

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

WARNING: Important safety information is provided in a boxed warning in the [full CMI](#). Read before using this medicine.

1. Why am I using THYROX?

THYROX contains the active ingredient levothyroxine sodium. THYROX is a thyroid hormone. It is used as replacement therapy in the treatment of thyroid hormone deficiency. For more information, see Section [1. Why am I using THYROX?](#) in the full CMI.

2. What should I know before I use THYROX?

Do not use if you have ever had an allergic reaction to THYROX or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use THYROX?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with THYROX and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use THYROX?

- Your doctor will decide on the right dose for you. The usual starting dose for adults is 50 to 100 micrograms daily.
- Swallow THYROX tablets with a glass of water.
- THYROX tablets should be taken first thing in the morning on an empty stomach, at least 30 minutes and preferably 60 minutes before any food or other medications.

More instructions can be found in Section [4. How do I use THYROX?](#) in the full CMI.

5. What should I know while using THYROX?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using THYROX.• Tell your doctor if you are pregnant or breastfeeding.• Visit your doctor regularly.• Immediately stop taking THYROX if a skin rash or other allergic reaction occurs.
Things you should not do	<ul style="list-style-type: none">• Do not switch or interchange with other brands unless advised by your doctor.• Do not change your dose unless your doctor tells you to do so.• Do not give this medicine to anyone else, even if his or her symptoms seem similar to yours.
Driving or using machines	<ul style="list-style-type: none">• Do not drive or operate machinery where alertness is required, until you know how the medicine affects you.
Drinking alcohol	<ul style="list-style-type: none">• Tell your doctor if you drink alcohol.
Looking after your medicine	<ul style="list-style-type: none">• Store below 25°C. Store in the original bottle. Keep the bottle tightly closed. Protect from light.• Do not take THYROX if the tablet's colour has changed.

For more information, see Section [5. What should I know while using THYROX?](#) in the full CMI.

6. Are there any side effects?

The less serious side effects are nervousness, anxiousness, restlessness, muscle weakness & cramps, headache, lack of concentration, sleep disturbances, hair loss, menstrual irregularities. Serious side effects include allergic reactions such as skin rash, chest pain, and irregular heartbeats.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

WARNING: THYROX cannot be switched for the same dose of ELTROXIN. If your doctor decides to switch treatment from ELTROXIN to THYROX, then they should have a plan for monitoring your blood tests and adjust your dose if needed. You should not change from THYROX to ELTROXIN unless your doctor decides to switch products, and there is a plan for monitoring your blood tests and reviewing your dose.

THYROX[®]

Active ingredient(s): *levothyroxine sodium*

Consumer Medicine Information (CMI)

This leaflet provides important information about using THYROX. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using THYROX.**

Where to find information in this leaflet:

- [1. Why am I using THYROX?](#)
- [2. What should I know before I use THYROX?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use THYROX?](#)
- [5. What should I know while using THYROX?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using THYROX?

THYROX contains the active ingredient levothyroxine sodium. THYROX is a thyroid hormone.

THYROX is used as replacement therapy in the treatment of thyroid hormone deficiency.

THYROX is used to treat:

Thyroid hormone deficiency also known as Hypothyroidism.

Hypothyroidism is a disease in which the thyroid gland is underactive and does not produce enough levothyroxine, a hormone, which is important for controlling your metabolism. Symptoms of hypothyroidism include tiredness, muscle weakness, and cramps, feeling the cold, a slow heart rate, dry and flaky skin, hair loss, a deep husky voice and weight gain.

TSH-responsive tumours (certain tumours of the thyroid gland) of the thyroid

For these conditions to be treated, patients need a supply of thyroid hormones in their body. THYROX replaces the shortage of thyroid hormones.

Use THYROX only as directed.

Your doctor may have prescribed THYROX for another condition.

Ask your doctor if you have any questions about why the medicine has been prescribed for you.

Ask your doctor if you have any concerns about taking it.

