PATIENT MEDICATION INFORMATION
READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

ELTROXIN®
Levothyroxine Sodium Tablets

Read this carefully before you start taking **ELTROXIN** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **ELTROXIN.**

Serious Warnings and Precautions
Thyroid hormones, including ELTROXIN, either alone or with other medicines, should not be used for the treatment of obesity or for weight loss. If used for these conditions, it could causeserious or even life-threatening side effects

What is ELTROXIN used for?

- To treat hypothyroidism. This condition happens when the thyroid gland does not produce enough of the hormone thyroxine
- To treat certain types of thyroid cancer. For these patients, ELTROXIN is given in combination with surgery and radioactive iodine therapy.

How does ELTROXIN work?
ELTROXIN contains levothyroxine sodium which is the synthetic (man-made) form of thyroxine. Thyroxine is a hormone normally produced by the thyroid gland. It helps the body to function properly.

Hypothyroidism occurs when the thyroid gland is unable to produce normal amounts of thyroxine. ELTROXIN treats the symptoms of hypothyroidism by helping to normalize the levels of thyroid hormones in the body.

What are the ingredients in ELTROXIN?
Medicinal ingredients: levothyroxine sodium
Non-medicinal ingredients: acacia powder, lactose magnesium stearate and maize starch.

ELTROXIN also include colouring agents:

- 25 mcg (orange): FD&C Yellow No. 6
- 50 mcg (white): no colour agent
- 75 mcg (violet): FD&C Red No. 40 and Colorcon Blue 5625
- 88 mcg (olive): FD&C Yellow No. 6, D&C Yellow No. 10 and FD&C Blue No.1
- 100 mcg (yellow): Colorcon Yellow LB282
- 112 mcg (rose): D&C Red No. 27

- 125 mcg (brown): FD&C Yellow No. 6, FD&C Red No. 40 and FD&C Blue No.1
- 137 mcg (turquoise): FD&C Blue No.1 and Colorcon Blue 5625
- 150 mcg (blue): Colorcon Blue 5625
- 175 mcg (lilac): D&C Red No. 27 and FD&C Blue No. 1
- 200 mcg (pink): Erythrosine

ELTROXIN comes in the following dosage forms:
Tablets: 25 mcg, 50 mcg, 75 mcg, 88 mcg, 100 mcg, 112 mcg, 125 mcg, 137 mcg, 150 mcg, 175 mcg and 200 mcg of levothyroxine sodium

Do not use ELTROXIN if:

- are allergic (hypersensitive) to levothyroxine sodium or to any of the other ingredients in ELTROXIN
- have thyrotoxicosis, a disease in which the thyroid gland is overactive and produces too much thyroxine
- have had a heart attack, inflammation of the heart muscles or other serious heart problem
- have a condition where your kidneys do not make enough of the hormone cortisol (uncorrected adrenal insufficiency)
- you are pregnant and are taking medication to treat hyperthyroidism (overactive thyroid)

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take ELTROXIN. Talk about any health conditions or problems you may have, including if you:

- have any clotting disorders or are taking medication to thin your blood such as warfarin
- have heart problems
- have high blood pressure
- have a history of problems with your thyroid, adrenal or pituitary gland
- have diabetes or another autoimmune disorder
- have trouble absorbing nutrients from your gut (malabsorption syndrome)
- are switching from a different brand of levothyroxine
- are pregnant or intend to become pregnant. Your healthcare professional may examine your blood during your pregnancy to measure the amount of THS (Thyroid Stimulating Hormone)
- are breast-feeding, or planning to breast-feed
- are 65 years of age or older
- have psychiatric disorders. Your healthcare professional may start your treatment of ELTROXIN at a lower dosage

Other warnings you should know about:
Surgery:
Tell your healthcare professional about any surgery you are planning to have. Before the surgery tell your dentist or surgeon that you are taking ELTROXIN.

Monitoring and blood tests

Taking a biotin supplement may affect blood tests done to check thyroid hormone levels (called thyroid function tests). Tell your healthcare professional if you are taking biotin. It may lead to false test results. Your healthcare professional may ask you to stop taking biotin at least 2 days before you have a thyroid function test.

Driving and Operating Machinery

While taking ELTROXIN, use caution when driving or operating potentially dangerous machinery.

Myxedema coma

Oral thyroid hormone medications, including ELTROXIN, are not recommended to treat myxedema coma. Myxedema coma is a severe hypothyroid condition that may cause irregular absorption of ELTROXIN. Thyroid hormone medications taken intravenously (through the vein) should be used instead of oral (by mouth) thyroid hormone medications.

Premature babies with very low birth weight: Blood pressure may be monitored regularly when levothyroxine treatment is started. This is because levothyroxine can cause a fast drop in blood pressure (known as circulatory collapse).

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with ELTROXIN:

- Nutritional Supplements
    - Biotin (vitamin B7, vitamin H; including for hair and nail)
    - Calcium carbonate
    - Ferrous sulfate (iron)
- Medicines used to treat digestion problems
    - Antacids (aluminum and magnesium types)
    - Simethicone
    - Proton-pump inhibitors
    - Sucralfate
- Medicines used to treat heart problems including high blood pressure
    - Digoxin
    - Amiodarone
    - Thiazide diuretics (hydrochlorothiazide)
    - Oral anticoagulants (warfarin sodium)
    - Beta blockers
- Medicines used to lower high cholesterol
    - Some statins (like lovastatin, simvastatin)
    - Cholestyramine
    - Colestipol
    - Clofibrate

