

Trinity Pharma (Pty) Ltd.

ROIDACE 25 / 50 / 75 / 100 / 200 µg Tablets

Reg. No: 56/21.3/0331; 56/21.3/0332; 56/21.3/0333; 56/21.3/0334; 56/21.3/0335

1.5.5.4 CLEAN AMENDED PATIENT INFORMATION LEAFLET

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S3**

ROIDACE 25, 50, 75, 100, 200

Levothyroxine sodium tablets

Sugar free

Read all of this leaflet carefully before you start taking ROIDACE

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or your pharmacist.
- ROIDACE 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 ROIDACE is and what it is used for
2. What you need to know before you take ROIDACE
3. How to take ROIDACE
4. Possible side effects
5. How to store ROIDACE
6. Contents of the pack and other information

1. What ROIDACE is and what it is used for

Thyroxine is a hormone which is produced naturally in the body by the thyroid gland.

ROIDACE is a synthetic version of this hormone and 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 ROIDACE

Do not take ROIDACE if:

- You have had an allergic reaction before, to levothyroxine or any of the other ingredients in ROIDACE (listed in section 6).
- 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 ROIDACE 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).

Warnings and precautions

Talk to your doctor or pharmacist before taking ROIDACE.

Special care should be taken with ROIDACE:

- If you have anginal pain (pain in the heart area), palpitations and cramps in the muscle when you start your therapy with ROIDACE.

- Before starting with ROIDACE make sure to tell your doctor if you have any heart disease, pituitary (gland in the brain) or other thyroid disease. Frequent thyroid checks should be done in these cases.
- If you are postmenopausal (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 ROIDACE).
- 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 ROIDACE.
- If your child is using ROIDACE, as the dosages must be monitored by your child’s doctor. Parents of children receiving ROIDACE 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 mellitus (high blood sugar levels) or diabetes insipidus (a condition in which the kidneys are unable to prevent the excretion of water).
- If you are taking medicines for diabetes mellitus (high blood sugar levels).
- ROIDACE 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 ROIDACE.
- If you suffer from a malabsorption syndrome (your small intestine cannot absorb nutrients from foods).

Other medicines and ROIDACE

Always tell your health care provider if you are taking any other medicine. (This includes all 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 and aluminium hydroxide*: medicine used to treat high acid levels in the stomach.
- *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 and indinavir*: 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 and proguanil*: medicine used to prevent malaria.
- *Some NSAIDs*: medicines used to treat pain and inflammation.
- *Soya-based infant formula*: used to feed infants.
- *Simvastatin*: medicine used to lower high cholesterol levels.

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- *High doses of furosemide* (water tablet or diuretic)
- *Weight reducing medicine orlistat*: used to treat obesity.

Pregnancy, breast-feeding and fertility

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

Patients should not drive, use machinery or perform any tasks that require concentration until they are certain that ROIDACE does not adversely affect your ability to do so safely.

3. How to take ROIDACE

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

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

Your doctor will tell you how many ROIDACE 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 ROIDACE.

Tablets should be swallowed with water preferably before breakfast or the first meal of the day.

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

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

If you take more ROIDACE 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.

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).

If you forget to take ROIDACE

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

4. Possible side effects

ROIDACE can have side effects.

Not all side effects reported for ROIDACE are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking ROIDACE, please consult your healthcare provider for advice.

If any of the following happens, stop taking ROIDACE 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 ROIDACE. 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:

Side effects with an unknown frequency:

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

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the “6.04 Adverse Drug Reaction 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 ROIDACE

5. How to store ROIDACE

Store at or below 25⁰ C

Store in the original package in order to protect from moisture.

KEEP OUT OF REACH OF CHILDREN.

6. Contents of the pack and other information

What ROIDACE contains

The active substance is levothyroxine sodium.

The other ingredients are:

- microcrystalline cellulose
- pregelatinized starch
- colloidal silicon dioxide
- talc
- magnesium stearate
- colourant

What ROIDACE looks like and contents of the pack

ROIDACE 25 µg – round orange colour tablets with score line on one side and “25” debossed on other side of the tablet.

ROIDACE 50 µg – round white colour tablets with score line on one side and “50” debossed on other side of the tablet.

ROIDACE 75 µg – round violet colour tablets with score line on one side and “75” debossed on other side of the tablet.

ROIDACE 100 µg – round yellow colour tablets with score line on one side and “100” debossed on other side of the tablet.

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ROIDACE 200 µg – round pink colour tablets with score line on one side and “200” debossed on other side of the tablet.

Tablets are packed in HDPE bottle pack comprises a white coloured bottle along with the white PP cap having induction sealing wad in packs of 30 or 60 tablets.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

Trinity Pharma (Pty) Ltd.

3 Gwen Lane, 4th Floor,

Sandton

2031

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