

1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

PROPRIETARY NAME AND DOSAGE FORM

ELTROXIN NEW FORMULATION 25 µg

ELTROXIN NEW FORMULATION 50 µg

ELTROXIN NEW FORMULATION 75 µg

ELTROXIN NEW FORMULATION 88 µg

ELTROXIN NEW FORMULATION 100 µg

ELTROXIN NEW FORMULATION 112 µg

ELTROXIN NEW FORMULATION 125 µg

ELTROXIN NEW FORMULATION 137 µg

ELTROXIN NEW FORMULATION 150 µg

ELTROXIN NEW FORMULATION 175 µg

ELTROXIN NEW FORMULATION 200 µg

Tablet

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 or your pharmacist.
- 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 ELTROXIN NEW FORMULATION CONTAINS

The active substance is levothyroxine sodium.

Each tablet of ELTROXIN NEW FORMULATION contains 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 inactive ingredients include:

Colloidal silica dioxide, magnesium stearate, microcrystalline cellulose, pregelatinised maize starch, talc.

Sugar free.

WHAT ELTROXIN NEW FORMULATION IS USED FOR

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.

BEFORE YOU TAKE ELTROXIN NEW FORMULATION

Do not take ELTROXIN NEW FORMULATION if:

- You have had an allergic reaction before, to the active ingredient or any of the other ingredients in ELTROXIN NEW FORMULATION listed above.
- 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).
- 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).
- Treatment with ELTROXIN NEW FORMULATION must not be given to you if you have

acute myocardial infarction (heart attack), acute myocarditis (inflammation of the heart muscle), acute pancarditis (inflammation of the heart or its surroundings).

Take special care with 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 heart beat, 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 hormones T₃ and T₄), your doctor will give you the lowest possible dose of ELTROXIN NEW FORMULATION.
- 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.
- If you are elderly.
- 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).

Taking ELTROXIN NEW FORMULATION with food and drink

Swallow ELTROXIN NEW FORMULATION tablets whole with a glass of water, preferably before breakfast.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, please consult your healthcare provider for advice before taking ELTROXIN NEW FORMULATION.

Driving and using machinery

ELTROXIN NEW FORMULATION is not expected to influence your ability to drive. However, you should not drive, use machinery or perform any tasks that require concentration until you are certain that ELTROXIN NEW FORMULATION does not adversely affect your ability to do so safely (see POSSIBLE SIDE EFFECTS).

Taking other medicines with ELTROXIN NEW FORMULATION

Always tell your healthcare provider 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:

- *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.
- *Cholestyramine*: medicine used to lower blood cholesterol levels.

- *Antacids such as cimetidine:* medicine used to treat high acid levels.
- *Proton pump inhibitors such as omeprazole:* medicine used to treat ulcers.
- *Bile acid sequestrants such as colestipol:* medicine used to lower blood cholesterol levels.
- *Cation exchange resins such as kayexalate:* medicine used to treat high blood levels of potassium.
- *Sucralfate:* medicine used to treat stomach ulcers.
- *Calcium carbonate and ferrous sulphate:* medicines used as supplements.
- *Oestrogen:* medicine that imitates the effect of oestrogen in the body.
- *Tamoxifen:* used to prevent some types of breast cancer.
- *Oral contraceptives:* medicines used to prevent pregnancy.
- *Clofibrate:* medicine used to lower blood cholesterol levels.
- *Methadone:* medicine used as a cough suppressant.
- *5-fluorouracil:* medicine used to treat certain cancers.
- *Imatinib:* medicine used to treat certain types of leukaemia.
- *Anabolic steroids:* medicine that has similar effects as testosterone.
- *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:* medicine used to treat high blood pressure.
- *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.
- *Simvastatin*: medicine used to lower high cholesterol levels.

HOW TO TAKE ELTROXIN NEW FORMULATION

Take ELTROXIN NEW FORMULATION exactly as your doctor has prescribed. 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.

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).

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/missed 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.

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 healthcare provider 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,
- heart attack, heart failure (the symptoms include pain or discomfort in one or both arms, the back, neck, jaw or stomach; shortness of breath with or without chest discomfort; other signs such as breaking out in a cold sweat, nausea or lightheadedness),
- seizures or convulsions (fits),
- difficulty in breathing,
- changes in the way your heart beats, for example, if you notice it beating faster,
- pseudotumour cerebri (benign intracranial hypertension) which can lead to blindness.

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

Tell your doctor if you notice any of the following:

The following side effects have been reported less frequently:

- Hyperthyroidism (condition in which your thyroid produces too much thyroid hormone), hypothyroidism (condition in which your thyroid produces too little thyroid hormone).

The following side effects have been reported with a frequency unknown:

- Eosinophilia (an increase in the number of white blood cells in response to some medicines), fever, liver problems,
- unable to tolerate heat, flushing,
- increased appetite,
- excitability, restlessness, confusion, agitation (irritation), insomnia (inability to sleep),
- headache, tremors (involuntary movement of body parts), cephalagia (pain in head),
- increased blood pressure,
- stomach cramps, nausea , vomiting, 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,
- menstrual irregularity (irregular menstrual periods), impaired fertility (problems conceiving), fatigue (tiredness), excessive 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.

STORAGE AND DISPOSING OF ELTROXIN NEW FORMULATION

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).

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

PRESENTATION OF ELTROXIN NEW FORMULATION

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 bottles are packed into an outer cardboard carton in pack sizes of 30's, 50's and 100's.

Not all packs and pack sizes are necessarily marketed.

IDENTIFICATION OF ELTROXIN NEW FORMULATION

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

ELTROXIN NEW FORMULATION 50 µg: 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: 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: 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: 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: 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: 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: 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: 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: 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: Round, white to off-white, flat, bevelled tablets debossed with '200' on the one side and 'L21' on the other side.

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 FORMULATION 125 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

**NAME, BUSINESS ADDRESS AND TELEPHONE NUMBER OF THE HOLDER OF THE
CERTIFICATE OF REGISTRATION**

PHARMACARE LIMITED

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DATE OF PUBLICATION

Date of registration: 30 September 2016

Date of most recent amendment to the patient information leaflet as approved by the

Authority: 30 September 2016

Namibia: NS2

25 µg 16/21.3/0096

50 µg 16/21.3/0097

75 µg 16/21.3/0098

88 µg 16/21.3/0099

100 µg 16/21.3/0100

112 µg 16/21.3/0101

125 µg 16/21.3/0102

137 µg 16/21.3/0103

150 µg 16/21.3/0104

175 µg 16/21.3/0105

200 µg 16/21.3/0106

Zimbabwe: P.P.10

50 µg 2017/17.8.1/5414

100 µg 2017/17.8.1/5413

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