SCHEDULING STATUS

S3

LAMITOR 25 (Tablets)

LAMITOR 50 (Tablets)

LAMITOR 100 (Tablets)

LAMITOR 200 (Tablets)

Lamotrigine

Contains sugar (lactose monohydrate)

LAMITOR 25 contains 48,75 mg lactose monohydrate per tablet.

LAMITOR 50 contains 97,50 mg lactose monohydrate per tablet.

LAMITOR 100 contains 195,00 mg lactose monohydrate per tablet.

LAMITOR 200 contains 390,00 mg lactose monohydrate per tablet.

Read all of this leaflet carefully before you start taking LAMITOR

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

1. What LAMITOR is and what it is used for

LAMITOR belongs to a group of medicines called anticonvulsants / antiepileptics.

It is used to treat two conditions - epilepsy and bipolar disorder.

LAMITOR treats epilepsy by blocking the signals in the brain that trigger epileptic seizures (fits)

- For adults and children aged 12 years and over, LAMITOR can be used on its own or with other medicines, to treat epilepsy.
- For children aged between 2 and 12 years, LAMITOR can be used with other medicines, to treat those conditions. It can be used on its own to treat a type of epilepsy called tonic-clonic seizures.
- LAMITOR can also be used with other medicines to treat the seizures that occur with a condition called Lennox-Gastaut syndrome.

LAMITOR also treats bipolar disorder

- People with bipolar disorder (sometimes called manic depression) have extreme mood swings, with periods of mania (excitement or euphoria) alternating with periods of depression (deep sadness or despair). For adults aged 18 years and over, LAMITOR can be used on its own or with other medicines, to prevent the periods of depression that occur in bipolar disorder. It is not yet known how LAMITOR works in the brain to have this effect.

2. What you need to know before you take LAMITOR

LAMITOR should not be administered to you:

- If you are hypersensitive (allergic) to lamotrigine or any of the other ingredients of LAMITOR (listed in section 6).

Warnings and precautions

Special care should be taken with LAMITOR:

- If you have any heart problems. Tell your doctor if you suffer from a condition called Brugada syndrome. Brugada syndrome is a genetic disease that results in abnormal electrical activity within the heart. Electrocardiogram (ECG) abnormalities which may lead to dysrhythmias (abnormal heart rhythm) can be triggered by LAMITOR.
- If you develop skin reactions (rashes): That can be severe (see section 4).
  Children have a higher risk of developing severe skin reactions. These reactions normally appear in the first 8 weeks of treatment. If fever, swelling of the face or neck, or skin reaction appear in children

during the first 8 weeks, contact your doctor immediately and stop LAMITOR immediately. The risk of skin reactions increases if a high initial dose of LAMITOR is taken, or if LAMITOR is taken with valproate.

- Contact your health care provider right away if you experience any symptom of haemaphagocytic lymphohistiocytosis (HLH), a condition which causes inflammation throughout your body, while taking LAMITOR. HLH can occur within days to weeks after starting your treatment. Signs and symptoms of HLH include but are not limited to: fever, an enlarged liver (pain, tenderness, or unusual swelling over the liver area in the upper right stomach area), swollen lymph nodes, skin rashes, yellow skin or eyes, unusual bleeding, nervous system problems, including seizures, trouble walking, difficulty seeing, or other visual disturbances.

If you have thoughts of harming yourself or suicide.

