

PACKAGE LEAFLET: INFORMATION FOR THE USER

Eltroxin™ 25 Microgram Tablets **Eltroxin™ 50 Microgram Tablets** **Eltroxin™ 100 Microgram Tablets** (levothyroxine sodium)

Please read this leaflet carefully before you start to take your medicine.

This leaflet does not contain all the information about your medicine. If you have any questions or you are not sure about anything ask your doctor or pharmacist.

THE NAME OF YOUR MEDICINE IS:

Eltroxin 25, 50 or 100 microgram Tablets.

THE ACTIVE INGREDIENT IS:

Each Eltroxin Tablet contains 25, 50 or 100 micrograms of levothyroxine sodium.

The active ingredient, levothyroxine sodium, although synthetic, is similar to the natural thyroid hormone (chemical messenger) in your body. Thyroid hormone is produced by the thyroid gland in your neck and regulates metabolism.

Each tablet also contains the following inactive ingredients: sodium citrate, lactose, maize starch, acacia powder, magnesium stearate and purified water.

WHAT ELTOXIN TABLETS LOOK LIKE AND CONTENTS OF THE PACK

Each 25 microgram tablet is white, scored on one side and is engraved with 'FW41' on the other side.

Each 50 microgram tablet is white, scored on one side and is engraved with 'FW21' on the other side.

Each 100 microgram tablet is white, scored on one side and is engraved with 'FW31' on the other side.

Eltroxin are supplied in blister packs of 28 tablets.

MANUFACTURER

Manufactured by: Custom Pharmaceuticals Ltd.,
Tecore House, Conway Street, Hove, East Sussex, BN3 3LW, UK.

Procured from within the EU by the Parallel Product Authorisation holder: Imbat Ltd.,
Unit L2, North Ring Business Park, Santry, Dublin 9.

The product is repackaged by:
Doncaster Pharmaceuticals Group Ltd.,
Kirk Sandall, Doncaster, South Yorkshire, DN3 1QR, UK.

Distributed by: Eurodrug Ltd., Santry, Dublin 9.

PPA No: 1151/64/1 – Eltroxin 25 microgram Tablets
PPA No: 1151/64/2 – Eltroxin 50 micrograms Tablets
PPA No: 1151/64/3 – Eltroxin 100 microgram Tablets

WHAT IS YOUR MEDICINE USED FOR?

Eltroxin Tablets are given to you by your doctor because you have low levels of thyroid hormone (hypothyroidism) and your metabolism is lower than normal. Thyroid hormone is vital for normal growth and development.

Eltroxin Tablets make up for this lack of naturally occurring thyroid hormone. These tablets can be used for long term treatment.

BEFORE YOU TAKE YOUR MEDICINE:

If the answer is yes to any of the following questions or you are not sure about the answer, tell your doctor or pharmacist.

- Have you ever been allergic to Eltroxin Tablets or to any of the ingredients of Eltroxin Tablets?
 - Have you ever been allergic to other thyroid treatments?
 - Have you been told that your thyroid gland is overactive?
 - Are you suffering from any heart disease such as angina, coronary artery disease, myocardial infarction or hypertension?
 - Have you been told that you suffer from adrenal insufficiency? (a condition in which the adrenal glands located above the kidneys do not produce adequate amounts of steroid hormones).
 - Are you suffering from epilepsy or ever suffered from fits in the past?
 - Are you over 50 years of age?
- Your doctor may advise an ECG before commencing treatment with Eltroxin tablets.
- Are you diabetic or being treated with tablets or injections for diabetes?
 - Do you have any heart condition requiring treatment (e.g. Digoxin or Amiodarone)?
 - Are you being treated to reduce cholesterol in your body (e.g. Colestyramine)?
 - Are you being treated with antacids to treat indigestion?
 - Are you being treated with beta-blockers (e.g. propranolol) to treat high blood pressure?
 - Are you being treated with anti-inflammatory drugs (e.g. phenylbutazone and aspirin)?
 - Are you being treated with adrenaline (for treatment of severe allergies)?
 - Are you being treated with imatinib, for the treatment of cancer?
 - Are you being treated with an anticoagulant (e.g. Warfarin) or an anticonvulsant for epilepsy (e.g. Phenytoin, carbamazepine, primidone, barbiturates)?
 - If female, are you pregnant or likely to become pregnant or taking the contraceptive pill?
 - Are you being treated with antidepressants (e.g. sertraline)?
 - Are you being treated with other hormone drugs?
 - Are you receiving any of the following drugs such as cimetidine, sodium polystyrene sulphonate, sucralfate, colestipol, rifampicin, corticosteroids, ketamine, lovastatin?
 - Are you being treated with any other drugs?
 - If you have been told by your doctor that you have an intolerance to some sugars, such as Lactose, contact your doctor before taking this medicinal product.
 - If you take iron or calcium supplements, then dosages of levothyroxine and iron or calcium need to be separated by an interval of several hours.

