

OROXINE tablets

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.

1. Why am I using OROXINE?

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

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

2. What should I know before I use OROXINE?

Do not use if you have ever had an allergic reaction to levothyroxine sodium, any another thyroid hormone 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, plan to become pregnant, are breastfeeding or plan to breastfeed.

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

3. What if I am taking other medicines?

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 OROXINE?

- The usual starting dose of OROXINE is 50-100 micrograms daily, which may be increased over time.
- Swallow the tablets whole with a glass of water.
- Take first thing in the morning on an empty stomach at least 30 minutes and preferably 60 minutes before any food or medications.
- Continue taking OROXINE as long as your doctor recommends it.

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

5. What should I know while using OROXINE?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using OROXINE.• Tell your doctor if you feel OROXINE is not helping your condition.• See your doctor if symptoms persist or recur.
Things you should not do	<ul style="list-style-type: none">• Do not switch or interchange with other brands unless advised by your doctor.• Stop taking OROXINE if a skin rash or other allergic reaction occurs.
Looking after your medicine	<ul style="list-style-type: none">• Store at 2°C-8°C (Refrigerate. Do not freeze).• A single blister strip can be removed from the carton and stored below 25°C for up to 14 days. This medicine can also be stored in Webster packs for 14 days below 25°C. After 14 days of storage below 25°C, discard any remaining tablets.

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

6. Are there any side effects?

All medicines can have side effects. If they do occur, they are usually minor and temporary. Do not be alarmed by this list. You may not experience any of them.

It is important to be aware of potential side effects so that you can identify any symptoms if they occur.

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.

OROXINE tablets

Active ingredient: *levothyroxine sodium*

Consumer Medicine Information (CMI)

This leaflet provides important information about using OROXINE.

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 OROXINE.

Where to find information in this leaflet:

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

1. Why am I using OROXINE?

OROXINE contains the active ingredient levothyroxine sodium, a thyroid hormone. This medicine is used as replacement therapy in the treatment of thyroid hormone deficiency.

OROXINE 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.
- 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. OROXINE replaces the shortage of thyroid hormones

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

Your doctor may have prescribed OROXINE for another purpose.

2. What should I know before I use OROXINE?

Warnings

Do not use OROXINE if:

- you are allergic to levothyroxine sodium, any other thyroid hormone or any of the ingredients listed at the end of this leaflet.
Some symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty in breathing; swelling of the face, lips, tongue, or any other parts of the body; rash, itching or hives on the skin.
- the expiry date printed on the pack has passed.
- the packaging is torn or shows signs of tampering.

Check with your doctor if you:

- have had any allergy to any other medicines, or any other substances, such as foods, preservatives, or dyes.**
- 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?](#)

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 OROXINE may need to be increased while you are pregnant.

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

Check with your doctor if you are breastfeeding or intend to breastfeed.

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

3. What if I am taking other medicines?

Tell your doctor 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 of these medicines may interfere with OROXINE. 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, 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 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)
- 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 OROXINE tablets.

4. How do I use OROXINE?

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.

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

Carefully follow the dosage instructions. Do not change your dose unless your doctor tells you to do so.

Talk to your doctor if you have any further questions.

How long to take it for

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

Continue taking OROXINE until as long as your doctor recommends it.

How to take it

Swallow the tablets with a glass of water.

When to take it

OROXINE 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 it

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 it 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 take too much

If you think that you have used too much OROXINE, 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 OROXINE you may experience the following symptoms: restlessness; vomiting; flushing; breathing difficulties; chest pain; convulsions or paralysis.

5. What should I know while using OROXINE?

Things you should do

Immediately stop taking OROXINE 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 OROXINE is not helping your condition.

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

Tell any other doctors, dentists and pharmacists who are treating you that you are using OROXINE.

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 OROXINE.

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

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

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 their symptoms seem similar to yours.

Driving or using machines

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

Looking after your medicine

Store at 2°C to 8°C (Refrigerate. Do not freeze).

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.

Laboratory tests have shown that if not stored correctly, there is a reduction in potency of the active ingredient levothyroxine sodium.

In-use blisters:

A single blister strip can be removed from the carton and stored below 25°C for up to 14 days (2 weeks).

After 14 days (2 weeks) of storage below 25°C, discard any remaining tablets.

Where unavoidable (e.g. in warm climates where temperatures regularly exceed 25°C), an in-use blister strip may continue to be stored in a refrigerator at 2°C to 8°C (Refrigerate. Do not freeze) for up to 14 days (2 weeks).

OROXINE tablets can also be stored in Webster packs for 14 days (2 weeks) below 25°C.

Do not store this medicine:

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

Heat and dampness can destroy some medicines.

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

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.

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.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none">• nervousness• anxiousness• excitation• restlessness• inability to sleep• sleep disturbances• headache• lack of concentration• diarrhoea• stomach cramp• nausea• vomiting• heat intolerance• excessive sweating• flushing• weight loss• menstrual irregularities• decreased libido• fever• increased blood pressure• irritability• increased appetite• tiredness• hair loss.	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none">muscle weakness & crampsunusual movements, including tremorshortness of breathrapid breathingirregular heart beatschest painallergic reactions such as skin rash.	Call your doctor straight away or go to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Tell your doctor 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 before you decide to stop taking any of your medicines.

7. Product details

OROXINE tablets are only available with a doctor's prescription.

What OROXINE tablets contain

Active ingredient (main ingredient)	<ul style="list-style-type: none">levothyroxine sodium <p><i>(Refer to below description for strength)</i></p>
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">maize starchlactose monohydratedextrinmagnesium stearate.
Potential allergens	<ul style="list-style-type: none">lactose monohydrate.

OROXINE tablets do not contain gluten, sucrose and azo dyes.

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

What OROXINE looks like

OROXINE tablets are round, biconvex, white tablets available in four different strengths as described below. Available in blister packs of 200 tablets.

- OROXINE 50 microgram**
Contains levothyroxine sodium 50 micrograms. The tablets are scored and marked '50' on one side and plain on the other side.
- OROXINE 75 microgram**
Contains levothyroxine sodium 75 micrograms. The tablets are scored and marked '75' on one side and scored on the other side.
- OROXINE 100 microgram**
Contains levothyroxine sodium 100 micrograms. The tablets are scored and marked '100' on one side and plain on the other side.
- OROXINE 200 microgram**
Contains levothyroxine sodium 200 micrograms. The tablets are scored and marked '200' on one side and plain on the other side.

Australian Registration numbers:

OROXINE 50 microgram: AUST R 125498
OROXINE 75 microgram: AUST R 144108
OROXINE 100 microgram: AUST R 125499
OROXINE 200 microgram: AUST R 125500

Who distributes OROXINE?

Aspen Pharmacare Australia Pty Ltd
34-36 Chandos St
St Leonards NSW 2065
Australia

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