- **LAMITOR is used to treat several conditions, including epilepsy and bipolar disorder. If you have bipolar disorder, you can sometimes have thoughts of harming yourself or committing suicide. If you have bipolar disorder, you may be more likely to have these thoughts: when you first start treatment, if you have previously had thoughts about harming yourself or about suicide, if you have distressing thoughts or experiences, or if you notice that you feel worse or develop new symptoms while you are taking LAMITOR. You may find it helpful to tell a family member, caregiver or close friend that you can become depressed or have significant changes in mood and ask them to read this leaflet. You might ask them to tell you, if they are worried about your depression and other changes in your behaviour. Contact your doctor immediately or go to the nearest hospital for help if at any time you have thoughts of harming or killing yourself.**
- If you are using hormonal contraceptives (such as "the pill") or plan to start using one. Talk to your doctor, who will discuss suitable methods of contraception with you as LAMITOR can also affect the way hormonal contraceptives work. If you are using a hormonal contraceptive and you notice any changes in your menstrual pattern, such as breakthrough bleeding or spotting between periods, tell your doctor. These may be signs that LAMITOR is affecting the way your contraceptive is working.
- If you have any blood hemoglobin problems.
- If you have any kidney problems. Your doctor will decide if LAMITOR is suitable for you, or whether your dose may need to be adjusted.

- If you are taking antiepileptic medicine. The addition of LAMITOR to existing treatment of epilepsy with other antiepileptic medicine may result in an increase in seizures. Contact your doctor if this should occur.
- If your epilepsy gets worse. Contact your doctor if you experience any worsening of your condition or develop other new symptoms at any time during your treatment.
- Withdrawal of LAMITOR may leads to the rebound seizures, unexplained rashes, fever, flu-like symptoms, drowsiness or worsening of seizure control may occur. patient should reduce the dosage over a period of two weeks.
- Symptoms may include fever, nausea, vomiting, headache, stiff neck and extreme sensitivity to bright light. Talk to your doctor.
- LAMITOR should not be given to people aged under 18 years to treat bipolar disorder. Medicines to treat depression and other mental health problems increase the risk of suicidal thoughts and behavior in children and adolescents aged under 18 years.

Other medicines and LAMITOR

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines).

Some medicines interact with LAMITOR or make it more likely that people will have side effects.

Tell your doctor or pharmacist if you are currently using:

- Carbamazepine, phenytoin, phenobarbitone, primidone, gabapentin, valproate, Oxcarbazepine, felbamate, levetiracetam, pregabalin, topiramate or zonisamide (used to treat epilepsy (seizures)).
- Rifampicin (used to treat tuberculosis (TB)).
- Oral contraceptives (e.g., ethinylestradiol or levonorgestrel, such as the Pill).
- Olanzapine or aripiprazole (used to treat mental health problems).
- Lithium (used to treat mood disorders).
- Amitriptyline, bupropion, fluoxetine, phenelzine, sertraline, trazodone (used to treat depression).
- Clonazepam (used to treat epilepsy (seizures) or panic disorders).
- Lorazepam (used to treat anxiety).
- Haloperidol, clozapine, risperidone (used to treat mental/mood disorders, e.g., schizophrenia).

- Bupropion, used to treat mental health problems or to stop smoking.
- A combination of lopinavir and ritonavir or atazanavir and ritonavir (used to treat human immunodeficiency virus (HIV) infection).

LAMITOR with food and drink

LAMITOR should be taken with or without food.

Pregnancy, breast feeding 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 health care provider for advice before taking this medicine.
- There is limited information on the safety of LAMITOR in pregnancy and lactation.

Driving and using machines

- LAMITOR can cause dizziness and double vision. It is not always possible to predict to what extent LAMITOR may interfere with the daily activities of a patient. Don't drive or use machines unless you are sure you're not affected.
- If you have epilepsy, talk to your doctor about driving and using machines.

Important information about some of the ingredients of LAMITOR

LAMITOR tablets contains sugar called lactose. If you have an intolerance to lactose or any other sugars you should check with your doctor or pharmacist.

3. How to take LAMITOR

Do no share medicines prescribed for you with any other person.

Always take LAMITOR exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

It may take a while to find the best dose of LAMITOR for you. The dose you take will depend on:

- your age
- whether you are taking LAMITOR with other medicines
- whether you have problems with your kidneys or liver.

Never take more LAMITOR than your doctor tells you to.

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

If you take more LAMITOR than you should

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

If you forget to take LAMITOR

Don't take extra tablets to make up for a missed dose.

