

Eltroxin Tablets 50 mcg

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Inactive ingredients and allergens in the preparation: see section 2 "Important information about some of the ingredients of the medicine" and section 6 "Further information" in this leaflet.

Read the leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine was prescribed for you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

The medicine is intended for the treatment of hypothyroidism; treatment of thyroid hormone deficiency causing cretinism in infants and for mucosal edema (myxoedema) in children.

Therapeutic group: Thyroid hormones.

2. BEFORE USING THE MEDICINE

In order to ensure the continuity of treatment with preparations containing levothyroxine sodium, changing from one levothyroxine sodium preparation to another should only be done following personal medical consultation and with close surveillance of the patient.

Do not use the medicine if:

- you are sensitive (allergic) to the active ingredient levothyroxine sodium, or to any of the other ingredients this medicine contains (see section 6 in this leaflet).
- you suffer from hyperthyroidism in which the thyroid gland produces excessive quantities of thyroxine (thyrotoxicosis), that is not being treated.
- you have a disease affecting the adrenal gland (check with your doctor if you are not sure) that is not being treated.
- you are suffering from an underactive adrenal gland (adrenal insufficiency) and you are not receiving adequate replacement treatment.
- you have high blood pressure and you are not being treated for it.
- you have a disease affecting the pituitary gland that is not being treated.
- you have a problem with your heart (for example heart infarction or acute myocarditis).

Eltroxin must not be used at the same time as medicines for an overactive thyroid (antithyroid medicines) during pregnancy.

Special warnings regarding use of the medicine

- Talk to your doctor or pharmacist before taking Eltroxin.
- A rapid increase in the number of tablets taken can cause side effects (listed in section 4). Tell your doctor if you get side effects.
- Do not use Eltroxin to treat obesity or for weight loss. Thyroid hormones are not suitable for weight loss. Taking thyroid hormones does not cause weight loss if your thyroid hormone levels are within the normal range. Serious or even life-threatening side effects may occur if you increase the dosage without consulting a doctor, especially if you are taking other slimming medicines at the same time. Tell your doctor if you are taking a medicine, such as Orlistat, for weight loss.
- If you need to undergo laboratory tests to monitor thyroid hormone levels, tell the doctor and/or laboratory staff that you are taking or have recently taken biotin (also called vitamin H, vitamin B7 or vitamin B8). Biotin may affect the results of your laboratory tests. Depending on the test, results may be falsely high or falsely low due to biotin. Your doctor may ask you to stop taking biotin before undergoing laboratory tests. You should also be aware that other products you may be taking, such as multivitamins or dietary supplements for hair, skin and nails, may also contain biotin and thus affect laboratory test results. Tell the doctor and/or laboratory staff if you are taking such medicines (please note the information in the section "Drug interactions").

Thyroid disorders may occur if you need to replace your medicine with another medicine containing levothyroxine. Contact your doctor or other qualified healthcare professional if you have any questions about changing your medicines. Close monitoring (clinical and biological) during the transition period is necessary. Tell your doctor if you get any side effects, as these may be signs that your dosage needs to be increased or decreased.

Tell the doctor before taking Eltroxin, if:

- you are more than 50 years old.
- you have a heart disease.
- you have diabetes.
- you are menopausal and have an increased risk of osteoporosis.
- you have the following symptoms: tiredness, cold sensitivity, dry and thickened skin, hair loss, slow heart rate (symptoms of hypothyroidism).
- you have an impaired metabolism as part of another hormonal disease.
- you have myxoedema - whitish skin color and soft edema of the skin and subcutaneous tissues.
- you have a malabsorption syndrome.
- you suffer from adrenal underactivity (adrenal insufficiency).
- you are pregnant.
- Your doctor will determine if you have dysfunction of the adrenal, pituitary or thyroid glands with uncontrolled over-production of thyroid hormones (thyroid autonomy), because these conditions should be treated with medications before you start taking Eltroxin or before a thyroid suppression test is performed.

Drug interactions:

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, inform the doctor or pharmacist.

Eltroxin may alter the effect of other medicines and other medicines may alter the effect of Eltroxin.

If you are taking or have recently taken biotin, tell your doctor and/or laboratory staff when you need to undergo laboratory tests for monitoring the level of thyroid hormone. Biotin may affect the laboratory test results (see "Special warnings regarding use of the medicine").

The following medicines may affect the absorption of Eltroxin:

- Medicines used for high cholesterol (cholestyramine, colestipol).
- Medicines used for a stomach ulcer (antacids, sucralfate).
- Medicines containing iron and supplements.
- Calcium, magnesium and aluminum supplements.
- Medicines used for treatment of high levels of potassium in the blood (kayexalate, sevelamer, lanthanum, and polystyrene sulfonates).
- Proton pump inhibitors (used to reduce the quantity of gastric 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 can decrease the absorption of levothyroxine from the gut and thus make it less effective. If you are taking levothyroxine while you are being treated with proton pump inhibitors, your doctor should monitor your thyroid function and may need to adjust the dose of Eltroxin.
- Weight loss medicines, such as Orlistat.

