

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr LEVOTHYROXINE SODIUM FOR INJECTION

Levothyroxine Sodium for Injection (powder for solution)

Read this carefully before you start taking **LEVOTHYROXINE SODIUM FOR INJECTION** 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 **LEVOTHYROXINE SODIUM FOR INJECTION**.

Serious Warnings and Precautions

- Thyroid hormones, including levothyroxine, either alone or with other therapeutic agents, should not be used for the treatment of obesity or for weight loss.
- These medicines can cause serious or life-threatening side effects.

What is LEVOTHYROXINE SODIUM FOR INJECTION used for?

- To treat hypothyroidism
- When rapid treatment is required or when oral medication cannot be taken.

How does LEVOTHYROXINE SODIUM FOR INJECTION work?

Levothyroxine is a synthetic (man-made) thyroid hormone. It is intended to replace the hormone thyroxine, produced by a normally functioning thyroid gland. In hypothyroidism, the thyroid gland does not produce enough thyroxine. This causes levels of thyroid hormones in the blood to drop. LEVOTHYROXINE SODIUM FOR INJECTION helps to replace or supplement thyroxine in the body when tablets or capsules cannot be used.

What are the ingredients in LEVOTHYROXINE SODIUM FOR INJECTION?

Medicinal ingredient: Levothyroxine sodium

Non-medicinal ingredients: Dibasic sodium phosphate heptahydrate, mannitol and sodium hydroxide.

LEVOTHYROXINE SODIUM FOR INJECTION comes in the following dosage forms:

- powder for solution; 200 mcg / vial
- powder for solution; 500 mcg / vial

Do not use LEVOTHYROXINE SODIUM FOR INJECTION if:

- you have an overactive thyroid gland;
- you have uncorrected or untreated adrenal insufficiency. This is a condition where your adrenal glands do not make enough of the hormone cortisol;
- you have recently had a heart attack;

- you are pregnant and taking medicines to treat an overactive thyroid;
- you are allergic to any of the ingredients in LEVOTHYROXINE SODIUM FOR INJECTION.

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

- are allergic to any foods or medicines;
- have any heart problems and whether or not you received treatment for them. This includes:
 - hardening of the arteries
 - angina
 - irregular heartbeat
 - heart failure
 - heart disease;
- have any other medicinal problems and whether or not you have received treatment for them. This includes:
 - high blood pressure
 - osteoporosis
 - blood clotting disorders
 - history of thyroid, adrenal, or pituitary gland problems;
- are taking blood thinners such as warfarin. Your dose may need to be changed after starting LEVOTHYROXINE SODIUM FOR INJECTION;
- have signs or symptoms of psychotic disorders;
- are a woman on long term levothyroxine treatment. This is because you may experience bone loss. This is also known as lowered bone mineral density;
- are or intend to become pregnant;
- are 65 years of age or older.

Other warnings you should know about:

Diabetes or adrenal insufficiency: If you are receiving treatment for these conditions, the doses of those treatments may need to be changed after starting LEVOTHYROXINE SODIUM FOR INJECTION. Monitor sugar levels in your blood and urine as directed by your doctor. Report any changes to your doctor right away.

Breast-feeding: Small amounts of thyroid hormones will pass into your breast milk. Your treatment with LEVOTHYROXINE SODIUM FOR INJECTION may continue while you are breast-feeding.

Monitoring and blood tests: You will need to have regular blood tests while you are receiving LEVOTHYROXINE SODIUM FOR INJECTION. These will be done to make sure that you are receiving the correct dose. As well, the results of these tests will help your doctor to know how your treatment is affecting your blood.

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 for at least 2 days before you have a thyroid function test.

Surgery: Tell your healthcare professional about any surgery (including dental surgery) you are planning. Before the surgery, tell your doctor or dentist that you are receiving LEVOTHYROXINE SODIUM FOR INJECTION.

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 LEVOTHYROXINE SODIUM FOR INJECTION:

- Nutritional supplements such as biotin (vitamin B7, vitamin H; including for hair and nail)
Some medicines or supplements may interfere with blood tests done to measure thyroid hormone in your blood. Be sure to tell your healthcare professional of all medicines or supplements you are taking before and at the time of any blood tests.
- Medicines used to treat heart problems including high blood pressure such as:
 - digitalis glycosides (e.g., digoxin)
 - beta-adrenergic antagonists, also called beta-blockers (e.g., metoprolol, atenolol, bisoprolol, propranolol)
 - blood thinners such as warfarin, dicumarol and coumarin derivatives
 - amiodarone
 - diuretics like furosemide
- Medicines used to treat diabetes including insulin and other medicines used to lower blood sugar levels.
- Medicines used to treat bacterial infections such as:
 - sulfonamides
 - ciprofloxacin
- Medicines used to treat inflammatory conditions such as:
 - glucocorticoids (corticosteroids)
 - salicylates
- Medicines used to lower high cholesterol such as clofibrate.
- Medicines used to treat mental health problems and seizures such as:
 - Diazepam
 - St. John's wort
 - antidepressants like amitriptyline, maprotiline and sertraline
 - lithium
 - phenytoin
 - barbiturates
 - carbamazepine
- Ritonavir, which is a medicine used in the treatment of HIV and AIDS.
- Iodide, which is used for imaging like x-rays and CT scans.
- Hormones such as estrogens that are taken by mouth including birth control.
- Medicines used to treat types of cancer such as tyrosine kinase inhibitors.
- Medicines used anesthesia such as ketamine.
- Beta-sympatholytics/sympathomimetics, which are used to stimulate the heart and treat breathing problems.
- Other medicines used to treat thyroid problems such as:

