1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

ELTROXIN NEW FORMULATION 25 µg/ 50 µg/ 75 µg/ 88 µg/ 100 µg/ 112/ 125 µg/ 137 µg µg/ 150 µg/ 175 µg/ 200 µg tablets

Levothyroxine sodium

Sugar free

Read all of this leaflet carefully before you start taking

ELTROXIN NEW FORMULATION

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor pharmacist, nurse or other healthcare provider.
- ELTROXIN NEW FORMULATION has been prescribed for you personally and you should not share ELTROXIN NEW FORMULATION with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

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

1. What ELTROXIN NEW FORMULATION is and what it is used for

ELTROXIN NEW FORMULATION belongs to a group of medicines called hormones.

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.
ELTROXIN NEW FORMULATION 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.

2. What you need to know before you take ELTROXIN NEW FORMULATION

Do not take ELTROXIN NEW FORMULATION :

- If you are hypersensitive (allergic) to levothyroxine or any of the other ingredients of ELTROXIN NEW FORMULATION (listed in section 6).
- If you have untreated hyperthyroidism, a disease in which the thyroid gland is overactive and produces too much thyroxine (this can lead to a life- threatening condition known as a thyroid storm where your heart rate, blood pressure, and body temperature can soar to dangerously high levels).
- If you have thyrotoxicosis (an overactive thyroid gland that produces too much thyroid hormone).
- If you have untreated adrenal insufficiency (condition where your adrenal gland does not produce enough steroid hormones), untreated pituitary insufficiency (decreased secretion of hormones produced by the pituitary gland).
- If you have acute myocardial infarction (heart attack), acute myocarditis (inflammation of the heart muscle), acute pancarditis (inflammation of the heart or its surroundings).

Warnings and precautions

Tell your doctor, pharmacist or nurse before taking ELTROXIN NEW FORMULATION:

- If you have anginal pain (pain in the heart area), palpitations and cramps in the muscle when you start your therapy with ELTROXIN NEW FORMULATION.
- Before starting with ELTROXIN NEW FORMULATION make sure to tell your doctor if you have any heart disease, pituitary (gland in the brain) or other thyroid disease. Thus, frequent thyroid checks should be done.
- If you are in menopause (when your menstrual period stops later in your life (for females)).
- If you start to have fits, abnormal heartbeat, heart failure as these are signs of a “thyroid storm” (overdosage when taking ELTROXIN NEW FORMULATION).
- When you begin your therapy, constant monitoring by your doctor is required.
- If you have panhypopituitarism (disease of the pituitary gland), notify your doctor if you have this disease.
- If you develop bone loss due to subclinical hyperthyroidism (low levels of the hormone TSH and normal level of the hormone T3 and T4), your doctor will give you the lowest possible dose of ELTROXIN NEW FORMULATION.
- If you are a post-menopausal woman on long-term therapy with ELTROXIN NEW FORMULATION, your doctor will give you the lowest possible dose of ELTROXIN NEW FORMULATION to prevent bone loss.
- If you are elderly and over 50 years.
- If you suffer from heart problems.
- If you suffer from diabetes (high blood sugar levels).
- If you are taking medicines for diabetes (high blood sugar levels).
- ELTROXIN NEW FORMULATON should not be used for the treatment of obesity or weight loss.
- If you suffer from myxoedema (severe hypothyroidism where you produce very low levels

of thyroid hormones) you may have an increased sensitivity to thyroid hormones. Your doctor will start you on a low dose of ELTROXIN NEW FORMULATION.

- If you suffer from a malabsorption syndrome (your small intestine cannot absorb nutrients from foods).

Children and adolescents

- If your child is using ELTROXIN NEW FORMULATION, as the dosages must be monitored by your child's doctor. Parents of children receiving ELTROXIN NEW FORMULATION should be aware that partial hair loss can occur during the first few months of therapy, but their hair may grow back.

Other medicines with ELTROXIN NEW FORMULATION

Always tell your healthcare professional if you are taking any other medicines. (This includes complementary or traditional medicines.)

Tell your doctor if you are taking any of the following medicines:

- *Anticoagulants* such as warfarin, blood thinning medicine.
- *Anticonvulsants such as phenytoin and carbamazepine:* medicine used to treat epilepsy.
- *Digoxin:* medicine used to treat heart problems.
- *Sympathomimetics:* examples are epinephrine (adrenaline), norepinephrine (noradrenaline) and dopamine.
- *Antidepressants such as amitriptyline, sertraline, imipramine:* medicines used to treat depression.
- *Colestyramine:* medicine used to lower blood cholesterol levels.
- *Antacids such as cimetidine and aluminium hydroxide:* medicine used to treat high acid levels in the stomach.
- *Proton pump inhibitors such as omeprazole:* medicine used to treat stomach ulcers, to

reduce the amount of acid produced by the stomach.

