

Package leaflet: Information for the patient

Oroxine 25 microgram tablets
Oroxine 50 microgram tablets
Oroxine 75 microgram tablets
Oroxine 100 microgram tablets
Oroxine 125 microgram tablets
Oroxine 150 microgram tablets
Oroxine 175 microgram tablets
Oroxine 200 microgram tablets

levothyroxine sodium

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet?

This leaflet answers some common questions about Oroxine tablets. It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the expected benefits of you taking Oroxine against the risks this medicine could have for you.

1. What Oroxine is and what it is used for
2. What you need to know before you take Oroxine
3. How to take Oroxine
4. Possible side effects
5. How to store Oroxine
6. Contents of the pack and other information

1. What Oroxine is and what it is used for

Levothyroxine sodium is a synthetic thyroid hormone that chemically identical to thyroxine produced by the thyroid gland.

The aim of treatment with Oroxine is to replace missing thyroid hormone and/or to relieve stress on the thyroid gland.

Oroxine is used:

- to replace the missing thyroid hormone in all forms of underactive thyroid function (hypothyroidism) or after the removal of the thyroid gland,
- to prevent the return of new goitres after goitre surgery in patients with normal thyroid function,
- to treat non malignant goitre (benign struma) in patients with normal thyroid function.

Oroxine 25 micrograms

- as add on therapy in the antithyroid treatment of an overactive thyroid, after normal metabolic status has been reached .
- for malignant thyroid tumours, particularly after surgery to suppress new tumour growth and as a supplement for missing thyroid hormone.

Oroxine 50 micrograms

- as add on therapy in the antithyroid treatment of an overactive thyroid, after normal metabolic status has been reached,
- for malignant thyroid tumours, particularly after surgery to suppress new tumour growth and as a supplement for missing thyroid hormone.

Oroxine 75 micrograms

- as add on therapy in the antithyroid treatment of an overactive thyroid, after normal metabolic status has been reached,
- for malignant thyroid tumours, particularly after surgery to suppress new tumour growth and as a supplement for missing thyroid hormone.

Oroxine 100 micrograms

- as add on therapy in the antithyroid treatment of an overactive thyroid, after normal metabolic status has been reached,
- for malignant thyroid tumours, particularly after surgery to suppress new tumour growth and as a supplement for missing thyroid hormone,
- in the thyroid suppression test.

Oroxine 125 micrograms

- for malignant thyroid tumours, particularly after surgery to suppress new tumour growth and as a supplement for missing thyroid hormone,

Oroxine 150 micrograms

- for malignant thyroid tumours, particularly after surgery to suppress new tumour growth and as a supplement for missing thyroid hormone,
- in the thyroid suppression test.

Oroxine 175 micrograms

- for malignant thyroid tumours, particularly after surgery to suppress new tumour growth and as a supplement for missing thyroid hormone,

Oroxine 200 micrograms

- for malignant thyroid tumours, particularly after surgery to suppress new tumour growth and as a supplement for missing thyroid hormone,
- in the thyroid suppression test.

2. What you need to know before you take Oroxine

Tell your doctor if you are allergic to any foods or medicines.

Do not take Oroxine:

- if you are allergic to levothyroxine sodium or any of the other ingredients (listed in section 6),
- if you have any of the following disorders or conditions:
 - an untreated overactive thyroid,
 - if you have untreated thyrotoxicosis (high levels of thyroid hormones in the blood),

- untreated adrenal cortex deficiency (a condition where the adrenal glands do not make enough hormones),
- untreated pituitary deficiency (a condition where the pituitary gland does not make enough hormones),
- recent heart attack,
- acute inflammation of the heart muscle (myocarditis),
- acute inflammation of all layers of the heart wall (pancarditis).

Before the start of treatment with Oroxine, the following disorders or conditions must be ruled out or treated:

- coronary heart disease,
- chest pain with tight chestedness (angina pectoris),
- high blood pressure (hypertension),
- pituitary and/or adrenal cortex deficiency (conditions where the pituitary/ adrenal glands do not produce enough hormones),
- areas in the thyroid that produce uncontrolled amounts of thyroid hormone (thyroid autonomy).

Warnings and precautions

You must not take Oroxine to achieve weight loss. If your thyroid hormone blood levels are within the normal range, additional intake of thyroid hormones will not cause weight loss. Such additional intake may cause serious or even life threatening side effects, particularly in combination with certain weight loss products. Tell your doctor if you are taking weight loss drugs, such as Orlistat.

