PATIENT INFORMATION LEAFLET

LAMILEPSY RANGE

SCHEDULING STATUS

S3

LAMILEPSY 25 mg tablets

LAMILEPSY 50 mg tablets

LAMILEPSY 100 mg tablets

LAMILEPSY 200 mg tablets

Lamotrigine

LAMILEPSY 25 mg contains sugar (lactose monohydrate 24,70 mg)

LAMILEPSY 50 mg contains sugar (lactose monohydrate 49,40 mg)

LAMILEPSY 100 mg contains sugar (lactose monohydrate 98,80 mg)

LAMILEPSY 200 mg contains sugar (lactose monohydrate 197,60 mg)

Read all of this leaflet carefully before you start taking LAMILEPSY

- 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.
- LAMILEPSY 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 LAMILEPSY is and what it is used for

LAMILEPSY belongs to a group of medicines called anti-epileptics. LAMILEPSY treats epilepsy by blocking the signals in the brain that trigger epileptic seizures (fits).

- LAMILEPSY tablets are used to treat various types of epilepsy, including seizures associated with Lennox-Gastaut syndrome.
- LAMILEPSY tablets are used to treat bipolar disorder (manic depression), specifically the periods of depression that occur in bipolar disorder.

2. What you need to know before you take LAMILEPSY

Do not take LAMILEPSY:

- if you are hypersensitive (allergic) to lamotrigine, or to any of the ingredients of LAMILEPSY (see section 6).

Warnings and precautions

Take special care with LAMILEPSY:

- tell your doctor immediately if you develop a skin rash or any other signs or symptoms of hypersensitivity e.g. fever, swollen face, flu-like symptoms, pain, tenderness or unusual swelling over the liver area in the upper belly, swollen lymph nodes, yellow skin or eyes, unusual bleeding, or nervous system conditions such as seizures, trouble walking, difficulty seeing or other visual disturbances. Your doctor will use a physical examination,

blood tests and other evaluations to determine if you have developed hemophagocytic lymphohistiocytosis (HLH), a very serious immune system reaction to LAMILEPSY

- tell your doctor if you have heart problems, including irregular or abnormal heartbeats and Brugada Syndrome, as LAMILEPSY may lead to a fast heartbeat. This may be worsened if you are using LAMILEPSY together with medicines that block sodium channels in the heart
- seizures in some types of epilepsy may occasionally become worse or happen more often while you are taking LAMILEPSY. Some patients may experience severe seizures, which may cause serious health problems. If your seizures happen more often or if you experience a severe seizure while you are taking this medicine, contact a doctor as soon as possible
- a small number of people taking LAMILEPSY get an allergic reaction (generally within the first 8 weeks of starting treatment) or potentially serious skin reaction, which may develop into more serious problems if they are not treated, especially in children and in patients also taking valproate. These can include Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN) and drug reaction with eosinophilia and systemic symptoms (DRESS). You need to know the symptoms to look out for while you are taking LAMILEPSY
- if you have thoughts of harming yourself or suicide. There have been reports of suicidal behaviour (including suicidal thoughts and suicide attempts) in patients being treated with anti-epileptic medicines such as LAMILEPSY If at any time you have these thoughts, contact your doctor immediately
- if you are taking LAMILEPSY to prevent extreme mood swings, you may

not experience the full effect for several weeks. Occasionally, the symptoms of depression or bipolar disorder may include thoughts of harming yourself or committing suicide. This risk may be higher:

- when starting treatment or changing dose
- for patients who currently have (or have previously had) thoughts of harming themselves or committing suicide
- for young adults.

If you have distressing thoughts or experiences, or if you notice that you feel worse or develop new symptoms while you're taking this medicine, contact a doctor immediately or go to the nearest hospital for help.

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 or other changes in your behaviour.

- tell your doctor if you are starting or stopping hormonal contraceptives, such as the pill
- do not stop taking your tablets abruptly
- if you are taking medicines called folate antagonists such as aminopterin, methotrexate, pyrimethamine, trimethoprim and triamterene (used to treat some types of cancer and inflammatory conditions, such as rheumatoid arthritis)
- if you have kidney failure
- if you are taking any other medicines containing lamotrigine.

LAMILEPSY should not be given to children and adolescents aged under 18

years for the treatment of bipolar disorder. Medicines to treat depression and other mental health problems increase the risk of suicidal thoughts and behaviour in children and adolescents aged under 18 years.

