PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

LAMICTIN 25, 50, 100 and 200 Tablets

Each LAMICTIN 25 tablet contains: 25 mg lamotrigine.

Contains sugar (lactose monohydrate, 24,7 mg/tablet).

Each LAMICTIN 50 tablet contains: 50 mg lamotrigine.

Contains sugar (lactose monohydrate, 49,4 mg/tablet).

Each LAMICTIN 100 tablet contains:100 mg lamotrigine.

Contains sugar (lactose monohydrate, 98,8 mg/tablet).

Each LAMICTIN 200 tablet contains:200 mg lamotrigine.

Contains sugar (lactose monohydrate, 114,7 mg/tablet).

LAMICTIN P2, P5, P25 and P50 Dispersible Tablets

Each LAMICTIN P2 dispersible tablet contains: 2 mg lamotrigine

Contains sweetener (saccharin sodium (0,4 mg/tablet))

Each LAMICTIN P5 dispersible tablet contains: 5 mg lamotrigine

Contains sweetener (saccharin sodium (1,0 mg/tablet))

Each LAMICTIN P25 dispersible tablet contains: 25 mg lamotrigine

Contains sweetener (saccharin sodium (0,625 mg/tablet))

Each LAMICTIN P50 dispersible tablet contains: 50 mg lamotrigine

Contains sweetener (saccharin sodium (1,25 mg/tablet))

Read all of this leaflet carefully before you start taking LAMICTIN.

- Keep this leaflet. You may need to read it again.

- If you have further questions, please ask your doctor, pharmacist, nurse or healthcare professional
- LAMICTIN 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 LAMICTIN is and what it is used for
2. What you need to know before you take LAMICTIN
3. How to take LAMICTIN
4. Possible side effects
5. How to store LAMICTIN
6. Contents of the pack and other information.

1. What LAMICTIN is and what it is used for:

LAMICTIN belongs to a group of medicines called anti-epileptics.

LAMICTIN can be used in two different conditions: **epilepsy**

and **bipolar disorder** (manic depression).

Epilepsy:

LAMICTIN is used to treat various types of epilepsy in adults and children.

LAMICTIN may be used on its own to treat adults and children over 12 years.

LAMICTIN can also be used in combination with other anti-epileptic medicines in both adults and children aged 2 years and over. Sometimes other anti-epileptic medicines may be stopped after LAMICTIN has been started.

Bipolar disorder:

LAMICTIN is used to prevent extreme mood swings - depression (sadness/despair) or mania (excitement/euphoria) - in adult patients with bipolar disorder (manic depression). LAMICTIN is useful for helping prevent depressive moods.

LAMICTIN should not be used to treat bipolar disorder in children (under 18 years of age).

2. What you need to know before you take LAMICTIN:

Do not take LAMICTIN:

- if you are hypersensitive (allergic) to lamotrigine or any of the other ingredients of LAMICTIN Tablets and/or LAMICTIN Dispersible Tablets.

Warnings and precautions:

Tell your doctor or healthcare provider before being given the medicine.

Take special care with LAMICTIN:

- if you have ever developed a rash after taking LAMICTIN or other medicines for bipolar disorder or epilepsy
- if you have ever developed meningitis after taking LAMICTIN (read the description of these symptoms in section 4 of this leaflet: Other side effects)
- if you are already taking medicine that contains lamotrigine
- if you have any liver or kidney problems.
- if you have a condition called Brugada syndrome (a genetic disease that affects the heart)
- if you are pregnant or want to become pregnant.

If any of these apply to you, **tell your doctor,** who may decide to lower the dose, or that LAMICTIN is not suitable for you.

Conditions you need to look out for:

- ***Important information about potentially serious skin reactions:***

  Some people taking LAMICTIN get an allergic reaction or potentially serious skin reaction, which may develop into more serious problems such as organ failure if they are not treated. You need to know the symptoms to look out for while you are taking LAMICTIN

  ► **Read the descriptions on these symptoms** in section 4 of this leaflet under 'Potentially serious skin reaction'.

- ***Serious immune system condition (haemophagocytic lymphosistiocytosis or HLH):***

  A serious immune system condition, in which the part of the body that fights disease is overactive. Although it has been reported very rarely in people taking LAMICTIN, it can be life-threatening. If you have any of the associated symptoms, immediately report them to your doctor.

