

Package leaflet: information for the user

Eltroxin 50 microgram tablets
Eltroxin 100 microgram tablets
Levothyroxine sodium

Read the entire leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- Do you have any questions? Contact your doctor or pharmacist.
- Do not pass this medicine on to others, as it has been prescribed only for you. It may harm them, even if their symptoms are the same as yours.
- Do you experience any side effects listed in section 4? Or do you experience a side effect not mentioned in this leaflet? Then contact your doctor or pharmacist.

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1. What is Eltroxin and what is it used for?

Eltroxin tablets contain anhydrous levothyroxine sodium; it is the monosodium salt of the levo-isomer of thyroxine.

Although the active ingredient, levothyroxine sodium, is synthetic, it resembles the natural thyroid hormone (chemical messenger) in your body. The thyroid hormone is produced by the thyroid gland in your neck and regulates metabolism, which is mainly related to growth and energy.

Eltroxin tablets are used for the treatment of an underactive thyroid that produces insufficient thyroxine.

2. When should you not use this medicine or be extra careful with it?

When should you not use this medicine?

You are allergic to levothyroxine sodium or any of the other ingredients in this medicine. These ingredients can be found in section 6.

You have been told that your thyroid is overactive.

You have a certain heart condition (such as a heart attack, acute pancarditis (inflammation of the heart), acute myocarditis (inflammation of the heart muscle), etc.).

You suffer from underactive adrenal glands (adrenal insufficiency) and do not have suitable replacement therapy.

During pregnancy, this medicine should not be used in combination with medications for an overactive thyroid (antithyroid drugs).

If you are about to undergo a laboratory test to check your thyroid hormone levels, you should inform your doctor and/or the laboratory staff that you are using or have recently used biotin (also known as vitamin H, vitamin B7, or vitamin B8). Biotin can affect the results of your laboratory test. Depending on the test, the results may be falsely high or low due to the use of biotin. Your doctor may ask you to stop using biotin prior to the laboratory test. You should also be aware that other medications you may be using, such as multivitamins or supplements for hair, skin, and nails, may also contain biotin. This can affect the results of the laboratory test. Inform your doctor and/or the laboratory staff if you are using such medications (Refer to the information in the section 'Are you using any other medicines?').

Tell your doctor if any of the situations mentioned above apply to you.

When should you be extra careful with this medicine?

Contact your doctor or pharmacist before using this medicine.

- If you have autonomous euthyroid goiter (a condition where the thyroid gland is enlarged).
- If you suffer from any of the following heart conditions
 - High blood pressure,
 - Rapid or irregular heartbeat,
 - Fat deposits in the arterial walls (arteriosclerosis),
 - Chest pain with a feeling of tightness (angina pectoris),
 - Insufficient blood flow in the coronary arteries (coronary insufficiency).
- If you have diabetes mellitus or diabetes insipidus.
- If you have an adrenal gland disorder.
- If you have myxedema (a disease caused by decreased thyroid activity in adults, characterized by dry skin, swelling around the lips and nose, and changes in mental state, etc.).
- If you suffer from malabsorption syndromes (a group of disorders where the ability of the intestines to absorb certain nutrients is affected).
- If you are pregnant (during pregnancy, levothyroxine hormone levels may change. Your doctor may frequently check your thyroid function).
- Postmenopausal women have an increased risk of osteoporosis when using Eltroxin.
- Are you pregnant or planning to become pregnant? Then contact your doctor as soon as possible. Your doctor will ensure careful monitoring of your pregnancy to adjust your dose if necessary (see the section "Pregnancy, breastfeeding, and fertility").
- If you have an underactive adrenal gland (adrenal insufficiency).

Elderly patients

If you are over 50 years old, it is especially important to strictly adhere to your doctor's dosage instructions.

If one or more of the above situations apply to you, you should inform your doctor or pharmacist before using Eltroxin.

Do not use Eltroxin for the treatment of obesity or to lose weight. Thyroid hormones are not suitable for weight loss. Taking thyroid hormones will not reduce your weight if your thyroid hormone levels are within normal values. Severe or even life-threatening side effects may occur if you increase the dose without specific consultation with your doctor, especially when using this medication in combination with other weight loss drugs. Tell your doctor if you are using a weight loss medication, such as Orlistat.