Other medicines and LAMILEPSY

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

- medicines that block sodium channels in the heart such as quinidine, procainamide, tocainide amiodarone and flecainide (used to treat irregular heartbeats), carbamazepine, oxcarbazepine and phenytoin (used to treat seizures)
- other anti-epileptic medicines (phenytoin, carbamazepine, phenobarbitone and primidone)
- antibiotics (rifampicin)
- HIV treatment (lopinavir/ritonavir and atazanavir/ritonavir)
- valproic acid, used in the treatment of epilepsy (fits)
- oral contraceptive tablets, such as the pill (for example, ethinylestradiol and levonorgestrel)
- lithium (used to treat mood disorders)
- aripiprazole, used to treat mental health problems
- folate antagonists (such as aminopterin, methotrexate (amethopterin), pyrimethamine, trimethoprim and triamterene) used to treat some types of cancer and inflammatory conditions, such as rheumatoid arthritis
- paracetamol (for the treatment of pain)
- metformin (used in the treatment of diabetes), gabapentin (prevent and

control partial seizures) and varenicline (to help people stop smoking).

Laboratory tests: LAMILEPSY may interfere with some laboratory tests to detect medicines. If you require a laboratory test, tell your doctor or hospital that you are taking LAMILEPSY.

LAMILEPSY with food drink, and alcohol

Avoid the use of alcohol. Food does not affect LAMILEPSY's function.

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 using this medicine.

Safety in pregnancy and breastfeeding has not been established, therefore do not take LAMILEPSY if you are pregnant or breastfeeding.

There may be an increased risk of babies developing a cleft lip or cleft palate if LAMILEPSY is taken during the first few months of pregnancy.

The active ingredient in LAMILEPSY passes into breast milk and may affect your baby.

Driving and using machines

LAMILEPSY may make you dizzy and cause double vision. You should wait and see how LAMILEPSY affects you before attempting to drive or operate machines.

It is not always possible to predict to what extent LAMILEPSY 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 LAMILEPSY affects them.

LAMILEPSY contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially ‘sodium-free’.

3. How to take/use LAMILEPSY

Do not share medicines prescribed for you with any other person. Always use LAMILEPSY exactly as your doctor has told you. You should check with your doctor or pharmacist if you are unsure.

Your doctor will prescribe a low dose to start and gradually increase the dose until you reach a dose that works for you. Either chew, or swallow the tablets whole, with a little water.

Your doctor will tell you how long your treatment with LAMILEPSY will last. Do not stop treatment early because your symptoms may return.

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

If you take/use more LAMILEPSY 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 take too much LAMILEPSY you may be more likely to have serious side effects which may be fatal.

Symptoms of overdose may include:

- rapid, involuntary eye movement, loss of full control of bodily movements, loss of awareness, violent muscle contractions, impaired or loss of consciousness, fits (convulsions) or coma.

If you forget to take/use LAMILEPSY

Do not take a double dose to make up for forgotten individual doses. Continue to take the next tablet at the usual time. If you have trouble remembering when to use your medicine, ask your pharmacist for some hints.

If you stop taking/using LAMILEPSY

LAMILEPSY tablets must be taken for as long as your doctor recommends. Don’t stop unless your doctor advises you to.

4. Possible side effects

LAMILEPSY can have side effects.

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

If any of the following happens, stop using LAMILEPSY and tell your doctor

immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching
- fainting
- symptoms of hemophagocytic lymphohistiocytosis (HLH), an immune system reaction, characterised by fever, multi organ failure, pain, tenderness or unusual swelling over the liver area in the upper belly, swollen lymph nodes, skin rash, yellow skin or eyes, unusual bleeding or, nervous system conditions such as seizures, trouble walking, difficulty seeing, or other visual disturbances.

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

- if you have a known heart problem and you experience a fast, slow, or pounding heartbeat, feel your heart skip a beat, have shortness of breath, chest pain or feel lightheaded
- blood disorders (characterised by pale skin colour, weakness, frequent infections, generally feel unwell)
- multiple bleeding sites, bruises, fever
- pancytopenia (characterised by infections, bleeding problems, rapid heart rate, pale skin)

- septic shock (characterised by high or very low temperature, chills, dizziness when standing, palpitations)
- increased seizures (fits)
- non-bacterial meningitis (characterised by fever, chills, headaches, vomiting, loss of appetite)
- liver problems (characterised by nausea, loss of appetite, fatigue, diarrhoea, yellowing of the skin or eyes)
- Stevens-Johnson syndrome (serious illness with blistering of the skin, mouth, eyes and genitals, skin rash)
- severe skin reaction, starting with a painful red area, developing into large blisters then peeling of layers of skin (toxic epidermal necrolysis)
- extended rashes with the liver, blood and other body organs involvement (DRESS)
- hallucinations (seeing or hearing things that aren't really there)
- worsening of Parkinson's disease.

