

Package leaflet: Information for the patient

Levothyroxine Aristo/Vencamil 12.5, 25, 50, 75, 100 micrograms 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 Aristo/Vencamil is and what it is used for
2. What you need to know before you take Levothyroxine Aristo/Vencamil
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1. What Levothyroxine Aristo/Vencamil is and what it is used for

Thyroxine is a hormone which is produced naturally in the body by the thyroid gland. Levothyroxine is a synthetic version of this hormone. Thyroxine controls how much energy your body uses. When the thyroid gland does not produce enough thyroxine (a condition known as hypothyroidism), many of the body's functions slow down. Some of the most common symptoms of hypothyroidism are:

- tiredness
- weight gain
- feeling depressed

Levothyroxine Aristo/Vencamil is used to replace the thyroxine that your thyroid gland cannot produce and prevent the symptoms of hypothyroidism. Before starting your treatment your doctor will carry out a blood test to work out how much levothyroxine you need.

2. What you need to know before you take Levothyroxine Aristo/Vencamil

Do not take Levothyroxine Aristo/Vencamil:

- if you are allergic to levothyroxine or any of the other ingredients of this medicine (listed in section 6);
- if you suffer from an overactive thyroid gland that produces too much thyroid hormone (thyrotoxicosis);
- if you have any condition that affects your adrenal glands (your doctor will be able to advise you if you are not sure);
- 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).

During pregnancy, Levothyroxine Aristo/Vencamil must not be used at the same time as medicines to treat an overactive thyroid gland (anti-thyroid medicines).

If any of these apply to you, do not take this medicine and go back to your doctor to discuss your treatment.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Levothyroxine Aristo/Vencamil,

- if you have suffered with an under active thyroid gland for a long time;
- if you suffer from heart problems including angina, coronary artery disease or high blood pressure. The doctor may require an ECG before starting treatment with levothyroxine, as changes induced by hypothyroidism may be confused with evidence of ischaemia (decreased oxygen in a tissue);
- if you have epilepsy (fits). Fits have been rarely reported when starting the treatment with levothyroxine;
- if you have a particular hormonal disorder called panhypopituitarism;
- 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;
- if you are over 50 years of age.

Subclinical hyperthyroidism (where the thyroid gland makes too much thyroxine) may occur if your dose is too high and this could be associated with bone loss (osteoporosis). This will usually disappear after reducing the dose or stopping the tablets. However, you must not change the dose or stop the tablets without talking to your doctor first.

Patients occasionally find that they feel less well when changing from one levothyroxine medicine to another. You should tell your doctor if you get any side effects so that your blood can be checked for levels of thyroid hormone. If your symptoms persist you may need a specific brand of levothyroxine to be prescribed.

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 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.

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 Aristo/Vencamil').

Children

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.

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

Other medicines and Levothyroxine Aristo/Vencamil

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.

The following may affect the way that levothyroxine works:

- medicines for epilepsy such as carbamazepine, phenytoin, primidone and barbiturates
- products containing St. John's Wort (a herbal medicine)
- sertraline – used to treat depression and anxiety disorders
- antacids – used to treat indigestion
- medicines containing calcium salts
- cimetidine – used to reduce excess stomach acid
- 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 Aristo/Vencamil
- sucralfate – used to treat and prevent stomach and duodenal ulcers
- cholestyramine and colestipol – used to treat high levels of fat in the blood
- polystyrene sulphone resin – used to reduce high levels of potassium in the blood
- medicines containing iron that are taken by mouth
- rifampicin – used to treat infections
- imatinib – used to treat certain types of cancer
- beta blockers such as 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
- corticosteroids such as hydrocortisone and prednisolone – used to treat inflammation
- amiodarone – used to treat an irregular heart beat
- orlistat – used to treat obesity
- ritonavir - used to control HIV and chronic hepatitis C virus
- lovastatin – used to treat high cholesterol.

The following may be affected by levothyroxine:

- anticoagulant medicines to prevent blood clots such as warfarin
- 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
- anti-inflammatory medicines such as phenylbutazone or aspirin
- propranolol – used to treat high blood pressure and heart problems
- ketamine – used as an anaesthetic. If you need to have an operation, please tell your doctor or anaesthetist that you are taking levothyroxine.

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’).

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. Your doctor will decide if you should continue treatment with levothyroxine whilst you are pregnant, particularly in the first three months of your pregnancy.

Driving and using machines

This medicine should not affect your ability to drive and use machines.

Information on sodium content

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

3. How to take Levothyroxine Aristo/Vencamil

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. You may be taking this medicine for the rest of your life.

Your dose will be decided by your doctor and will depend on the results of your blood tests. The dose you should take will be on the label attached by your pharmacist.

