

PART III: CONSUMER INFORMATION

**Pr ELTROXIN[®]
levothyroxine sodium tablet, USP**

This leaflet is part III of a three-part "Product Monograph" published when ELTROXIN[®] was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about ELTROXIN[®]. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

ELTROXIN[®] contains the active ingredient levothyroxine sodium which is the same as the hormone, thyroxine. Thyroxine and another hormone, liothyronine, are two hormones produced and released by the thyroid gland. These hormones are responsible for maintaining a normal rate of metabolism in the body.

In other areas of the body, thyroxine is converted into liothyronine, which is a more active form of thyroxine.

Hypothyroidism occurs when the thyroid gland is unable to produce normal amounts of thyroxine resulting in the level of thyroid hormones in the blood to decrease. The body cannot function properly without this hormone, resulting in poor growth, slow speech, lack of energy, weight gain, hair loss, dry thick skin, and increased sensitivity to cold.

What it does:

ELTROXIN[®] is given to replace the thyroxine that would normally be produced naturally by the thyroid gland. ELTROXIN[®], when taken correctly, reverses the symptoms of hypothyroidism.

Once the thyroid gland becomes unable to produce thyroxine, it will not generally return to normal function. Therefore, once ELTROXIN is started, it usually needs to be taken for the rest of a person's life.

ELTROXIN is also used to treat goiter (enlarged thyroid gland) and congenital hypothyroidism (cretinism).

When it should not be used:

Do not use this medication if:

- If you have had an allergic reaction before to any of the ingredients in ELTROXIN[®]
- If you have thyrotoxicosis, a disease in which the thyroid gland is overactive and produces too much thyroxine.

- If you have had an acute myocardial infarction (heart attack).
- If you have had uncorrected adrenal insufficiency (kidney problems).

What the medicinal ingredient is:

Levothyroxine sodium

What the important nonmedicinal ingredients are:

Acacia powder, corn starch, lactose, magnesium stearate and coloring agents.

What dosage forms it comes in:

Tablets: 50, 100, 150, 200 and 300 mcg

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

Thyroid hormones, including ELTROXIN[®], either by itself or with other medications should not be used for weight loss. Larger doses may cause serious side effects especially when taken together with medications used for weight loss.

BEFORE you use ELTROXIN[®] talk to your doctor or pharmacist if:

- you have any other medical problems, especially:
 - Clotting disorders
 - Heart disease
 - A history of problems with your thyroid, adrenal or pituitary gland
 - Diabetes
 - Allergic to any foods or medicines
 - Are pregnant or intend to become pregnant
 - Are breast-feeding, or planning to breast-feed
 - Are taking any other medications, including prescription and over-the-counter medications as well as vitamins and other supplements
 - Are taking medication to thin your blood such as warfarin
 - You are taking orlistat
- Tell your doctor about any surgery you are planning. Before the surgery tell your dentist or surgeon that you are taking ELTROXIN[®].

INTERACTIONS WITH THIS MEDICATION

Some medications and foods can interfere with the effectiveness of your thyroid medication or your overall treatment – these are called “drug and food interactions”.

Make sure your doctor or healthcare provider has a complete

list of all prescription medications, vitamins, or over-the-counter medications you are currently taking. In some cases, your condition or therapy may need additional monitoring. Your doctor may ask you to take your thyroid medication at a different time of the day, separately from some medications, to avoid potential interactions.

This is not a complete list of drug interactions. For more information, contact your doctor or pharmacist.

Drugs that may interact with ELTROXIN[®] include:

Nutritional Supplements

- Calcium Carbonate
- Ferrous Sulfate (Iron)

GI Therapies

- Antacids (aluminum and magnesium types)

Cardiovascular Therapies like:

- Digoxin
- Thiazide Diuretics (Hydrochlorothiazide)
- Oral Anticoagulants (Coumadin[®] - Warfarin Sodium)
- Beta Blockers

Cholesterol Therapies

- Some statins

Antidepressants

- Tricyclics (Amitriptyline)
- Tetracyclics (Maprotiline)
- Reuptake Inhibitors (SSRIs like Prozac[®] - Fluoxetine)

Other (CNS) Therapies Neurologic/Psychiatric

- Lithium
- Carbamazepine
- Phenobarbital
- Diazepam
- Phenytoin (Dilantin[®])

Some Cancer Therapies

General or other Therapies

- Antidiabetic Agents (such as Insulin)
- Oral contraceptive pill
- Drugs used for weight reduction (such as Orlistat)

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 decrease absorption of your medicine (levothyroxine sodium).

Please discuss with your doctor whether a dose adjustment of your medicine is necessary.

PROPER USE OF THIS MEDICATION

Usual dose:

The usual dose of ELTROXIN[®] is different for everyone.

Your doctor will take into account your age, weight, presence of any other illness and the severity and length of time you have been ill prior to beginning treatment with ELTROXIN[®].

Overdose:

Symptoms are not always evident or may not appear until several days after taking your ELTROXIN[®] medication.

Signs and symptoms of overdose include, but are not limited to: weight loss, increased appetite, heart palpitations (fast or irregular beating of heart), nervousness, diarrhea, abdominal cramps, sweating, increased pulse and blood pressure, fever, and menstrual irregularities.

If you suspect that you or anyone else has taken too much ELTROXIN[®] you may need to seek immediate medical attention.

For management of a suspected overdose, contact your regional Poison Control Centre.

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.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

ELTROXIN can cause some side effects. Tell your doctor if any of these symptoms are severe or do not go away:

- weight loss, tremor, headache, upset stomach, diarrhea, stomach cramps, nervousness, irritability, insomnia, excessive sweating, increased appetite, fever, changes in menstrual cycle, sensitivity to heat, temporary hair loss (particularly in children during the first month of therapy)

Seek emergency medical attention or contact your doctor immediately if you experience any of the following:

- an allergic reaction (difficulty breathing; closing of the throat; swelling of the lips, tongue, or face; or hives);
- vomiting; or
- chest pain, irregular heartbeat, shortness of breath.

This is not a complete list of side effects. For any unexpected effects while taking ELTROXIN[®], contact your doctor or pharmacist.

HOW TO STORE IT

Store your medication between 15°C and 25°C and protect from light.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following three ways:

- **Report online at**
www.healthcanada.gc.ca/medeffect
- **Call toll-free at 1-866-234-2345**
- **Complete a Canada Vigilance Reporting Form and:**
 - **Fax toll-free to 1-866-678-6789, or**
 - **Mail to: Canada Vigilance Program**
Health Canada
Postal Locator 0701D
Ottawa, ON K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of the side effect, contact your health care professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at:

www.tritonpharma.ca or by contacting the sponsor,

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