- *Bile acid sequestrants such as colestipol:* medicine used to lower blood cholesterol levels.
- *Anion/cation exchange resins such as sevelamer or kayexalate:* medicine used to treat high blood levels of potassium.
- *Sucralfate:* medicine used to treat stomach ulcers.
- *Calcium ,aluminium, magnesium and iron supplements:* medicines used as supplements.
- *Oestrogen:* medicine that imitates the effect of oestrogen in the body, used for hormone replacement therapy (HRT) and contraception (the 'pill').
- *Androgen containing medicines*: for male hormone replacement therapy.
- *Tamoxifen:* used to prevent some types of breast cancer.
- *Clofibrate:* medicine used to lower blood cholesterol levels.
- *Methadone:* medicine used as a cough suppressant.
- *5-fluorouracil:* medicine used to treat certain cancers.
- *Imatinib and sunitinib:* medicine used to treat certain types of leukaemia.
- *Anabolic steroids:* medicine that have similar effects as testosterone.
- *Corticosteroids such as hydrocortisone and prednisolone:* used to treat inflammation and allergic reactions.
- *Amiodarone:* medicine used to treat heart rhythm problems.
- *Antibacterials such as rifampicin and ciprofloxacin:* medicine used to treat bacterial infections.
- *Antidiabetics such as metformin, glipizide:* medicine used to treat high blood sugar levels.
- *Lithium:* medicine used to treat mood disorders.
- *Antivirals such as ritonavir:* medicine used to treat viral infections.
- *Beta-blockers such as propranolol, sotalol:* medicine used to treat high blood pressure

and heart problems.

- *General anaesthetics such as ketamine:* medicine used to make you sleep before an operation.
- *Antimalarials such as chloroquine:* medicine used to prevent malaria.
- *NSAIDs such as ibuprofen:* medicines used to treat pain and inflammation.
- *Soya-based infant formula:* used to feed infants.
- *Soy-containing compounds and high-fibre diets:* Soy-containing compounds and high-fibre diets can decrease the intestinal absorption of ELTROXIN NEW FORMULATION. Therefore, a dosage adjustment of thyroxine may be necessary, in particular at the beginning or after termination of nutrition with soy supplements.
- *Simvastatin and lovastatin:* medicine used to lower high cholesterol levels.
- *Furosemide:* a water pill that is used to treat fluid build-up in the body.
- *Iodide or oral contrast medicines:* medicines used to produce pictures of the bowel.
- *Propylthiouracil:* is an oral medication that is used to manage hyperthyroidism (when your thyroid gland produces too much of the hormone thyroxine).
- *Cardiac glycosides:* medicines used to treat congestive heart failure (stage of heart disease in which fluid builds up within the heart and causes it to pump inefficiently).
- Weight reducing medicine orlistat: used to treat obesity.

ELTROXIN NEW FORMULATION with food and drink

Swallow ELTROXIN NEW FORMULATION tablets whole with a glass of water, preferably at least half an hour before breakfast.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking this medicine.

Driving and using machines

ELTROXIN NEW FORMULATION has negligible influence on ability to drive and use machines.

It is not always possible to predict to what extent ELTROXIN NEW FORMULATION may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which ELTROXIN NEW FORMULATION affects them (see section 4).

3. How to take ELTROXIN NEW FORMULATION

Do not share medicines prescribed for you with any other person.

Always take ELTROXIN NEW FORMULATION exactly as your doctor or pharmacist has told you. Check with your doctor of pharmacist if you are not sure.

Your doctor will tell you how many ELTROXIN NEW FORMULATION 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 NEW FORMULATION.

ELTROXIN NEW FORMULATION should preferably be taken on an empty stomach in the morning at least half an hour before breakfast. The tablets are swallowed whole, without chewing, with some liquid. For **ELTROXIN NEW FORMULATION 25 µg** tablets the break line facilitates breaking to ensure uniform 12,5 µg dosing. Your healthcare provider will explain this to you if this dosing is applicable to you.

When applicable:

Tablets are to be disintegrated in some water (10 ml to 15 ml) and the resultant suspension, which must be prepared freshly as required, is to be administered with some more liquid (5 ml to 10 ml).

The usual dose of ELTROXIN NEW FORMULATION:

Adults

The recommended starting dose is 50 to 100 micrograms every day. Your doctor may increase the dose you take every 4 to 6 weeks by 50 micrograms until your thyroxine levels are correct. Your final daily dose may be up to 100 to 200 micrograms daily.