Separate the doses of Eltroxin and the above medicines as much as possible to avoid interaction between the medicinal products in the stomach or in the small intestine.

The following medicines may affect the effect of Eltroxin

- Medicines used for epilepsy (carbamazepine, phenytoin, barbiturates)
- Medicines containing St. John's wort (a herbal medicine)
- Medicines used for treating infections (rifampicin)
- Antihypertensive medicines (beta blockers)
- Medicines used for heart insufficiency (amiodarone)
- Medicines containing lithium or iodine
- Contrast agents containing iodine, used in X-ray examinations.
- Medicines used for increased metabolism (propylthiouracil)
- Adrenal hormones used for the treatment of inflammation or allergic reactions (cortisol, dexamethasone)
- Medicines used for cancer (tamoxifen, 5-fluorouracil, imatinib, sunitinib)
- Medicines used for depression (sertraline)
- Hormonal supplements or if you take oral contraception (oestrogen)
- Methadone
- Medicines used for malaria (proguanil, chloroquine)
- Medicines used for high cholesterol (clofibrate, simvastatin, lovastatin)
- Medicines used for fluid accumulation and for high blood pressure (furosemide)
- Ritonavir, Indinavir, Lopinavir used to control HIV and chronic hepatitis C

Many medicines may affect the results of laboratory tests or the function of the thyroid gland.

The effect of the following medicines may be affected by Eltroxin:

- Medicines used for diabetes (e.g., insulin). Eltroxin may **reduce** the effect of the anti-diabetes medicine you are taking; therefore, you may need additional blood sugar level tests, especially at the beginning of treatment with Eltroxin. During the course of treatment with Eltroxin, it may be necessary to adjust the dosage of the anti-diabetic medicine you are taking.
- Medicines used to prevent blood clots (anticoagulants), used to thin the blood and to treat blood clots: Eltroxin may **increase** the effect of these medicines and consequently may increase the risk of bleeding. Therefore, regular testing of your blood clotting values may be required at the beginning and during Eltroxin treatment. During the course of treatment with Eltroxin, it may be necessary to adjust the dosage of any medicine of the coumarin group you are taking.
- Phenytoin (used to treat epilepsy)
- Cardiac glycosides (used to treat heart insufficiency)
- Medicines used for depression (tricyclic antidepressants)
- Sympathomimetic agents (medicines which stimulate the sympathetic nervous system)

If you take following medicines you must contact your doctor, as they may affect certain medical or laboratory tests and may lead to false test results:

- Hormone supplements or medicines containing testosterone (androgens, anabolic steroids)
- Painkillers (acetylsalicylic acid)

Use of the medicine and food:

Products containing soy and high fiber diet may reduce the absorption of Eltroxin. Dosage adjustment of Eltroxin may be relevant especially at initiation and discontinuation of a diet.

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.

The function of the thyroid gland must be monitored closely during pregnancy, as too low or too high levels of thyroid hormones may be harmful to the development and well-being of the foetus.

Your doctor will determine if the dosage of Eltroxin should be adjusted.

Do not take during pregnancy if you are also taking a medicine that inhibits thyroid activity to treat hyperthyroidism.

Small quantities of the active substance are excreted in breast-milk. Tell your doctor if you are breast-feeding or if you plan to breast-feed.

Blood pressure will be checked routinely when levothyroxine treatment has been initiated in **premature infants** with a very low birth weight, as a rapid drop in blood pressure may occur (called circulatory collapse).

Driving and using machines:

Eltroxin has no influence on the ability to use machines or drive.

Important information about some of the ingredients of the medicine This medicine contains less than 23 mg sodium per tablet, that is to say it is essentially 'sodium-free'.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the medicine according to the doctor's instructions. Check with the doctor or pharmacist if you are not sure regarding the dosage and treatment regimen of the medicine. The dosage and treatment regimen will be determined by the doctor only and will depend on the results of your blood tests.

Do not exceed the recommended dose.

Method of administration

Swallow the tablets with a glass of water, preferably before breakfast. Take the tablets on an empty stomach.

Do not halve or crush the tablets! There is no information regarding chewing.

Tests and medical follow-up:

During the course of treatment with the medicine periodic tests of thyroid hormones should be performed.

In adults: After a few weeks, the dosage may need to be adjusted in accordance with your response to treatment and blood test monitoring.

In children below the age of 12: Medical monitoring is necessary to ensure that the child receives the correct dosage for him.

If you accidentally took too high a dosage:

If you took an overdose or if a child or anyone else has accidentally swallowed the medicine, immediately refer to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you.