2. What should I know before I use THYROX?

Warnings

Do not use THYROX if:

- you are allergic to levothyroxine sodium, or any other thyroid hormone (eg. Tertroxin) or any of the ingredients listed at the end of this leaflet. Some of the symptoms of an allergic reaction to THYROX may include red, itchy skin rashes, difficulty in breathing, swelling of the face or throat or faintness.
- Always check the ingredients to make sure you can use this medicine.

Do not use THYROX if the packaging shows signs of tampering.

Check with your doctor if you:

- have any other medical conditions including:
 - Overactive thyroid gland
 - Adrenal gland problem
 - Hyperthyroidism
 - Heart problems such as cardiovascular disorder
 - High blood pressure
 - Diabetes
 - Long-standing hypothyroidism, an underactive thyroid gland
 - Problems absorbing nutrients from the gastrointestinal tract take any medicines for any other condition

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Ask your doctor about the risks and benefits of taking THYROX during pregnancy.

Levothyroxine levels will need to be watched carefully during pregnancy. Your dosage of THYROX may need to be increased while you are pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Although small amounts of THYROX are found in breast milk, women who are breastfeeding should continue treatment with THYROX.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with THYROX and affect how it works or react with it resulting in unwanted or sometimes serious side effects. These include:

- Anticoagulants, medicines used to thin your blood (eg. Warfarin)
- Antidepressants, medicines used to treat depression (e.g. Lithium, SSRIs, Tricyclic antidepressants)
- Antivirals, medicines used to treat HIV/AIDS infection (e.g. ritonavir)
- Antimalarials, medicines used to treat and prevent malaria (e.g. chloroquine and proguanil)
- Medicines used to treat diabetes (e.g. insulin)
- Beta-blockers, medicines used to treat high blood pressure and heart conditions (e.g. propranolol)
- Ion-exchange resins, medicines used to decrease cholesterol in the blood (e.g. colestyramine)
- Corticosteroids, anti-inflammatory medicines (e.g. prednisolone and dexamethasone)
- Oral contraceptives and hormone replacement medicines such as oestrogens, androgens or anabolic steroids
- Medicines used for epilepsy (e.g. phenytoin and carbamazepine)
- Medicines used to treat heart failure (e.g. digoxin)
- Iron supplements
- Calcium, magnesium, and aluminium supplements
- Rifampicin, an antibiotic used to treat tuberculosis and other serious infections
- Ciprofloxacin, an antibiotic used to treat various infections
- Soyabean flour (e.g. some infant formula and other products)
- Antacids (e.g. aluminium hydroxide, magnesium hydroxide and calcium carbonate) and proton pump inhibitors, used to reduce stomach acid
- Amiodarone, a medicine used to treat irregular heart beat
- Oral contrast agents, used before X-ray and scans
- Propylthiouracil, a medicine used to treat overactive thyroid and Graves disease
- Non-steroidal anti-inflammatory drugs (NSAIDs), medicines used to relieve pain and/or inflammatory conditions including arthritis.
- Weight loss drugs (e.g. orlistat)

This list is not exhaustive. Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking it.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect THYROX.

4. How do I use THYROX?

How much to take

- The usual starting dose for adults is 50 to 100 micrograms daily. The dose may be increased over time. The average adult maintenance dose is 100 to 200 micrograms. Lower doses are used in the elderly and

children. Your doctor will calculate the dose required for you.

- Follow the instructions provided and use THYROX until your doctor tells you to stop.
- It may take a few weeks for THYROX to begin working. Until it begins working you may not notice any change in your symptoms.
- Your doctor will monitor your blood tests to make sure THYROX is working for you.
- Do not change your dose unless your doctor tells you to do so.

When to take THYROX

- THYROX should be taken first thing in the morning on an empty stomach, at least 30 minutes and preferably 60 minutes before any food or other medications.

How to take THYROX

- Swallow THYROX tablets with a glass of water.

If you forget to use THYROX

THYROX should be used regularly at the same time each day.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take your dose as soon as you remember, and then go back to taking it as you would normally.

Do not take a double dose to make up for the dose you missed.