  ► **Read the descriptions on these symptoms** in section 4 of this leaflet under 'Serious immune system condition'.

- ***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 LAMICTIN. If at any time you have these thoughts, **contact your doctor immediately.**

  If you are taking LAMICTIN 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 LAMICTIN:

► **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.

LAMICTIN 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 behaviour in children and adolescents aged under 18 years.

- ***If you are taking LAMICTIN for epilepsy:*** The seizures in some types of epilepsy may occasionally become worse or happen more often while you are taking LAMICTIN. 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 LAMICTIN:

  ► **Contact a doctor as soon as possible.**

Other medicines and LAMICTIN:

Always tell your healthcare professional if you are taking any other medicine. (This includes complimentary and traditional medicines.)

Some medicines may affect how LAMICTIN works or make it more likely that people will have side effects. LAMICTIN can also affect how some other medicines work. These include:

- phenytoin, primidone or phenobarbitone, used to treat epilepsy
- risperidone and aripiprazole, used to treat mental health problems
- valproate and carbamazepine, used to treat both epilepsy and mental health problems
- rifampicin, which is an antibiotic used in the treatment of tuberculosis
- medicines used to treat Human Immunodeficiency Virus (HIV) infection (a combination of lopinavir and ritonavir or atazanavir and ritonavir)

- hormonal contraceptives and hormone replacement therapy (HRT) *(see below)*.

Tell your doctor or pharmacist if you are taking any of these, or if you start or stop taking any. Your doctor may decide to adjust your dose.

Hormonal contraceptive pills can affect the way LAMICTIN works:

Your doctor may recommend that you take a particular type of hormonal contraceptive pill, or use another method of contraception, such as condoms, a cap or coil. If you are taking a hormonal contraceptive pill, or if you plan to start or stop taking one:

► **Talk to your doctor,** who will discuss suitable methods of contraception with you.

LAMICTIN may also affect the way hormonal contraceptives work:

If you are taking a hormonal contraceptive pill, LAMICTIN may affect how well this works. If you notice any changes in your menstrual pattern, such as breakthrough bleeding or spotting between periods:

► **Tell your doctor**. These may be signs that LAMICTIN is affecting how well your contraceptive pill is working.

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

Pregnancy and 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 professional for advice before taking LAMICTIN.

- Talk to your doctor if you are pregnant, if you might be pregnant, or if you are planning to become pregnant. There may be an increased risk of babies developing a cleft lip or cleft palate if LAMICTIN is taken during the first few months of pregnancy.
- Talk to your doctor if you are breastfeeding or planning to breastfeed. The active ingredient in LAMICTIN passes into breast milk and may affect your baby.

Driving and using machines:

- LAMICTIN can cause drowsiness, dizziness and double vision.
- Don't drive or operate machines unless you are sure you are not affected.
- If you have epilepsy, talk to your doctor about driving and using machines.

LAMICTIN contains lactose:

LAMICTIN tablets contain lactose. Patients with the rare hereditary conditions of lactose/fructose or galactose tolerance should not take LAMICTIN. Lactose may have an effect on the control of your blood sugar if you have diabetes mellitus.

3. How to take LAMICTIN:

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

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

Your doctor will decide on a dose that is suitable for you.

Your doctor will tell you how long your treatment with LAMICTIN will last. Do not stop treatment early. If you have the impression that the effect of LAMICTIN is too strong or too weak, tell your doctor or pharmacist.

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

- your age and weight
- whether you are taking LAMICTIN with other medications
- whether you have any kidney or liver problems.

Your doctor will prescribe a low dose to start, and gradually increase the dose over a few weeks until you reach a dose that works for you (the *effective dose*). **Never take more LAMICTIN than your doctor tells you to.**

How to take/use LAMICTIN tablets:

Swallow LAMICTIN tablets with a little water. Do not chew.

Your doctor may also advise you to start or stop taking other medicines, depending on what condition you are being treated for and the way you respond to treatment.

How to take/use LAMICTIN dispersible tablets:

- A tablet can be swallowed whole with a little water, chewed or can be dissolved in water to make a liquid medicine.
- If the tablet is chewed, you may need to drink a little water at the same time. This is because the tablet needs water when dissolving in the mouth. Then sip a little more water to make sure all of the medicine has been taken.
- To make a liquid medicine, add the tablet to a little water, in a glass. Use enough water to cover the whole tablet. Leave for about a minute, until the tablet has fully dissolved, and then drink all of the liquid. Add a little more water to the glass and drink this to make sure all of the medicine has been taken.
- Do not try to take half a tablet or give half a tablet to your child.