- An imbalance in thyroid hormones may occur if you need to switch to another product containing levothyroxine. Contact your doctor or another qualified healthcare professional if you have questions about changing your medication. During the transition period, close monitoring (clinical and biological) is necessary. You should inform your doctor if you experience side effects, as they may indicate that your dose needs to be increased or decreased.
- High doses can lead to severe or even life-threatening results. If you experience side effects, contact your doctor or pharmacist.

Are you using any other medications?

Are you using any other medications besides Eltroxin, or have you done so recently, or is there a possibility that you will use other medications in the near future? Then tell your doctor or pharmacist.

If you are using biotin or have recently used it, you must inform your doctor and/or the laboratory staff when you are about to undergo a laboratory test to check your thyroid hormone levels. Biotin can affect the results of the laboratory test (see the section 'When should you be extra careful with this medicine?').

The following medicines can affect the absorption of Eltroxin

Used for lowering cholesterol levels (Cholestyramine and colestipol).

Medicines containing calcium, aluminum, magnesium, or iron.

Used for treating intestinal ulcers (Sucralfate).

Used for treating kidney failure (Polystyrene sulfonate, lanthanum, kayexalate, and sevelamer).

Proton pump inhibitors (such as omeprazole, esomeprazole, pantoprazole, rabeprazole, and lansoprazole) are used to reduce the amount of acid produced by the stomach, which can hinder the absorption of levothyroxine from the intestines and thus reduce the efficacy of levothyroxine. If you are using levothyroxine while being treated with proton pump inhibitors, your doctor should monitor your thyroid function and possibly adjust the dose of Eltroxin.

Medicines for weight loss, such as Orlistat.

Separate the dosages of Eltroxin and the aforementioned medicines as much as possible to avoid interaction in the stomach or small intestine as much as possible.

The following medicines can affect the action of Eltroxin

Medicines used for the treatment of epilepsy (e.g., carbamazepine, phenytoin, and barbiturates).

Products containing St. John's wort (an herbal medicine).

Medicines used for the treatment of certain infections (e.g., Rifampicin and ciprofloxacin).

Beta-blockers, used for the treatment of high blood pressure (e.g., propranolol).

Medicines used for the treatment of an abnormal heart rhythm (e.g., amiodarone).

Medicines containing lithium or iodine.

Liquids used for X-rays (e.g., oral contrast medicines).

Medicines for the treatment of hyperthyroidism, an overactive thyroid (e.g., propylthiouracil).

Glucocorticoids, used for the treatment of inflammatory reactions and allergic reactions (e.g., dexamethasone)

Tyrosine kinase inhibitors used for the treatment of cancer (e.g., imatinib and sunitinib, tamoxifen and 5-fluorouracil).

Medications used for the treatment of depression and anxiety disorders (e.g., sertraline).

Oral contraceptives.

Medications used for hormone replacement therapy (e.g., medications containing estrogen)

Morphine-like painkillers, used for the treatment of addiction (e.g., methadone).

Clofibrate and statins used to lower cholesterol levels (e.g., lovastatin and simvastatin).

Ritonavir – if you have HIV and/or chronic hepatitis C virus and are using the medication ritonavir.

Many medications can affect the results of laboratory tests of thyroid function.

The action of the following medications can be affected by Eltroxin

Medications used for the treatment of diabetes mellitus (e.g., insulin and oral antidiabetics).

Blood thinners, used to prevent blood clots (e.g., anticoagulants).

Medications used for the treatment of epilepsy (e.g., phenytoin).

Medications used for the treatment of heart failure (e.g., cardiac glycosides).

Medications used for the treatment of depression (e.g., tricyclic antidepressants).

Medications used to stimulate the sympathetic nervous system (e.g., sympathomimetics).

If you are using the following medications, you should contact your doctor, as they interfere with laboratory tests, leading to unreliable test results

Medications used for hormone replacement therapy (e.g., androgens and anabolic steroids).