Patients over 50 years of age

The recommended starting dose will be no more than 50 micrograms every day. The dose may then be increased by 50 micrograms every 3 to 4 weeks until your thyroxine levels are correct. Your final daily dose will be between 50 to 200 micrograms daily.

Patients over 50 years of age with heart problems:

The recommended 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 to 200 micrograms daily.

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 is 10 to 15 micrograms/kg bodyweight per day 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 is 12,5 to 50 micrograms per day. The dose will then be increased every 2 to 4 weeks depending on how your child responds to the medicine.

Juvenile myxoedema:

This is a condition where children and adolescents develop severe hypothyroidism (produce very low levels of thyroid hormones). The starting dose is 25 micrograms every day. The dose will then be increased by 25 micrograms every 2 to 4 weeks until your child shows mild symptoms of hyperthyroidism (a condition where the thyroid gland produces too much thyroxine). The dose will then be reduced slightly.

If you have the impression that the effect of ELTROXIN NEW FORMULATION is too strong or too weak, tell your doctor or pharmacist.

If you take more ELTROXIN NEW FORMULATION than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take a dose of ELTROXIN NEW FORMULATION

Take your missed dose as soon as you remember, if within a few hours after missing a dose.

Do not take a double dose to make up for forgotten individual doses.

If you forget to give your child the dose, contact your doctor or pharmacist for further advice.

4. Possible side effects

ELTROXIN NEW FORMULATION can have side effects.

Not all side effects reported for ELTROXIN NEW FORMULATION are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking ELTROXIN NEW FORMULATION, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking ELTROXIN NEW FORMULATION and tell your doctor immediately or go to the casualty department at your nearest hospital:

- allergic reactions such as swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to ELTROXIN NEW FORMULATION. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- chest pain, very high temperature; fast heart rate,
- irregular heartbeat, low blood pressure, heart failure
- jaundice, confusion, fits, coma,
- heart attack (the symptoms include: chest pain or discomfort radiating to the jaw, neck or back; feeling weak; light-headed or faint; pain or discomfort in one or both arms or shoulders; shortness of breath),
- heart failure (the symptoms include shortness of breath with or without chest discomfort; fatigue and weakness, swelling in your legs, ankles and feet, irregular heartbeat, reduced ability to exercise, persistent cough or wheezing with white or pink blood-tinged sputum,

cold sweat, nausea or light-headedness),

- changes in the way your heart beats, for example, if you notice it beating faster,
- pseudotumour cerebri (means “false brain tumour”). Results in “benign intracranial hypertension” with headaches, blurry or double vision, blindness, nausea, vomiting, neck stiffness and trouble walking.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Side effects with an unknown frequency

- hypothyroidism (condition in which your thyroid produces too little thyroid hormone),
- hyperthyroidism (condition in which your thyroid produces too much thyroid hormone),
- unable to tolerate heat, flushing,
- weight increased,
- increased appetite,
- excitability, restlessness, confusion, agitation (irritation), insomnia (inability to sleep), anxiety, affect lability (exaggerated changes in mood), nervousness,
- headache, tremors (involuntary movement of body parts), cephalalgia (pain in head),
- increased blood pressure,
- stomach cramps, nausea, vomiting (being sick), diarrhoea,
- sweating, hair loss,
- muscle cramps, muscle weakness, decrease in bone density, in children, premature closure of the fibrous joints between the bones of the skull before the brain has stopped growing may occur with excessive dosage, growth in children may be slow or stop due to change in bone growth.
- menstrual irregularity (irregular menstrual periods), impaired fertility (problems conceiving), fatigue (tiredness), abnormal loss of weight (a lot of weight loss).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to:

SAHPRA: https://www.sahpra.org.za/health-products-vigilance/

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088/ +27 (0)11 239-6200

By reporting side effects, you can help provide more information on the safety of ELTROXIN NEW FORMULATION.

5. How to store ELTROXIN NEW FORMULATION

Store all medicines out of reach of children.

Store at or below 25 °C.

Protect from light.

Keep container tightly closed.

Keep in original packaging until required for use.

Do not store in a bathroom.

Do not use after the expiry date stated on the label.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What ELTROXIN NEW FORMULATION contains

The active substance is 25 µg, 50 µg, 75 µg, 88 µg, 100 µg, 112 µg, 125 µg, 137 µg, 150 µg, 175 µg, or 200 µg of levothyroxine sodium.

The other ingredients are colloidal silica dioxide, magnesium stearate, microcrystalline cellulose, pregelatinised maize starch, talc.

What ELTROXIN NEW FORMULATION looks like and contents of the pack

ELTROXIN NEW FORMULATION 25 µg tablets are round, white to off-white tablets debossed with '25' on the one side and a breakline on the other side.

