

PART III: CONSUMER INFORMATION

Pr LEVOTHYROXINE SODIUM FOR INJECTION (Levothyroxine Sodium for Injection)

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

ABOUT THIS MEDICATION

What the medication is used for:

Levothyroxine is a synthetic thyroid hormone used for treatment of hypothyroidism (low thyroid hormones secretion).

What it does:

The levothyroxine in LEVOTHYROXINE SODIUM FOR INJECTION is intended to replace a hormone that is normally produced by your thyroid gland. Generally, replacement therapy is to be taken for life, except in cases of transient (temporary) hypothyroidism, which is usually associated with an inflammation of the thyroid gland (thyroiditis). LEVOTHYROXINE SODIUM FOR INJECTION is used as a substitute for oral levothyroxine tablets when rapid treatment is required or when oral medication cannot be taken.

When it should not be used:

LEVOTHYROXINE SODIUM FOR INJECTION should not be used in patients:

- with overactive thyroid glands;
- with uncorrected adrenal insufficiency (not enough adrenal hormones);
- with acute myocardial infarction (heart attack);
- who are pregnant and taking drugs for hyperthyroidism;
- who are sensitivity to any of the ingredients.

What the medicinal ingredient is:

Levothyroxine sodium.

What the nonmedicinal ingredients are:

Mannitol, dibasic sodium phosphate heptahydrate, and sodium hydroxide.

What dosage forms it comes in:

LEVOTHYROXINE SODIUM FOR INJECTION is available as a sterile lyophilized powder for reconstitution.

WARNINGS AND PRECAUTIONS

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.
- In patients with normal thyroid function, doses within the range of daily hormonal requirements are ineffective for weight reduction.
- Larger doses may produce serious or even life-threatening toxic effects, particularly when taken with products used for their appetite suppressing effects.

Tell your doctor before and while using LEVOTHYROXINE SODIUM FOR INJECTION:

- if you are allergic to any foods or medicines;
- if you are taking any other prescription, non-prescription (over-the-counter) medications, or herbal/alternative supplements;
- if you have, either presently or in the past, any other medical problems, whether or not you have received treatment for them (especially hardening of the arteries, irregular heartbeat, heart failure, coronary insufficiency, heart disease, high blood pressure, osteoporosis, blood clotting disorders, or history of thyroid, adrenal, or pituitary gland problems);
- if you have diabetes, your dose of insulin or oral antidiabetic agent may need to be changed after starting LEVOTHYROXINE SODIUM FOR INJECTION. You should monitor your blood and urinary glucose levels as directed by your doctor and report any changes to your doctor immediately;
- if you are taking an oral anticoagulant drug (blood thinner) such as warfarin, your dose may need to be changed after starting LEVOTHYROXINE SODIUM FOR INJECTION. Your coagulation status should be checked often to determine if a change in dose is required;
- if you are or intend to become pregnant, or are breast-feeding. Your dose of LEVOTHYROXINE SODIUM FOR INJECTION will likely have to be increased while you are pregnant.

Other Precautions:

You should inform your doctor or dentist that you are taking LEVOTHYROXINE SODIUM FOR INJECTION before having any kind of surgery.

INTERACTIONS WITH THIS MEDICATION

As with most medicines, interactions with other drugs are possible. Tell your doctor, nurse, or pharmacist about all the medicines you take, including drugs prescribed by other doctors, vitamins, minerals, natural supplements, or alternative medicines.

The following may interact with LEVOTHYROXINE SODIUM FOR INJECTION:

- oral anticoagulants, used as blood thinners;
- digitalis glycosides (e.g., digoxin), a heart medication;

- antidiabetic agents (insulin or oral hypoglycemic drugs), used to normalize blood sugar;
- beta-adrenergic antagonists, also called beta-blockers (e.g., metoprolol, atenolol, bisoprolol, propranolol), used to decrease heart rate;
- glucocorticoids (corticosteroids), used to decrease inflammation;
- amiodarone, used to normalize heart rhythm;
- diazepam (e.g. Valium), used to treat seizure, anxiety and other neurological diseases;
- antidepressants;
- lithium, used to treat bipolar disease;
- beta-sympatholytics/sympathomimetics, used to stimulate the heart and treat breathing problems [e.g., Ventolin (salbutamol)];
- propylthiouracil (PTU), used to treat thyroid disease;
- sulphonamides, used to treat infection;
- methimazole, used to reduce the production of thyroid hormone;
- iodide, iodine containing contrast media;
- coumarin derivatives, used as blood thinners;
- ketamine, used mainly for anesthesia;
- phenytoin, used to prevent seizures;
- salicylates, used to relieve pain;
- dicumarol, used as a blood thinner;
- furosemide, known as water pill, helps eliminate excess water;
- clofibrate, used to lower cholesterol;
- sevelamer used to decrease high phosphate levels;
- tyrosine kinase inhibitors, used to treat some types of cancers;
- estrogen contraceptives, hormone replacement therapy;
- barbiturates (e.g. phenobarbital), taken for their calming or sleep-inducing effect;
- carbamazepine, used to treat seizure/fit and nerve pain;
- proton pump inhibitors, used to reduce excessive gastric acid secretion.

- menstrual irregularities, and impaired fertility
- osteoporosis

SERIOUS SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Symptom/effect	Talk with your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
chest pain, rapid or irregular heartbeat, palpitations, increased blood pressure, heart failure, angina, heart attack, shortness of breath			✓
elevations in liver enzymes		✓	
decreased bone mineral density		✓	
hypersensitivity, hives or skin rash, angioedema		✓	
seizures			✓
fatigue, sleeplessness, restlessness	✓		
change in appetite, weight gain or loss	✓		
heat intolerance, fever, flushing		✓	
hyperactivity, nervousness, anxiety, irritability, emotional lability		✓	
tremors, muscle weakness, abdominal and leg cramps		✓	
excessive sweating		✓	
headache	✓		
diarrhea, vomiting	✓		

This is not a complete list of side effects. For any unexpected effects while taking LEVOTHYROXINE SODIUM FOR INJECTION, contact your doctor or pharmacist.

PROPER USE OF THIS MEDICATION

Usual dose:

Your doctor will decide and adjust your dosage depending upon your response to the medication. The starting dose of levothyroxine sodium, the frequency of dose adjustment, and the optimal full replacement dose must be individualized for every patient, and will be influenced by such factors as age, weight, cardiovascular status, presence of other illness, and the severity and duration of hypothyroid symptoms.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Adverse reactions associated with LEVOTHYROXINE SODIUM FOR INJECTION are primarily due to therapeutic overdosage.

- incomplete bone growth
- hair loss

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.

HOW TO STORE IT

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

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

Keep out of reach and sight of children.

MORE INFORMATION

If you want more information about with 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://health-products.canada.ca/dpd-bdpp/index-eng.jsp>); the manufacturer's website www.avirpharma.com or by calling 1-800-363-7988.

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