Abbott Laboratories South Africa (Pty) Ltd	**Reg No.: 25 µg: 42/21.3/0670** **Reg No.: 50 µg: 42/21.3/0671** **Reg No.: 75 µg: 42/21.3/0672** **Reg No.: 100 µg: 42/21.3/0674**
SYNTHROID 25 µg /50 µg / 75 µg / 100 µg	**Tablets - 25 µg, 50 µg, 75 µg, 100 µg**

APPROVED CLEAN PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

SYNTHROID 25 µg tablets

SYNTHROID 50 µg tablets

SYNTHROID 75 µg tablets

SYNTHROID 100 µg tablets

Levothyroxine sodium

Contains sugar: 62,8 mg sucrose per each tablet.

Read all of this leaflet carefully before you start taking SYNTHROID

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- SYNTHROID has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What SYNTHROID is and what it is used for.
2. What you need to know before you take SYNTHROID.
3. How to take SYNTHROID.
4. Possible side effects.

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5. How to store SYNTHROID.
6. Contents of the pack and other information.

1. What SYNTHROID is and what it 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 gland (known as goiter) and as additional treatment of some thyroid cancers.

2. What you need to know before you take SYNTHROID

WARNING: 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.

Do not take SYNTHROID:

- If you are hypersensitive (allergic) to levothyroxine sodium or any of the other ingredients of SYNTHROID (listed in section 6);
- If you have an overactive thyroid gland (thyrotoxicosis) of any cause; If you have uncorrected adrenal gland under-activity.

Warnings and precautions

Take special care with SYNTHROID:

- If you have any heart problems, whether or not you have received treatment for them (especially history of heart attack, heart disease, hardening of the arteries);
- You are elderly;
- 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 medicine may need to be changed after starting SYNTHROID. You should monitor you 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 medication (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;
- You are a woman on long-term therapy. You may experience decrease in bone density.

Other medicines and SYNTHROID

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Medicines that may interact with SYNTHROID include but are not limited to the following:

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- Dopamine (used to treat shock and low blood pressure caused by heart attack, trauma, infections or surgery)
- Dopamine agonists (used to treat Parkinson's disease)
- Octreotide (used to treat severe watery diarrhoea and sudden reddening of the face and neck caused by certain types of tumours)
- Medicines for epilepsy such as carbamazepine, hydantoins, phenobarbital, phenytoin and barbiturates
- Rifampicin (used to treat infections)
- Medicines used for heart problems (digitalis glycosides (e.g. Digoxin), amiodarone)
- Sulfonamides (medicines used to treat bacterial infections, urinary tract infections (UTIs) and bronchitis)
- Anti-diabetic medicines (insulin or oral hypoglycaemic medicines, such as biguanides, meglitinides, sulfonylureas or thiazolidinediones)
- Glucocorticoids (corticosteroids such as dexamethasone or prednisone, used to treat inflammation)
- Antacids containing aluminium and magnesium (e.g. aluminium and magnesium hydroxides, simethicone) (used to treat indigestion)
- Phosphate binders such as sevelamer and lanthanum (used to reduce blood levels of phosphate in people with kidney disease)
- Medicines containing calcium salts
- Diazepam
- Kayexalate (used to treat a high level of potassium in your blood)

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- Medicines containing iron that are taken by mouth
- Proton pump inhibitors (used to reduce the amount of acid produced by the stomach)
- Antidepressants (used to treat depression, such as tricyclic depressants, tetracyclic depressants or selective serotonin reuptake inhibitors (SSRIs))
- Sucralfate (used to treat and prevent stomach and duodenal ulcers)
- Lithium (used to treat some types of depression)
- Medicines used to treat hyperthyroidism – when your thyroid gland produces too much thyroid hormone (such as methimazole, propylthiouracil or carbimazole)
- Iodide
- Anticoagulants (blood thinners, such as heparin)
- Orlistat (used to treat obesity)
- Clofibrate or lovastatin (used to lower high levels of cholesterol (a type of fat) in your blood)
- Androgen containing medicines for male hormone replacement therapy
- Oestrogen containing medicines for hormone replacement therapy (HRT) and contraception (the ‘pill’)
- Asparaginase (used to treat acute lymphoblastic leukaemia (ALL)
- Heroin (an illegal, highly addictive drug processed from morphine)
- Methadone (medicine used for pain relief and treatment of drug addiction)
- Aminoglutethimide (used to treat breast cancer in postmenopausal women and prostate cancer in men)
- Medicines used to treat cancer ,such as 5-Fluorouracil, interferon-alpha and interleukin-2 or imatinib

