PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

MITHYRO 25/50/75/100 µg tablets

Levothyroxine sodium

Sugar free

Read all of this leaflet carefully before you take MITHYRO

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

What is in this leaflet

1. What MITHYRO is and what it is used for

2. What you need to know before you take MITHYRO

3. How to take MITHYRO

4. Possible side effects

5. How to store MITHYRO

6. Contents of the pack and other information

1.What MITHYRO is and what it is used for

The name of your medicine is MITHYRO. MITHYRO contains levothyroxine sodium. This belongs to a group of medicines called thyroid hormones.

MITHYRO is 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 MITHYRO

Do not take MITHYRO:

- If you are hypersensitive (allergic) to levothyroxine or any of the other ingredients of MITHYRO (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 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 MITHYRO 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).

Do not take MITHYRO if any of the above applies to you. If you are not sure, talk to your doctor, nurse or pharmacist before you take MITHYRO.

Warnings and Precautions

Special care should be taken with MITHYRO:

- If you have anginal pain (pain in the heart area), palpitations and cramps in the muscle when you

start your therapy with MITHYRO.

- Before starting with MITHYRO 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".
- 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 MITHYRO.
- If your child is using MITHYRO, as the dosages must be monitored by your child's doctor. Parents of children receiving MITHYRO 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).
- If you have a history of epilepsy.

Blood pressure will be regularly monitored when MITHYRO treatment is started in very low birth weight preterm neonates because rapid fall in blood pressure (known as circulatory collapse) may occur.

Other medicines and MITHYRO

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

This is because MITHYRO can affect the way some other medicines work. Also some medicines can affect the way that MITHYRO works.

Tell your doctor if you are taking:

- 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.
- 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.
- Orlistat: some medicine used to treat obesity.

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 healthcare provider for advice before taking MITHYRO.

Driving and using machines

MITHYRO 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 MITHYRO does

not adversely affect your ability to do so safely (see Possible side effects).

MITHYRO contains:

Less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take MITHYRO

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

Always take MITHYRO exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Your doctor will tell you how many MITHYRO 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 MITHYRO.

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 take more MITHYRO 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 and diarrhoea.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the

nearest hospital or poison centre.

If you forget to take MITHYRO

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.

4. Possible side effects

MITHYRO can have side effects.

Not all side effects reported for MITHYRO are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving this medicine, please consult your healthcare provider for advice.

If any of the following happens, stop taking MITHYRO and tell your doctor immediately or go to the casualty department at your nearest hospital.

- swelling of your 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 reaction to MITHYRO 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 unknown frequency:

- 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,
- menstrual irregularity (irregular menstrual periods), impaired fertility (problems conceiving), fatigue (tiredness), excessive loss of weight (a lot of weight loss),
- 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,
- intolerance to heat, temporary hair loss in children.

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 or pharmacist. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reactions Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of MITHYRO.

5. How to store MITHYRO

Store at or below 25 ºC.

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.

6. Contents of the pack and other information

What MITHYRO contains

The active substance is levothyroxine sodium hydrate. Each tablet contains levothyroxine sodium hydrate equivalent to levothyroxine sodium 0,025 mg, 0,050 mg, 0,075 mg or 0,100 mg respectively.

The other ingredients are cellulose powdered (Arbosel M80), cellulose microcrystalline (Type 101), magnesium stearate, silicon dioxide colloidal (anhydrous), sodium croscarmellose.

What MITHYRO looks like and contents of the pack

White tablets engraved with “25”, “50”, “75” or “100” on one side, depending on the respective strength.

MITHYRO tablets are packed in clear transparent PVC/TE/PVDC/Silver Aluminium blisters.

The blisters are further packaged in cardboard boxes. Each cardboard box (BT) contains 30 (2 blister x 15 tablets), 50 (2 blister x 25 tablets), 60 (4 blister x 15 tablets), or 100 tablets (4 blister x 25 tablets), presented in multiple blister strips of 15 or 25 tablets, along with a Patient Information Leaflet.

Holder of Certificate of Registration

Biotech Laboratories (Pty) Ltd

Ground Floor Block K West Central Park

400 16th Road, Randjespark

Halfway House

Midrand, 1685

Tel. nr: 011 848 3050

This leaflet was last revised in

31 October 2023

Registration /Application number

MITHYRO 25 µg – 52/21.3/0882

MITHYRO 50 µg – 52/21.3/0883

MITHYRO 75 µg – 52/21.3/0884

MITHYRO 100 µg – 52/21.3/0885