For ELTROXIN NEW FORMULATION 25 µg tablets the break line facilitates breaking to ensure uniform 12,5 µg dosing.

ELTROXIN NEW FORMULATION 50 µg tablets are round, white to off-white flat, bevelled tablets debossed with '50' on the one side and 'L01' on the other side.

ELTROXIN NEW FORMULATION 75 µg tablets are round, white to off-white flat, bevelled tablets debossed with '75' on the one side and 'L02' on the other side.

ELTROXIN NEW FORMULATION 88 µg tablets are round, white to off-white flat, bevelled tablets debossed with '88' on the one side and 'L07' on the other side.

ELTROXIN NEW FORMULATION 100 µg tablets are round, white to off-white, flat, bevelled tablets debossed with '100' on the one side and 'L10' on the other side.

ELTROXIN NEW FORMULATION 112 µg tablets are round, white to off-white, flat, bevelled tablets debossed with '112' on the one side and 'L11' on the other side.

ELTROXIN NEW FORMULATION 125 µg tablets are round, white to off-white, flat, bevelled tablets debossed with ‘125’ on the one side and ‘L12’ on the other side.

ELTROXIN NEW FORMULATION 137 µg tablets are round, white to off-white, flat, bevelled tablets debossed with ‘137’ on the one side and ‘L15’ on the other side.

ELTROXIN NEW FORMULATION 150 µg tablets are round, white to off-white flat, bevelled tablets debossed with ‘150’ on the one side and ‘L17’ on the other side.

ELTROXIN NEW FORMULATION 175 µg tablets are round, white to off-white, flat, bevelled tablets debossed with ‘175’ on the one side and ‘L20’ on the other side.

ELTROXIN NEW FORMULATION 200 µg tablets are round, white to off-white, flat, bevelled tablets debossed with ‘200’ on the one side and ‘L21’ on the other side.

The tablets are packed in 40 ml white multilayer HDPE bottles, closed with white polypropylene child-resistant caps with foil heat induction seals, and with a 1 g white polypropylene canister containing oxygen absorber. The tablets are packed in pack sizes of 30’s, 50’s and 100’s.

Not all packs and pack sizes are necessarily marketed.

Holder of Certificate of Registration

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

Hotline: 0800 122 912

This leaflet was last revised in

30 June 2022

Registration number

ELTROXIN NEW FORMULATION 25 µg: 47/21.3/0614

ELTROXIN NEW FORMULATION 50 µg: 47/21.3/0615

ELTROXIN NEW FORMULATION 75 µg: 47/21.3/0616

ELTROXIN NEW FORMULATION 88 µg: 47/21.3/0617

ELTROXIN NEW FORMULATION 100 µg: 47/21.3/0618

ELTROXIN NEW FORMULATION 112 µg: 47/21.3/0619

ELTROXIN NEW FORMULATION125 µg: 47/21.3/0620

ELTROXIN NEW FORMULATION 137 µg: 47/21.3/0621

ELTROXIN NEW FORMULATION 150 µg: 47/21.3/0622

ELTROXIN NEW FORMULATION 175 µg: 47/21.3/0623

ELTROXIN NEW FORMULATION 200 µg: 47/21.3/0624

Access to the corresponding Professional Information

SAHPRA Repository of Professional Information and Patient Information Leaflets:

https://www.sahpra.org.za/pi-pil-repository/

Aspen Pharmacare:

E-mail: Medinfo@aspenpharma.com

Tel: 0800 118 088

Namibia: NS2	
ELTROXIN NEW FORMULATION 25 µg:	16/21.3/0096
ELTROXIN NEW FORMULATION 50 µg:	16/21.3/0097
ELTROXIN NEW FORMULATION 75 µg:	16/21.3/0098
ELTROXIN NEW FORMULATION 88 µg:	16/21.3/0099
ELTROXIN NEW FORMULATION 100 µg:	16/21.3/0100
ELTROXIN NEW FORMULATION 112 µg:	16/21.3/0101
ELTROXIN NEW FORMULATION 125 µg:	16/21.3/0102
ELTROXIN NEW FORMULATION 137 µg:	16/21.3/0103
ELTROXIN NEW FORMULATION 150 µg:	16/21.3/0104
ELTROXIN NEW FORMULATION 175 µg:	16/21.3/0105
ELTROXIN NEW FORMULATION 200 µg:	16/21.3/0106

Zimbabwe: P.P.10	
ELTROXIN NEW FORMULATION 50 µg:	2017/17.8.1/5414
ELTROXIN NEW FORMULATION 100 µg:	2017/17.8.1/5413

ZA_ELTRNFTAB_2206_00