

# APO-Levothyroxine

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

You should not interchange APO-LEVOTHYROXINE and ELTROXIN 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 APO-Levothyroxine?

APO-Levothyroxine contains the active ingredient levothyroxine sodium. APO-Levothyroxine is used as replacement therapy in the treatment of thyroid hormone deficiency (hypothyroidism) or for treatment of TSH-responsive tumours.

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

### 2. What should I know before I use APO-Levothyroxine?

Do not use 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 APO-Levothyroxine?](#) in the full CMI.

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

Some medicines may interfere with levothyroxine sodium 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 APO-Levothyroxine?

- Swallow your tablets whole with a glass of water first thing in the morning on an empty stomach.

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

### 5. What should I know while using APO-Levothyroxine?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctors, dentists and pharmacists treating you that you are taking APO-Levothyroxine.</li><li>• Use it exactly as your doctor has prescribed. Discuss with your doctor any problems during or after taking the medicine.</li><li>• Visit your doctor regularly and attend all of your blood tests, so your doctor can check your progress and see whether your dose of APO-Levothyroxine requires adjustment.</li><li>• If you plan to have surgery, tell your doctor or dentist that you are taking APO-Levothyroxine.</li><li>• If you are about to start taking any new medicines, remind your doctor and pharmacist that you are taking APO-Levothyroxine.</li><li>• Ensure you do not run out of medicine over the weekend or on holidays.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not stop using this medicine suddenly or change the dose unless your doctor tells you to.</li><li>• Do not switch with other brands unless advised by your doctor.</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 APO-Levothyroxine affects you. APO-Levothyroxine may cause lack of concentration or tiredness in some people.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Store APO-Levothyroxine below 25°C in the original blister strips.</li></ul>

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

### 6. Are there any side effects?

Some of the common side effects include nervousness, anxiousness, excitation, restlessness, muscle weakness & cramps. Serious side effects include fever, shortness of breath, rapid breathing, irregular heart-beats, chest pain, increased blood pressure, allergic reactions such as skin rash.

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.

# APO-Levothyroxine

Active ingredient: levothyroxine sodium

## Consumer Medicine Information (CMI)

This leaflet provides important information about using APO-Levothyroxine. **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 APO-Levothyroxine.**

**Where to find information in this leaflet:**

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

## 1. Why am I using APO-Levothyroxine?

**APO-Levothyroxine contains the active ingredient levothyroxine sodium.** APO-Levothyroxine is a thyroid hormone which is used as replacement therapy in the treatment of thyroid hormone deficiency. APO-Levothyroxine replaces the shortage of thyroid hormones.

**APO-Levothyroxine 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 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.

**APO-Levothyroxine is also used to treat 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.

## 2. What should I know before I use APO-Levothyroxine?

### Warnings

**Do not use APO-Levothyroxine if:**

- you are allergic to levothyroxine sodium, any other thyroid hormone, or any of the ingredients listed at the end of this leaflet.

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

Do not use APO-Levothyroxine after the expiry date (EXP.) printed on the pack.

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

Always check the ingredients to make sure you can use this medicine.

- you have untreated hyperthyroidism (overactive thyroid)
- you have untreated adrenal insufficiency
- you have thyrotoxicosis (symptomatic excess thyroid hormone)
- you have acute myocardial infarction (heart attack), acute myocarditis or acute pancarditis (inflamed heart muscle or surrounding tissues)

**Check with your doctor if you:**

- you are allergic to any other medicines or any foods, dyes or preservatives.
- you have or have had any other medical conditions or 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?](#)

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

### Pregnancy and breastfeeding

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

Thyroxine levels need to be watched carefully during pregnancy. Your dosage of APO-Levothyroxine may

need to be increased while you are pregnant.

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

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

Although small amounts of levothyroxine are found in breast milk, women who are breastfeeding should continue treatment with APO-Levothyroxine.

If you have not told your doctor about any of the above, tell them before you start to take any APO-Levothyroxine

### 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 APO-Levothyroxine. 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. cholestyramine)
- corticosteroids, anti-inflammatory 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 anti-inflammatory drugs (NSAIDs), medicines used to relieve pain and/or inflammatory conditions including arthritis

- weight loss drugs (e.g. orlistat)
- ketamine, an anaesthetic
- pentobarbitone, a sedative
- dihydrotachysterol, a form of vitamin D

These medicines may affect how well APO-Levothyroxine works or react with it resulting in unwanted or sometimes serious side effects.

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

### 4. How do I take APO-Levothyroxine?

#### How much to take

- It may take a few weeks for APO-Levothyroxine 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.
- 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.
- If you do not understand the instructions on the blister pack, ask your doctor or pharmacist for help.
- Your doctor will monitor your blood tests to make sure APO-Levothyroxine is working for you.
- Do not change your dose of APO-Levothyroxine unless your doctor tells you to do so.
- Swallow APO-Levothyroxine tablets with a glass of water.