Swallow the tablets with plenty of water. The tablets may start to disintegrate in the mouth in contact with saliva. You should usually take your tablets before breakfast or your first meal of the day.

Adults

The recommended starting dose is 50-100 micrograms every day. Your doctor may increase the dose you take every 3-4 weeks by 50 micrograms until your thyroxine levels are correct. Your final daily dose may be up to 100-200 micrograms daily.

Patients over 50 years of age

The recommended starting dose will be no more than 50 micrograms every day. The dose may then be increased by 50 micrograms every 3-4 weeks until your thyroxine levels are correct. Your final daily dose will be between 50-200 micrograms daily.

Patients over 50 years of age with heart problems

The recommended starting dose will be 25 micrograms every day or 50 micrograms every other day. The dose may be increased by 25 micrograms every 4 weeks until your thyroxine levels are correct. Your final daily dose will usually be between 50-200 micrograms daily.

Use in children and adolescents

For young children, your doctor is likely to prescribe Levothyroxine Oral Solution instead of tablets.

Congenital hypothyroidism in infants

This is a condition where your baby has been born with a thyroid gland that does not produce enough thyroxine. The starting dose is 10-15 micrograms/kg bodyweight per day for the first three months. The dose will then be adjusted depending on how your baby responds to the treatment.

Acquired hypothyroidism in children

This is a condition where your child's thyroid gland stops working properly because it has been attacked by their immune system, e.g. in children with an autoimmune disease or following a viral infection. The starting dose is 12.5-50 micrograms per day. The dose will then be increased every 2-4 weeks depending on how your child responds to the medicine.

Juvenile myxoedema

This is a condition where children and adolescents develop severe hypothyroidism (produce very low levels of thyroid hormones). The starting dose is 25 micrograms every day. The dose will then be increased by 25 micrograms every 2-4 weeks until your child shows mild symptoms of hyperthyroidism (a condition where the thyroid gland produces too much thyroxine). The dose will then be reduced slightly.

If you take more Levothyroxine Aristo/Vencamil than you should

If you (or someone else) swallow a lot of the tablets at the same time, or you think a child may have swallowed some, contact your nearest hospital casualty department or tell your doctor immediately. Signs of an overdose may include: fever, chest pain (angina), racing or irregular heartbeat, muscle cramps, headache, restlessness, flushing, sweating, diarrhoea, shaking (tremor), difficulty sleeping (insomnia) and very high temperature (hyperpyrexia). These signs can take up to 5 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 Aristo/Vencamil

If you forget to take a dose, take it as soon as you remember unless it is nearly time for your next dose. Do not take a double dose to make up for a forgotten dose. If you forget to give your child their dose, contact your doctor or pharmacist for further advice.

If you stop taking Levothyroxine Aristo/Vencamil

These tablets are for long term use. You may need to take them for the rest of your life. Do not stop taking the tablets unless your doctor has told you to do so.

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:

- a rare allergic reaction such as swelling of the face, tongue, lips and throat, difficulty breathing, severe itching of your skin with raised lumps, joint pain, sensitivity to the sun, general feeling of being unwell. 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" and you should contact your doctor immediately if you have any of the following symptoms:

- 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. 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)

- headache
- flushing
- high temperature, sweating
- hair loss
- weight loss
- tremor, restlessness, excitability, difficulty sleeping (insomnia)
- increased pressure around the brain in children that is not caused by a tumour or other diseases (benign intracranial hypertension)
- chest pain (angina), pounding, irregular or fast heartbeat
- diarrhoea, vomiting
- muscle cramps, muscle weakness

- deformity of the skull in infants caused by the early closure of joints in the skull bone (craniostenosis)
- growth in children may slow or stop due to changes in bone growth
- irregular periods
- intolerance to heat and temporary hair loss in children.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly via the Yellow Card Scheme at:

www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Levothyroxine Aristo/Vencamil

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

Levothyroxine Aristo/Vencamil 12.5 micrograms tablets: Do not store above 25°C.

Levothyroxine Aristo/Vencamil 25, 50, 75 & 100 micrograms tablets: 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 Aristo/Vencamil contains

The active substance is anhydrous levothyroxine sodium.

Each tablet contains 12.5, 25, 50, 75 or 100 micrograms of anhydrous levothyroxine sodium respectively.

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

What Levothyroxine Aristo/Vencamil looks like and contents of the pack

Levothyroxine Aristo/Vencamil tablets are white, round tablets with a score-line on one side and the numeric strength (i.e. “12.5”, “25”, “50”, “75” or “100”) embossed on the other.

The score-line on the 12.5 micrograms tablet is not intended for breaking the tablet.

The tablets are packed in a blister pack of 28 tablets.

Marketing Authorisation Holder and Manufacturer

Aristo Pharma GmbH

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