Your doctor should measure the values of thyroid hormones four to six weeks after switching over from another levothyroxine product to this product. Special care should be taken to maintain thyroid balance if you:

- Are pregnant or are planning to become pregnant;
- If you have, an underactive thyroid since birth or acquired during childhood;
- If you are undergoing suppressive therapy for previous thyroid cancer, especially if you are frail or elderly;
- If you have central underactive thyroid (due to a disorder of one of your glands that produce hormones);
- If you have any heart symptoms, or diabetes
- If you are about to undergo laboratory testing for monitoring your thyroid hormone levels, you must inform your doctor and/or the laboratory personnel that you are taking or have recently taken biotin (also known as vitamin H, vitamin B7 or vitamin B8). Biotin may affect results of your laboratory tests. Depending on the test, the results may be falsely high or falsely low due to biotin. Your doctor may ask you to stop taking biotin before performing laboratory tests. You should also be aware that other products that you may take, such as multivitamins or supplements for hair, skin, and nails could also contain biotin. This could affect the results of laboratory tests. Please inform your doctor and/or the laboratory personnel, if you are taking such products (Please note the information in section Other medicines and Oroxine).

Talk to your doctor or pharmacist before taking Oroxine:

- if you have coronary heart disease, weak heart muscle, heart rhythm disorders with a rapid heartbeat, chronic underactive thyroid function, or if you have suffered a heart attack. Particular

care is required for milder signs of overactive thyroid function caused by taking Levothyroxine sodium, so as to avoid very high hormone levels in the blood. In these cases, more frequent checks on thyroid levels should be made (see "How to take Oroxine").

- if you have an underactive thyroid caused by a disease of the pituitary gland. Checks must be made to find out whether you also have adrenal cortex deficiency (a problem with a gland that releases hormones). This condition must be treated (with steroids) before introducing Levothyroxine sodium.
- if you have uncontrolled production of thyroid hormones. Further tests are recommended before the start of treatment to check the hormone system is working well.
- if you have gone through the menopause. Your thyroid function should be checked more frequently to avoid increased blood levels of levothyroxine, which can cause osteoporosis (brittle bones).
- if you have diabetes, as the dosage of your diabetic treatment may need to be altered.
- if you have epilepsy (fits). Fits have been rarely reported when starting the treatment with levothyroxine.
- if you have a condition called myxoedema (skin and subcutaneous tissue swelling), as the dosage of Levothyroxine sodium may need to be reduced.
- if you have any conditions that affect how your gut absorbs nutrients from food (e.g. coeliac disease, lactose intolerance), as this may need to be treated to ensure that your Levothyroxine sodium treatment works well.

If you are being treated with certain blood anti-clotting agents, (see "Other medicines and Levothyroxine sodium").

In the elderly, the dose should be carefully and individually tailored, e.g. for those with heart problems, and they should be monitored by their doctor.

Children

If your child is receiving Levothyroxine sodium, partial loss of hair may occur during the first few months of taking this medicine, but this is usually short-term and hair usually grows back.

Blood pressure will be regularly monitored when levothyroxine treatment is started in very low birth weight preterm neonates because rapid fall in blood pressure (known as circulatory collapse) may occur.

Other medicines and Oroxine

Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines. If you are about to have a test with iodinated contrast media you should tell your doctor that you are taking Oroxine.

If you are taking or have recently taken biotin, you must inform your doctor and/or the laboratory personnel when you are about to undergo laboratory testing for monitoring your thyroid hormone levels. Biotin may affect results of your laboratory tests (see warnings and precautions).

The following medicines may affect the way Oroxine works:

