

OROXINE TABLET

Levothyroxine Sodium (50mcg, 100mcg)

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What Oroxine is used for

Oroxine is used to treat thyroid hormone deficiency also known as hypothyroidism.

How Oroxine works

Oroxine contains Levothyroxine Sodium. Levothyroxine Sodium is a thyroid hormone. It is used as replacement therapy in the treatment of thyroid hormone deficiency.

Thyroxine (T_4) is a naturally occurring hormone produced by the thyroid gland and converted to the more active hormone tri-iodothyronine (T_3). The thyroid hormone are required for normal growth and development, particularly of the nervous system. Thyroid hormones enhance lipolysis and the utilization of carbohydrate.

Ask your doctor if you have any questions about why this medicine has been prescribed for you. Your doctor may have prescribed it for another reason.

Before you use Oroxine

- When you must not use it

Do not take this medicine if you have an allergy to:

- levothyroxine sodium

- any other thyroid hormone
- any of the other ingredients listed at the end of this leaflet

Do not take this medicine if you have:

- overactive thyroid gland, which is resulting in a rapid heartbeat and an increased rate of metabolism.
- heart disease and inflammation of the cardiac muscle

underactive adrenal glands (adrenal insufficiency) and you do not have an adequate replacement treatment

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering. If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

- Before you start to use it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following conditions:

- Adrenal gland problem
- Heart problems
- Diabetes

If you have not told your doctor any of the above, talk to he/she before taking Oroxine.

Premature babies with very low birth weight require regular blood pressure monitoring when started with

levothyroxine treatment because a rapid fall in blood pressure may occur.

Thyroid hormones are not suitable for weight reduction. Intake of thyroid hormones will not reduce your weight, if your thyroid hormone level is in a normal range. Serious or even life-threatening side effects may occur if you increase the dose without special advice from your doctor, especially when taken together with other medicines for weight reduction.

Thyroid imbalance may occur if you need to change your medication to another levothyroxine containing product. Talk to your doctor if you have any questions about changing your medication. A close monitoring (clinical and biological) is required during the transition period. You should tell your doctor if you experience any side effects as this may indicate that your dose needs to be increased or decreased.

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.

- Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

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.

The effect of Oroxine is influenced by products containing St. John's Wort (a herbal medicinal product).

Some medicines and Oroxine may interfere with each other. These include:

- Anticoagulants, medicines used to thin your blood
- Medicines used for epilepsy (e.g. phenytoin and carbamazepine)
- Rifampicin and ciprofloxacin used to treat infections
- Cardiac glycosides used to treat heart failure
- Tricyclic antidepressants used to treat depression
- Cholestyramine
- Oral contraceptives
- HMG-CoA reductase inhibitors (statins)
- Proton pump inhibitors (e.g. 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 reduce the effectiveness of Oroxine. 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

- Weight loss drug (e.g. orlistat)

These medicines may be affected by Oroxine or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to use Oroxine

Follow all directions given to you by your doctor and pharmacist carefully.

These directions may differ from the information contained in this leaflet.

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

- How much to use

The usual starting dose for adults is 50 to 100 micrograms daily. The dose may be increased by 50 micrograms at 4 to 6 weeks. The average adult dose is 100 to 200 micrograms daily.

Lower doses are used in the elderly and children.

Your doctor may order regular blood tests while you are taking Oroxine.

- When to use it

Take Oroxine on an empty stomach, preferably before breakfast.

- How long to use it

Continue taking Oroxine for as long as your doctor recommends.

- If you forget to use it

Take your dose as soon as you remember, and continue to take 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 that you missed. This may increase the chance of you getting an unwanted side effect.

- If you use too much (overdose)

Immediately telephone your doctor for advice or go to Emergency Department at your nearest hospital if you think that you or anyone else may have taken too much Oroxine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Taking too many tablets may cause agitation, confusion, irritability, fever, irregular heartbeat, headache, sweating, hyperactivity, dilation of eye pupil, increased heartbeat, abnormally rapid breathing, increased bowel movements and convulsions.

While you are using it

- Things you must do

Tell all the doctors, dentists and pharmacists who are treating you that you are taking Oroxine.

Tell your doctor if you are pregnant, plan to become pregnant or breast-feeding.

During pregnancy, levothyroxine must not be used at the same time with medicines against an overactive thyroid gland (antithyroid drugs).

Levothyroxine sodium is passed into breast milk. Your doctor will discuss the risks and benefits of taking Oroxine during breast feeding.

If you are about to start taking any new medicine tell your doctor and pharmacist that you are taking Oroxine.

- Things you must not do

Do not stop taking your medicine or lower the dosage without checking with your doctor.

Do not take Oroxine to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

- Things to be careful of

Be careful driving or operating machinery until you know how Oroxine affects you.

Side effects

All medicines can have side effects. Sometimes they are serious, most of the time they are not.

Ask for the advice of your doctor or pharmacist if you have any concerns about the effects of taking this medicine.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

The following side effects have been reported with Oroxine:

- Chest pain
- Irregular heart beats
- Increased blood pressure
- Muscle weakness and cramps
- Diarrhea
- Vomiting
- Nausea
- Tremor
- Restlessness
- Inability to sleep
- Headache
- Weight loss
- Menstruation irregular and infertility
- Difficulty in breathing
- Angioedema, rash and urticaria

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell. Other side effects not listed above may also occur in some people.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Oroxine

- Storage

Keep your medicine in its original packaging until it is time to take them.

If you take the tablets out of the pack, they may not keep well.

Do not keep your medicine in a place where the temperature will stay above 25°C. Store in the original container, protected from light. Keep the container tightly closed.

Do not store your medicine, or any other medicine, in the bathroom or near a sink.

Keep it where children cannot reach it.

- Disposal

If your doctor or pharmacist tells you to stop taking this medicine or it has passed its expiry date, ask your pharmacist what to do with any medicine that is left over.

Product Description

- What it looks like

Oroxine 50mcg Tablet:
White to off-white, round, biconvex tablets imprinted GS 11E on one face and 50 on the other.

Oroxine 100mcg Tablet:
White to off-white, round, biconvex tablets imprinted GS 21C on one face and 100 on the other.

- Ingredients

Active ingredient:

- Levothyroxine (as sodium)

Inactive ingredients:

- Talc
- Microcrystalline cellulose
- Magnesium stearate
- Silica colloidal anhydrous
- Starch pregelatinized
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- MAL number

Oroxine 50mcg Tablet:
MAL06071059AZ

Oroxine 100mcg Tablet:
MAL06071058AZ

Manufacturer

Aspen Bad Oldesloe GmbH,
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Product Registration Holder

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