Just take your next dose at the usual time.

In case you forget to take multiple doses of LAMITOR, ask your doctor for advice on how to start taking it again. It's important that you do this.

If you stop taking LAMITOR

LAMITOR must be taken for as long as your doctor recommends.

Don't stop unless your doctor advises you to.

A sudden withdrawal may make your epilepsy come back, make your seizures worse, or change your behaviour. Should your doctor advise you to stop, your dose will be gradually reduced.

Do not restart LAMITOR without consulting your doctor

4. Possible side effects

LAMITOR can have side effects.

Not all side effects reported for LAMITOR are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking LAMITOR, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking LAMITOR and tell your doctor, pharmacist or healthcare provider 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
- fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to LAMITOR. 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:

- Haemophagocytic lymphohistiocytosis (HLH), a condition which causes inflammation throughout your body (fever, an enlarged liver (pain, tenderness, or unusual swelling over the liver area in the upper right stomach area), swollen lymph nodes, skin rashes, yellow skin or eyes, unusual bleeding, nervous system problems, including seizures, trouble walking, difficulty seeing, or other visual disturbances)
- Skin rashes or redness, which may develop into severe skin reactions including widespread rash with blisters and peeling skin, particularly occurring around the mouth, nose, eyes and genitals (Stevens-Johnson syndrome), extensive peeling of the skin (more than 30 % of the body surface – toxic epidermal necrolysis) or extended rashes with the liver, blood and other body organs involvement (DRESS)
- Tubulointerstitial nephritis (passing more or less urine than is normal for you, blood in your urine, dark urine, nausea, vomiting)
- Seizures happening more often if you already have epilepsy
- Chest pain
- A high temperature (fever).

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

Tell your doctor, pharmacist or healthcare provider if you notice any of the following:

Frequent side effects

- Aggression (feeling of anger) or irritability (the state of being irritable)

- Headache.
- Difficulty in sleeping (insomnia)
- Feeling dizzy (a sensation of spinning around and losing one's balance)
- Shaking or tremors
- Feeling sleepy or drowsy
- Feeling agitated (nervous)
- Feeling sick (nausea)
- A sensation of whirling and loss of balance (vertigo)
- Uncontrollable eye movements (nystagmus)
- Vomiting (eject matter from the stomach through the mouth)
- Diarrhoea (loose and watery stool during a bowel movement)
- Dry mouth
- Skin rash
- Pus formation on the wounds
- Pain in your back or joints, or elsewhere.
- Protein in the urine
- Urinary infections
- Feeling tired
- Back pains

Less Frequent side effects

- Changes which may show up in blood tests - including reduced numbers of red blood cells (anaemia), reduced numbers of white blood cells (leucopenia, neutropenia, agranulocytosis), reduced numbers of platelets (thrombocytopenia), reduced numbers of all these types of cell (pancytopenia) and a disorder of the bone marrow called aplastic anaemia.
- Haemophagocytic lymphohistiocytosis (HLH) (see section 2)
- A group of symptoms together including: fever, nausea, vomiting, headache, stiff neck and extreme sensitivity to bright light. This may be caused by an inflammation of the membranes that cover

the brain and spinal cord (meningitis). These symptoms usually disappear once treatment is stopped however if the symptoms continue or get worse contact your doctor