#### When to take APO-Levothyroxine

APO-Levothyroxine 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 APO-Levothyroxine

**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 APO-Levothyroxine

If you think that you have used too much APO-Levothyroxine, 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.**

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

## 5. What should I know while using APO-Levothyroxine?

### Things you should do

- Tell any other doctors, dentists and pharmacists who are treating you that you are taking APO-Levothyroxine.
- Use it exactly as your doctor has prescribed.
- Tell your doctor if you feel the medicine is not helping your condition.
- Always discuss with your doctor any problems or difficulties during or after taking the medicine.
- Visit your doctor regularly and attend your blood tests. Your doctor needs to check your progress and see whether you need to stop taking APO-Levothyroxine or adjust your dose.
- If you plan to have surgery, tell your doctor or dentist that you are taking APO-Levothyroxine.
- If you are about to start taking any new medicines, remind your doctor and pharmacist that you are taking APO-Levothyroxine.
- Ensure you do not run out of medicine over the weekend or on holidays.

**Call your doctor straight away and immediately stop taking APO-Levothyroxine if a skin rash or other allergic reaction occurs.**

### Things you should not do

- Do not stop using this medicine suddenly or change the dose unless your doctor tells you to.
- Do not switch 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 APO-Levothyroxine affects you.**

APO-Levothyroxine may cause lack of concentration or tiredness in some people.

### Looking after your medicine

- Store below 25°C. Protect from light.

- Always store tablets in their original blister strips. If you do not keep the tablets in the blister strip they may not keep as well.

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
<p><b>Mental function-related:</b></p> <ul style="list-style-type: none"> <li>• nervousness, anxiousness, excitation, restlessness</li> <li>• lack of concentration</li> <li>• irritability</li> </ul> <p><b>Muscle-related:</b></p> <ul style="list-style-type: none"> <li>• muscle weakness &amp; cramps</li> <li>• unusual movements including tremor</li> </ul> <p><b>Sleep-related:</b></p> <ul style="list-style-type: none"> <li>• inability to sleep, sleep disturbances</li> </ul> <p><b>Digestive track-related:</b></p> <ul style="list-style-type: none"> <li>• diarrhoea, stomach cramp, nausea, vomiting</li> <li>• increased appetite</li> </ul> <p><b>Body temperature-related:</b></p> <ul style="list-style-type: none"> <li>• heat intolerance, excessive sweating, flushing</li> </ul> <p><b>Pain-related:</b></p> <ul style="list-style-type: none"> <li>• headache</li> </ul> <p><b>Weight changes-related</b></p> <ul style="list-style-type: none"> <li>• weight loss</li> </ul> <p><b>Menstrual cycle-related:</b></p> <ul style="list-style-type: none"> <li>• menstrual irregularities</li> </ul> <p><b>Sex drive-related:</b></p> <ul style="list-style-type: none"> <li>• decreased libido</li> </ul> <p><b>Hair-related:</b></p> <ul style="list-style-type: none"> <li>• hair loss</li> </ul> <p><b>Exhaustion-related:</b></p> <ul style="list-style-type: none"> <li>• tiredness</li> </ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

## Serious side effects

Serious side effects	What to do
<b>Body temperature-related:</b> <ul style="list-style-type: none"><li>• fever</li></ul> <b>Breathing-related:</b> <ul style="list-style-type: none"><li>• shortness of breath</li><li>• rapid breathing</li></ul> <b>Heart-related:</b> <ul style="list-style-type: none"><li>• irregular heart beats</li></ul> <b>Pain-related</b> <ul style="list-style-type: none"><li>• chest pain</li></ul> <b>Blood pressure-related:</b> <ul style="list-style-type: none"><li>• increased blood pressure</li></ul> <b>Allergic reactions-related:</b> <ul style="list-style-type: none"><li>• skin rash</li></ul>	<b>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.</b>

**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 APO-Levothyroxine contains

<b>Active ingredient (main ingredient)</b>	levothyroxine sodium
<b>Other ingredients (inactive ingredients)</b>	lactose monohydrate, maize starch, gelatin, croscarmellose sodium, magnesium stearate
<b>Potential allergens</b>	sugars as lactose

**This medicine includes sugars as lactose monohydrate.**

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

### What APO-Levothyroxine looks like

APO-Levothyroxine comes in tablets of 7 strengths:

**25 µg tablets:** Round and white tablets with debossed on one side with "25" and scored in the shape of "+" sign on the other side. (AUST R 374890)

**50 µg tablets:** Round and white tablets with debossed on one side with "50" and scored in the shape of "+" sign on the other side. (AUST R 374892)

**75 µg tablets:** Round and white tablets with debossed on one side with "75" and scored in the shape of "+" sign on the other side. (AUST R 374910)

**100 µg tablets:** Round and white tablets with debossed on one side with "100" and scored in the shape of "+" sign on the other side. (AUST R 374922)

**125 µg tablets:** Round and white tablets with debossed on one side with "125" and scored in the shape of "+" sign on the other side. (AUST R 374923)

**150 µg tablets:** Round and white tablets with debossed on one side with "150" and scored in the shape of "+" sign on the other side. (AUST R 374924)

**200 µg tablets:** Round and white tablets with debossed on one side with "200" and scored in the shape of "+" sign on the other side. (AUST R 374925)

## Who distributes APO-Levothyroxine

Arrotex Pharmaceuticals Pty Ltd

15-17 Chapel Street

Cremorne VIC 3121

[www.arrotex.com.au](http://www.arrotex.com.au)

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