If you take more LAMICTIN than you should:

If you take too much LAMICTIN you may be more likely to have serious side effects which may be fatal. Possible side effects if you take too much LAMICTIN include:

- rapid, uncontrollable eye movements (*nystagmus*)
- clumsiness and lack of co-ordination, affecting your balance (*ataxia*)
- impaired or loss of consciousness, fits (*convulsions*) or coma.

► **If you take too much LAMICTIN contact your doctor or your nearest hospital emergency department immediately**. If possible, show them the LAMICTIN pack.

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 a dose of LAMICTIN:

If you forget to take a single dose, take it as soon as you remember unless your next dose is due in less than 4 hours, in which case skip the missed dose and carry on with your next dose at its normal time. Do not take two doses at the same time.

If you forget to take several doses of LAMICTIN, ask your doctor for advice on how to start taking it again, **even if you only stop for a few days.**

Contact your doctor before restarting LAMICTIN, even if you only stop for a few days.

If you stop taking LAMICTIN:

Take LAMICTIN for as long as your doctor recommends. Don't stop unless your doctor advises you to.

- **If you are taking LAMICTIN for epilepsy:** To stop taking LAMICTIN, it is important that the dose is reduced gradually, over about 2 weeks. If you suddenly stop taking LAMICTIN, your epilepsy may come back or get worse. **Speak to your doctor before stopping** LAMICTIN.

- ***If you're taking LAMICTIN for bipolar disorder:*** If you are taking LAMICTIN to prevent extreme mood swings, you may not experience the full effect for several weeks. If you stop taking LAMICTIN, your dose will not need to be reduced gradually. But you should still talk to your doctor first if you want to stop taking LAMICTIN.

4. Possible side effects:

LAMICTIN can have side effects.

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

Conditions you need to look out for:

- ***Potentially serious skin reaction:*** A small number of people taking LAMICTIN get an allergic reaction or potentially serious skin reaction, which may develop into more serious problems if they are not treated.

  These symptoms are more likely to happen during the first few months of treatment with LAMICTIN, especially if the dose is too high or if the dose is increased too quickly, or if LAMICTIN is taken together with a medicine called *valproate*. Serious skin reactions are more common in children. Symptoms of these allergic reactions include:

  - skin rashes or redness, which may develop into severe skin reactions including widespread rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals (*Stevens-Johnson syndrome* and *toxic epidermal necrolysis*) or extended rashes with liver, blood and other body organs involvement (Drug Reaction with Eosinophilia and Systemic Symptoms which is also known as DRESS hypersensitivity syndrome)
  - a sore mouth or eyes

- a high temperature (fever), flu-like symptoms or drowsiness
- swelling around your face, or swollen glands in your neck, armpit or groin

  In many cases, these symptoms will be signs of less serious side effects. But you must be aware that they are potentially serious and can develop into more serious problems, such as organ failure (kidney and liver failure) and a serious blood clotting disorder which can cause unexpected bruising or bleeding (*disseminated intravascular coagulation*).

  ► These are all very serious side effects. If you have them, you may have had a serious allergic reaction to LAMICTIN. You may need urgent medical attention or hospitalisation. **Contact your doctor immediately.**

- ***Serious immune system condition (haemophagocytic lymphohistiocytosis or HLH)***

  A serious immune system condition, in which the part of the body system that fights disease is overactive, has been reported while taking LAMICTIN. Although, it has been reported very rarely, it can be life-threatening, so it is important that you know the symptoms to look out for. Symptoms include:

  - a high temperature (fever),
  - skin rashes
  - trouble walking or seeing, and fits (seizures) for the first time or happening more often
  - enlarged liver and/or spleen with pain and/or tenderness in the region towards the top of the stomach
  - yellowing of the skin and/or eyes
  - swollen glands in the neck, armpit and/or groin
  - bleeding and/or bruising more easily; looking pale, feeling tired.

In most cases these symptoms may be signs of less serious side effects, but you must be aware that they can be signs of a condition which can be serious if not recognised early.

➔ Contact a doctor immediately if you have any of these symptoms.

