

## Important Update to the Prescribing Information for SYNTHROID® (levothyroxine sodium) tablets, for oral use<sup>1</sup>

On August 30, 2022, the Prescribing Information (PI) for SYNTHROID was approved as a result of the U.S. Food and Drug Administration (FDA) prior approval supplement request dated March 16, 2022. The following describes the major changes in the SYNTHROID PI. Please refer to the full PI to review all the changes.

### **The following sections have been updated in the PI:**

#### **1 INDICATIONS AND USAGE**

##### **Hypothyroidism**

SYNTHROID is indicated in adult and pediatric patients, including neonates, as a replacement therapy in primary (thyroidal), secondary (pituitary), and tertiary (hypothalamic) congenital or acquired hypothyroidism.

##### **Pituitary Thyrotropin (Thyroid-Stimulating Hormone, TSH) Suppression**

SYNTHROID is indicated in adult and pediatric patients, including neonates, as an adjunct to surgery and radioiodine therapy in the management of thyrotropin-dependent well-differentiated thyroid cancer.

##### **Limitations of Use**

- SYNTHROID is not indicated for suppression of benign thyroid nodules and nontoxic diffuse goiter in iodine-sufficient patients as there are no clinical benefits and overtreatment with SYNTHROID may induce hyperthyroidism [see *Warnings and Precautions (5.1)*].
- SYNTHROID is not indicated for treatment of hypothyroidism during the recovery phase of subacute thyroiditis.

#### **5 WARNINGS AND PRECAUTIONS**

##### **5.1 Serious Risks Related to Overtreatment or Undertreatment with SYNTHROID**

SYNTHROID has a narrow therapeutic index. Overtreatment or undertreatment with SYNTHROID may have negative effects on growth and development, cardiovascular function, bone metabolism, reproductive function, cognitive function, gastrointestinal function, and glucose and lipid metabolism in adult or pediatric patients.

In pediatric patients with congenital and acquired hypothyroidism, undertreatment may adversely affect cognitive development and linear growth, and overtreatment is associated with craniosynostosis and acceleration of bone age [see *Use in Specific Populations (8.4)*].

Titrate the dose of SYNTHROID carefully and monitor response to titration to avoid these effects [see *Dosage and Administration (2.4)*]. Consider the potential for food or drug interactions and adjust the administration or dosage of SYNTHROID as needed [see *Dosage and Administration (2.1)*, *Drug Interactions (7.1)*, and *Clinical Pharmacology (12.3)*].

**This is not a complete list of all the changes made to the Prescribing Information for SYNTHROID. Please refer to the full Prescribing Information for more details.**

## Use

SYNTHROID® (levothyroxine sodium) tablets, for oral use is a prescription, man-made thyroid hormone that is used to treat a condition called hypothyroidism in adults and children, including infants. It is meant to replace a hormone that is usually made by your thyroid gland. Generally, thyroid replacement treatment is to be taken for life. SYNTHROID should not be used to treat noncancerous growths or enlargement of the thyroid in patients with normal iodine levels, or in cases of temporary hypothyroidism caused by inflammation of the thyroid gland (thyroiditis).

## Important Safety Information

- **Thyroid hormones, including SYNTHROID, should not be used either alone or in combination with other drugs for the treatment of obesity or weight loss. In patients with normal thyroid levels, doses of SYNTHROID used daily for hormone replacement are not helpful for weight loss. Larger doses may result in serious or even life-threatening events, especially when used in combination with certain other drugs used to reduce appetite.**
- Do not use SYNTHROID if you have uncorrected adrenal problems.
- Use SYNTHROID only as ordered by your doctor. Taking too much or too little SYNTHROID may lead to negative effects on growth and development, heart function, bone health, reproductive function, mental health, digestive function, and changes in blood sugar and cholesterol metabolism in adult or pediatric patients.
- Taking too much levothyroxine may affect your heart, especially if you are elderly or have heart disease. Tell your doctor immediately if you have any signs of increased heart rate, chest pain, or an irregular heartbeat.
- Tell your doctor about any other medical conditions you may have, especially heart disease, diabetes, blood clotting problems, and adrenal or pituitary gland problems. The dose of other drugs you may be taking to control these conditions may have to be changed while you are taking SYNTHROID. If you have diabetes, check your blood sugar levels and/or the glucose in your urine, as ordered by your doctor, and immediately tell your doctor if there are any changes. If you are taking blood thinners, your blood clotting status should be checked often.
- Taking too much levothyroxine has been associated with increased bone loss, especially in women after menopause.
- Tell your doctor if you are pregnant or breastfeeding or are thinking of becoming pregnant while taking SYNTHROID. Your dose of SYNTHROID may need to be increased during your pregnancy.
- Tell your doctor if you start experiencing any of the following symptoms: rapid or abnormal heartbeat, chest pain, difficulty catching your breath, leg cramps, headache, nervousness, irritability, sleeplessness, shaking, change in appetite, weight gain or loss, vomiting, diarrhea, increased sweating, difficulty tolerating heat, fever, changes in menstrual periods, swollen red bumps on the skin (hives) or skin rash, or any other unusual medical event.
- Partial hair loss may occur during the first few months you are taking SYNTHROID.
- Tell your doctor if you are taking any other drugs, including prescription and over-the-counter products.
- Products such as iron and calcium supplements and antacids can lower your body's ability to absorb levothyroxine, so SYNTHROID should be taken 4 hours before or after taking these products.

### **Important Safety Information (cont'd)**

- Tell your doctor or dentist that you are taking SYNTHROID before any surgery.
- Use SYNTHROID only as ordered by your doctor. Take SYNTHROID as a single dose, preferably on an empty stomach, one-half to one hour before breakfast.
- Once your doctor has found your specific SYNTHROID dose, it is important to have periodic lab tests and clinical evaluations to assess your treatment response.
- Foods like soybean flour, cottonseed meal, walnuts, and dietary fiber may cause your body to absorb less SYNTHROID from the gastrointestinal tract. Grapefruit juice may cause your body to absorb less levothyroxine and may reduce its effect. Let your doctor know if you eat these foods, as your dose of SYNTHROID may need to be adjusted.
- It may take several weeks before you notice an improvement in your symptoms.

**This is the most important safety information you should know about SYNTHROID.  
For more information, talk with your doctor.**

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

**If you are having difficulty paying for your medicine, AbbVie may be able to help.  
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**Please see accompanying full Prescribing Information or visit  
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