

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 - see section 6.

Read this leaflet carefully in its entirety before using the medicine. This leaflet contains important concise information about the medicine. Keep this leaflet; you may want to read it again. If you have further questions, refer to the doctor or pharmacist.

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

Refer to the doctor or pharmacist if you experience side effects, including side effects not mentioned in this leaflet.

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 (myxedema) in adults.

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 of Eltroxin tablets (see section 6 in this leaflet).
- you suffer from hyperthyroidism (thyrotoxicosis) for any reason.
- you suffer from myocardial infarction, myocarditis.
- you suffer from hypoadrenalism (underactivity of the adrenal gland) that is not controlled.
- you suffer from hypopituitarism (underactivity of the pituitary gland) that is not controlled.
- you are pregnant and are taking a medicine that inhibits thyroid activity to treat hyperthyroidism.

Refer to the doctor if any of the above apply to you.

Special warnings regarding use of the medicine

❑ Special attention is required if:

- you have any of the following heart diseases: disturbances in coronary blood flow (angina pectoris); heart failure; rapid or irregular heartbeat; high blood pressure; fatty deposits on the arterial walls (atherosclerosis, arteriosclerosis).

These diseases must be treated with medications before you start taking Eltroxin or before a thyroid suppression test is performed. Your thyroid hormone levels must be frequently checked during therapy with Eltroxin. If you are not sure whether any of these conditions apply to you, or if you have any of these diseases but have not yet received treatment, contact your doctor.

- you suffer from diabetes - there may be a need to alter the dosage of the diabetes treatment.

- 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 must be treated with medications before you start taking Eltroxin or before a thyroid suppression test is performed.

- you suffer from any condition which affects the adrenal gland (the doctor may recommend additional treatment).

- you are elderly.
- you have a long-standing medical history of low thyroxine levels.
- you suffer from epileptic seizures, as they may occur more frequently.

❑ Report to the doctor if:

- you are experiencing menopause or are postmenopausal. Due to the danger of developing osteoporosis, there may be a need to regularly check thyroid function.
- you have myxedema - lightening and mild edema of the skin and subcutaneous tissues.
- you have malabsorption syndrome.
- 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.

❑ If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, inform the doctor or pharmacist. The effect of Eltroxin may change, especially if you are taking:

- anti-diabetes medicines (medicines which lower blood sugar levels): Eltroxin may **lower** the effect of the anti-diabetes medicine you are taking; therefore, you may need to perform additional tests of blood sugar levels, especially at the beginning of Eltroxin treatment. During the course of treatment with Eltroxin, there may be a need to adjust the dosage of the anti-diabetic medicine you are taking.
- anticoagulants from the coumarin family (e.g., warfarin), 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, especially among the elderly. Therefore, you may be told to have regular tests of your blood clotting values performed at the beginning of and during treatment with Eltroxin. During the course of treatment with Eltroxin, there may be a need to adjust the dosage of the coumarinic medicine you are taking.
- anticonvulsants (e.g., phenytoin, carbamazepine, barbiturates) used to prevent seizures.
- medicines called cardiac glycosides (e.g., digoxin) used to treat the heart in conditions such as heart failure.
- medicines which stimulate the sympathetic nervous system, e.g., adrenaline.
- antihypertensives of the beta-blocker group.
- antidepressants (e.g., tricyclic medicines or sertraline).
- medicines to prevent or treat malaria (e.g., chloroquine or proguanil).
- cholestyramine, which lowers the cholesterol (lipids) level in the blood, medicines which bind bile acids (e.g., colestipol): make sure that you take Eltroxin four to five hours **before** taking these medicines, as they may block the absorption of Eltroxin in the intestine.
- antacids (medicines used to relieve abdominal pain and heartburn), sucralfate (for the treatment of gastric and duodenal ulcers), other aluminum- or magnesium-containing medicines, medicines containing iron, calcium carbonate: make sure that you take Eltroxin at least 2 hours **before** taking these medicines, as these may reduce the effect of Eltroxin.
- sevelamer, lanthanum - phosphate-binding medicines used to treat patients with chronic renal failure.
- protein pump inhibitors (PPIs) used to reduce level of acidity in stomach.
- rifampicin - a medicine to treat infections.
- medicines containing hormones, such as: oral contraceptives, androgenic and anabolic steroids.
- tamoxifen, clofibrate, methadone and 5-fluorouracil.
- statins (e.g., simvastatin and lovastatin).
- tyrosine kinase inhibitors (e.g., imatinib and sunitinib).
- medicines to regulate your heart rhythm (e.g., amiodarone).
- medicines containing iodine or lithium.
- medicines to treat cold, sinus problems, hay fever or other allergies (including nose drops and nasal sprays).
- protease inhibitors, for the treatment of HIV infection (e.g., ritonavir, indinavir, lopinavir).

Inform your doctor if you are taking any of the following medicines, as they may **increase** the effect of Eltroxin:

- salicylates (medicines used to relieve pain or reduce fever).
- dicalmarol (anticoagulant).
- furosemide at a high dosage of 250 mg or more (diuretic).
- clofibrate (a medicine used to lower blood lipid levels).

