

ELTROXIN[®]

levothyroxine sodium 50 micrograms and 100 micrograms tablets

Consumer Medicine Information (CMI)

What is in this leaflet

This leaflet answers some common questions about ELTROXIN 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 ELTROXIN against the risks this medicine could have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with your medicine.

You may need to read it again.

What ELTROXIN is used for

ELTROXIN contains the active ingredient levothyroxine sodium. It belongs to a small group of medicines called thyroid hormones, which work by replacing the body's low levels of thyroxine.

ELTROXIN is used to treat hypothyroidism, 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, cramps, feeling the cold, a slow heart rate, dry and flaky skin, hair loss, a deep husky voice and weight gain.

ELTROXIN is also used to treat children born with hypothyroidism (congenital), those who develop hypothyroidism in the first year of life (neonatal) and children who have hypothyroidism as part of juvenile myxoedema, a condition in which the amount of thyroxine produced by the body is low.

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

Your doctor may have prescribed ELTROXIN for another purpose. ELTROXIN is available only with a doctor's prescription.

Before you take it

When you must not take it

Do not take ELTROXIN if:

- you have or have had an allergic reaction to any of the ingredients in ELTROXIN listed at the end of this leaflet.
- the packaging is torn or shows signs of interference, or the tablets look damaged or discoloured.
- the expiry date on the packaging has passed. If you take this medicine after the expiry date has passed, it may not work as well. If the pharmacist has repacked the medicine for you, there may not be an expiry date on the pack.

- you have thyrotoxicosis, a disease in which the thyroid gland is overactive and produces too much thyroxine.

Before you start taking it

Tell your doctor if:

- you are allergic to any other medicines, foods, dyes or preservatives.
- you are pregnant or plan to become pregnant.
- ELTROXIN is not thought to be harmful to an unborn baby when taken by a pregnant woman. However, thyroxine levels need to be watched carefully during pregnancy because too much or too little thyroxine in the mother's bloodstream could affect the well-being of an unborn baby.
- you are breastfeeding or planning to breastfeed.
- Although the active ingredient in ELTROXIN, thyroxine, passes into breast milk, it is not likely to have a harmful effect on a baby. However, it might interfere with the results of tests to detect congenital hypothyroidism in the baby. You should not breastfeed unless your doctor says you can.
- you have any other health problems, especially diabetes, heart disease, high blood pressure, osteoporosis and underactive adrenal glands.

If you have not told your doctor about any of the above, tell them before starting to take ELTROXIN.

Taking other medicines

Tell your doctor if you are taking any other medicines, including the oral contraceptive pill or medicines you buy without a prescription from a pharmacy, supermarket or health food shop.

Some medicines may affect the way others work.

If you are taking any of the following types of medicines, please let your doctor know before taking ELTROXIN:

- drugs to thin your blood
- drugs for epilepsy
- drugs for mental depression • drugs used to treat diabetes (e.g. insulin)
- drugs used to treat high blood pressure and heart conditions (e.g. propranolol, amiodarone)
- cholestyramine (Questran™), a drug used to lower blood cholesterol levels
- digoxin (Lanoxin™), or drugs known as cardiac glycosides
- drugs to relieve asthma attacks
- drugs used for weight reduction
- oral contraceptive pill
- iron, calcium, magnesium and aluminium supplements
- drugs used to treat tuberculosis and other 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
- oral contrast agents, used before X-ray and scans
- propylthiouracil, a drug used to treat overactive thyroid and Graves disease
- non-steroidal anti-inflammatory drugs (NSAIDs), drugs used to relieve pain and/or inflammatory conditions including arthritis.
- Antivirals, medicines used to treat HIV/AIDS infection (e.g. ritonavir)
- • tyrosine kinase inhibitors, medicines used to treat cancer (ie 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)

Your doctor or pharmacist will be able to tell you more about what to do when taking ELTROXIN with other medicines.

Taking ELTROXIN

How much to take

Take ELTROXIN exactly as your doctor has prescribed.

Your doctor will tell you how many ELTROXIN tablets to take each day. Your doctor will calculate the dose based on your weight.

Never take more tablets than your doctor has prescribed.

Your doctor may vary your dose depending on how you respond to ELTROXIN.

In adults, the usual dose is 50 microgram to 100 micrograms daily, increased every 4 to 6 weeks as needed. The maximum dose is 200 micrograms daily.