- medicines to treat diabetes (e.g. insulin, metformin)
- anticoagulants such as warfarin, dicoumarol (used to thin the blood)
- amiodarone (used to treat some heart conditions)
- aspirin
- medicines containing oestrogen (e.g. used for hormone replacement therapy or oral contraceptives)
- antidepressants (e.g. sertraline and tricyclic antidepressants such as amitriptyline, imipramine)
- chloroquine and proguanil (medicines used in malaria and rheumatic diseases)
- 5-flouracil, imatinib and sunitinib (used for the treatment of cancer)
- medicines to control your heart rate such as digoxin
- medicines that stimulate the sympathetic nervous system such as adrenaline
- carbamazepine, phenytoin or barbiturates (medicines to treat epilepsy or seizures), products containing St. John's Wort (an herbal medicinal product)
- furosemide (used to treat high blood pressure or oedema)
- rifampicin, ciprofloxacin (used to treat serious infections)
- ritonavir (used to control HIV and chronic hepatitis C virus)
- propylthiouracil (used to treat overactive thyroid)
- medicines used for treating abnormal heart rhythms (beta receptor blockers such as propranolol)
- glucocorticoids (such as cortisone, hydrocortisone, prednisone, and dexamethasone)
- lithium (used to treat depression and other mood disorders)
- iodide (used to protect the thyroid gland from radiation)
- oral contrast agents (taken before certain scans to make parts of the body show up better on the scan)
- statins such as simvastatin and lovastatin (used to treat high cholesterol)
- methadone (used to treat drug addiction)
- weight loss medications (e.g. orlistat)
- Proton pump inhibitors (such as omeprazole, esomeprazole, pantoprazole, rabeprazole, and lansoprazole) are used to reduce the amount of acid produced by the stomach, which may reduce the absorption of levothyroxine from the intestine and thereby make it less effective.
If you are taking levothyroxine while receiving treatment with proton pump inhibitors, your doctor should monitor your thyroid function and may have to adjust the dose of Oroxine.

Levothyroxine sodium should be taken at least 4 hours before taking the following medicines.

- cholestyramine, colestipol or clofibrate (used to reduce cholesterol levels in the blood)
- sodium polystyrene sulphonic acid (used to treat kidney disease)
- orlistat (weight loss medication)

Oroxine should be taken at least 2 hours before taking the following medicines:

- calcium, magnesium, aluminium or iron supplements
- medicines to treat stomach ulcers such as sucralfate, antacids
- medicines used to treat an excess of acid in the stomach (proton pump inhibitors such as omeprazole, esomeprazole).

Levothyroxine sodium with food or drink:

Soya containing products and foods that are high in fibre may affect the absorption of Levothyroxine sodium. Your doctor may need to adjust the dose of Levothyroxine as a result.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Consistent treatment with thyroid hormones is particularly important during pregnancy and breast-feeding and must therefore be continued under the supervision of the treating doctor.

The need for levothyroxine may increase during pregnancy due to increased blood levels of oestrogen (female sex hormone). Thyroid function should therefore be monitored both during and after pregnancy and the thyroid hormone dose adjusted as appropriate.

Even during high dose levothyroxine therapy, the amount of thyroid hormone passing into breast milk during lactation is very low and therefore harmless.

Driving and using machines

Oroxine should not interfere with your ability to drive or use machinery.

3. How to take Oroxine

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The individual daily dose should be determined by your doctor by means of laboratory diagnostic tests and clinical examinations.

If any residual thyroid function remains, a lower dose of thyroid hormone may be sufficient.

In elderly patients, patients with coronary heart disease and patients with severe or chronic underactive thyroid function, particular caution is required when starting treatment with thyroid hormones. This means that a lower starting dose must be selected, which is then increased slowly and at longer intervals, with frequent thyroid hormone monitoring. Experience has shown that a lower dose is also sufficient in patients with a low body weight and in patients with large goitres.

Dosage

For individual treatment, tablets are available with graduated levels ranging from 25-200 micrograms of Oroxine , which means that only one tablet daily needs to be taken in most cases.

For the treatment of underactive thyroid function, adults initially take 25-50 micrograms of Oroxine daily. If instructed by the doctor, this dose can be increased by 25-50 micrograms of Oroxine at two to four week intervals, up to a daily dose of 100-200 micrograms of Oroxine .

To prevent the formation of new goitres after goitre removal and for the treatment of benign goitres, 75-200 micrograms of Oroxine are taken daily (up to 2 Oroxine 100 microgram tablets).

Use in infants and children

For newborns and infants with inborn thyroid hormone deficiency, where it is particularly important to start treatment as soon as possible, in order to achieve normal mental and physical development, the initial recommended dosage is 10 to 15 micrograms per kg per day for the first 3 months. Thereafter, the dose would be adjusted individually according to the clinical findings and thyroid hormone and TSH values measured in blood.

Children with acquired hypothyroidism start on 12.5-50 micrograms of Oroxine daily. The dose should be increased gradually every 2 to 4 weeks according to the clinical findings thyroid function test values until the full replacement dose is reached. As well as other values, the dosage in long term treatment will depend on the age and body weight of the individual child.