Anti-inflammatory drugs (e.g., aspirin and phenylbutazone).

What should you pay attention to with food and drink?

Soy-containing supplements and a high-fiber diet can lead to lower absorption of Eltroxin. Adjustment of the Eltroxin dose may be particularly necessary at the beginning or end of a diet.

Pregnancy, breastfeeding, and fertility

Are you pregnant, do you think you might be pregnant, do you want to become pregnant, or are you breastfeeding? Then contact your doctor or pharmacist before using this medicine.

Pregnancy

For a good course of your pregnancy, it is necessary that your thyroid hormones are well balanced throughout the entire pregnancy. Therefore, you must continue treatment with levothyroxine throughout the entire pregnancy, and your doctor may need to adjust the dose of your medication at the beginning of or during your pregnancy.

Therefore, careful monitoring of your thyroid function is carried out as soon as possible, and especially during the first half of your pregnancy. After delivery, a check of your baby's thyroid is recommended.

During pregnancy, Eltroxin should not be used together with medications for an overactive thyroid (antithyroid drugs). Only very small amounts of Eltroxin pass through the placenta, but antithyroid drugs pass through the placenta easily. This could lead to a risk of an underactive thyroid (hypothyroidism) in the newborn child.

Breastfeeding

Replacement therapy with levothyroxine substitution therapy is possible during breastfeeding.

Fertility

No studies on fertility have been conducted with this medicine. An underactive or overactive thyroid (hypothyroidism or hyperthyroidism, respectively) can affect fertility.

Blood pressure should be regularly monitored when starting treatment with levothyroxine in preterm infants with very low birth weight, as a rapid drop in blood pressure (known as circulatory collapse) may occur.

Driving and using machines

Eltroxin should not affect your ability to drive and operate machines.

3. How do you take this medicine?

Always use this medicine exactly as your doctor or pharmacist has told you. Are you unsure about the correct use? Then contact your doctor or pharmacist.

Do NOT take more than your doctor tells you.

Swallow the tablets with a glass of water, preferably before breakfast. Eltroxin tablets should be taken on an empty stomach.

The usual starting dose for adults is 50 to 100 micrograms per day. This dosage may be adjusted at your doctor's discretion.

After a few weeks, it may be adjusted depending on the response to your treatment, which will be monitored through blood tests.

Elderly and patients with heart disease

The recommended starting dose of Eltroxin for patients over 50 years old is 50 micrograms once daily.

The recommended starting dose of Eltroxin for patients with heart disease is 25 micrograms per day. Then the doctor can increase the daily dose taken by the patient by 25 micrograms every four weeks until the optimal response to the treatment is achieved.

Use in children:

The dose for children depends on their age, weight, and the condition being treated. Your child will be monitored to ensure they receive the correct dose. Give your child this medication at least half an hour before the first meal of the day.

The recommended starting dose of Eltroxin for infants with congenital hyperthyroidism is 25 micrograms per day. Then the doctor can increase the daily dose used by the patient by 25 micrograms until the optimal response to the treatment is achieved. The same dosing regimen also applies to children with juvenile myxedema, but the recommended starting dose for children is 2.5 to 5 micrograms per kilogram of body weight per day. The actual daily dose will be calculated by your doctor and rounded to the next 25 micrograms.

If necessary, the tablets can be dissolved in 10 to 15 ml of drinkable water and given as a fresh preparation with a little more fluid (5 to 10 ml).

When the treatment is discontinued, Eltroxin tablets should be gradually withdrawn under your doctor's supervision.

Have you taken too much of this medication?

In case of overdose: If you are prescribed too much Eltroxin or accidentally take more tablets than your doctor has prescribed, you may experience side effects such as irritability, confusion, irritability, hyperactivity, headache, sweating, mydriasis (dilated pupils), rapid heartbeat, irregular heartbeat, rapid breathing, fever, anxiety, emotional lability, frequent bowel movements, and seizures (convulsions). Severe and potentially life-threatening overactivity of the thyroid gland rarely occurs after chronic overdose and leads to irregular heartbeat, heart failure, and coma (thyrotoxic crisis). If you think you or someone else has taken too many tablets, contact your doctor or the hospital emergency department immediately. Remember to take the packaging and any remaining tablets as well as this leaflet with you, so the medical staff knows exactly what you have taken.

