

# LEVOXINE

## 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:** LEVOXINE is not interchangeable on a same-dose basis with ELTROXIN or LEVOTHOX. If your doctor decides to switch treatment from ELTROXIN or LEVOTHOX to LEVOXINE, then they should have a plan for monitoring your blood tests and adjusting your dose, if required.

You should not interchange LEVOXINE and ELTROXIN or LEVOTHOX unless your doctor decides to switch products, and there is a plan for monitoring your blood tests and reviewing your dose.

### 1. Why am I using LEVOXINE?

LEVOXINE contains the active ingredient levothyroxine sodium. LEVOXINE is used to treat thyroid hormone deficiency also known as Hypothyroidism and TSH-responsive tumours (certain tumours of the thyroid gland) of the thyroid.

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

### 2. What should I know before I take LEVOXINE?

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

### 3. What if I am taking other medicines?

Some medicines may interfere with LEVOXINE 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 LEVOXINE?

- 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.

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

### 5. What should I know while using LEVOXINE?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are using LEVOXINE.</li><li>• Immediately stop taking LEVOXINE if a skin rash or other allergic reaction occurs.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not give this medicine to anyone else, even if his or her symptoms seem similar to yours.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• Be careful before you drive or use any machines or tools until you know how LEVOXINE affects you.</li><li>• Do not drive or operate machinery where alertness is required, until you know how the medicine affects you.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Store below 25°C. Store in original pack and protect from light and moisture.</li><li>• Product can also be stored in Webster pack for up to 14 days (2weeks) below 25°C.</li><li>• Do not take LEVOXINE tablets if the tablet's appearance has changed during storage.</li></ul>

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

### 6. Are there any side effects?

Some of the side effects are nervousness, anxiousness, excitation, restlessness, muscle weakness & cramps.

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.

# LEVOXINE

Active ingredient(s): *levothyroxine sodium*

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You should not interchange LEVOXINE and ELTROXIN or LEVOTHOX unless your doctor decides to switch products, and there is a plan for monitoring your blood tests and reviewing your dose.

## Consumer Medicine Information (CMI)

This leaflet provides important information about using LEVOXINE. **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 LEVOXINE.**

Where to find information in this leaflet:

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

## 1. Why am I using LEVOXINE?

LEVOXINE contains the active ingredient **levothyroxine sodium**. LEVOXINE is a thyroid hormone. It is used as replacement therapy in the treatment of thyroid hormone deficiency.

LEVOXINE 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 thyroxine, 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. LEVOXINE replaces the shortage of thyroid hormones.

**Use LEVOXINE only as directed.**

Your doctor may have prescribed LEVOXINE for another condition.

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

LEVOXINE tablets are only available with a doctor's

prescription.

## 2. What should I know before I use LEVOXINE?

### Warnings

**Do not use LEVOXINE if:**

- you are allergic to levothyroxine sodium, any other thyroid hormone (eg. Tertroxin), or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.

Some of the symptoms of an allergic reaction to LEVOXINE may include red, itchy skin rashes, difficulty in breathing, swelling of the face or throat or faintness.

**Do not use LEVOXINE after the expiry date (EXP.) printed on the pack.**

If you take the medicine after the expiry date has passed, it may not work as well.

**Do not take the medicine if the packaging shows signs of tampering.**

**Check with your doctor if you:**

- are allergic to any other medicines or any foods, dyes or preservatives.
- have any other medical conditions/health problems, 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

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.

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

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

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

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

If you have not told your doctor about any of the above, tell them before you start to take any LEVOXINE.

## 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 LEVOXINE and affect how it works.

- 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. cholestyramine)
- Corticosteroids, antiinflammatory medicines (e.g. prednisolone and dexamethasone)
- Oral contraceptives and hormone replacement medicines such as oestrogens and androgens
- Medicines used for epilepsy (e.g. phenytoin and carbamazepine)
- Medicines used to treat heart failure (e.g. digoxin)
- Iron supplements
- Calcium 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)
- 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 antiinflammatory drugs (NSAIDs), medicines used to relieve pain and/or inflammatory conditions including arthritis.
- Weight loss drugs (e.g. orlistat)
- Tyrosine kinase inhibitors, medicines used to treat cancer (ie imatinib and sunitinib)
- Statins, medicines used to lower cholesterol
- Tamoxifen and 5-fluorouracil, medicines used to treat tumours
- Methadone (a narcotic)
- St John's wort, a herbal medicine
- Biotin (also known as Vitamin H, Vitamin B7 or Vitamin B8)

These medicines may affect how well LEVOXINE 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.

Before you start to take any other medicine, tell your doctor or pharmacist that you are taking LEVOXINE.

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

## 4. How do I take LEVOXINE?

### 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.

It may take a few weeks for LEVOXINE to begin working. Until it begins working you may not notice any change in your symptoms.

Follow your doctor's instructions carefully, as they may differ from the information contained in this leaflet.

Do not change your dose unless your doctor tells you to do so.

