

PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986
The medicine is dispensed with a doctor's prescription only

Eltroxin Tablets 50 mcg

Eltroxin Tablets 50 mcg

Each tablet contains the active ingredient Levothyroxine sodium 50 mcg (microgram).

Eltroxin Tablets 100 mcg

Each tablet contains the active ingredient Levothyroxine sodium 100 mcg (microgram).

Inactive ingredients and allergens in the medicine - see section 6.

Read this 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 be done only with 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 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).
- you are pregnant and are taking a medicine that inhibits thyroid activity to treat hyperthyroidism.

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. High doses may result in serious life-threatening adverse events. Tell your doctor if you take medicine for weight loss, such as Orlistat.

Tell your doctor before taking Eltroxin, if:

- you are more than 50 years old.
- you have a heart disease.
- you have diabetes.
- you are experiencing menopause 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 malabsorption syndrome.
- 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.
- you have changed your current levothyroxine medicine to another medicine. The effect of each of them can be slightly different from one another and there may be a need for you to be checked more often. There may also be a need to readjust the dosage.

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.

The following medicines may affect the absorption of Eltroxin:

- Medicines used for high cholesterol (cholestyramine, colestipol)
- Medicines used for stomach ulcer (antacids, sucralfate)
- Medicines containing iron and iron supplements.
- Calcium, magnesium and aluminum supplements.
- Medicines used for treatment of high levels of potassium in the blood (kayexalate, sevelamer, lanthanum, polystyrene sulfonates)
- Proton pump inhibitors (used to reduce the quantity of gastric acid)
- 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 used for treating infections (rifampicin)
- Antihypertensive medicines (beta blockers)
- Medicines used for heart insufficiency (amiodarone)
- Medicines containing lithium or iodine
- Contrast agents containing iodine, which is used in connection with 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 medicinal products 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 testing, 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 (anticogagulants), 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 the coumarinic medicine 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/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. Dose 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 dose of Eltroxin should be adjusted. Do not take during pregnancy if you are also taking 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.

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

Driving and use of 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 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 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 remember to 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 this 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 ask your doctor when you consider stopping. 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 (may affect 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 been determined yet):

- 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 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 been determined yet):

- Rapid heart rate. May become serious. If you have 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 to bone fractures due to osteoporosis (decrease of bone density). Talk to your doctor.
- Increased blood pressure. Talk to your doctor. Increased blood pressure must be treated. Very increased blood pressure is serious.
- Muscular weakness, muscle cramps. May be or could become serious. Talk to your doctor.
- Irritability.
- Agitation (affect), tremor (trembling), 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.

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 this 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 the 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 closed tightly.
- 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. 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 Rakfeket St., Shoam
- Manufacturer name and address: Aspen Bad Oldesloe GmbH, Bad Oldesloe, Germany.
- Revised in February 2022 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