Package leaflet: Information for the user

Eltroxin™ 25, 50, 100 micrograms 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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4

• Thyroxine is a hormone produced by the thyroid gland. Levothyroxine is used to replace thyroxine in people whose thyroid gland does not work properly. You will usually need to take this medicine for the rest of your life and must not stop taking it, or change the dose, without speaking to your doctor first.
• This medicine can affect the way other medicines work (See Section 2 'Taking other medicines'). If you take medicines to control diabetes or warfarin to prevent blood clots, the dose may need to be adjusted by your doctor when you start taking Eltroxin tablets.
• You will start off taking a low dose of this medicine (See Section 3 'How to take'). Your doctor will then increase the dose gradually at 3 – 4 week intervals until your thyroxine levels are corrected. This will help to reduce the chance of side effects.
• You will need regular blood tests whilst you are taking this medicine.
• These tablets can be taken by both adults and children. If you are giving this medicine to your child make sure you know how many and when to give the tablets (See Section 3 'How to take') and what side effects to look out for (See Section 4 'Possible side effects').

What is in this leaflet

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

1. What Eltroxin Tablets are and what they are used for

Thyroxine is a hormone which is produced naturally in the body by the thyroid gland. Levothyroxine is a synthetic version of this hormone. Thyroxine controls how much energy your body uses. When the thyroid gland does not produce enough thyroxine (a condition known as hypothyroidism), many of the body's functions slow down. Some of the most common symptoms of hypothyroidism are:
• tiredness
• weight gain
• feeling depressed

Eltroxin tablets are used to replace the thyroxine that your thyroid gland cannot produce and prevent the symptoms of hypothyroidism. Before starting your treatment your doctor will carry out a blood test to work out how much levothyroxine you need.

2. What you need to know before you take Eltroxin Tablets
Do not take Eltroxin Tablets:
• if you are allergic to levothyroxine or to any of the other ingredients of this medicine (see section 6)
• if you suffer from an overactive thyroid gland that produces too much thyroid hormone (thyrotoxicosis)
• if you have any condition that affects your adrenal glands which is not treated (your doctor will be able to advise you if you are not sure).
• if you have the following diseases or conditions:
  - o an acute myocardial infarction,
  - o acute inflammation of the heart muscle (myocarditis),
  - o acute inflammation of all the heart walls (pancarditis)

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

If any of these apply to you, do not take this medicine and go back to your doctor to discuss your treatment.

Warnings and precautions:
Talk to your doctor, pharmacist or nurse before taking Eltroxin tablets -
• if you have suffered with an under active thyroid gland for a long time
• if you suffer from heart problems including angina, coronary artery disease or high blood pressure. The doctor may require ECG before starting treatment with levothyroxine, as changes induced by hypothyroidism may be confused with evidence of ischaemia (decreased oxygen in a tissue)
• if you suffer from fits (epilepsy). Fits have been rarely reported when starting the treatment with levothyroxine
• if you have a particular hormonal disorder called panhypopituitarism
• if you are being treated for diabetes. The dose of your anti-diabetic medicine may need to be changed as levothyroxine can raise blood sugar levels
• if you are over 50 years of age.

Subclinical hyperthyroidism (where the thyroid gland makes too much thyroxine) may occur if your dose is too high and this could be associated with bone loss (osteoporosis). This will usually disappear after reducing the dose or stopping the tablets. However, you must not change the dose or stop the tablets without talking to your doctor first.

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 get any side effects as this may indicate that your dose needs to be adjusted up or down.

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.

Children
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.
Children receiving thyroid agent may experience partial loss of hair may occur during the first few months of therapy, but this effect is usually temporary and subsequent regrowth usually occurs.

Blood tests:
Before you start taking levothyroxine your doctor will do a blood test to see how much thyroxine your thyroid gland is making and what dose of the medicine you will need. Once you start taking the medicine your doctor will want you to have regular blood tests to see how well the medicine is working.

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 Eltroxin tablets)

Other medicines and Eltroxin tablets
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.
Many medicines affect the way levothyroxine works. The effects of other drugs may also be affected by levothyroxine.

