

Package leaflet: Information for the patient

Levothyroxine sodium Aristo 150 microgram tablets

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

1. What Levothyroxine sodium Aristo is and what it is used for

Thyroxine is a hormone which is produced naturally in the body by the thyroid gland. Levothyroxine sodium is a synthetic version of this hormone.

Levothyroxine sodium Aristo is used to replace the missing thyroid hormone and/or to relieve stress on the thyroid gland.

Levothyroxine sodium Aristo is used

- to replace the missing thyroid hormone in all forms of underactive thyroid function (*hypothyroidism*) or after the removal of the thyroid gland,
- to prevent the return of new goitres after goitre surgery in patients with normal thyroid function,
- to treat non-malignant goitre (*benign struma*) in patients with normal thyroid function,
- for malignant thyroid tumours, particularly after surgery to suppress new tumour growth and as a supplement for missing thyroid hormone,
- in the thyroid suppression test.

2. What you need to know before you take Levothyroxine sodium Aristo

Do not take Levothyroxine sodium Aristo

- if you are allergic to levothyroxine sodium or any of the other ingredients of this medicine (listed in section 6),
- if you suffer from an untreated overactive thyroid gland (*hyperthyroidism*, *thyrotoxicosis*),
- if you suffer from underactive adrenal glands (*adrenal insufficiency*) and you do not have an adequate replacement treatment,
- if you suffer from untreated deficiency of the pituitary gland,
- if you have the following diseases or conditions:
 - an acute myocardial infarction,
 - acute inflammation of the heart muscle (myocarditis),

- acute inflammation of all the heart walls (pancarditis),
- if you are pregnant, Levothyroxine sodium Aristo must not be used at the same time as medicines to treat an overactive thyroid gland (*anti-thyroid medicines*).

Before the start of treatment with Levothyroxine sodium Aristo, the following disorders or conditions must be ruled out or treated:

- coronary heart disease,
- chest pain with tight-chestedness (*angina pectoris*),
- fatty deposits in your arteries (*arteriosclerosis*),
- high blood pressure (*hypertension*),
- conditions where the pituitary/adrenal glands do not produce enough hormones (pituitary and/or adrenal cortex deficiency),
- areas in the thyroid that produce uncontrolled amounts of thyroid hormone (*thyroid autonomy*).

Warnings and precautions

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 (see section 2 ‘Other medicines and Levothyroxine sodium Aristo’).

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. 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 or pharmacist before taking Levothyroxine sodium Aristo,

- if you have suffered with an under active thyroid gland for a long time, i.e. since birth or acquired during childhood,
- if you suffer from heart problems including angina pectoris, coronary artery disease, weak heart muscle, heart rhythm disorders or high blood pressure or arteriosclerosis,
- if you have suffered from a heart attack recently,
- if you are taking medicine to prevent blood clotting (e.g. phenprocoumon). The dose of this medicine may need to be changed (see section 2. “Other medicines and Levothyroxine sodium Aristo”),
- if you are being treated for diabetes. The dose of your anti-diabetic medicine may need to be changed as levothyroxine can raise blood sugar levels (see section 2. “Other medicines and Levothyroxine sodium Aristo”),
- if you have gone through the menopause. Your thyroid function should be checked more frequently to avoid increased blood levels of levothyroxine, which can cause *osteoporosis* (brittle bones),
- if you suffer from epilepsy (fits). Fits have been rarely reported when starting the treatment with levothyroxine or when the dose is increased rapidly,
- if you suffer from *myxoedema* (skin and subcutaneous tissue swelling) as the dosage of Levothyroxine sodium Aristo may need to be reduced,
- if you suffer from a disease of your small bowels, as that can also inhibit the absorption of the drug (malabsorption syndromes) e.g. coeliac disease, lactose intolerance) and may need to be treated to ensure that your Levothyroxine sodium Aristo treatment works well,
- if you are suffering from an underactive adrenal gland (*adrenal insufficiency*), dysfunction of the pituitary gland or dysfunction of the thyroid gland with uncontrolled overproduction of thyroid hormones, because this must be medically controlled before you start taking Levothyroxine sodium Aristo,
- 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 2 ‘Other medicines and Levothyroxine sodium Aristo).

Talk to your doctor if you experience signs of psychotic disorders.

Blood pressure will be regularly monitored when levothyroxine treatment is started in very low birth weight preterm neonates because a rapid fall in blood pressure (known as circulatory collapse) may occur.

