

LEVOTHOX

Consumer Medicine Information (CMI) summary

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

1. Why am I taking LEVOTHOX?

LEVOTHOX contains the active ingredient Levothyroxine sodium. LEVOTHOX is used to treat thyroid hormone deficiency also known as Hypothyroidism and TSH-responsive tumours of the thyroid.

For more information, see Section [1. Why am I taking LEVOTHOX?](#) in the full CMI.

2. What should I know before I take LEVOTHOX?

Do not take if you have ever had an allergic reaction to LEVOTHOX 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 take LEVOTHOX?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with LEVOTHOX 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 take LEVOTHOX?

- Your doctor will calculate the right dose for you.

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

5. What should I know while taking LEVOTHOX?

Things you should do

- Remind any doctor, dentist or pharmacist you visit that you are taking LEVOTHOX.
- Do not switch or interchange with other brands unless advised by your doctor.

	<ul style="list-style-type: none"> • Use it exactly as directed or as your doctor has prescribed.
Things you should not do	<ul style="list-style-type: none"> • Do not stop using this medicine suddenly.
Driving or using machines	<ul style="list-style-type: none"> • Be careful before you drive or use any machines or tools where alertness is required, until you know how LEVOTHOX 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 the medicine in a cool dry place where the temperature stays below 25°C. Protect from light.

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

6. Are there any side effects?

There is a number of common side effects associated with the use of LEVOTHOX, if they worry you talk to your doctor or pharmacist. There are no serious side effects associated with LEVOTHOX.

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.

LEVOTHOX

Active ingredient(s): *Levothyroxine sodium*

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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

1. Why am I taking LEVOTHOX?

LEVOTHOX contains the active ingredient Levothyroxine sodium. Levothyroxine sodium is a thyroid hormone. It is used as replacement therapy in the treatment of thyroid hormone deficiency.

LEVOTHOX is used to treat:

1. 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.

2. 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. LEVOTHOX replaces the shortage of thyroid hormones.

Your doctor may have prescribed LEVOTHOX for another reason. Ask your doctor if you have any questions about why this medicine has been prescribed for you.

2. What should I know before I take LEVOTHOX?

Warnings

Do not take LEVOTHOX if:

- you are allergic to Levothyroxine sodium thyroid hormone (eg. Tertroxin)

- you are allergic to any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can take this medicine. Some of the symptoms of an allergic reaction may include:
 - difficulty in breathing
 - faintness
 - swelling of the face, lips, tongue or other parts of the body
 - red, itchy skin rashes
- Do not take LEVOTHOX tablets if the tablet's colour has changed.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

Check with your doctor if you:

- if you have allergies to any other medicines, foods, preservatives or dyes.
- take any medicines for any other condition
- if you have or have had any other medical conditions/ health problems, including:
 - Over active thyroid gland
 - Adrenal gland problem
 - Hyperthyroidism
 - Heart problems such as cardiovascular disorder
 - High blood pressure
 - Diabetes
 - Long-standing hypothyroidism, an under active thyroid gland

- Problems absorbing nutrients from the gastrointestinal tract

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

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

Talk to your doctor if you are breastfeeding or intend to breastfeed. Although small amounts of LEVOTHOX are found in breast milk, women who are breastfeeding should continue treatment with LEVOTHOX.

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 LEVOTHOX and affect how it works.

- Anticoagulants, medicines used to thin your blood (e.g. 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 estrogens, 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)

These medicines may affect how well LEVOTHOX works, or react with it resulting in unwanted or sometimes serious side effects.

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 LEVOTHOX.

4. How do I take LEVOTHOX?

How much to take

- Your doctor will calculate the right dose for you.
- 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.
- **Take LEVOTHOX only as directed.**
- **Follow your doctor's instructions carefully**, as they may differ from the information contained in this leaflet.
- It may take a few weeks for LEVOTHOX to begin working. Until it begins working you may not notice any change in your symptoms.
- Do not change your dosage unless your doctor tells you to do so.
- Your doctor will monitor your blood tests to make sure LEVOTHOX is working for you.
- Use LEVOTHOX, until your doctor tells you to stop.
- Talk to your doctor if you have any questions.
- Swallow LEVOTHOX tablets with a glass of water.

When to take LEVOTHOX

- LEVOTHOX 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.

If you forget to take LEVOTHOX

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

If you miss your dose at the usual time, and 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 LEVOTHOX

If you think that you have used too much LEVOTHOX, you may need urgent medical attention. If you take too much you may have the following symptoms: restlessness; vomiting; flushing; breathing difficulties; chest pain; convulsions or paralysis.

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.