The following may affect the way that Eltroxin tablet works:
• medicines for epilepsy such as carbamazepine, phenytoin, primidone and barbiturates
• sertraline – used to treat depression and anxiety disorders
• antacids – used to treat indigestion
• medicines containing calcium salts
• cimetidine – used to reduce excess stomach acid
• proton pump inhibitors (such as omeprazole, esomeprazole, pantoprazole, rabeprazole and lanzoprazole) 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 *TM*.
• sucralfate – used to treat and prevent stomach and duodenal ulcers
• cholestyramine and colestipol – used to treat high level of fat in the blood
• polystyrene sulphone resin – used to reduce high levels of potassium in the blood
• medicines containing iron that are taken by mouth
• rifampicin – used to treat infections
• imatinib – used to treat certain types of cancer
• beta blockers such as atenolol and sotalol – used to treat high blood pressure and heart problems
• oestrogen containing medicines for hormone replacement therapy (HRT) and contraception (the 'pill')
• androgen containing medicines for male hormone replacement therapy
• corticosteroids such as hydrocortisone and prednisolone – used to treat inflammation
• amiodarone – used to treat an irregular heart beat
• orlistat – used to treat obesity
• Ritonavir- used to control HIV and chronic hepatitis C virus
• products containing St. John's Wort (a herbal medicinal product)

The following may be affected by Eltroxin tablets:
• anti-coagulant medicines to prevent blood clots such as warfarin
• medicines to treat diabetes such as insulin and metformin
• tricyclic antidepressants such as amitriptyline, imipramine and dosulepin
• medicines that stimulate the sympathetic nervous system such as adrenaline (used to treat severe allergic reactions) or phenylephrine (a decongestant found in many cold and flu treatments)
• digoxin – used to treat heart problems
• anti-inflammatory medicines such as phenylbutazone or aspirin
• propanolol – used to treat high blood pressure and heart problems
• ketamine – used as an anaesthetic. If you need to have an operation, please tell your doctor or anaesthetist that you are taking levothyroxine.

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).

Pregnancy and breast-feeding
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.

Driving and using machines
This medicine should not affect your ability to drive and use machines.

Eltroxin tablets contain Lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Information on Sodium content
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Eltroxin Tablets
You may be taking this medicine for the rest of your life. 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 recommended dosage is-
Adults:
The usual starting dose is 50 – 100 micrograms every day. Your doctor may increase the dose you take every 3 – 4 weeks by 50 micrograms until your thyroxine levels are correct. Your final daily dose may be up to 100 – 200 micrograms daily.

Patients over 50 years of age:
The usual starting dose will be no more than 50 micrograms every day. The dose may then be increased by 50 micrograms every 3 – 4 weeks until your thyroxine levels are correct. Your final daily dose will be between 50 – 200 micrograms daily.

Patients over 50 years of age with heart problems:
The starting dose will be 25 micrograms every day or 50 micrograms every other day. The dose may be increased by 25 micrograms every 4 weeks until your thyroxine levels are correct. Your final daily dose will usually be between 50 – 200 micrograms daily.

Use in children and adolescents:
For young children, your doctor is likely to prescribe Levothyroxine Oral Solution instead of tablets.
Congenital hypothyroidism in infants:
This is a condition where your baby has been born with a thyroid gland that does not produce enough thyroxine. The starting dose depends on their age and weight, for the first three months. The dose will then be adjusted depending on how your baby responds to the treatment.

Acquired hypothyroidism in children:
This is a condition where your child's thyroid gland stops working properly because it has been attacked by their immune system, e.g. in children with an autoimmune disease or following a viral infection. The starting dose depends on their age and weight. The dose will then be increased every 2 - 4 weeks depending on how your child responds to the medicine.