In the elderly, the dose should be carefully and individually tailored, e.g. for those with heart problems, and they should be monitored by their doctor.

Blood tests

Before you start taking levothyroxine your doctor will do a blood test to see how much thyroxine your thyroid gland is making and what dose of the medicine you will need. Once you start taking the medicine your doctor will want you to have regular blood tests to see how well the medicine is working.

Other medicines and Levothyroxine sodium Aristo

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes over the counter medicines, herbal remedies and vitamin supplements. Many medicines affect the way levothyroxine works. The effects of other drugs may also be affected by levothyroxine.

If you are about to have a test with iodinated contrast media, you should tell your doctor that you are taking Levothyroxine sodium Aristo.

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 section 2 ‘warnings and precautions’).

The following medicines may affect the way that levothyroxine works:

- medicines for epilepsy or seizures such as carbamazepine, phenytoin, primidone and barbiturates,
- products containing St. John’s Wort (a herbal medicinal product),
- sertraline, lithium – used to treat depression, mood and anxiety disorders,
- statins such as simvastatin and lovastatin (used to treat high cholesterol),
- rifampicin – used to treat infections,
- imatinib, sunitinib, 5-fluorouracil – used to treat certain types of cancer,
- beta blockers such as propranolol, atenolol and sotalol – used to treat high blood pressure and heart problems,
- oestrogen containing medicines for hormone replacement therapy (HRT) and contraception (“the pill”),
- androgen containing medicines for male hormone replacement therapy,
- glucocorticoids such as cortisone, hydrocortisone, prednisolone and dexamethasone – used to treat inflammation,
- amiodarone – used to treat an irregular heart beat,
- anti-inflammatory medicines such as phenylbutazone or acetylsalicylic acid,
- methadone – used for opioid substitution treatment,
- furosemide – used to treat high blood pressure or oedema,
- propylthiouracil – used to treat overactive thyroid,
- iodide – used to protect the thyroid gland from radiation,
- oral contrast agents – taken before certain scans to make parts of the body show up better on the scan,

- chloroquine/proguanil – used for malaria prophylaxis and in rheumatic diseases,
- ritonavir - used to control HIV and chronic hepatitis C virus,
- orlistat – 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 sodium Aristo.

Levothyroxine sodium Aristo should be taken at least 4-5 hours before taking the following medicines:

- calcium, magnesium, aluminium or iron supplements, lanthanum,
- cholestyramine, colestipol or clofibrate - used to reduce cholesterol levels in the blood,
- sodium polystyrene sulphonate - used to treat kidney disease,
- orlistat – used for weight loss,
- cimetidine – used to reduce excess stomach acid,
- proton pump inhibitors such as omeprazole, esomeprazole - used to treat an excess of acid in the stomach,
- sucralfate, antacids - to treat stomach ulcers.

The following medicines may be affected by levothyroxine:

- anticoagulant medicines to prevent blood clots such as warfarin, dicoumarol and phenprocoumon,
- medicines to treat diabetes such as insulin and metformin,
- tricyclic antidepressants such as amitriptyline, imipramine and dosulepin,
- medicines that stimulate the sympathetic nervous system such as adrenaline (used to treat severe allergic reactions) or phenylephrine (a decongestant found in many cold and flu treatments),
- digoxin – used to treat heart problems,
- phenytoin – anti-epileptic medicine.

Levothyroxine sodium Aristo with food and drink

Soya containing products and foods that are high in fibre may affect the absorption of levothyroxine. Your doctor may need to adjust the dose of levothyroxine as a result.

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.

Consistent treatment with thyroid hormones is particularly important during pregnancy and breast-feeding and must therefore be continued under the supervision of the treating doctor.

The need for levothyroxine may increase during pregnancy due to increased blood levels of oestrogen (female sex hormone). Thyroid function should therefore be monitored both during and after pregnancy and the levothyroxine dose adjusted as appropriate.

Even during high dose levothyroxine therapy, the amount of thyroid hormone passing into breast milk during lactation is very low and therefore harmless.

Suppression tests must not be performed during pregnancy and breastfeeding.

Driving and using machines

It is not expected that Levothyroxine sodium Aristo has any influence on the ability to drive and use machines, because levothyroxine is identical to the naturally occurring thyroid hormone.

Levothyroxine sodium Aristo contains sodium

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

3. How to take Levothyroxine sodium Aristo

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

In elderly patients, patients with coronary heart disease and patients with severe or chronic underactive thyroid function, particular caution is required when starting treatment with thyroid hormones. This means that a lower starting dose must be selected, which is then increased slowly and at longer intervals, with frequent thyroid hormone monitoring.