During the first 6 months of life, measurement of the levothyroxine blood level is more reliable as a control than measurement of TSH blood levels (thyroid stimulating hormone). In individual cases, it may take up to two years for the TSH level to normalise, despite adequate administration of levothyroxine.

Method of administration

The total daily dose is taken in the morning on an empty stomach, at least half an hour before breakfast, as the active substance is better absorbed on an empty stomach than before or after a meal. The tablets are swallowed whole without chewing, with a glass of water.

Infants are given the total daily dose at least half an hour before their first meal of the day. For this, the tablet is allowed to dissolve in some water (10-15 ml) and the resulting fine dispersion (note: to be freshly prepared for each dose) is administered with some more liquid (5-10 ml).

Duration of administration

You should take this medicine for as long as your doctor tells you.

- If you have an underactive thyroid gland or have had thyroid surgery for a malignant tumour of the thyroid, you will usually take Oroxine for life.
- For benign goitre and for prevention of recurrent goitre growth, you must take Oroxine for anything between several months or years to the rest of your life.
- In supportive therapy for the treatment of an overactive thyroid, you must take Oroxine as long as you take a thyreostatic medicine.
- For the treatment of benign goitre with normal thyroid function, a treatment period of 6 months to 2 years is necessary. If the treatment with Oroxine has not produced the desired result within this period, other treatment options should be considered.

Do not remove the canister (oxygen absorber) from the bottle. After opening the container the tablets should be used within 2 months.

If you take more Oroxine than you should

In the event of an overdose, consult your doctor or pharmacist immediately. If neither is available, seek immediate help at the nearest hospital or poison control centre.

If you are an epileptic, seizures may occur if the dose of levothyroxine is increased rapidly.

Symptoms of an overactive thyroid (such as agitation, feeling confused, feeling irritable, anxious or nervous, hyperactivity, feeling tired or emotional, headache, sweating, dilated pupils, rapid or irregular heartbeats, rapid breathing, fever, loose stools or seizures) may occur in the event of an overdose (see "Possible side effects").

Excessive levothyroxine use may cause a decrease in the density of the bones, particularly in women who have gone through the menopause.

If you forget to take Oroxine

If you miss a dose, take the usual dose when your next dose is due. Do not take a double dose to make up for forgotten individual doses. If you are unsure, please seek advice from your doctor or pharmacist.

If you stop taking Oroxine

For your treatment to be successful, you must take Oroxine regularly at the dosage prescribed by your doctor. On no account should you change, suspend or stop the prescribed treatment without talking to your doctor.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible Side Effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

All medicines can cause allergic reactions although serious allergic reactions are rare. Any sudden wheeziness, difficulty in breathing, swelling of the eyelids, face or lips, rash or itching (especially affecting your whole body) should be reported to a doctor immediately.

If the dosage strength is not tolerated, or in the case of an overdose, symptoms similar to having an overactive thyroid may occur, particularly if the dose is increased too quickly at the start of treatment.

The below reactions have been observed (frequency not known):

- Headache, flushing, excessive sweating,
- Loss of weight,
- Tremor (shaking), restlessness, excitability
- Seizures
- Difficulty sleeping,
- Rapid heartbeat (tachycardia) or angina (chest pain with tight chestedness),
- Irregular heartbeats, palpitations (thumping heart beats)
- High blood pressure (hypertension), heart failure, heart attack
- Shortness of breath (dyspnoea)
- Increased appetite, feeling sick (nausea), being sick (vomiting), loose stools (diarrhoea), stomach cramps
- Muscle weakness and muscle cramps
- Fever
- In women – changes in your menstrual cycle (period)
- A decrease in the density of your bones, particularly in women who have gone through the menopause and are taking high doses for long periods
- Overactive thyroid (hyperthyroidism)

You should check with your doctor if any of the above effects occur. The effects usually go away when the dose has been changed.

Additional side effects in children

Increased brain pressure (especially in children) may also be observed (rare: may affect up to 1 in 1,000 people) as atypical symptoms.

In children, overdosing with levothyroxine may cause early fusion of the skull bones and a premature halt in the child's growth.

Mild hair loss has also been seen in children – this is usually short-term. Heat intolerance is also seen in children.

In the case of hypersensitivity to levothyroxine sodium or any of the other ingredients of Oroxine, allergic reactions of the skin and respiratory tract region may occur.