- Medicines used to treat depression (antidepressants)
    - St John's Wort
    - Tricyclics (amitriptyline)
    - Tetracyclics (maprotiline)
    - Reuptake inhibitors (SSRIs like fluoxetine, sertraline)
- Medicines used to other treat mental health problems and seizures
    - Lithium
    - Carbamazepine
    - Phenobarbital
    - Diazepam
    - Phenytoin
    - Methadone
- Medicines used to treat diabetes
    - Insulin
    - Tolbutamine
    - Biguanides
    - Meglitinides
    - Sulfonylureas
    - Thiazolidinediones
- Hormones
    - Birth control pills
    - Hormone replacement therapy
    - Testosterone
    - Growth hormones (like somatrem, somatropin)
- Some cancer therapies
- Medicines used for weight reduction
    - Orlistat
- Medicines used to treat inflammatory conditions
    - Dexamethasone
    - Prednisone
    - Hydrocortisone
- Medicines used to treat bacterial infections
    - Sulfonamides
    - Rifampin
    - Ciprofloxacin
- Medicines used to treat Human immunodeficiency viruses (HIV)
    - Ritonavir
- Medicines used to treat kidney problems
    - Sevelamer
    - Kayexalate
    - Lanthanum
- Medicines used to treat high levels of potassium in the blood (hyperkalemia)
    - Polystyrene sulfonates
- Other medicines used to treat thyroid problems
    - Methimazole
    - Propylthiouracil (PTU)
    - Carbimazole
- Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)

    - Fenamates
    - Phenylbutazone
    - Salicylates
- Oral contrast agents used in imaging like x-rays and CT scans
    - Iodide
- Drug-food interactions
    - Eating certain foods like soybean flour (infant formula), cotton seed meal, walnuts,calcium and calcium-fortified orange juice, and dietary fibre may cause less ELTROXIN to be absorbed.

How to take ELTROXIN:
Your healthcare professional will tell you how and when to take ELTROXIN. They may ask you to take ELTROXIN at a different time of the day, separately from other medications, to avoid potential drug interactions.

Take ELTROXIN once a day. It is recommended you take ELTROXIN:
- on an empty stomach;
- 30 minutes to one hour before breakfast;
- at least 4 hours before or after you take medications that can impact the absorption of ELTROXIN.

For infants and children who cannot swallow ELTROXIN, the tablets can be crushed and added to a small amount (5 to 10 mL) of water, breast milk or non-soybean based formula.

The tablet and liquid mixture can be given by spoon or dropper. **If the tablet and liquid mixture is not consumed immediately it must be thrown out.**

ELTROXIN tablets can also be crushed and sprinkled over a small amount of food such as apple sauce. Do **not** add the crushed tablets to foods containing large amounts of soybean, fiber, or iron. **If the tablet and food mixture is not consumed immediately it must be thrownout.**

Usual Dose:
The usual dose of ELTROXIN is different for everyone.

Your healthcare professional will decide on the dose that is right for you based on your age, your weight, if you have any other illness and how long you were sick before beginning treatment with ELTROXIN.

Overdose:
Symptoms may not appear until several days after taking too much ELTROXIN.

Signs and symptoms of overdose may include: weight loss, increased appetite, heart palpitations (fast or irregular beating of the heart), nervousness, diarrhea, abdominal cramps,

sweating, fast heartbeat, fever, menstrual irregularities, convulsions and seizures (fits) and in some cases coma and death.

If you think that you or a person you are caring for have taken too much ELTROXIN, contact your healthcare professional, hospital emergency department, regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs or symptoms.

Missed Dose:
Take the missed dose as soon as you remember it. However, if it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule. Do not take a double dose to make up for a missed one. If you miss more than two doses, contact your healthcare professional.

What are possible side effects from using ELTROXIN?
These are not all the possible side effects you may have when taking ELTROXIN. If you experience any side effects not listed here, tell your healthcare professional.

- changes in menstrual cycle
- diarrhea, nausea, vomiting, stomach cramps
- fatigue, sleepiness
- fever
- headache
- heat intolerance, flushing, excessive sweating
- infertility
- muscle spasms and/or weakness, tremors
- reduced adult height in children due to early closure of growth plates in bones
- restlessness, anxiety, nervousness, agitation, rapid changes in emotions
- temporary hair loss (particularly in children during the first month of therapy)
- trouble sleeping (insomnia)

ELTROXIN can cause abnormal test results. Your healthcare professional will decide when to perform blood tests and other diagnostic tests and will interpret the results.

Serious Side Effects and What To Do About Them			
Symptom / Effect	**Talk to your healthcare professional**		**Stop taking drugand get immediate medical help**
	Only if severe	**In all cases**	
Unknown			
Heart Problems: chest pain,rapid or irregular heartbeat, palpitations, shortness of breath			**√**
Heart Attack: crushing chest pain that radiates to the left armand/or jaw, sweating, nausea, vomiting, shortness of breath			**√**
Heart Failure: shortness of breath when you exert yourself or lie down, fatigue, weakness, swelling in the legs, ankles and feet, rapid or irregular heartbeat, persistent cough			**√**
Serious Allergic Reactions: rash, hives, swelling of the face,lips, tongue or throat, difficulty swallowing or breathing			**√**
Seizures (fits)			**√**
Change in appetite, weight gain or loss	**√**		
Increased Pressure in the Brain (in children): headaches,vison problems or complete vision loss, seeing double, ringing in the ears, pain in the arms			**√**

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (canada.ca/drug-device-reporting) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:
Store ELTROXIN at room temperature (15°C to 25°C) and protect from light.
Keep out of reach and sight of children.

If you want more information about ELTROXIN.

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html; the manufacturer's website: https://aspenpharma.ca or by calling 1 (844) 330-1213.

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