Have you forgotten to take this medication?

If you have missed a dose, take the normal amount as soon as you remember, unless it is almost time for the next dose. Do not take a double dose to make up for a forgotten dose.

Do you have any other questions about the use of this medicine? Then contact your doctor or pharmacist.

If you stop using Eltroxin

You should not suddenly stop using this medicine; it may cause your original symptoms to return. Always consult your doctor if you are considering stopping. It may be necessary to adjust the dose gradually.

Contact your doctor or pharmacist if you have further questions.

4. Possible Side Effects

Like any medicine, this medicine can cause side effects, although not everyone gets them.

The following side effects may occur if your initial dose of Eltroxin is too high.

Stop using Eltroxin and consult your doctor or seek immediate medical help if you have an allergic reaction. Signs of an allergic reaction include, among others: shortness of breath, rash or itching, and a warm feeling with redness of the skin, etc.

Other serious side effects:

Pain in the heart area or palpitations, chest pain, irregular heartbeat, heart failure, or heart attack.

Overactivity of the thyroid gland producing excessive amounts of thyroid hormone (hyperthyroidism)

Very rarely, especially in children, increased intracranial pressure (increased pressure in the head, with swelling of the eyes) has been reported.

If you notice one or more of these symptoms, you should stop using Eltroxin and seek immediate medical care.

Other side effects that may occur:

- Increased heart rate, increased blood pressure.
- Seizure (spasms, convulsions).
- Decreased bone density (weaker and more brittle bones).
- Tremors.
- Headaches.
- Nervousness.
- Restlessness, irritability, insomnia (sleep problems).
- Muscle cramps, muscle weakness.
- Diarrhea, stomach cramps, nausea, vomiting.
- Increased appetite, severe weight loss.
- Fever, sweating.
- Hair loss.

- Intolerance to heat.
- Fatigue (exhaustion, tiredness).
- Irregular menstruation, reduced fertility.
- You suddenly get:
 - a swollen tongue;
 - swollen lips;
 - a swollen face;
 - a swollen throat;
 - (angioedema).
- skin rash, rash on the skin with pink bumps and severe itching (hives or urticaria).

Contact your doctor if any of the above side effects occur. Usually, the side effects disappear when the dose is adjusted.

Reporting side effects

If you experience side effects, contact your doctor or pharmacist. This also applies to possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system: Netherlands Pharmacovigilance Centre Lareb.

Website: www.lareb.nl. By reporting side effects, you can help us obtain more information about the safety of this medicine.

5. How should you store this medicine?

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

Do not use this medicine after the expiry date. You can find it on the box after "EXP". It includes a month and a year. The last day of that month is the expiry date.

Store below 25°C. Store in the original package to protect from light. Keep the package tightly closed to protect from moisture.

Do not flush medicines down the sink or toilet and do not throw them in the trash. Ask your pharmacist what to do with medicines you no longer use. They will be destroyed responsibly and will not enter the environment.

6. Contents of the package and other information

What substances are in this medicine?

- The active substance in this medicine is levothyroxine sodium. Each Eltroxin 50 microgram tablet contains 50 micrograms of levothyroxine sodium. Each Eltroxin 100 microgram tablet contains 100 micrograms of levothyroxine sodium.
- The other substances in this medicine are microcrystalline cellulose (E460), pregelatinized starch (maize), talc (E553b), magnesium stearate (E470b), and anhydrous silica.

What does Eltroxin look like and what is in a package?

Eltroxin 50 microgram are white, round tablets with “GS 51F” on one side and a score line on both sides.

Eltroxin 100 microgram are white, round tablets without a score line, with “GS 21C” on one side and “100” on the other side.

The tablets are packed in a white polypropylene bottle with 100 pieces.

In the register listed under:

RVG 08451 Eltroxin 50 microgram

RVG 08452 Eltroxin 100 microgram

Holder of the marketing authorization and manufacturer

Aspen Pharma Trading Limited

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