You may experience palpitations (abnormal heart rate), anxiety, restlessness, irritability, confusion, sweating, heart rhythm disturbances (irregular or rapid heart rate), agitation, involuntary movements, dilated pupils, very rapid respiration, fever, convulsions and headaches.

Thyrotoxic crisis occurs on rare occasions after a chronic overdose and causes irregular heart rate, heart insufficiency and coma.

If you forgot to take the medicine:

If you have forgotten to take a dose, you should take it as soon as you remember. If it is time for you to take the next dose, then skip the forgotten dose. Do not take a double dose.

Adhere to the treatment as recommended by the doctor.

If you discontinue taking the medicine:

You must not stop taking this medicine abruptly. It may trigger the return of your original symptoms. Always consult your doctor when you are considering stopping taking the medicine. It may be necessary to adjust the dose.

Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.

If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Eltroxin tablets may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Contact your doctor immediately if you get any of the following side effects:

Signs of an allergic reaction such as:

- Shortness of breath. Skin reactions such as: skin rash and itching.
- Redness, hot flushes.

If you experience serious side effects, you must immediately contact your doctor or the emergency room.

Serious side effects:

Rare side effects (occurring in 1-10 users out of 10,000):

- False brain tumor (pseudotumor cerebri) (increasing pressure in the head with oedema of the eyes), especially in children.

Side effects that their frequency is unknown (their frequency has not yet been determined):

- Pain in the chest (angina pectoris). Contact a doctor or emergency room.
- Palpitations (discomfort caused by rapid or forceful heart beats).
- Heart rate disturbances (irregular heart rate). May be or could become serious. Talk to your doctor.
- Heart failure.
- Cardiac infarction.
- Symptoms of overdose caused by increased hormone production in the thyroid gland (if the initial dose is increased too rapidly). Talk to your doctor.
- An overdose in children may cause craniosynostosis (premature closure of the bone plates in the cranium before the brain is fully developed) and premature closure of the epiphysis, which may affect the adult height.

Other side effects may occur:

Side effects that their frequency is unknown (their frequency has not yet been determined):

- Rapid heart rate. May become serious. If you have a rapid and irregular heart rate or if you feel unwell or faint, you must contact a doctor or emergency room.
- Convulsions (muscle spasms, spasms).
- Sudden back pain and a tendency for bone fractures due to osteoporosis (decrease of bone density). Talk to your doctor.
- Elevated blood pressure. Talk to your doctor. Elevated blood pressure must be treated. Very high blood pressure is serious.
- Muscular weakness, muscle cramps. May be or could become serious. Talk to your doctor.
- Irritability.
- Agitation, tremor (shaking), headache, restlessness, insomnia (problems sleeping).
- Anxiety, emotional mood lability, nervousness.
- Sweating, hair loss.
- Increased appetite, stomach pain, nausea, diarrhoea, vomiting.
- Irregular menstrual periods, infertility.
- Tiredness (exhaustion), heat intolerance, fever.
- Very excessive weight loss.
- Swelling of the face, lips, mouth, tongue or throat (angioedema), rash, hives. The side effects often disappear when the dose is decreased.

If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.

Reporting side effects:

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link: <https://sideeffects.health.gov.il> In addition, you can report to Padagis company via the following address: Padagis.co.il

5. HOW SHOULD THE MEDICINE BE STORED?

• Avoid poisoning! This medicine and any other medicine must be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.

- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- Store below 25°C. Store in the original package to protect from light.
- After first opening can be used for 114 days, but not later than the expiry date. Keep the bottle tightly closed.
- Do not throw away medicines via wastewater or household waste. Ask your pharmacist how to throw away the medicine. These measures will help protect the environment.

6. FURTHER INFORMATION

• In addition to the active ingredient, the medicine also contains the following inactive ingredients: Microcrystalline cellulose, Pre-gelatinised starch (Maize starch 1500), Talc, Microcrystalline cellulose (in triturate), Silica colloidal anhydrous, Magnesium stearate.

• What the medicine looks like and the contents of the package:

Eltroxin 50 mcg tablets: white to off-white, round, biconvex tablets, with "GS 11E" imprinted on one side and "50" on the other side, in a plastic bottle with a safety cap and closure, containing 100 tablets.

Eltroxin 100 mcg tablets: white to off-white, round, biconvex tablets, with "GS 21C" imprinted on one side and "100" on the other side, in a plastic bottle with a safety cap and closure, containing 100 tablets.

• Registration holder and address: Padagis Israel Agencies Ltd., 1 Rakefet St., Shoham.

• Manufacturer name and address: Aspen Bad Oldesloe GmbH, Bad Oldesloe, Germany.

• Revised in June 2023 according to MOHs guidelines.

• Registration number of the medicine in the National Drug Registry of the Ministry of Health:

Eltroxin Tablets 50 mcg: 055-82-20571

Eltroxin Tablets 100 mcg: 027-92-22062