- Confusion
- Hallucinations ('seeing' or 'hearing' things that aren't really there)
- Clumsiness and lack of co-ordination (ataxia)
- Uncontrollable body movements (tics), uncontrollable muscle spasms affecting the eyes, head and torso (choreoathetosis) or other unusual body movements such as jerking, shaking or stiffness.
- In people who already have epilepsy, seizures happening more often.
- Double vision or blurred vision
- Itchy eyes, with discharge and crusty eyelids (conjunctivitis).
- Swelling around the face (oedema) or swollen glands in the neck,
- Constipation, heartburn (a form of indigestion felt as a burning sensation in the chest, caused by acid regurgitation into the oesophagus).
- Unusual hair loss or thinning (alopecia)
- Skin rash or sunburn after exposure to sun or artificial light (photosensitivity)
- A life-threatening skin reaction (Stevens-Johnson syndrome): (see also the information at the beginning of Section 4)
- Life-threatening skin reaction (toxic epidermal necrolysis): (see section 4)
- Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS): (see section 4)
- High temperature (fever): (see section 4)
- Changes in liver function, which will show up in blood tests, or liver failure: (see section 4)
- Feeling 'wobbly' or unsteady when you move.
- In people who already have Parkinson's disease, worsening of the symptoms.
- Lupus-like reaction (symptoms may include: back or joint pain which sometimes may be accompanied by fever and/or general ill health).

Frequency unknown side effects

- Armpit or groin (lymphadenopathy): (see section 4)

- Lower immunity because of lower levels of antibodies called immunoglobulins in the blood which help protect against infection.
- Serious disorder of blood clotting, which can cause unexpected bleeding or bruising (disseminated intravascular coagulation).
- Nightmares
- There have been reports of bone disorders including osteopenia and osteoporosis (thinning of the bone) and fractures. Check with your doctor or pharmacist if you are on long-term anti-epileptic medication, have a history of osteoporosis or take steroids.
- Inflammation of the kidney (tubulointerstitial nephritis), or inflammation of both the kidney and the eye (tubulointerstitial nephritis and uveitis syndrome).
- Temporary cessation of breathing (apnoea), runny nose (rhinitis)
- Inflammation of the oesophagus (food tube)
- Muscle injury
- Multi-organ failure (altered organ function, involving two or more organ systems).

Reporting of side effects

If you get 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 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 this medicine.

5. How to store LAMITOR

Keep this medicine out of the sight and reach of children.

Do not store above 25 °C

Do not store in a bathroom, near the kitchen sink, or in other damp places. Heat or moisture may cause the medicine to break down.

Do not use this medicine after the expiry date which refers to the last day of that month.

Do not dispose medicines in drains or sewerage systems (e.g., toilets). Return all unused and expired medicines to your pharmacist.

6. Contents of the pack and other information

What LAMITOR contains

The active substance is lamotrigine

The other ingredients are -

Cellulose microcrystalline

Ferric Oxide Yellow

Lactose Monohydrate

Magnesium Stearate

Polyvinyl Pyrrolidone

Purified Talc

Purified Water

Silica colloidal anhydrous

Sodium Starch Glycolate.

What LAMITOR looks like and contents of the pack

LAMITOR 25: Light yellow coloured, round, flat uncoated tablets, with bisecting line on one side.

LAMITOR 50: Light yellow coloured, round, flat uncoated tablets, with bisecting line on one side.

LAMITOR 100: Light yellow coloured, round, flat uncoated tablets, with bisecting line on one side.

LAMITOR 200: Light yellow coloured, round, flat uncoated tablets, with bisecting line on one side.

LAMITOR 25: PVC/Aluminium blister pack of 60 tablets

LAMITOR 50: PVC/Aluminium blister pack of 60 tablets

LAMITOR 100: PVC/Aluminium blister pack of 60 tablets

LAMITOR 200: PVC/Aluminium blister pack of 60 tablets

Holder of Certificate of Registration

Dr Reddy's Laboratories (Pty) Ltd.

Block B, 204 Rivonia Road

Morningside

Sandton

2057

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LAMITOR 25: 37/2.5/0051

LAMITOR 50: 37/2.5/0052

LAMITOR 100: 37/2.5/0053

LAMITOR 200: 41/2.5/0375

Access to the corresponding Professional Information

For any information about this medicine, please contact the local representative of the Holder of Certificate of Registration:

Dr. Reddy's Laboratories (Pty) Ltd. Tel: +27 11 324 2100

Detailed information on this medicine is available on the Dr. Reddy's Laboratories website:

http://www.drreddys.co.za