If you need to undergo x-ray screening or other diagnostic examinations with iodine-containing contrast materials, tell your doctor that you are taking Eltroxin. You may be required to

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receive an injection that will affect your thyroid function.

Thyroid hormones are not intended for weight reduction. The intake of thyroid hormones will not cause weight loss, if your thyroid hormone level is within a normal range. Severe or even life-threatening side effects may occur if you increase the dosage without having consulted your doctor.

❑ Taking Eltroxin with food and beverages

Tell your doctor if you are on a high fiber diet or you eat soybean products, especially if you alter the proportion of soybean products consumed in your diet. Soybean products may reduce the absorption of Eltroxin from the intestine. Your Eltroxin dosage may need to be changed.

❑ Pregnancy and breastfeeding

Consult the doctor regarding treatment if you are pregnant or planning to become pregnant or are breastfeeding. The doctor will decide if Eltroxin tablets are the best treatment for you during pregnancy and when breastfeeding.

Thyroid activity needs to be closely monitored during pregnancy, since very low or very high levels of thyroid hormones can be harmful for the development and wellbeing of the fetus. Do not take during pregnancy if you are also treated with medicine that inhibits thyroid activity to treat hyperthyroidism. Consult with the doctor or pharmacist before taking any medicine.

❑ Driving and use of machines

Eltroxin tablets should not impair your ability to drive or use machines.

3. HOW SHOULD YOU USE THE MEDICINE?

- Always use exactly according to the doctor's instructions. The dosage and the treatment regimen will be determined by the doctor only.

- **Do not exceed the recommended dose.**

- Check with the doctor or pharmacist if you are not sure how to use the medicine.

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

Do not chew, halve or crush the tablets!

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, there may be a need to adjust the dosage 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

You may experience palpitations, anxiety, restlessness, irritability, confusion, sweating, heart rhythm disturbances, involuntary movements, dilated pupils, very rapid respiration, fever, convulsions and headaches. Thyrotoxic crisis can occur rarely after chronically overdosing and causes irregular heart rate, heart insufficiency and coma.

If you took an overdose or if a child 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, the remaining tablets and the leaflet with you.

If you discontinue taking the medicine:

Discontinuation of treatment with **Eltroxin tablets** must be done gradually, under the medical supervision of your doctor.

- Adhere to the treatment recommended by the doctor.

- **If you forgot to take this medicine** at the required time, take the dose as soon as you remember, but not if it is almost time for the next dose. Never take a double dose.

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.

All medicines may cause allergic effects; however, severe allergic effects are rare.

Refer to the doctor immediately in case of an allergic reaction which can be manifested by one of the following symptoms:

- **Swelling of the face, eyelids, lips and throat.**
- **Rash or itching (especially if it appears on the whole body).**
- **Sudden wheezing, difficulty breathing and low blood pressure.**

The following side effects may occur if your starting dosage is too high: fever; intolerance to heat; hair loss; loose stools; tremor (trembling); restlessness; excitability; difficulty sleeping; rapid heart rate or angina pectoris (chest pain during physical activity); fluid accumulation (edema); in children: premature closure of the skull bones before completion of brain growth. Consult with your doctor if any of the above effects occur. The effects usually pass when the dosage is changed.

You may experience additional side effects: cardiac arrhythmias, rapid pulse, palpitations; increased blood pressure; muscle cramps or muscle weakness; vomiting; nausea; fatigue; headache, flushing, sweating; anxiety, emotional mood lability, irritability, restlessness; weight loss; irregular menstrual cycle; epileptic seizures in patients with a known medical history of epilepsy; pseudotumor cerebri, increased intracranial pressure with swelling of the eyes; impaired fertility; decreased bone mineral density; increased appetite; abdominal pain; diarrhea.

If you notice any of these side effects, or if you suffer from a side effect not mentioned in this leaflet, refer to your doctor. Your doctor will decide whether to continue treatment or to interrupt it for a few days or to reduce the daily dosage until the side effects have disappeared.

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://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic&cmoh.gov.il>

In addition, you can report to Perrigo via the following address: www.perrigo-pharma.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 take medicines in the dark! Check the label and the dose **each time** you take medicine. Wear glasses if you need them.

- 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. If the tablets have reached the expiry date, bring them to the pharmacy to dispose of them in a safe manner.
- Store in the original package below 25°C. Protect from light.
- After first opening can be used for 114 days.
- Keep the bottle closed tightly.

6. FURTHER INFORMATION

- In addition to the active ingredient, the medicine also contains the following inactive ingredients:

Microcrystalline cellulose (in triturate), Microcrystalline cellulose, Pre-gelatinised starch (Maize starch 1500), Talc, Silica colloidal anhydrous, Magnesium stearate.

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

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

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

Registration holder and address: Perrigo Israel Agencies Ltd., 29 Lehi St., Bnei Brak 51200.

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

This leaflet was checked and approved by the Ministry of Health in February 2016.

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