If you are unsure about whether to take your next dose, speak to your doctor or pharmacist. If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

If you use too much THYROX

If you think that you have used too much THYROX, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

If you take too much you may have the following symptoms: restlessness; vomiting; flushing; breathing difficulties; chest pain; convulsions or paralysis.

Keep your doctor, pharmacist, Emergency Department phone numbers handy.

5. What should I know while using THYROX?

Things you should do

- Immediately stop taking THYROX if a skin rash or other allergic reaction occurs.
- Use it exactly as directed or as your doctor has prescribed.
- If you plan to have surgery, tell your doctor or dentist that you are taking THYROX.

- If you are about to start taking any new medicines, remind your doctor and pharmacist that you are taking THYROX.
- Ensure you do not run out of medicine over the weekend or on holidays.
- Visit your doctor regularly. Your doctor needs to check your progress.

Call your doctor straight away if you:

- feel THYROX is not helping your condition.
- do not feel well while you are taking it.

Remind any doctor, dentist or pharmacist you visit that you are using THYROX.

Things you should not do

- Do not switch or interchange with other brands unless advised by your doctor.
- Do not give this medicine to anyone else, even if his or her symptoms seem similar to yours.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how THYROX affects you.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

- Store below 25°C.
- Store in the original bottle.
- Keep the bottle tightly closed.
- Protect from light.
- Do not take THYROX tablets if the tablet's colour has changed.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Gastrointestinal related: <ul style="list-style-type: none"> • Nausea • Diarrhoea 	Speak to your doctor if you have any of

Less serious side effects	What to do
<ul style="list-style-type: none"> • Stomach cramp • Vomiting • Increased appetite Nervous system related: <ul style="list-style-type: none"> • Nervousness • Anxiousness • Excitation • Restlessness • Headache • Lack of concentration • Irritability • Tiredness • inability to sleep • sleep disturbances Other side effects: <ul style="list-style-type: none"> • hair loss • increased appetite • muscle weakness & cramps • heat intolerance • excessive sweating • flushing • weight loss • menstrual irregularities • decreased libido • fever 	these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
Skin related: <ul style="list-style-type: none"> • allergic reactions such as skin rash Heart related: <ul style="list-style-type: none"> • chest pain • irregular heartbeats Nervous system related: <ul style="list-style-type: none"> • unusual movements, including tremor Other side effects: <ul style="list-style-type: none"> • shortness of breath • rapid breathing • increased blood pressure 	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What THYROX contains

Active ingredient (main ingredient)	levothyroxine sodium
Other ingredients (inactive ingredients)	microcrystalline cellulose maize starch purified talc colloidal anhydrous silica magnesium stearate sunset yellow FCF aluminium lake in THYROX 25 mcg and 100 mcg allura red AC aluminium lake in THYROX 75 mcg and 200 mcg indigo carmine aluminium lake in THYROX 75 mcg quinoline yellow aluminium lake in THYROX 100 mcg

Do not take this medicine if you are allergic to any of these ingredients.

What THYROX looks like

THYROX 25 microgram tablets are round, orange coloured, with score line on one side and '25' debossed on the other side (Aust R 391799).

THYROX 50 microgram tablets are round, white coloured, with score line on one side and '50' debossed on the other side. (Aust R 391800).

THYROX 75 microgram tablets are round, violet coloured, with score line on one side and '75' debossed on the other side. (Aust R 391474).

THYROX 100 microgram tablets are round, yellow coloured, with score line on one side and '100' debossed on the other side. (Aust R 391801).

THYROX 200 microgram tablets are round, pink coloured, with score line on one side and "200" debossed on the other side. (Aust R 391802).

THYROX is available in one or two* HDPE bottles containing 100 tabs. Each bottle contains a CAN TRI-SORB 2G desiccant and AGELESS ZM-1 oxygen absorber.

*Note: Not all pack sizes may be marketed.

Who distributes THYROX

THYROX is supplied in Australia by:

Clinect Pty Ltd
120 - 132 Atlantic Drive
Keysborough VIC 3173
Australia
Ph: 1 800 899 005

Sponsor:

Waymade Australia Pty Ltd