5. What should I know while taking LEVOTHOX?

Things you should do

Do not switch or interchange with other brands unless advised by your doctor.

Immediately stop taking LEVOTHOX if a skin rash or other allergic reaction occurs.

Use it exactly as directed or as your doctor has prescribed.

Tell your doctor if you feel LEVOTHOX is not helping your condition.

Always discuss with your doctor any problems or difficulties during or after taking it.

Visit your doctor regularly. Your doctor needs to check your progress.

Ensure you do not run out of medicine over the weekend or on holidays.

Call your doctor straight away if you:

- plan to have surgery.
- are about to start taking any new medicines.

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

Things you should not do

- Do not stop using this medicine suddenly.
- 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 where alertness is required, until you know how LEVOTHOX affects you.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

- Store in the original package
- Store the medicine in a cool dry place where the temperature stays below 25°C. Protect from light.

Do not take LEVOTHOX tablets if the tablet's colour has changed.

Follow the instructions 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.

When to discard your medicine

Store If your doctor tells you to stop taking this medicine or it has passed its expiry date, ask your pharmacist what to do with any left over.

Getting rid of any unwanted medicine

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

Do not take 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
General disorders: <ul style="list-style-type: none">• Nervousness• Anxiousness• Excitation• Restlessness	Speak to your doctor if you have any of these less serious side effects and they worry you.

Less serious side effects	What to do
<ul style="list-style-type: none"> ● Increased blood pressure ● Muscle weakness and cramps ● Inability to sleep ● Sleep disturbance ● Unusual movements, including tremor ● Headache ● Lack of concentration ● Heat intolerance ● Excessive sweating ● Flushing ● Weight loss ● Fever ● Hair loss ● Irritability ● Tiredness <p>Gastrointestinal disorders:</p> <ul style="list-style-type: none"> ● Diarrhoea ● Stomach cramp ● Nausea ● Vomiting ● Increased appetite 	

Less serious side effects	What to do
<p>Respiratory tract disorders:</p> <ul style="list-style-type: none"> • Shortness of breath • Rapid breathing • Irregular heart beats • Chest pain <p>Skin and subcutaneous tissue disorders:</p> <ul style="list-style-type: none"> • Allergic reaction such as skin rash <p>Reproductive system disorders:</p> <ul style="list-style-type: none"> • Menstrual irregularities • Decreased libido 	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell even if you do not think the problems are connected with medicine or are not listed in this leaflet.

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 LEVOTHOX contains

Active ingredient (main ingredient)	Levothyroxine sodium
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">• microcrystalline cellulose• light magnesium oxide• sodium starch glycollate• sodium stearyl fumarate <p>The coating contains Lake blend as below:</p> <p>25 microgram tablets: Sunset yellow FCF Aluminium lake.</p>

75 microgram tablets:

Lake Blend LB-505008
Purple (ID#110747)

88 microgram tablets:

Lake Blend LB-510028
Green (ID#117692)

100 microgram tablets:

Lake Blend LB-520044
Yellow (ID#117693)

112 microgram tablets:

Lake Blend LB-540042
Pink (ID#117694)

125 microgram tablets:

Lake Blend LB-575003
Brown (ID#110743)

137 microgram tablets:

Brilliant Blue FCF
Aluminium Lake

150 microgram tablets:

Indigo Carmine Aluminium
Lake

175 microgram tablets:

Lake Blend LB-500017
Purple (ID#117689)

200 microgram tablets:

Allura

Red AC Aluminium Lake

Potential allergens	Not applicable
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Do not take this medicine if you are allergic to any of these ingredients.

What LEVOTHOX looks like

LEVOTHOX 50 microgram: Round shaped, White coloured, uncoated tablets, break line on both sides and debossed with "P" and "2" on one side and plain on other side (AUST R 364022).

LEVOTHOX 75 microgram: Round shaped, Violet coloured, uncoated tablets, break line on both sides and debossed with "P" and "3" on one side and plain on other side (AUST R 363982).

LEVOTHOX 100 microgram: Round shaped, Yellow coloured, uncoated tablets, break line on both sides and debossed with "P" and "14" on one side and plain on other side (AUST R 364002).

LEVOTHOX 200 microgram: Round shaped, Pink coloured, uncoated tablets, break line on both sides and debossed with "P" and "11" on one side and plain on other side (AUST R 364009).

Who distributes LEVOTHOX

Sponsor

Accord Healthcare Pty Ltd
Level 24, 570 Bourke St

Melbourne VIC 3000

Australia

Phone: 1800 134 988

Email: ds@commercialeyes.com.au

Distributor

LEVOTHOX is distributed in Australia by:

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.viatris.com.au

Phone: 1800 274 276

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