Experience has shown that a lower dose is also sufficient in patients with a low body weight and in patients with large goitres.

Dosage

For individual treatment, tablets are available with graduated levels ranging from 25–200 microgram of Levothyroxine sodium Aristo, which means that only one tablet daily needs to be taken in most cases.

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.

Use of Levothyroxine sodium Aristo	Recommended daily dose of Levothyroxine sodium Aristo	
- to replace natural thyroid hormones, when your or your child's thyroid gland does not produce enough - initial dose - maintenance dose	adults	children
	25–50 microgram 100–200 microgram	12.5–50 microgram 100–150 microgram per m ² of body surface
- to replace natural thyroid hormones, when your baby's thyroid gland does not produce enough - initial dose for the first 3 months - maintenance dose	newborns and infants 10–15 microgram per kg individual dose as recommended by the doctor	
- to prevent recurrence of goitre after surgery	75–200 microgram	
- to treat benign goitre in patients with normal thyroid function	75–200 microgram	
- 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	<u>Levothyroxine sodium Aristo 150 microgram tablets</u> 150 microgram (1 tablet)/day starting 2 weeks before the test	
	<u>Levothyroxine sodium Aristo 200 microgram tablets</u> 200 microgram (1 tablet)/day starting 2 weeks before the test	

Method of administration

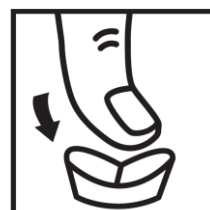
The total daily dose is taken in the morning on an empty stomach, at least half an hour before breakfast, as the active substance is better absorbed on an empty stomach than before or after a meal. The tablets are swallowed whole without chewing, with a glass of water.

Infants are given the total daily dose at least half an hour before their first meal of the day, preferably with some water to facilitate swallowing. If necessary the tablet can be divided. It is not recommended that tablets are crushed and dispersed in water or other liquids, which could lead to dosing inaccuracy.

Levothyroxine sodium Aristo tablets can be divided into equal doses.

Notice on divisibility

Place the tablet with the score line facing up on a hard flat surface. To divide the tablet push with your thumb straight in the middle of the tablet.



Duration of administration

You should take this medicine for as long as your doctor tells you.

If you have an underactive thyroid gland or have had thyroid surgery for a malignant tumour of the thyroid, you will usually take Levothyroxine sodium Aristo for life.

For benign goitre and for prevention of recurrent goitre growth, you must take Levothyroxine sodium Aristo for anything between several months or years to the rest of your life.

In supportive therapy for the treatment of an overactive thyroid, you must take Levothyroxine sodium Aristo as long as you take a thyreostatic medicine.

For the treatment of benign goitre with normal thyroid function, a treatment period of 6 months to 2 years is necessary. If the treatment with Levothyroxine sodium Aristo has not produced the desired result within this period, other treatment options should be considered.

For performing thyroid suppression tests, 150 or 200 microgram of Levothyroxine sodium Aristo is taken daily for 14 days.

If you take more Levothyroxine sodium Aristo than you should

If you (or someone else) swallow more tablets at the same time than you should, or you think a child may have swallowed some, contact your doctor, nearest hospital casualty department or poison control centre immediately.

Signs of an overdose may include: agitation, feeling confused, feeling irritable, fever, chest pain (angina), rapid or irregular heartbeat, rapid breathing, muscle cramps, headache, restlessness, hyperactivity, flushing, sweating, dilated pupils, diarrhoea, shaking, difficulty sleeping, anxiety or nervousness, feeling tired or emotional, seizures.

These signs can take up to 6 days to appear. Take any remaining tablets and this leaflet with you so that the medical staff know exactly what you have taken.

If you forget to take Levothyroxine sodium Aristo

If you miss a dose, take the usual dose when your next dose is due. Do not take a double dose to make up for forgotten individual doses. If you are unsure, please seek advice from your doctor or pharmacist.

If you stop taking Levothyroxine sodium Aristo

For your treatment to be successful, you must take Levothyroxine sodium Aristo regularly at the dosage prescribed by your doctor. On no account should you change, suspend or stop the prescribed treatment without talking to your doctor otherwise 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.