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- aggression, irritability
- headache, inability to sleep, dizziness, drowsiness, tremor, agitation, coordination problems, vertigo (spinning sensation)
- paraesthesia (prickling, tingling, itching, burning or coldness of skin)
- vision problems including blurred or double vision
- feeling sick (nausea) or being sick (vomiting)
- severe skin rashes, skin rash

- joint pain, muscle pain and weakness
- weight loss, tiredness, back pain, dryness of mouth.

Less frequent side effects:

- lymph node disorder (you may experience fever or night sweats, more tiredness than usual, a painful, warm or red lump under your skin), immune system problems, painless swelling under the skin
- tics (spasms in the face), confusion
- ataxia (lack of control of bodily movements)
- rapid involuntary eye movements
- rhinitis (stuffy, runny nose, sneezing), heartburn, temporary failure to breathe when sleeping
- constipation, diarrhoea, indigestion
- abnormal physical weakness or lack of energy, pain, joint pain sometimes with swelling, tired feeling
- fever, general discomfort/ illness (malaise), extreme sensitivity to light, flu-like symptoms.

The following side effects have been reported but the frequency for them to occur is not known:

- nightmares
- anxiety, depression, forgetfulness, agitation, slurred speech, agitation, unsteadiness, movement disorders, involuntary movements throughout the body

- pink-eye (conjunctivitis)
- dry cough
- maculopapular skin rash (a flat or raised red bump on the skin), hair loss
- bone fractures, delayed growth or development (occurs with long-term treatment)
- inflammation of the kidney (tubulointerstitial nephritis), which may occur in association with inflammation of the eye (uveitis).

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 any side effects to SAHPRA via the online service for adverse drug reaction reporting by following the link: https://www.sahpra.org.za/Publications/Index/8 or http://www.sahpra.org.za/document/adverse-drug-reactions-and-quality-problem-reporting-form/. By reporting side effects, you can help provide more information on the safety of LAMILEPSY. You can also send an email directly to the company, pharmacovigilance@pharmadynamics.co.za, to ensure safety of the product.

5. How to store LAMILEPSY

Store all medicines out of reach of children.

Store at or below 25 ºC in original pack.

Protect against moisture and light.

Do not remove the blisters from the outer carton until required for use.

Do not use after the expiry date stated on the carton. 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 LAMILEPSY contains:

The active ingredient is lamotrigine. Each tablet contains either 25, 50, 100 or 200 mg lamotrigine.

The other ingredients are:

Iron oxide yellow E172, lactose monohydrate, magnesium stearate, microcrystalline cellulose, povidone, sodium starch glycolate.

What LAMILEPSY looks like and contents of the pack

LAMILEPSY 25 mg: Beige, round, flat tablets, embossed “MC” with diameter 6,0 mm.

LAMILEPSY 50 mg: Beige, round, flat, scored tablets with diameter 8,0 mm.

LAMILEPSY 100 mg: Beige, round, flat, scored tablets with diameter 9,5 mm.

LAMILEPSY 200 mg: Beige, round, flat, scored tablets with diameter 12,7 mm.

LAMILEPSY 25 mg, 50 mg, 100 mg and 200 mg are packed in PVC/Aluminium blister packs of 60 tablets in an outer carton.

Holder of Certificate of Registration

Pharma Dynamics (Pty) Ltd

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PATIENT INFORMATION LEAFLET

LAMILEPSY RANGE

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LAMILEPSY 25 mg: A40/2.5/0173

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LAMILEPSY 100 mg: A40/2.5/0166

LAMILEPSY 200 mg: A40/2.5/0167

NAMIBIA:

LAMILEPSY 25 mg: NAM NS2 08/2.5/0177

LAMILEPSY 50 mg: NAM NS2 08/2.5/0178

LAMILEPSY 100 mg: NAM NS2 08/2.5/0179

LAMILEPSY 200 mg: NAM NS2 08/2.5/0180