- Mitotane (used to treat cancer of the adrenal gland)
- Tamoxifen (used to treat breast cancer)
- 6-Mercaptopurine (used to treat leukaemia (cancer of the blood))
- Diuretics, such as furosemide, used to remove excess fluid in your body)
- Anti-inflammatory medicines such as fenamates, phenylbutazone or aspirin
- Beta-blockers (medicines used to lower your blood pressure, such as propranolol)
- Cholestyramine, colesevelam and colestipol (used to treat high level of fat in the blood)
- Medicines for asthma or other breathing problems, such as theophylline
- Medicines for colds, sinus problems, or hay fever or other
- Allergies (including nose drops and sprays)
- Growth hormones, such as somatrem or somatropin (used in the treatment of growth failure in children)
- Ketamine (used as an anaesthetic). If you need to have an operation, please tell your doctor or anaesthetist that you are taking SYNTHROID.
- Chloral hydrate (medicine used to calm you before surgery or other procedures)
- Ethionamide, para-aminosalicylate (used to treat tuberculosis (TB))
- Metoclopramide (used to help stop you feeling or being sick (nausea or vomiting) including after radiotherapy or chemotherapy (treatment for cancer)
- Nitroprusside (used to treat congestive heart failure and life-threatening high blood pressure)
- Perphenazine (used to treat psychotic disorders such as schizophrenia and to control severe nausea and vomiting)

- Resorcinol (used to treat acne, itchy or dry skin). Excessive topical use can have an influence on how well your SYNTHROID medicine is working.

SYNTHROID with food and drink

SYNTHROID should preferably be taken on an empty stomach, one half- to one hour before breakfast. SYNTHROID should be taken with a full glass of water.

Certain foods affect the absorption of levothyroxine such as soybean flour (infant formula), cotton seed meal, walnuts, calcium and calcium-fortified orange juice and dietary fibre.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking SYNTHROID.

If you become pregnant while taking SYNTHROID, your dose will likely have to be increased.

Driving and using machines

SYNTHROID is unlikely to have an effect on your ability to drive a vehicle and use machines.

Do not drive a vehicle, operate machinery, or do anything else that requires your attention until you know how SYNTHROID affects you.

SYNTHROID contains sucrose

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If you have been told by your doctor that you have an intolerance to some sugars, consult your doctor before taking SYNTHROID.

3. How to take SYNTHROID

Do not share medicines prescribed for you with any other person.

Always take SYNTHROID exactly as your doctor or pharmacist has instructed you. You should check with your doctor or pharmacist if you are not sure.

If you have the impression that the effect of SYNTHROID is too strong or too weak, tell your doctor or pharmacist.

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.

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 on 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].

The dose of this medicine will be different for different patients.

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

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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.

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 normalised or signs and symptoms resolve.

If you take more SYNTHROID than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control centre.

Tell your doctor or hospital how much was taken. Treat even small overdoses seriously.

If you forget to take SYNTHROID

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

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

Do not take a double dose to make up for the forgotten individual doses.

If you stop taking SYNTHROID

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These tablets are for long term use. You may need to take SYNTHROID for the rest of your life.

Do not stop taking the tablets unless your doctor has told you to do so.

4. Possible side effects

SYNTHROID can have side effects.

Not all side effects are reported for this medicine are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or health care provider for advice.

If any of the following happens, stop taking SYNTHROID and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of your hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing;
- rash or itching;
- fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to SYNTHROID. You may need urgent medical attention or hospitalisation.

Side effects with SYNTHROID are usually related to overdosing.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Chest pain
- Fast or irregular heartbeat

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These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Side effects occurring with unknown frequency:

- Weight loss or gain
- Sweating
- Nervousness
- Temporary hair loss
- Decrease of bone mineral density
- Diarrhoea
- Vomiting

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reactions Reporting Form**", found online under SAHPRA's publications: http://www.sahpra.org.za/Publications/Index/8.

By reporting side effects, you can help provide more information on the safety of SYNTHROID.

5. How to store SYNTHROID

- Store at or below 25 °C.

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- Protect form light and moisture.
- Keep well closed.
- **KEEP ALL MEDICINES OUT OF REACH AND SIGHT OF CHILDREN**.
- Do not store in the bathroom.
- Do not use after the expiry date stated on the label.
- Keep in the original container.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drain or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What SYNTHROID contains

SYNTHROID 25 µg: Each tablet contains 25 µg of Levothyroxine sodium

SYNTHROID 50 µg: Each tablet contains 50 µg of Levothyroxine sodium

SYNTHROID 75 µg: Each tablet contains 75 µg of Levothyroxine sodium

SYNTHROID 100 µg: Each tablet contains 100 µg of Levothyroxine sodium

The other ingredients are acacia, colourants, lactose monohydrate, magnesium stearate (E572), povidone and talc (E553b).

What SYNTHROID looks like and contents of the pack

SYNTHROID 25 µg: an orange, round tablet, debossed on one side with “FLINT”, the opposite side partially scored and debossed with “25”

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SYNTHROID 50 µg: a white, round tablet, debossed on one side with “FLINT”, the opposite side partially scored and debossed with “50”

SYNTHROID 75 µg: a violet, round tablet, debossed on one side with “FLINT” the opposite side partially scored and debossed with “75”

SYNTHROID 100 µg: a yellow, round tablet, debossed on one side with “FLINT”, the opposite side partially scored and debossed with “100”

PVC/Aluminium/OPA blister strips placed in an outer carton containing 30, 90 or 100 tablets.

Holder of certificate of registration

Abbott Laboratories South Africa (Pty) Ltd

Abbott Place

219 Golf Club Terrace

Constantia Kloof

1709

This leaflet was last revised in

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Registration numbers

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