

Overview

Hypothyroidism, an underactive thyroid gland, is a common condition where the thyroid gland can't produce enough thyroid hormone to keep the body functioning properly.¹

The thyroid gland is a butterfly-shaped endocrine gland located in the lower front of the neck. Its function is to produce thyroid hormones that help the body use energy, stay warm and keep the brain, heart, muscles, and other organs working as they should.¹

Thyroid conditions affect an estimated 30 million individuals in the U.S.² and approximately one out of eight women will develop a thyroid condition in her lifetime.³

Causes

Hypothyroidism may be caused by a number of factors. Among the most common are:

- **Autoimmune Disease:** Autoimmune disease, the most common cause of hypothyroidism, occurs when the immune system that protects the body from invading infections mistakes thyroid gland cells and other enzymes for invaders and attacks them. As a result, there aren't enough thyroid cells and enzymes left to produce thyroid hormone.¹
- **Thyroid Surgery:** Some individuals may need to have a portion or all of their thyroid gland removed, due to thyroid cancer, thyroid nodules or other conditions.¹ Removing all or a large portion of the thyroid gland can halt or diminish hormone production.⁴
- **Radiation Therapy:** Radiation used to treat cancers of the head and neck can affect the thyroid gland and may lead to hypothyroidism.⁴

Symptoms

The signs and symptoms of hypothyroidism can vary.¹ Some people with hypothyroidism experience only a few mild symptoms, or sometimes, no symptoms at all. While this is not a comprehensive list, some common symptoms include:

Physical ^{3,5}	Cognitive and Mood-related ³	Others ^{3,5}
Weight gain	Difficulty concentrating	Infertility
Dry skin	Trouble remembering things	Elevated blood cholesterol level
Hair loss, including the eyebrows	Feeling down or depressed	Slow heart rate
Swollen face, hands, legs, ankles, or feet		Enlarged thyroid gland (a doctor can check for this during an exam)
Feeling cold		
Aches and pains in muscles or joints		
Hoarse or raspy voice		
Constipation		
Heavy menstrual bleeding or irregular periods		
Fatigue		

Please see the next page for Use and Important Safety Information for Synthroid (levothyroxine sodium tablets, USP), including warning about misuse in weight loss.

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Diagnosis

A diagnosis of hypothyroidism depends on a variety of factors including symptoms, medical/family history, physical exams and blood tests. The most important and sensitive test for hypothyroidism is the thyroid-stimulating hormone (TSH) test.¹ The TSH test measures how much of the thyroid hormone thyroxine (T4) the thyroid gland is being asked to make.¹

Treatment & Follow-up

Hypothyroidism is treated by replacing the amount of hormone the thyroid can no longer produce.¹ This is usually done with an oral tablet or pill of the thyroid hormone thyroxine (T4 or levothyroxine).¹ Individuals should have their TSH checked every six to 10 weeks after a thyroxine dose change.¹ Once an individual with hypothyroidism is on the dose of medicine that's right for them, their physician may change the frequency of their TSH tests to about once a year, depending on the patient's individual situation.¹

Hypothyroidism can't be cured, but in most patients, hypothyroidism can be managed.¹

Use

SYNTHROID® (levothyroxine sodium tablets, USP) is a prescription synthetic thyroid hormone that is used to treat a condition called hypothyroidism. It is intended to replace a hormone that is normally produced by your thyroid gland. Generally, thyroid replacement therapy is to be taken for life.

Important Safety Information

- Thyroid hormones, including SYNTHROID, should not be used either alone or in combination with other medicines for the treatment of obesity or weight loss. In patients with normal thyroid levels, doses of SYNTHROID within the typical range used for hormone replacement are not effective for weight loss. Larger doses may result in serious or even life-threatening effects, especially when used in combination with certain other drugs used to reduce appetite.
- Notify your physician if you are allergic to any foods or medicines, are pregnant or intend to become pregnant, are breast-feeding or are taking any other medications, including prescription and over-the-counter preparations.
- Notify your physician of any other medical conditions you may have, particularly heart disease, diabetes, clotting disorders, and adrenal or pituitary gland problems. Your dose of medications used to control these other conditions may need to be adjusted while you are taking SYNTHROID. If you have diabetes, monitor your blood and/or urinary glucose levels as directed by your physician and immediately report any changes to your physician. If you are taking anticoagulants (blood thinners), your clotting status should be checked frequently.
- Use SYNTHROID only as prescribed by your physician. Do not discontinue or change the amount you take, or how often you take it, unless directed to do so by your physician.

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- Agents such as iron and calcium supplements and antacids can decrease the absorption of levothyroxine sodium tablets. Therefore, levothyroxine sodium tablets should not be administered within 4 hours of these agents.
- Take SYNTHROID® (levothyroxine sodium tablets, USP) as a single dose, preferably on an empty stomach, one-half to one hour before breakfast. Levothyroxine absorption is increased on an empty stomach.
- Notify your physician if you experience any of the following symptoms: rapid or irregular heartbeat, chest pain, shortness of breath, leg cramps, headache, nervousness, irritability, sleeplessness, tremors, change in appetite, weight gain or loss, vomiting, diarrhea, excessive sweating, heat intolerance, fever, changes in menstrual periods, hives or skin rash, or any other unusual medical event.
- Notify your physician or dentist that you are taking SYNTHROID prior to any surgery.
- After a stable response has been established, it is important to have follow-up laboratory tests done, as ordered by your health care provider, at least annually.

This is the most important information to know about SYNTHROID. For more information, talk with your health care provider.

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Synthroid is a prescription medication. For more information, visit www.synthroid.com

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088 (1-800-323-1088).

If you cannot afford your medication, contact www.pparx.org or call the toll free phone number (1-888-4PPA-NOW) (1-888-477-2669) for assistance.

¹ American Thyroid Association. Hypothyroidism. http://www.thyroid.org/wp-content/uploads/patients/brochures/Hypo_brochure.pdf. Accessed January 9, 2013.

² American Association of Clinical Endocrinologists (AACE). EmPower Website. <http://www.empoweryourhealth.org/thyroid-top-ten>. Accessed January 9, 2013.

³ Georgetown University Medical Center. Basic Thyroid Information. <http://medicine.georgetown.edu/divisions/endocrinology/knowledge/204446.html>. Accessed January 9, 2013.

⁴ Mayo Clinic. Hypothyroidism. <http://www.mayoclinic.com/health/hypothyroidism/DS00353/DSECTION=causes>. Accessed January 9, 2013.

⁵ Mayo Clinic. Hypothyroidism. <http://www.mayoclinic.com/health/hypothyroidism/DS00353/DSECTION=symptoms>. Accessed January 9, 2013.