Your doctor will monitor your blood tests to make sure LEVOXINE is working for you.

If you do not understand the instructions on the bottle pack, ask your doctor or pharmacist for help.

#### **How to take it**

- Swallow LEVOXINE tablets with a glass of water.

#### **When to take LEVOXINE**

- LEVOXINE tablets should be taken with a glass of water, first thing in the morning on an empty stomach, at least 30 minutes and preferably 60 minutes before any food or other medications.

#### **How long to take LEVOXINE**

- Continue taking it as long as your doctor recommends it.

#### **If you forget to take LEVOXINE**

LEVOXINE should be used regularly at the same time each day. If you miss your dose at the usual time, take your dose as soon as you remember, and then go back to taking it as you would normally.

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

**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 take too much LEVOXINE**

If you think that you have used too much LEVOXINE, 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, Accident and Emergency phone numbers handy.**

## **5. What should I know while using LEVOXINE?**

### **Things you should do**

Immediately stop taking LEVOXINE 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 LEVOXINE is not helping your condition.

Visit your doctor regularly. Your doctor needs to check your progress and see whether you need to stop taking the medicine.

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

If you plan to have surgery, tell your doctor or dentist that you are taking LEVOXINE.

If you are about to start taking any new medicines, remind your doctor and pharmacist that you are taking LEVOXINE.

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

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

### **Things you should not do**

- 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 LEVOXINE affects you.**

Do not drive or operate machinery where alertness is required, until you know how the medicine affects you

### **Looking after your medicine**

- Store below 25°C. Store in original pack and protect from light and moisture.
- Product can also be stored in Webster pack for up to 14 days (2weeks) below 25°C.
- Do not take LEVOXINE tablets if the tablet's appearance has changed during storage.

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.

## Side effects

Side effects	What to do
<ul style="list-style-type: none"><li>nervousness</li><li>anxiousness</li><li>excitation</li><li>restlessness</li><li>muscle weakness &amp; cramps</li><li>inability to sleep</li><li>sleep disturbances</li><li>unusual movements, including tremor</li><li>headache</li><li>lack of concentration</li><li>diarrhoea</li><li>Stomach cramp</li><li>nausea</li><li>vomiting</li><li>heat intolerance</li><li>excessive sweating</li><li>flushing</li><li>weight loss</li><li>menstrual irregularities</li><li>decreased libido</li><li>fever</li><li>shortness of breath</li><li>rapid breathing</li><li>irregular heart beats</li><li>chest pain</li><li>increased blood pressure</li><li>allergic reactions such as skin rash</li><li>hair loss</li><li>irritability.</li><li>increased appetite</li><li>tiredness</li></ul>	<p><b>Speak to your doctor if you have any of these side and they worry you</b></p>

**Check with your doctor as soon as possible if you have any problems while taking it even if you do not think the problems are connected with this medicine or are not listed in this leaflet.**

**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](http://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 LEVOXINE contains

<b>Active ingredient (main ingredient)</b>	Levothyroxine sodium
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<b>Other ingredients (inactive ingredients)</b>	Microcrystalline cellulose, pregelatinised starch, hypolose, magnesium stearate, Titanium Lake Blend TLB-964 WHITE (PI 138484) for the 50 microgram tablets, Lake Blend LB-505008 PURPLE (PI 110747) for the 75 microgram tablets, Lake Blend LB-520006 YELLOW (PI 110744) for the 100 microgram tablets and Allura Red AC Aluminium Lake for the 200 microgram tablets.
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**Do not take this medicine if you are allergic to any of these ingredients.**

### What LEVOXINE looks like

**LEVOXINE 50 microgram tablets** are white to off white, round shaped, flat faced beveled edge tablets debossed with 'A' and '6' on either side of break line on one side and plain on the other.

**LEVOXINE 75 microgram tablets** are violet coloured, round shaped, flat faced beveled edge tablets debossed with 'A' and '7' on either side of break line on one side and plain on the other.

**LEVOXINE 100 microgram tablets** are yellow coloured, round shaped, flat faced beveled edge tablets debossed with 'A' and '9' on either side of break line on one side and plain on the other.

**LEVOXINE 200 microgram tablets** are pink coloured, round shaped, flat faced beveled edge tablets debossed with 'B' and '6' on either side of break line on one side and plain on the other.

LEVOXINE is available in bottle packs (200 tablets in 2 bottles, each bottle contains 100 tablets).

### The Australian Registration Numbers are:

- LEVOXINE 50 micrograms: AUST R 333525
- LEVOXINE 75 micrograms: AUST R 333528
- LEVOXINE 100 micrograms: AUST R 333527
- LEVOXINE 200 micrograms: AUST R 333526

### Who distributes LEVOXINE

Sun Pharma ANZ Pty Ltd

12 Waterloo Road

Macquarie Park NSW 2113

Email: [customerservice.aus@sunpharma.com](mailto:customerservice.aus@sunpharma.com)

Tel No. 1800 726 229

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