

NEW ZEALAND CONSUMER MEDICINE INFORMATION

SYNTHROID®

*levothyroxine sodium, 25 mcg, 50 mcg and 100 mcg
Tablets*



What is in this leaflet

This leaflet answers some common questions about SYNTHROID.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist. Please read it carefully and keep it for future reference.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking SYNTHROID against the benefits they expect it will have for you.

Talk to your doctor, nurse or pharmacist if you have any concerns about taking SYNTHROID.

Your doctor and pharmacist have more information.

What SYNTHROID is used for

SYNTHROID is used to replace a hormone that is normally produced by your thyroid gland. It is also used to help decrease the size of enlarged thyroid glands (known as goiter) and to treat thyroid cancer.

The thyroid gland produces and releases two hormones: thyroxine and liothyronine. 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 and interferes with the proper function of many body organs.

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

Generally, replacement therapy is to be taken for life, except in cases of transient (temporary) hypothyroidism, which is usually associated with inflammation of the thyroid gland (thyroiditis).

Ask your doctor if you have questions about why SYNTHROID has been prescribed for you.

Your doctor may have prescribed SYNTHROID for another reason.

Before you take SYNTHROID

When you must not take it

SYNTHROID should not be used in patients with:

- Over active thyroid gland (thyrotoxicosis) of any cause.
- Uncorrected/untreated adrenal gland under-activity.
- A history of any cardiac event.
- Pregnant patients taking anti-thyroid agents.
- Any unusual or allergic reaction to, levothyroxine, other thyroid hormones or any of the inactive ingredients.

Some of the symptoms of an allergic reaction may include: shortness of breath; wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

Talk to your doctor or pharmacist if you are not sure whether you should take SYNTHROID.

Before you start to take it

Tell your doctor 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 levothyroxine was changed.

If you are on long-term therapy, you may experience decreases in bone density.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop, or if you have received a vaccine.

Some medicines and SYNTHROID may interfere with each other.

These include:

- Antacids containing calcium, aluminium and magnesium.
- Phosphate binders such as sevelamer and lanthanum carbonate.
- Anticoagulants (blood thinners) such as warfarin and aspirin.
- Medicines for depression or other mental health conditions (e.g. lithium, amitriptyline, diazepam).
- Anti-diabetic agents (insulin or oral hypoglycaemic drugs, e.g. metformin).
- Medicines used to treat blood pressure and heart problems, such as atenolol, propranolol, metoprolol and sotalol.
- Cytokines (e.g. interferon-alpha and interleukin-2), medicines used for the immune system.
- Digitalis glycosides (e.g. digoxin).
- Ferrous sulfate, e.g. iron supplements.
- Glucocorticoids (corticosteroids such as dexamethasone or prednisone).
- Medicines used to lower cholesterol such as statins (e.g. simvastatin,

lovastatin), bile acid sequestrants (e.g. colestipol), cholestyramine (e.g. Questran), and clofibrate.

- Medicines for asthma or other breathing problems.
- Medicines for colds, sinus problems, or hay fever or other allergies (including nose drops or sprays).
- Medicines used to treat certain infections such as rifampicin and ritonavir.
- Medicines used to treat certain forms of cancer (e.g. imatinib, tamoxifen and 5-fluorouracil).
- Medicines used for weight loss.
- Protein pump inhibitors (medicines used to reduce the amount of stomach acid produced), such as omeprazole, lansoprazole and pantoprazole.
- Epilepsy medication e.g. phenytoin, carbamazepine.
- Pain & anti-inflammatory medications (e.g. ibuprofen, paracetamol).
- Oestrogen containing medicines for hormone replacement therapy (HRT) and oral contraceptives.

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

How to take SYNTHROID

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]. SYNTHROID absorption is increased on an empty stomach.

SYNTHROID tablets may be crushed and added to 5-10mL of water, breast milk or non-soybean based formula for infants and children who cannot swallow the tablets whole.

Talk to your doctor, nurse or pharmacist if you have any concerns about how this medicine should be given.

How much to take

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

Treatment may be 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 25 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.

If you forget to take it

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.

If you take too much (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.

Immediately telephone your doctor or the National Poisons Information Centre (0800 POISON or 0800 764 766) for advice, or go to Accident and Emergency at the 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.

While you are taking SYNTHROID

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking SYNTHROID.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine. It may affect other medicines used during surgery.

If you become pregnant while taking this medicine, tell your doctor immediately.

If you are about to have any blood tests, tell your doctor that you are taking this medicine. It may interfere with the results of some tests.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

Things you must not do

Do not take SYNTHROID to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking your medicine or lower the dosage without checking with your doctor.

If you stop taking it suddenly, your condition may worsen or you may have unwanted side effects. If possible, your doctor will gradually reduce the amount you take each day before stopping the medicine completely.

Do not use SYNTHROID as a weight loss treatment.

Things to be careful of

Be careful driving or operating machinery until you know how SYNTHROID affects you.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well during or after having had a dose of SYNTHROID.

Side effects with SYNTHROID are rare and usually related to overdosing. They are including:

- Menstrual irregularities.
- Chest pain.
- Fast or irregular heart beat.
- Sweating or heat intolerance.
- Nervousness, anxiety or depression.
- Temporary hair loss.
- Decrease of bone mineral density.
- Diarrhoea.
- Vomiting.
- Weight loss or gain.
- Seizures.
- Muscle weakness.

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

Ask your doctor or pharmacist to answer any questions you may have.

After taking SYNTHROID

Storage

Keep SYNTHROID and all other medicines out of reach of children. A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines

SYNTHROID tablets should be stored at or below 25°C, protected from light and moisture. Do not store SYNTHROID or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

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.

Ask your pharmacist what to do with any leftover SYNTHROID that has expired or has not been used.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any SYNTHROID that has expired or has not been used.

Product description

What it looks like

SYNTHROID is a round, colour coded, scored tablet debossed with "SYNTHROID."

25 microgram - orange colour

50 microgram - white colour

100 microgram - yellow colour

Ingredients

Each tablet of SYNTHROID contains the active ingredient levothyroxine sodium, USP.

It also contains:

- Acacia
- Sucrose
- Lactose
- Magnesium stearate
- Povidone
- Talc.

SYNTHROID 25 mcg and 100 mcg tablets contain sunset yellow aluminium lake as a colourant. SYNTHROID 100 mcg tablets also contain quinoline yellow as a colourant.

SYNTHROID tablets are gluten-free.

If you want to know more

Should you have any questions regarding this product, please contact your pharmacist or doctor.

Who supplies this medicine

Distributed in New Zealand by:

Mylan New Zealand Ltd,
PO Box 11183,
Ellerslie,
Auckland.

Telephone: (09) 579 2792.

Date of Information

27 March 2020
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