

LEVOTHYROXINE SODIUM

Levothyroxine is a man-made form of a hormone that is normally produced by the thyroid gland to regulate the body's energy and metabolism. Levothyroxine is given when the thyroid does not produce enough of this hormone on its own. Levothyroxine treats hypothyroidism (low thyroid hormone). Levothyroxine is also used to treat or prevent goiter (enlarged thyroid gland), and is also given as part of a medical tests for thyroid disorders. Levothyroxine should not be used to treat obesity or weight problems. Levothyroxine may also be used for purposes not listed in this medication guide.

Chemical: Levothyroxine sodium
CAS Name: Sodium 4-O-(4-hydroxy-3,5-diiodophenyl)-3,5-diiodo-L-tyrosine
Molecular Formula: C₁₅H₁₀I₄NNaO₄
Molecular Weight: 798.86

Prescription Medicine

INDICATIONS AND USAGE

Take levothyroxine exactly as prescribed by your doctor. Follow all directions on your prescription label. Your doctor may occasionally change your dose to make sure you get the best results. Do not take this medicine in larger or smaller amounts or for longer than recommended.

Do not share this medication with another person, even if they have the same symptoms you have.

Levothyroxine works best if you take it on an empty stomach, at least 30 minutes before breakfast. Follow your doctor's dosing instructions and try to take the medicine at the same time each day. It is very important to take Levothyroxine with a full glass (8 ounces) of water. The Levothyroxine tablet can dissolve very quickly and swell in the throat, possibly causing choking or gagging.

While using levothyroxine, you may need frequent medical tests. Tell any doctor or dentist who treats you that you are using levothyroxine.

Store at room temperature away from moisture and heat.

It may take several weeks before your body starts to respond to levothyroxine.

Keep using this medicine even if you feel well. You may need to use this medicine

for the rest of your life to replace the thyroid hormone your body cannot produce.

CONTRAINDICATIONS

Levothyroxine should not be used to treat obesity or weight problems. Dangerous side effects or death can occur from the misuse of levothyroxine, especially if you are taking any other weight-loss medications or appetite suppressants.

Since thyroid hormone occurs naturally in the body, almost anyone can take levothyroxine. However, you may not be able to take this medication if you have certain medical conditions.

To make sure levothyroxine is safe for you, tell your doctor if you have:

- a thyroid disorder called thyrotoxicosis;
- heart disease, coronary artery disease, or a history of blood clots;
- diabetes (insulin or oral diabetes medication doses may need to be changed when you start taking levothyroxine);
- anemia (lack of red blood cells);
- osteoporosis, or low bone mineral density;
- problems with your pituitary gland;
- any food or drug allergies;
- an untreated or uncontrolled adrenal gland disorder; or if you have recently had a heart attack, or are having any symptoms of a heart attack (chest pain or heavy feeling, pain spreading to the jaw or shoulder, nausea, sweating, general ill feeling).

Tell your doctor if you have recently received radiation therapy with iodine (such as I-131).

FDA pregnancy category A.

Levothyroxine is not expected to harm an unborn baby. If you become pregnant while taking this medicine, do not stop taking the medicine without your doctor's advice. Having low thyroid hormone levels during pregnancy could harm both mother and baby. Your dose needs may be different during pregnancy.

Levothyroxine can pass into breast milk, but it is not expected to be harmful to a nursing baby. Do not use this medication without telling your doctor if you are breast-feeding a baby. Your dose needs may be different while you are nursing.

SIDE EFFECTS

Certain medicines can make levothyroxine less effective if taken at the same time.

If you use any of the following drugs, avoid taking them within 4 hours before or 4

hours after you take levothyroxine:

- calcium carbonate (Alka-Mints, Calcium Oyster Shell, Caltrate, Os-Cal,
- oyster Shell Calcium, Roloids Soft Chew, Tums, and others);
- cholestyramine, colestipol;
- ferrous sulfate iron supplement;
- sucralfate;

- sodium polystyrene sulfonate (Kalexate, Kayexalate, Kionex); or antacids that contain aluminum or magnesium - Acid Gone, Gaviscon, Maalox, Milk of Magnesia, Mintox, Mylanta, Pepcid Complete, and others).

Avoid the following food products, which can make your body absorb less levothyroxine; infant soy formula, cotton seed meal, walnuts, and high-fiber foods.

DOSAGE AND ADMINISTRATION

The initial dose is 12.5 to 50 mcg orally once a day. The dosage can be increased in 12.5 to 25 mcg/day increments every 2 to 4 weeks. In older patients or in younger patients with a history of cardiovascular disease, the dosage should be increased in 12.5 to 25 mcg increments every 3 to 6 weeks.

Few patients require doses higher than 200 mcg. Inadequate response to doses higher than 200 mcg is rare and may suggest malabsorption, poor patient compliance and/or drug interactions. Usual Adult Dose for TSH Suppression

Oral:

The initial dose is 50 mcg orally once a day. The dosage may be increased in 25 to 50 mcg increments every 2 to 4 weeks. The typical maintenance dose is 100 to 200 mcg orally once a day.

Oral: 2.6 mcg/kg/day for 7 to 10 days.

Parenteral: The usual IV or IM dose is 50 to 75% of the oral dose.

Congenital hypothyroidism:

Neonatal:

Oral: 10 to 15 mcg/kg/day; if patient is at risk for development of cardiac failure, begin with a lower dose. In severe cases of hypothyroidism (T4 less than 5 mcg/dL), a higher initial dose of 12 to 17 mcg/kg/day may be considered.

Oral:

0 to 3 months: 10 to 15 mcg/kg orally once per day; if the infant is at risk for development of cardiac failure use a lower starting dose of approximately 25 mcg/day; if the initial serum T4 is very low (less than 5 mcg/dL) begin treatment at a higher dosage of approximately 50 mcg/day.

-3 to 6 months: 8 to 10 mcg/kg or 25 to 50 mcg orally once per day

-6 to 12 months: 6 to 8 mcg/kg or 50 to 75 mcg orally once per day

-1 to 5 years: 5 to 6 mcg/kg or 75 to 100 mcg orally once per day

-6 to 12 years: 4 to 5 mcg/kg or 100 to 125 mcg orally once per day

-12 years: 2 to 3 mcg/kg or greater than or equal to 150 mcg orally once per day

Patients in which growth and puberty are complete: 1.7 mcg/kg orally once per day.

For chronic or severe hypothyroidism: 25 mcg orally once per day and increase dosage as needed in increments of 25 mcg every 2 to 4 weeks until the desired effect is achieved.

STORAGE

Store at room temperature between 59-86 degrees Fahrenheit (15-30 degrees Celsius)- away from light and moisture. Do not store in the bathroom. Keep all medicines away from children and pets. Do not flush medications down the toilet or pour them into a drain unless instructed to do so. Properly discard this product when it is expired or no longer needed. Consult your pharmacist or local waste disposal company for more details about how to safely discard your product.

PRESENTATION:

0.1mg tablets in blister packs of 10 tablets – 5 blisters per box (50 tablets).

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