If you are unsure, talk to your doctor or pharmacist.

WHAT PRECAUTIONS SHOULD YOU TAKE?

Do not take more Eltroxin Tablets than your doctor tells you to. Discuss with your doctor or pharmacist if you are worried about anything.

TAKING YOUR TABLETS:

- Before starting this treatment, your doctor may record your heart activity (ECG)
- The usual adult starting dose of Eltroxin Tablets is 50 to 100 micrograms. This dosage may be adjusted depending on the assessment by your doctor
- The doctor will prescribe the dose in children depending on the age and weight of your child
- The dose is preferably taken before breakfast, once a day
- Initially your doctor may prescribe a low dose and adjust this to meet your individual needs after taking blood for laboratory analysis of your thyroid function or after assessing your condition
- Read the label on your medicine container to see how many tablets you should take and when you should take them
- Swallow the tablets whole with a drink of water
- Do not take more tablets than your doctor tells you to
- Do not stop taking your tablets except on your doctor's advice. Suddenly stopping this treatment can cause problems such as rebound hypothyroidism or effects on other treatments you may be taking. Your doctor will gradually reduce and stop your treatment with Eltroxin Tablets over several weeks to avoid these problems
- If you miss a dose but remember within two or three hours, you can still take that dose. If you miss a dose for longer, miss that dose and take the next one when it is due. Remember that ideally the dose should be taken before breakfast.

DO NOT TAKE DOUBLE THE AMOUNT OF TABLETS IF YOU MISS A DOSE

- If you accidentally take too many Eltroxin Tablets, tell your doctor immediately or contact your nearest Hospital Casualty/Accident & Emergency Department.

WHILE TAKING YOUR MEDICINE:

- Be sure to take the tablets as your doctor tells you to
- Keep taking them until your doctor tells you to stop
- Your doctor may change your dose depending on the result of blood tests or your overall condition
- If you are female and think that you may have become pregnant, tell your doctor.

AFTER TAKING YOUR MEDICINE:

Eltroxin Tablets may cause unwanted effects in some people. 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 you experience any of the following, tell your doctor.

- Angina pain (pain in the chest, particularly when taking exercise e.g. walking up hill)
- Fever
- Intolerance to heat
- Mild hair loss seen in children
- In women-changes to your periods
- Irregular heart beats
- Palpitations (loud, thumping heartbeat)
- Muscle cramps or weakness
- Rapid heart beat
- Diarrhoea and vomiting
- Tremor (shaking)
- Restlessness, excitability
- Insomnia
- Headaches
- Flushing
- Sweating
- Loss of weight
- Rash, itching, oedema (fluid retention)
- Osteoporosis (bone loss).

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.

PRECAUTIONS:

- Do not store above 25°C.
- Store in the original package in order to protect from light and moisture.
- Keep out of the sight and reach of children.
- Do not take the tablets after the expiry date (Exp) which is printed on the blister and outer carton.
- If your doctor tells you to stop taking your medicine, you should return any you have not used to your pharmacist for safe disposal.
- If your tablets appear to be discoloured or show any other signs of deterioration, please return to your pharmacist who will advise you.

Remember: This medicine is only for you. Only a doctor can prescribe it for you. Never give this medicine to someone else. It could harm them, even if their symptoms seem the same as yours.

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