In children, the dose is reduced according to other pre-existing health conditions, weight and age.

Elderly people or people with pre-existing health conditions usually need a smaller dose because they are more sensitive to the effects of thyroxine.

Many people need treatment with ELTROXIN long term.

Your doctor will do regular blood tests to make sure ELTROXIN is working for you.

How to take it

Swallow tablets whole with a glass of water. Tablets should preferably be taken on an empty stomach, at least 30 minutes before breakfast.

If you forget to take it

Do not take an extra dose.

Wait until the next dose and take your normal dose then.

Do not try to make up for the dose that you missed by taking more than one dose at a time. If you are not sure what to do, ask your doctor or pharmacist.

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Information Centre [telephone 0800 POISON or 0800 764 766] for advice, or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else has taken too much ELTROXIN. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

An overdose of ELTROXIN can cause agitation, confusion, irritability, hyperactivity, sweating, headaches, fever, widened pupils, fits, palpitations and diarrhoea.

If you are not sure what to do, contact your doctor or pharmacist.

While you are taking it

Things you must do

Tell all doctors and pharmacists involved in your health care that you are taking ELTROXIN.

Tell your doctor if you are pregnant or planning to become pregnant or are breastfeeding while taking ELTROXIN.

Tell your doctor if, for any reason, you have not taken ELTROXIN exactly as prescribed. Otherwise, your doctor may think it is not working for you and change your dose unnecessarily.

Tell your doctor if you feel that ELTROXIN is not helping your condition.

Things you must not do

Do not stop taking ELTROXIN or change the dose without first checking with your doctor, or your symptoms could return.

Do not let yourself run out of medicine over the weekend or on holidays.

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

Do not take any other medicines whether they require a prescription or not without first asking your doctor or a pharmacist.

Do not drive or operate machinery until you know how your ELTROXIN dose is affecting you.

Side effects

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor immediately if you think you are having an allergic (hypersensitivity) reaction to ELTROXIN.

Allergic type reactions and symptoms may include:

- severe skin rash, itching or hives.
- swelling of the face, lips, mouth or throat.
- difficulty breathing or swallowing.
- fever.
- low blood pressure (feeling faint or dizzy).

Tell your doctor if you notice any of the following:

- partial hair loss in children (this usually is short term during the first few months of therapy. Subsequent growth usually occurs.)
- diarrhoea
- vomiting
- palpitations (irregular heartbeat)
- chest pain
- sweating/flushing
- weight loss
- muscle weakness/cramps, tremors
- rapid breathing
- fever
- headache
- inability to sleep
- feeling restless/excited.

Some of the above side effects occur when the daily dose is too high. Your doctor may recommend that you change your dose of ELTROXIN if you experience any of these side effects.

Tell your doctor if you notice anything else that is making you feel unwell.

Other side effects not listed above may also occur in some people.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

After taking it

Storage

Keep your tablets in the bottle until it is time to take them.

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

Keep ELTROXIN in a cool dry place, protected from light, where the temperature stays below 25°C.

Do not store ELTROXIN or any other medicine in a bathroom or near a sink. Do not leave it in a car or on a window sill.

Heat and dampness can destroy some medicines.

Keep ELTROXIN where young children cannot reach it.

A locked cupboard at least one and a half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking ELTROXIN, or the medicine has passed its expiry date, ask your pharmacist what to do with any tablets that are left.

Product description

What ELTROXIN looks like

Eltroxin 50 microgram (0.05 mg) tablets are white coloured, flat, bevelled tablets, imprinted with '50' on one face and 'L01' on the other.

Eltroxin 100 microgram (0.1 mg) tablets are white coloured, flat, bevelled tablets, imprinted with '100' on one face and 'L10' on the other.

Ingredients

Each tablet contains either 50 or 100 micrograms of the active ingredient thyroxine (as anhydrous levothyroxine sodium).

They also contain the inactive ingredients microcrystalline cellulose, pregelatinised maize starch, purified talc, colloidal silicon dioxide and magnesium stearate.

Further information

Your doctor is the best person to give you advice on the treatment of your illness.

You may also be able to find general information about hypothyroidism and its treatment from other sources, for example, books in public libraries and on the Internet.

Manufacturer

ELTROXIN tablets are supplied by:

Pharmacy Retailing (NZ) Limited
Trading as Healthcare Logistics 58
Richard Pearse Drive
Airport Oaks
Auckland New
Zealand

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