Stop taking the tablets and go to hospital at once if you have:

- an allergic reaction such as swelling of the face, tongue, lips and/or throat, and/or difficulty swallowing or hives potentially with difficulty breathing (*angioedema*), severe itching of your skin with raised lumps, joint pain, sensitivity to the sun, general feeling of being unwell (frequency not known). You may need urgent medical attention.

Some patients may experience a severe reaction to high levels of thyroid hormone. This is called a "thyroid crisis". Stop taking the tablets and go to hospital immediately if you have any of the following symptoms (frequency not known):

- very high temperature, fast heart rate, irregular heartbeat, low blood pressure, heart failure, jaundice, confusion, fits and coma.

Tell your doctor or pharmacist if any of the following side effects continue, get worse or if you notice any other side effects not listed.

Most of the side effects are similar to the symptoms of hyperthyroidism (where the thyroid gland makes too much thyroxine) and are due to your dose of the medicine being too high. They will usually disappear after reducing the dose or stopping the tablets. Tell your doctor if side effects occur. He/she will decide whether the daily dose should be reduced or whether you should stop taking your tablets for a few days. However, you must not change the dose or stop the tablets without talking to your doctor first.

Not known: frequency cannot be estimated from the available data

- increased appetite
- restlessness, excitability, difficulty sleeping (*insomnia*)
- shaking (*tremor*), headache, fits
- chest pain (*angina pectoris*), pounding, irregular or fast heartbeat, heart failure, heart attack
- high blood pressure (*hypertension*), flushing
- shortness of breath (*dyspnoea*)
- diarrhoea, being sick (*vomiting*), feeling sick (*nausea*), stomach pains
- increased sweating, itching, skin rash, urticaria
- muscle cramps, muscle weakness, joint pain
- a decrease in the density of bones (*osteoporosis*), particularly in women who have gone through the menopause and are taking high doses for long periods
- in women: irregular periods
- fever (high temperature), swelling (*oedema*), general feeling of being unwell
- weight loss
- overactive thyroid (*hyperthyroidism*)

Additional side effects in children

Rare: may affect up to 1 in 1,000 people

- increased pressure around the brain in children that is not caused by a tumour or other diseases (*benign intracranial hypertension*)

Not known: frequency cannot be estimated from the available data

- growth in children may slow or stop due to changes in bone growth

- temporary hair loss in children
- deformity of the skull in infants caused by the early closure of joints in the skull bone (*craniosynostosis*)
- intolerance to heat

In the case of hypersensitivity to levothyroxine or any of the other ingredients of Levothyroxine sodium Aristo, allergic reactions of the skin and respiratory tract region may occur.

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 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 sodium Aristo

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 after “EXP:”. The expiry date refers to the last day of that month.

Do not store above 30 °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 Levothyroxine sodium Aristo contains

The active substance is anhydrous levothyroxine sodium.

Levothyroxine sodium Aristo 150 microgram tablets

Each tablet contains 150 microgram of anhydrous levothyroxine sodium.

Levothyroxine sodium Aristo 200 microgram tablets

Each tablet contains 200 microgram of anhydrous levothyroxine sodium.

The other ingredients are microcrystalline cellulose, maize starch, heavy magnesium oxide, sodium starch glycolate type A and magnesium stearate [vegetable].

What Levothyroxine sodium Aristo looks like and contents of the pack

Levothyroxine sodium Aristo are white, round, uncoated vaulted tablets (snap tab) with a break mark on one side and the numeric strength (i.e. “150” or “200”) embossed on the other. The tablets have an approximate diameter of 7 mm and an approximate height of 3 mm.

Levothyroxine sodium Aristo 150 microgram tablets are packed in a blister pack of 20, 25, 30, 50, 60, 90 and 100 tablets.

Levothyroxine sodium Aristo 200 microgram tablets are packed in a blister pack of 15, 20, 25, 30, 50, 60, 84, 90 and 100 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Aristo Pharma GmbH
Wallenroder Straße 8-10
13435 Berlin
Germany

Manufacturer

Lindopharm GmbH
Neustraße 82
40721 Hilden
Germany

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

Austria:	Levothyroxin Aristo
Czech Republic:	Levothyroxine Aristo
Germany:	L-Thyroxin Aristo
Finland:	Levothyroxine Aristo
Ireland:	Levothyroxine sodium Aristo
Italy:	Levotiroxina Aristo
Netherlands:	Levothyroxinenatrium Aristo
Poland:	Eferox
Portugal:	Levotiroxina Aristo
Spain:	Levotiroxina Aristo
Sweden:	Levothyroxine Aristo

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