- propylthiouracil (PTU)
- methimazole

How to take LEVOTHYROXINE SODIUM FOR INJECTION:

LEVOTHYROXINE SODIUM FOR INJECTION powder will be first mixed into a solution.

- LEVOTHYROXINE SODIUM FOR INJECTION will be given to you by a healthcare professional.
- Your healthcare professional will check the solution to make sure it is not cloudy or leaking.
- The solution of LEVOTHYROXINE SODIUM FOR INJECTION will then be given through a needle placed in a vein in your arm. This is called an intravenous (IV) injection. It may also be given through an injection in your muscle. This is called an intramuscular (IM) injection.
- Any unused portion will be discarded.

Usual dose:

The usual dose of LEVOTHYROXINE SODIUM FOR INJECTION will be different for everyone. Your healthcare professional will decide on the dose that is right for you. Your dose will depend on:

- your age,
- your weight,
- other conditions or illnesses you have, including any heart problems,
- how long you had symptoms of thyroid problems, and
- how severe your symptoms are.

Overdose:

You may not experience symptoms of an overdose until several days after receiving too much of LEVOTHYROXINE SODIUM FOR INJECTION.

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, fever, changes in period bleeding, convulsions and seizures (fits). Coma and death are also possible.

If you think you, or a person you are caring for, have taken too much LEVOTHYROXINE SODIUM FOR INJECTION, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If you miss a dose, make sure it is administered as soon as possible. If it is almost time for your next dose, the missed dose should not be administered. Instead, the next regularly scheduled dose should be administered. Doses should not be doubled.

What are possible side effects from using LEVOTHYROXINE SODIUM FOR INJECTION?

These are not all the possible side effects you may have when taking LEVOTHYROXINE SODIUM FOR INJECTION. If you experience any side effects not listed here, tell your healthcare professional.

Side effects may include:

- hair loss
- changes in menstrual cycle

- osteoporosis (bone loss)
- diarrhea
- vomiting
- headache
- excessive sweating
- tremors
- muscle weakness
- abdominal and leg cramps
- nervousness
- anxiety or irritability
- rapid changes in emotions
- fever
- flushing
- inability to tolerate heat
- fatigue
- trouble sleeping
- restlessness

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, increased blood pressure, shortness of breath			✓
Heart Failure (heart does not pump blood as well as it should): shortness of breath, fatigue and weakness, swelling in ankles, legs and feet, cough, fluid retention, lack of appetite, nausea, rapid or irregular heartbeat, reduced ability to exercise			✓
Heart Attack: crushing chest pain that radiates to the left arm and/or jaw, sweating, nausea, vomiting, shortness of breath			✓
Angina (not enough oxygen to the heart muscle): discomfort in the shoulder, arm, back, throat, jaw or teeth; pain or pressure in the chest			✓
Allergic Reaction: difficulty swallowing or breathing, wheezing, drop in blood pressure, feeling sick to your stomach and throwing up, hives or rash, swelling of the face, lips, tongue or throat			✓

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	
Angioedema (swelling of tissue under the skin): difficulty breathing; swollen face, hands and feet, genitals tongue, throat; Swelling of the digestive tract causing diarrhea, nausea or vomiting		✓	
Elevations in liver enzymes		✓	
Pseudomotor cerebri (increased pressure in the brain in children): headaches, vision problems or complete vision loss, seeing double, ringing in the ears, pain in the arms			✓
Hives or skin rash		✓	
Seizures (fits): muscle twitching, changes in emotions, confusion, loss of consciousness with uncontrollable shaking			✓

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 (<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.

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 at room temperature (15°C to 30°C), protected from light.

Use immediately after reconstitution. The reconstituted drug product is stable for a period of 4 hours at 25°C. Discard any unused portion.

Keep in a safe place out of the reach and sight of children.

If you want more information about LEVOTHYROXINE SODIUM FOR INJECTION:

- 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 (www.avirpharma.com), or by calling 1-888-430-0436.

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Last Revised: August 2, 2024