- ***Liver and blood problems:*** These have been reported less frequently while taking LAMICTIN. The following symptoms may be accompanied by a general feeling of being sick or unwell:
  - yellowing of the skin
  - itching
  - abdominal pain and/or tenderness
  - feeling very tired
  - unexpected bleeding or bruising, or the fingers turning blue
  - a sore throat, or more infections (such as colds) than usual.

    ► **Contact a doctor immediately if you notice any of these symptoms.** Your doctor may decide to carry out tests on your liver, kidneys, or blood, and may tell you to stop taking LAMICTIN.
- ***Seizures in Epilepsy worsening:*** In people who already have epilepsy: seizures happening more often. Tell your doctor as soon as possible if this happens.
- ***Thoughts of harming yourself or suicide:*** Occasionally, the symptoms of depression or bipolar disorder may include thoughts of harming yourself or committing suicide. If you have distressing thoughts or experiences, or if you notice that you feel worse or develop new symptoms while you are taking LAMICTIN, **contact a doctor immediately or go to the nearest hospital for help.**

Frequent side effects include:

- headache

- skin rash
- feeling sleepy, clumsiness and lack of co-ordination (ataxia), feeling dizzy
- aggression, agitation or irritability
- feeling drowsy, difficulty sleeping (*insomnia*), tremors, rapid, uncontrollable eye movements (*nystagmus*)
- feeling sick (*nausea)* or being sick (*vomiting*), diarrhoea
- feeling tired
- pain in your back, joints or elsewhere.

Less frequent side effects include:

- blurred or double vision
- a severe skin reaction (*Stevens-Johnson syndrome*)
- itchy eyes with discharge and crusty eyelids (*conjunctivitis*)
- a group of side effects together including: headache, fever, nausea, vomiting, stiff neck, rash, unusual sensitivity to light, muscle pains, chills, confusion, and drowsiness. This may be caused by an inflammation of the membranes that cover the brain and spinal cord (*meningitis*).
- unusual hair loss or thinning (*alopecia*)
- a severe skin reaction including extensive peeling of the skin (*toxic epidermal necrolysis*)
- multi-organ failure or a serious blood clotting disorder which can cause unexpected bruising or bleeding *(disseminated intravascular coagulation)*
- a serious immune system condition (haemophagocytic lymphohistiocytosis or HLH), see also the information at the beginning of Section 4
- swelling of the face (*oedema*) or swollen glands in the neck, armpits or groin (*lymphadenopathy*)
- a high temperature (*fever)*

- in people who already have epilepsy, seizures happening more often
- inflammation of the kidney (tubulointerstitial nephritis), which may occur in association with inflammation of the eye (uveitis)
- uncontrollable bodily movements (*tics*), uncontrollable muscle spasms affecting the eyes, head and torso (*choreoathetosis*), or other unusual body movements such as jerking, shaking or stiffness
- feeling wobbly or unsteady when you move around
- confusion or agitation
- seeing or hearing things that aren't really there (*hallucinations*)
- nightmares
- in people who already have Parkinson's disease, a worsening of the symptoms
- lupus (symptoms may include: back or joint pain which sometimes may be accompanied by fever and/or general ill health)
- changes in liver function
- reduced numbers of red blood cells (*anaemia*)
- reduced numbers of white blood cells (*neutropenia, leukopenia, agranulocytosis*)
- reduced numbers of blood platelets, the cells that help blood to clot (*thrombocytopenia*)
- a reduced number of all these types of cells (*pancytopenia*)
- a disorder of the bone marrow called *aplastic anaemia*
- a decrease in antibodies (immunoglobulins).

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, or nurse. 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 LAMICTIN.

5. How to store LAMICTIN:

Keep your tablets dry. Store all medicines out of reach of children.

LAMICTIN tablets: Store at or below 30 ºC.

LAMICTIN dispersible tablets: Store at or below 30 ºC. Protect from light.

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).

6. Contents of the pack and other information:

What Lamictin Contains:

The active substance is lamotrigine.

Each LAMICTIN 25 tablet contains: 25 mg lamotrigine.

Contains sugar (lactose monohydrate, 24,7 mg/tablet).

Each LAMICTIN 50 tablet contains: 50 mg lamotrigine.

Contains sugar (lactose monohydrate, 49,4 mg/tablet).

Each LAMICTIN 100 tablet contains: 100 mg lamotrigine.

