

PART III: CONSUMER INFORMATION

Pr **SYNTHROID[®]**
levothyroxine sodium tablets, USP

This leaflet is PART III of a three-part "Product Monograph" published when SYNTHROID[®] was approved for sale in Canada and is designed specifically for consumers. This leaflet is a summary and will not tell you everything about SYNTHROID[®]. Contact your doctor or pharmacist if you have any questions about the drug.

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;
- overactive 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.

For a full listing of non-medicinal ingredients see PART I of the Product Monograph.

What dosage forms it comes in:

SYNTHROID[®] comes as tablets in the following strengths:

25 mcg (List No. 04341), 50 mcg (List No. 04552), 75 mcg (List No. 05182), 88 mcg (List No. 06594), 100 mcg (List No. 06624), 112 mcg (List No. 09296), 125 mcg (List No. 07068), 137 mcg (List No. 03727), 150 mcg (List No. 07069), 175 mcg (List No. 07070), 200 mcg (List No. 07148), and 300 mcg (List No. 07149).

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[®] talk to 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 anti-diabetic 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 have signs or symptoms of psychotic disorders;
- 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 levothyroxine was changed;
- you are a woman on long-term therapy. You may experience decrease in bone density;
- you have any allergies to this drug or its ingredients or components of the container;
- you are taking orlistat.

INTERACTIONS WITH THIS MEDICATION

Drugs that may interact with SYNTHROID[®] includes but are not limited to the following:

- digitalis glycosides (e.g. digoxin)
- anti-diabetic agents (insulin or oral hypoglycemic drugs)
- glucocorticoids (corticosteroids e.g., dexamethasone, prednisone)
- antacids containing aluminium and magnesium (e.g. aluminium and magnesium hydroxides, simethicone)
- calcium carbonate
- diazepam (e.g., Valium[®])
- ferrous sulphate
- antidepressants
- lithium
- iodide
- anticoagulants (blood thinners e.g., warfarin)
- appetite suppressants (diet pills)
- beta blockers (e.g., propranolol, atenolol, metoprolol)
- cholestyramine (e.g., Olestyr[®])
- colestipol (e.g., Colestid[®])
- medicines for asthma or other breathing problems
- medicines for colds, sinus problems, hay fever or other allergies (including nose drops or sprays)
- orlistat (e.g., Xenical[®])
- tyrosine kinase inhibitors (e.g., imatinib, sunitinib).
- proton pump inhibitors

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 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 years): Therapy is usually initiated at the anticipated full replacement dose. The dosage is adjusted by 12.5 to 25 mcg increments.

Patients older than 50 years or patients younger than 50 years with a history of cardiovascular disease: The starting dose should be 25 to 50 mcg once daily with adjustments every 6 to 8 weeks as needed.

Elderly patients with cardiac disease: The recommended starting dose is 12.5 to 25 mcg/day, with gradual dose increments at 4 to 6 week intervals.

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.

For management of a suspected drug overdose, contact your regional Poison Control Centre

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

SYNTHROID[®] can cause some side effects. They include:

- chest pain
- fast or irregular heart beat
- weight loss or gain
- sweating
- nervousness
- temporary hair loss
- decrease of bone mineral density
- diarrhea
- vomiting

HOW TO STORE IT

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

SYNTHROID[®] tablets should be stored at room temperature (15 to 25° C or 59 to 77° F) 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.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following three ways:

- **Report online at:**
www.healthcanada.gc.ca/medeffect
- **Call toll-free at 1-866-234-2345**
- **Complete a Canada Vigilance Reporting Form and:**
 - **Fax toll-free to 1-866-678-6789, or**
 - **Mail to: Canada Vigilance Program**
Health Canada
Postal Locator 0701E
Ottawa, ON K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect[™] Canada Web site at <http://www.healthcanada.gc.ca/medeffect>

NOTE: Should you require information related to the management of side effect, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

The most recent version of this document plus the full Product Monograph, prepared for health professionals can be found at:

www.mylan.ca

or by contacting the sponsor, BGP Pharma ULC, Etobicoke, Ontario, M8Z 2S6 at:

1-844-596-9526

This leaflet was prepared by BGP Pharma ULC.

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