Measures to treat an overdose

Tell your doctor if side effects occur. He/she will decide whether the daily dose should be reduced or whether you should stop taking your tablets for a few days. As soon as the side effect has disappeared, treatment can be started again.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL -Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Oroxine

KEEP THIS MEDICINE OUT OF THE SIGHT AND REACH OF CHILDREN.

Do not use this medicine after the expiry date which is stated on the box and bottle. The expiry date refers to the last day of that month.

After opening of the HDPE container the tablets should be used:

For Oroxine 25 and 50 microgram tablets: within 2 months.

For Oroxine 75, 100, 125, 150, 175, 200 microgram tablets: within 112 days

For Oroxine 25 and 125 micrograms tablets:

Store below 25°C

For Oroxine 50 and 100 micrograms tablets:

Store below 30°C

For Oroxine 75 and 150-200 micrograms tablets:

This medicinal product does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Oroxine contains

The active substance is levothyroxine sodium.

Each tablet of Oroxine 25 microgram contains 27.8 microgram of levothyroxine sodium pentahydrate equivalent to 25 microgram of levothyroxine sodium.

Each tablet of Oroxine 50 microgram contains 55.6 microgram of levothyroxine sodium pentahydrate equivalent to 50 microgram of levothyroxine sodium.

Each tablet of Oroxine 75 microgram contains 83.4 microgram of levothyroxine sodium pentahydrate equivalent to 75 microgram of levothyroxine sodium.

Each tablet of Oroxine 100 microgram contains 111.3 microgram of levothyroxine sodium pentahydrate equivalent to 100 microgram of levothyroxine sodium.

Each tablet of Oroxine 125 microgram contains 139.1 microgram of levothyroxine sodium pentahydrate equivalent to 125 microgram of levothyroxine sodium.

Each tablet of Oroxine 150 microgram contains 166.9 microgram of levothyroxine sodium pentahydrate equivalent to 150 microgram of levothyroxine sodium.

Each tablet of Oroxine 175 microgram contains 194.7 microgram of levothyroxine sodium pentahydrate equivalent to 175 microgram of levothyroxine sodium.

Each tablet of Oroxine 200 microgram contains 222.5 microgram of levothyroxine sodium pentahydrate equivalent to 200 microgram of levothyroxine sodium.

The other ingredients are:

Microcrystalline cellulose PH101 (E460)

Pregelatinised maize starch

Talc (E553b)

Colloidal anhydrous silica (E551)

Magnesium stearate (E470b)

What Oroxine looks like and contents of the pack

Oroxine tablets are packed in high density polyethylene (HDPE) bottles, closed with white polypropylene (PP) screw caps with foil heat induction seals, and with a 1.0 g white polypropylene canister containing oxygen absorber.

For Oroxine 25 and 50 microgram tablets:

28, 50, 60 tablets.

For Oroxine 75, 100, 125, 150, 175, 200 microgram tablets:

28, 50, 60, 84, 90, 100, 112 tablets.

Not all pack sizes may be marketed.

Oroxine 25 microgram tablets are round, 6.5mm in diameter , white coloured, flat, bevelled tablets debossed with '25' on the one side and a breakline on the other side. The tablet can be divided into equal doses.

Oroxine 50 microgram tablets are round, 6.5mm in diameter , white coloured, flat, bevelled tablets debossed with '50' on the one side and 'L01' on the other side.

Oroxine 75 microgram tablets are round, 6.5mm in diameter , white coloured, flat, bevelled tablets debossed with '75' on the one side and 'L02' on the other side.

Oroxine 100 microgram tablets are round, 6.5mm in diameter , white coloured, flat, bevelled tablets debossed with '100' on the one side and 'L10' on the other side.

Oroxine 125 microgram tablets are round, 6.5mm in diameter , white coloured, flat, bevelled tablets debossed with '125' on the one side and 'L12' on the other side.

Oroxine 150 microgram tablets are round, 6.5mm in diameter , white coloured, flat, bevelled tablets debossed with '150' on the one side and 'L17' on the other side.

Oroxine 175 microgram tablets are round, 6.5mm in diameter , white coloured, flat, bevelled tablets debossed with '175' on the one side and 'L20' on the other side.

Oroxine 200 microgram tablets are round, 6.5mm in diameter , white coloured, flat, bevelled tablets debossed with ‘200’ on the one side and ‘L21’ on the other side.

Marketing Authorisation Holder and Manufacturer

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This medicinal product is authorised in the Member States of the EEA under the following names:

Ireland Oroxine

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