

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrSYNTHROID®

levothyroxine sodium tablets, USP

Read this carefully before you start taking **SYNTHROID®** 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 **SYNTHROID®**.

Serious Warnings and Precautions

Thyroid hormones, including **SYNTHROID®**, either alone or with other medicines, should not be used to treat obesity or for weight loss. These medicines can cause serious or life threatening side effects.

What is SYNTHROID® used for?

- To treat hypothyroidism. This condition happens when the thyroid gland does not produce enough of the hormone thyroxine;
- To treat certain types of thyroid cancer. For these patients, **SYNTHROID®** is given in combination with surgery and radioactive iodine therapy.

How does SYNTHROID® work?

SYNTHROID® contains levothyroxine sodium, which is the man-made form of thyroxine. Thyroxine is the hormone 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 and leads to changes in metabolism and the proper function of many organs. **SYNTHROID®** helps to replace or supplement thyroxine in the body.

Thyroid hormone replacement is usually taken for life.

What are the ingredients in SYNTHROID®?

Medicinal ingredients: Levothyroxine sodium USP

Non-medicinal ingredients: Acacia, confectioner's sugar, lactose, magnesium stearate, povidone, and talc. Most strengths of **SYNTHROID®** also include colour additives. These are different for each strength; however, the 50 mcg strength has no colour additives.

SYNTHROID® comes in the following dosage forms:

Tablets: 25 mcg, 50 mcg, 75 mcg, 88 mcg, 100 mcg, 112 mcg, 125 mcg, 137 mcg, 150 mcg, 175 mcg, 200 mcg and 300 mcg

Do not use SYNTHROID® if:

- you are allergic to thyroid hormones or any other ingredients in SYNTHROID®;
- you have thyrotoxicosis. This is also known as an overactive thyroid gland;
- you have recently had:
 - a heart attack,
 - acute myocarditis (inflammation/ swelling of the heart muscle), or
 - acute pancarditis (general inflammation/ swelling of the heart);
- you have uncorrected or untreated adrenal insufficiency. This is a condition where your adrenal glands do not make enough of the hormone cortisol;
- you are pregnant and also using medicines to treat an overactive thyroid.

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

- are pregnant or plan to become pregnant. This is because your dose will likely need to be increased;
- have any heart problems, whether or not you have received treatment for them. This includes a history of heart attack, heart disease or hardening of the arteries;
- have other medical problems, whether or not you have received treatment for them, including:
 - high blood pressure,
 - osteoporosis,
 - blood clotting disorders,
 - a history of thyroid, adrenal and/or pituitary gland problems;
- have signs or symptoms of psychotic disorders;
- are switching from a different brand of levothyroxine;
- are a woman on long-term SYNTHROID® therapy. This is because you may experience decrease in bone density;
- develop myxedema coma, a medical emergency, which is a type of severe hypothyroidism.
- have malabsorption syndromes (inability to absorb nutrients, vitamins, and minerals from the intestinal tract into the bloodstream), since SYNTHROID® absorption will be decreased.

Other warnings you should know about:

Diabetes: If you are receiving treatment for diabetes, the dose of your diabetes medication may need to be changed after starting SYNTHROID®. Monitor sugar levels in your blood and urine as directed by your healthcare professional. Report any changes to your healthcare professional right away.

Surgery: Tell your healthcare professional about any surgery (including dental surgery) you are planning. Before the surgery, tell your dentist or surgeon that you are taking SYNTHROID®.

Breast-feeding: Small amounts of thyroid hormones will pass into your breast milk. Regardless, you can continue to take SYNTHROID® while you are breast-feeding. In fact, you should not stop your treatment, as normal levels of thyroid hormones will help maintain milk production.

Blood tests: You will need to have regular blood tests while you are receiving SYNTHROID®. 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.

If you are pregnant you will have blood tests done about every 4 weeks for the first half of your pregnancy. These tests will then be done at least once per week between weeks 26 and 32 of your pregnancy. Based on the results of these blood tests, your dose of SYNTHROID® may be changed.

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.

Driving and using machines: SYNTHROID® may affect your ability to drive and use machines. Before engaging in tasks that require special attention, wait until you know how SYNTHROID® affects you.

Premature babies with very low birth weight: Blood pressure may be monitored regularly when levothyroxine treatment is started. This is because levothyroxine can cause a fast drop in blood pressure (known as circulatory collapse).

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 SYNTHROID®:

- Nutritional supplements such as:
 - biotin (vitamin B7, vitamin H; including for hair and nail)
 - calcium carbonate
 - ferrous sulfate
 - vitamin B3 (niacin / nicotinic acid)
- Medicines used to treat heart problems including high blood pressure such as:
 - digitalis glycosides (e.g. digoxin)
 - beta blockers like propranolol, atenolol, and metoprolol
 - blood thinners like warfarin and heparin

