

Levothyroxine Sandoz®

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 Levothyroxine Sandoz?

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

2. What should I know before I use Levothyroxine Sandoz?

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

3. What if I am taking other medicines?

Some medicines may interfere with Levothyroxine Sandoz 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 Levothyroxine Sandoz?

- 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.
- Swallow the tablets with a glass of water in the morning on an empty stomach, at least 30 minutes and preferably 60 minutes before any food or other medicines. More instructions can be found in Section [4. How do I use Levothyroxine Sandoz?](#) in the full CMI.

5. What should I know while using Levothyroxine Sandoz?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using Levothyroxine Sandoz.• Do not switch or interchange with other brands unless advised by your doctor.• Ensure you do not run out of medicine over the weekend or on holidays.
Things you should not do	<ul style="list-style-type: none">• 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 it 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. Protect from light.

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

6. Are there any side effects?

Common side effects: nervousness, anxiousness, excitation, inability to sleep, diarrhoea, stomach cramp, headache, muscle weakness and cramps. **Serious side effects:** allergic reactions such as skin rash, irregular heart beats, chest pain, shortness of breath. 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: Levothyroxine Sandoz cannot be switched for the same dose of ELTROXIN. If your doctor decides to switch treatment from ELTROXIN to Levothyroxine Sandoz, then they should have a plan for monitoring your blood tests and adjust your dose if needed.

You should not change from Levothyroxine Sandoz to ELTROXIN unless your doctor decides to switch products, and there is a plan for monitoring your blood tests and reviewing your dose.

Levothyroxine Sandoz®

Active ingredient(s): *levothyroxine sodium*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Levothyroxine Sandoz. **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 Levothyroxine Sandoz.**

Where to find information in this leaflet:

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

1. Why am I using Levothyroxine Sandoz?

Levothyroxine Sandoz contains the active ingredient levothyroxine sodium, which is a thyroid hormone.

Levothyroxine Sandoz is used as replacement therapy in the treatment of thyroid deficiency.

2. What should I know before I use Levothyroxine Sandoz?

Warnings

Do not use Levothyroxine Sandoz if:

- you are allergic to levothyroxine sodium, 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 may include:
 - red, itchy skin rashes
 - difficulty in breathing
 - swelling of the face or throat
 - faintness
- the packaging shows signs of tampering.

Check with your doctor if you:

- are allergic to any other medicines or foods, dyes or preservatives.
- have any other medical conditions:
 - 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 [list any notable ones for the medicine / medical condition here]
- 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.

Thyroxine levels will need to be watched carefully during pregnancy. Your dosage of Levothyroxine Sandoz 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 the medicine are found in breast milk, women who are breastfeeding should continue treatment with Levothyroxine Sandoz.

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 Levothyroxine Sandoz and affect how it works. These include:

- 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 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 anti-inflammatory 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 (i.e. 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)

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

4. How do I use Levothyroxine Sandoz?

How much to take

- Follow the instructions and dosage provided by your doctor.

- It may take a few weeks for Levothyroxine Sandoz to begin working. Until it begins working you may not notice any change in your symptoms.
- 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.
- Your doctor will monitor your blood tests to make sure Levothyroxine Sandoz is working for you.
- Do not change your dose of Levothyroxine Sandoz unless your doctor tells you to do so.

When to take Levothyroxine Sandoz

- Levothyroxine Sandoz 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 Levothyroxine Sandoz

- Swallow Levothyroxine Sandoz tablets with a glass of water.

How to long to take Levothyroxine Sandoz

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

If you forget to use Levothyroxine Sandoz

Levothyroxine Sandoz 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 Levothyroxine Sandoz

If you think that you have used too much Levothyroxine Sandoz, 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.

Symptoms of overdose include restlessness; vomiting; flushing; breathing difficulties; chest pain; convulsions or paralysis.

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

5. What should I know while using Levothyroxine Sandoz?

Things you should do

- Do not switch or interchange with other brands unless advised by your doctor.
- Immediately stop taking Levothyroxine Sandoz if a skin rash or other allergic reaction occurs.
- Use it exactly as your doctor has prescribed.
- Tell your doctor if you feel the medicine is not helping your condition.
- Visit your doctor regularly.
Your doctor needs to check your progress and see whether you need to stop taking Levothyroxine Sandoz.
- Always discuss with your doctor any problems or difficulties during or after taking the medicine.
- If you plan to have surgery, tell your doctor or dentist that you are taking Levothyroxine Sandoz.
- If you are about to start taking any new medicines, remind your doctor and pharmacist that you are taking Levothyroxine Sandoz.
- 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 Levothyroxine Sandoz.

Things you should not do

- Do not stop 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 Levothyroxine Sandoz affects you.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

- Store below 25°C. Protect from light.

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
<p>Mood related</p> <ul style="list-style-type: none"> • nervousness • anxiousness • excitement • restlessness • inability to sleep • sleep disturbances • lack of concentration • irritability <p>Gastrointestinal/ Gut related</p> <ul style="list-style-type: none"> • diarrhoea • stomach cramp • nausea • vomiting <p>Metabolism related</p> <ul style="list-style-type: none"> • weight loss • tiredness • excessive sweating • flushing • increased appetite <p>Skin related</p> <ul style="list-style-type: none"> • hair loss <p>Others</p> <ul style="list-style-type: none"> • headache • muscle weakness & cramps • heat intolerance • menstrual irregularities • decreased libido • fever • unusual movements, including tremor 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p> <p>They are generally mild and do not cause patients to stop taking Levothyroxine Sandoz.</p>

Serious side effects

Serious side effects	What to do
<p>Allergy related</p> <ul style="list-style-type: none"> • allergic reactions such as skin rash <p>Lungs related</p> <ul style="list-style-type: none"> • shortness of breath • rapid breathing 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you</p>

Heart related <ul style="list-style-type: none"> • chest pain • increased blood pressure • irregular heart beats 	notice any of these serious side effects.
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Who distributes Levothyroxine Sandoz

Sandoz Pty Ltd
100 Pacific Highway
North Sydney, NSW 2060
Australia
Tel 1800 726 369

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.

6. Product details

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

What Levothyroxine Sandoz contains

Active ingredient (main ingredient)	levothyroxine sodium
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> • maize starch • lactose monohydrate • gelatin • croscarmellose sodium • magnesium stearate
Potential allergens	<ul style="list-style-type: none"> • Sugars as lactose (50 mcg, 75 mcg, 100 mcg) • Lactose (200 mcg)

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

What Levothyroxine Sandoz looks like

Levothyroxine Sandoz 50 microgram – white, round tablet, debossed “50” on one side, and scored in the shape of “+” sign on the other side (Aust R 387274).

Levothyroxine Sandoz 75 microgram – white, round tablet, debossed “75” on one side and scored in the shape of “+” sign on the other side (Aust R 387277).

Levothyroxine Sandoz 100 microgram – white, round tablet, debossed “100” on one side, and scored in the shape of “+” sign on the other side (Aust R 387276).

Levothyroxine Sandoz 200 microgram – white, round tablet, debossed “200” on one side, and scored in the shape of “+” sign on the other side (Aust R 387275).

Pack size of 200.