

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

ELTROXIN®
levothyroxine tablets, BP

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 cause serious or even life threatening side effects.

What is ELTROXIN used for?

- **ELTROXIN** is given to replace the thyroid hormone thyroxine, which is normally produced by the thyroid gland, in patients with an underactive thyroid gland (hypothyroidism) who do not produce enough of this hormone on their own.
- **ELTROXIN** is used to treat goiter (enlarged thyroid gland) and congenital hypothyroidism (cretinism).
- **ELTROXIN** is used together with surgery and radioactive iodine therapy to manage certain types of thyroid cancer (thyrotropin-dependent well-differentiated papillary or follicular thyroid cancer).

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, colorcon blue (150 mcg), colorcon yellow (100 mcg), corn starch, erythrosine (200 mcg), lactose, and magnesium stearate.

ELTROXIN comes in the following dosage forms:

Tablets: 50 mcg, 100 mcg, 150 mcg and 200 mcg of levothyroxine sodium

Do not use ELTROXIN if you:

- 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)

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 pregnant or intend to become pregnant
- are breast-feeding, or planning to breast-feed
- are 65 years of age or older

Other warnings you should know about:

Tell your healthcare professional about any surgery you are planning. Before the surgery tell your dentist or surgeon that you are taking ELTROXIN.

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

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
 - 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)
 - 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
- 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.

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 thrown out.**

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 you have taken too much ELTROXIN, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no 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 feel when taking ELTROXIN. If you experience any side effects not listed here, contact your healthcare professional.

Side effects may include:

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

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 drug and 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 arm and/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, vision problems or complete vision loss, seeing double,			√

Serious Side Effects and What To Do About Them			
Symptom / Effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
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, talk to your healthcare professional.

<p>Reporting Side Effects</p> <p>You can report any suspected side effects associated with the use of health products to Health Canada by:</p> <ul style="list-style-type: none"> • Visiting the Web page on Adverse Reaction Reporting (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html) for information on how to report online, by mail or by fax; or • Calling toll-free at 1-866-234-2345. <p><i>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.</i></p>
--

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 (<http://hc-sc.gc.ca/index-eng.php>); the manufacturer’s website www.aspenpharma.ca, or by calling 1-844-330-1213.

This leaflet was prepared by Aspen Pharmacare Canada Inc.
8 – 1155 North Service Road West, Oakville, ON, L6M 3E3

Last Revised: January 30, 2020