- amiodarone
- nitroprusside
- diuretics like furosemide
- Medicines to treat diabetes including insulin, tolbutamide and other medicines to lower blood sugar levels
- Medicines used to treat digestion problems such as:
 - antacids that contain aluminium and magnesium (e.g. aluminium and magnesium hydroxides, simethicone)
 - proton pump inhibitors
 - metoclopramide
 - sucralfate
- Medicines used to lower high cholesterol such as:
 - colestipol
 - cholestyramine
 - lovastatin
- Medicines to lower levels of phosphorus in the blood such as:
 - polystyrene sulfonate
 - sevelamer
 - lanthanum carbonate
- Medicines used to treat mental health problems and seizures such as:
 - antidepressants like sertraline, maprotiline, amitriptyline, St. John's Wort
 - lithium
 - perphenazine
 - carbamazepine
 - diazepam
 - methadone, heroin
 - phenobarbital
 - amionoglutethemide
 - hydantoins
- Medicines used to treat some cancers such as:
 - tyrosine kinase inhibitors like imatinib and sunitinib
 - tamoxifen
 - 5-fluorouracil
 - Mitotane
 - Mercaptopurine
 - Octreotide
 - Interferon alpha (IFN-a)
 - Interleukin-2
- Medicines used for weight loss including orlistat and other diet pills.
- Medicines used to treat inflammatory conditions such as:
 - glucocorticoids (including the corticosteroids dexamethasone and prednisone)
 - non-steroidal anti-inflammatory drugs (NSAIDs) like fenamates, phenylbutazone and salicylates

- Iodide, which is used for imaging like x-rays and CT scans
- Medicines for asthma or other breathing problems
- Medicines for colds, sinus problems, hay fever or other allergies (including nose drops or sprays)
- A medicine to treat Parkinson's disease and restless leg syndrome called dopamine
- Medicines to treat bacterial, viral or fungal infections such as:
 - a medicine to treat HIV and AIDS called ritonavir
 - medicines to treat tuberculosis such as para-aminosalicylate, ethionamide
 - ciprofloxacin
 - sulfonamides
 - rifampin
 - resorcinol
- Hormones such as
 - estrogens that are taken by mouth including birth control pills
 - growth hormones such as somatotropin
 - muscle building hormones including anabolic steroids
- Other medicines used to treat thyroid problems such as:
 - methimazole or carbimazole
 - propylthiouracil (PTU)

Some medicines or supplements may interfere with any blood tests done to determine thyroid hormone levels (thyroid function tests). It is important to inform your healthcare professional of all medicines or supplements you are taking before and at the time of blood tests.

Eating certain foods such as soybean flour, soybean infant formula, cotton seed, walnuts and dietary fiber may decrease absorption of levothyroxine. You may require a change in the dose.

How to take SYNTHROID®:

- Exactly as your healthcare professional tells you.
- Take your dose once per day at the same time every day.
- You should take your dose on an empty stomach, 30 minutes to 1 hour before breakfast.
- Food and drink can affect how your body absorbs SYNTHROID®. For this reason, if you do take your dose with food or drink, be sure to take it this way each time. You must be consistent with how you take your dose.
- Swallow tablet whole with a full glass of water.
- If you are using other medicines, your healthcare professional may recommend that you take SYNTHROID® 4 hours before or 4 hours after these other medicines.

If your infant or child cannot swallow SYNTHROID® tablets whole, they can still take this medicine. For these patients, use the following steps to prepare the dose:

- crush tablet(s),

- mix the freshly crushed tablet(s) in about 5 to 10 mL of water, breast milk or non-soybean based formula,
- give this mixture to the child by spoon or dropper;

OR

- sprinkle the freshly crushed tablet(s) over a small amount of food like apple sauce.
- Avoid mixing SYNTHROID® with foods or formula that contain large amounts of soybean, fibre, or iron.
- **Do not store the mixture for any period of time.**

Usual dose:

The usual dose of SYNTHROID® is 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,
- the type of thyroid condition you have,
- any other illnesses that you have (including if you are pregnant),
- how long you have had symptoms of thyroid problems, and
- how severe your symptoms are.

You are likely to start treatment at a lower dose. Your dose may be increased a little at a time to prevent side effects.

A child's dose will change as they grow and get older.

Do not change the amount of SYNTHROID® you take or how often you take it, unless your healthcare professional tells you to.

Do not stop taking SYNTHROID® without first talking to your healthcare professional.

Overdose:

You may not experience symptoms of an overdose until several days after taking too much SYNTHROID®.

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, 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 SYNTHROID®, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If you forget to take one dose, take it as soon as you remember, unless it is almost time for your next dose. If it is, skip the missed dose and continue with your regular dosing schedule. Do not take two doses at once to make up for a missed dose. If you miss 2 or more doses in a row, check with your doctor.

What are possible side effects from using SYNTHROID®?

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

- fever, flushing and excessive sweating
- restlessness, nervousness, anxiety, rapid changes in emotion
- trouble sleeping
- temporary hair loss
- diarrhea, vomiting, nausea, stomach cramps
- changes in menstrual cycle, trouble having a child (impaired fertility)
- fatigue
- headache
- muscle weakness, tremors
- reduced adult height due to early closure of growth plates in bones
- change in appetite, weight gain or loss

SYNTHROID® 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			✓
Serious Allergic Reactions: rash, hives, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing			✓

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	
Osteoporosis (decrease in bone mineral density): back pain, loss of height over time, stooped posture, broken bones	✓		
Seizure (fits): muscle twitching, changes in emotions, confusion, loss of consciousness with uncontrollable shaking			✓
Increased Pressure in the Brain (in children) : headaches, vision problems or complete vision loss, seeing double, ringing in the ears, pain in the arms			✓
Slipped capital femoral epiphysis (a weakened hip joint in children): stiffness or pain in the knee or groin, walking with a limp, inability to bear weight on the affected side		✓	

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.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 SYNTHROID® tablets at room temperature (15 to 25° C). Protect SYNTHROID® from light

and moisture.

Do not take your tablets after the expiry date shown on the label.

It is important to keep the SYNTHROID® tablets in the original package.

Keep out of reach and sight of children.

If you want more information about SYNTHROID®:

- 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.mylan.ca), or by calling 1-844-596-9526.

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