbances, sweating, weight loss, diarrhea.

Consult your doctor if such adverse effects occur. Your doctor will decide whether to discontinue the treatment for a few days or reduce the dose until the adverse effects have disappeared

Allergic reactions to the other components of Levothyroxine Abdi are possible (see section 6 "What does Levothyroxine Abdi contain"). The frequency of incidence is not known. Allergic reactions may be seen as facial and throat swelling (angioedema), rash and urticaria. In this case, contact your doctor immediately.

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 het Nederlands Bijwerkingen Centrum Lareb, website: www.lareb.nl. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Levothyroxine Abdi

Keep this medicine out of the sight and reach of children.

Do not use after the expiry date which is stated on the blister and carton. The expiry date refers to the last day of the 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. Content of the pack and other information

What Levothyroxine Abdi contain

- The active substance is Levothyroxine sodium.
- Each tablet contains 25 micrograms of Levothyroxine sodium.
- Each tablet contains 50 micrograms of Levothyroxine sodium.
- Each tablet contains 75 micrograms of Levothyroxine sodium.
- Each tablet contains 100 micrograms of Levothyroxine sodium.
- Each tablet contains 125 micrograms of Levothyroxine sodium.
- Each tablet contains 150 micrograms of Levothyroxine sodium.
- Each tablet contains 175 micrograms of Levothyroxine sodium.
- Each tablet contains 200 micrograms of Levothyroxine sodium.
- The other components are maize starch, croscarmellose sodium, gelatin, lactose monohydrate and magnesium stearate.

What Levothyroxine Abdi looks like and contents of the pack

Levothyroxine Abdi 25 microgram tabletten are round and white tablets with debossed on one side with “25” and scored in the shape of “+” sign on the other side.

Levothyroxine Abdi 50 microgram tabletten are round and white tablets with debossed on one side with “50” and scored in the shape of “+” sign on the other side.

Levothyroxine Abdi 75 microgram tabletten are round and white tablets with debossed on one side with “75” and scored in the shape of “+” sign on the other side.

Levothyroxine Abdi 100 microgram tabletten are round and white tablets with debossed on one side with “100” and scored in the shape of “+” sign on the other side.

Levothyroxine Abdi 125 microgram tabletten are round and white tablets with debossed on one side with “125” and scored in the shape of “+” sign on the other side.

Levothyroxine Abdi 150 microgram tabletten are round and white tablets with debossed on one side with “150” and scored in the shape of “+” sign on the other side.

Levothyroxine Abdi 175 microgram tabletten are round and white tablets with debossed on one side with “175” and scored in the shape of “+” sign on the other side.

Levothyroxine Abdi 200 microgram tabletten are round and white tablets with debossed on one side with “200” and scored in the shape of “+” sign on the other side.

The tablets are supplied in PVC/PE/PVDC aluminum blisters of 30, 50, 84, 90 and 100 tablets in cartons.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Abdi Farma, Unip. Lda.
Quinta da Fonte, Rua dos Malhões,
Edifício D. Pedro I
2770-071 Paço de Arcos,
Portugal

Manufacturer

Interpharma Services Ltd.
43A Cherni Vrach Blvd. 1407- Sofia
Bulgarije

In het register ingeschreven onder:

Levothyroxine Abdi 25 microgram tabletten	RVG 123126
Levothyroxine Abdi 50 microgram tabletten	RVG 123129
Levothyroxine Abdi 75 microgram tabletten	RVG 123130
Levothyroxine Abdi 100 microgram tabletten	RVG 123131
Levothyroxine Abdi 125 microgram tabletten	RVG 123132
Levothyroxine Abdi 150 microgram tabletten	RVG 123133
Levothyroxine Abdi 175 microgram tabletten	RVG 123134
Levothyroxine Abdi 200 microgram tabletten	RVG 123135

Deze bijsluiter is voor het laatst goedgekeurd in december 2023.