Method of administration:
Your dose will be decided by your doctor and will depend on the results of your blood tests. The dose you should take will be on the label attached by your pharmacist. Swallow the tablets with

plenty of water. You should usually take your tablets on an empty stomach, ideally an hour before breakfast or your first meal of the day.
If necessary, the tablets can be dissolved in 10 - 15ml of water and given with some more liquid (5 - 10ml). The dissolved tablets should be taken straight away. Do not keep the solution to be taken later.

If you take more Eltroxin Tablets than you should

If you (or someone else) swallow a lot of the tablets at the same time, or you think a child may have swallowed some, contact your nearest hospital casualty department or tell your doctor immediately. Signs of an overdose may include: fever, chest pain (angina), racing or irregular heartbeat, muscle cramps, headache, restlessness, flushing, sweating, diarrhoea, shaking (tremor), difficulty sleeping (insomnia) and very high temperature (hyperpyrexia). These signs can take up to 5 days to appear. Take any remaining tablets and this leaflet with you so that the medical staff knows exactly what you have taken.

If you forget to take Eltroxin Tablets
If you forget to take a dose take it as soon as you remember unless it is nearly time for your next dose. Do not take a double dose to make up for a forgotten dose. If you forget to give your child their dose, contact your doctor or pharmacist for further advice.

If you stop taking Eltroxin Tablets
These tablets are for long term use. You may need to take them for the rest of your life. Do not stop taking the tablets unless your doctor has told you to do so.

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

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

Stop taking the tablets and go to hospital at once if you have:
• a rare allergic reaction such as swelling of the face, tongue, lips and throat, difficulty breathing, severe itching of your skin with raised lumps, joint pain, sensitivity to the sun, general feeling of being unwell. You may need urgent medical attention.

Some patients may experience a severe reaction to high levels of thyroid hormone. This is called a “thyroid crisis” and you should contact your doctor immediately if you have any of the following symptoms:
• very high temperature; fast heart rate; irregular heartbeat; low blood pressure; heart failure; jaundice; confusion; fits and coma.

Tell your doctor or pharmacist if any of the following side effects continue, get worse or if you notice any other side effects not listed.
Most of the side effects are similar to the symptoms of hyperthyroidism (where the thyroid gland makes too much thyroxine) and are due to your dose of the medicine being too high. They

will usually disappear after reducing the dose or stopping the tablets. However, you must not change the dose or stop the tablets without talking to your doctor first.

Not known (frequency cannot be estimated from the available data)
• headache
• flushing
• high temperature, sweating
• hair loss
• weight loss
• tremor, restlessness, excitability, difficulty sleeping (insomnia)
• increased pressure around the brain in children that is not caused by a tumour or other diseases (benign intracranial hypertension)
• chest pain (angina), pounding, irregular or fast heartbeat
• diarrhoea, vomiting
• muscle cramps, muscle weakness,
• deformity of the skull in infants caused by the early closure of joints in the skull bone (craniostenosis)
• growth in children may slow or stop due to changes in bone growth
• irregular periods
• intolerance to heat and temporary hair loss in children.

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,
Website: www.hpra.ie.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Eltroxin Tablets

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 carton after EXP. The expiry date refers to the last day of that month.
Do not store above 25°C. Store in the original package in order to protect from light and moisture.
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 Eltroxin tablets contain
- The active substance is anhydrous levothyroxine sodium.
Each tablet contains respectively Anhydrous Levothyroxine Sodium 25 micrograms, 50 micrograms and 100 micrograms.

- The other ingredients are Sodium citrate, Lactose monohydrate, Maize Starch, Acacia Powder and Magnesium Stearate.

What Eltroxin tablets look like and contents of the pack
Each white tablet is scored on one side and is engraved on the other side with either
25mcg - FW41
50mcg - Eltroxin 50
100mcg - Eltroxin 100.
Eltroxin 25, 50 and 100 microgram tablets are available in blister packs of 28, 56 or 112 tablets and polypropylene containers of 100 or 1000 tablets. Eltroxin 25 microgram tablets are also available in polypropylene containers of 28, 56 and 112 tablets. Not all pack sizes may be marketed.

Marketing Authorization Holder:
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OTHER USEFUL INFORMATION:
For further information about this product contact

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