

## CONSUMER INFORMATION

### SYNTHROID® levothyroxine sodium, USP

#### ABOUT THIS MEDICATION

##### What the medication is used for:

SYNTHROID® is used when the thyroid gland does not produce enough hormone (hypothyroidism). It is also used to help decrease the size of enlarged thyroid glands (known as goiter) and to treat thyroid cancer.

##### What it does:

SYNTHROID® contains levothyroxine sodium, the same as the thyroxine hormone, produced by the normally functioning thyroid gland.

The thyroid gland produces and releases two hormones: thyroxine and liothyronine. In other areas of the body, thyroxine is changed into liothyronine, which is a more active form of thyroid hormone. These hormones are responsible for maintaining a normal rate of metabolism in the body.

When the thyroid gland is unable to produce normal amounts of thyroxine, the level of thyroid hormones in the blood decreases (hypothyroidism). This results in a reduced rate of metabolism.

Levothyroxine sodium in SYNTHROID® 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). Low levels of thyroid hormone interfere with the proper function of many organs and affect metabolism.

##### When it should not be used:

SYNTHROID® should not be used in patients with:

- Any unusual or allergic reaction to thyroid hormones or any of the inactive ingredients.
- Over active thyroid gland (Thyrotoxicosis) of any cause.
- Uncorrected adrenal gland under-activity.

##### What the medicinal ingredient is:

Levothyroxine sodium, USP

##### What the important non-medicinal ingredients are:

Acacia, confectioner's sugar, lactose, magnesium stearate, povidone, talc and colour additives.

##### What dosage forms it comes in:

SYNTHROID® comes as tablets in the following strengths: 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\*.

\* Presentations currently not marketed in New Zealand

#### WARNINGS AND PRECAUTIONS

##### Serious Warnings and Precautions

**Thyroid hormones, including SYNTHROID®, either alone or with other medicines, should not be used for the treatment of obesity or for weight loss as they could produce serious or even life threatening side effects.**

##### **BEFORE or WHILE you use SYNTHROID® tell your doctor or pharmacist if:**

- You are allergic to any foods or medication.
- You are pregnant or intend to become pregnant, or are breast-feeding. If you become pregnant while taking SYNTHROID®, your dose of SYNTHROID® will likely have to be increased.
- You have any heart problem, whether or not you have received treatment for them (especially history of heart attack, heart disease, hardening of the arteries).
- You have other medical problems, whether or not you have received treatment for them (especially high blood pressure, osteoporosis, blood clotting disorder, or history of thyroid, adrenal and/or pituitary gland problems).
- You have diabetes, your dose of insulin or oral antidiabetic agent may need to be changed after starting SYNTHROID®. You should monitor your blood and urinary sugar levels as directed by your doctor and report any changes to your doctor immediately.
- You are taking an oral anticoagulant (blood thinner) such as warfarin, your dose may need to be changed after starting SYNTHROID®.
- You are taking any other medications (prescription or over-the-counter)
- You are planning to have any kind of surgery (including dental surgery) or emergency treatment. You should inform your doctor or dentist that you are taking SYNTHROID® before having any kind of surgery.
- Your brand of levothyroxin was changed.
- You are a woman on long-term therapy. You may experience decrease in bone density.

- Any allergies to this drug or its ingredients or components of the container.

## INTERACTIONS WITH THIS MEDICATION

**Drugs that may interact with SYNTHROID® include but are not limited to the following:**

- Antacids containing aluminium and magnesium (e.g. Aluminium and magnesium hydroxides, simethicone)
- Anticoagulants (blood thinners).
- Antidepressants
- Anti-diabetic agents (insulin or oral hypoglycaemic drugs)
- Appetite suppressants (diet pills).
- Beta-blockers
- Calcium carbonate
- Cholestyramine (e.g., Questran).
- Colestipol (e.g., Colestid)
- Diazepam (e.g. Valium)
- Digitalis glycosides (e.g. digoxin)
- Ferrous sulphate
- Glucocorticoids (corticosteroids such as dexamethasone or prednisone)
- Iodide
- Lithium
- Medicines for asthma or other breathing problems
- Medicines for colds, sinus problems, or hay fever or other allergies (including nose drops or sprays)
- Orlistat

Some medicines may interfere with any blood tests done to determine thyroid hormone levels (thyroid function tests). It is important to inform your doctor of all medicines 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.

## PROPER USE OF THIS MEDICATION

Use SYNTHROID® only as prescribed by your doctor. Thyroid hormone replacement is usually taken for life. Do not change the amount you take or how often you take it, unless directed to do so by your doctor. Like all medicines obtained from your doctor, SYNTHROID® must be used only by you and for the condition determined appropriate by your doctor. Do not stop taking levothyroxine sodium without talking to your doctor.

Take SYNTHROID® as a single dose, preferably on an empty stomach, one half-to one hour before breakfast. SYNTHROID® should be taken with a full glass of water. As food and drink can significantly change the absorption of SYNTHROID®, you are advised to take SYNTHROID® at the same time every day and be

consistent in how you take it with regards to meals [i.e. either always take it on an empty stomach (preferred method) or always take it with food]. Levothyroxine sodium absorption is increased on an empty stomach.

### Usual dose:

The dose of these medicines will be different for different patients. *Follow your doctor's orders or the directions on the label.*

Treatment is usually started with lower doses that are increased a little at a time to prevent side effects.

**Adults and children (>12):** Therapy is usually initiated at the anticipated full replacement dose. The dosage is adjusted by 12.5 to 25 mcg increments.

**Older (> 50 years) or in younger (<12 years) patients:** with a history of cardiovascular disease, the starting dose should be 12.5 to 50 mcg once daily with adjustments of 12.5 to 25 mcg every 3 to 6 weeks until TSH is normalized or signs and symptoms resolve.

### Overdose:

If you or someone you know accidentally takes more than the prescribed dose, contact your doctor immediately or go to the nearest hospital with the tablets. Tell your doctor or hospital how much was taken. Treat even small overdoses seriously.

### **If you take too much Synthroid (overdose)**

**Immediately telephone your doctor, pharmacist or Poisons Information Centre (New Zealand: Telephone – 0800 POISON or 0800 764 766) for advice, or go to Accident and Emergency at your nearest hospital if you think that you or anyone else may have taken too much Synthroid. Do this even if there are no signs of discomfort or poisoning.**

**You may need urgent medical attention. Keep telephone numbers for these places/services handy.**

### Missed Dose:

If you forget to take one tablet, take another as soon as you remember, unless it is almost time for your next dose. If it is, take the dose you missed with your next dose.

If you miss 2 or more doses in a row or if you have any questions about this, check with your doctor.

## SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Side effects with SYNTHROID® are rare and usually related to

overdosing. They are including:

- Chest pain
- Fast or irregular heart beat
- Weight loss or gain
- Sweating
- Nervousness
- Temporary hair loss
- Decrease of bone mineral density
- Diarrhea
- Vomiting

Other side effects not listed above may also occur in some patients. Ask your doctor or pharmacist for more information about side effects, as they have a more complete list of side effects. Inform your doctor promptly about these or any other symptoms. If the condition persists or worsens, seek medical attention.

Do not be alarmed by this list of possible side effects. You may not experience any of them or only some of them.

**Tell your doctor if you notice anything that is making you feel unwell.**

## HOW TO STORE IT

Keep SYNTHROID® and all other medicines out of reach of children.

SYNTHROID® tablets should be stored at or below 25°C, protected 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.

## MORE INFORMATION

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