Contains sugar (lactose monohydrate, 98,8 mg/tablet).

Each LAMICTIN 200 tablet contains: 200 mg lamotrigine.

Contains sugar (lactose monohydrate, 114,7 mg/tablet).

The other ingredients of LAMICTIN tablets are, microcrystalline cellulose, lactose monohydrate, povidone, sodium starch glycollate, magnesium stearate and iron oxide yellow (E172).

Each LAMICTIN P2 dispersible tablet contains: 2 mg lamotrigine

Contains sweetener (saccharin sodium (0,4 mg/tablet))

Each LAMICTIN P5 dispersible tablet contains: 5 mg lamotrigine

Contains sweetener (saccharin sodium (1,0 mg/tablet))

Each LAMICTIN P25 dispersible tablet contains: 25 mg lamotrigine

Contains sweetener (saccharin sodium (0,625 mg/tablet))

Each LAMICTIN P50 dispersible tablet contains: 50 mg lamotrigine

Contains sweetener (saccharin sodium (1,25 mg/tablet))

The other ingredients of LAMICTIN dispersible tablets are calcium carbonate, low substituted hydroxypropyl cellulose, aluminium magnesium silicate, sodium starch glycollate, povidone, saccharin sodium, blackcurrant flavour and magnesium stearate.

What LAMICTIN looks like and contents of the pack

LAMICTIN 25:

Pale, yellowish-brown, multifaceted, superelliptical, unscored tablet, branded ‘GSEC7’ on one side, with ‘25’ on the reverse.

LAMICTIN 25 tablets are packed into:

- PVC-PVdC/aluminium foil blister packs of 60 tablets, or
- PVC blisters with aluminium foil lidding blisters of 56 tablets or
- Child-resistant PVC/aluminium paper lidding blisters of 56 tablets.

LAMICTIN 50:

Pale, yellowish-brown, multifaceted, superelliptical, unscored tablet, branded ‘GSEE1’ on one side, with ‘50’ on the reverse.

LAMICTIN 50 tablets are packed into:

- PVC-PVdC/aluminium foil blister packs of 60 tablets, or
- PVC blisters with aluminium foil lidding blisters of 56 tablets or
- Child-resistant PVC/aluminium paper lidding blisters of 56 tablets.

LAMICTIN 100:

Pale, yellowish-brown, multifaceted, superelliptical, unscored tablet, branded ‘GSEE5’ on one side, with ‘100’ on the reverse.

LAMICTIN 100 tablets are packed into:

- PVC-PVdC/aluminium foil blister packs of 60 tablets, or
- PVC blisters with aluminium foil lidding blisters of 56 tablets or
- Child-resistant PVC/aluminium paper lidding blisters of 56 tablets.

LAMICTIN 200:

Pale, yellowish-brown, multifaceted, superelliptical, unscored tablet, branded ‘GSEE7’ on one side, with ‘200’ on the reverse.

LAMICTIN 200 tablets are packed into:

- PVC-PVdC/aluminium foil blister packs of 60 tablets, or
- PVC blisters with aluminium foil lidding blisters of 56 tablets or
- Child-resistant PVC/aluminium paper lidding blisters of 56 tablets.

LAMICTIN P2:

White to off-white round tablets with a blackcurrant odour. One side has a bevelled edge and is engraved LTG above the number 2. The other side is engraved with two overlapping super-ellipses at right angles.

LAMICTIN P2 dispersible tablets are packed in white plastic bottles, with child-resistant closures containing 30 tablets

LAMICTIN P5:

White to off-white with odour of blackcurrant. Elongated, biconvex tablets, unscored. Branded 'GS CL2' on one side and '5' on the reverse. The tablets may be slightly mottled.

LAMICTIN P5 dispersible tablets are packed into:

- Amber glass bottles containing 100 tablets, or
- PVC-PVdC/aluminium foil blister packs containing 100 tablets, or
- White HDPE bottles with a child resistant/tamper evident closure containing 60 tablets.

LAMICTIN P25:

White to off-white with odour of blackcurrant. Multifaceted, superelliptical, unscored. Branded 'GS CL5' on one side and '25' on the reverse. The tablets may be slightly mottled

LAMICTIN P25 dispersible tablets are packed into:

- Amber glass bottles containing 60 tablets, or
- PVC-PVdC/aluminium foil blister packs containing 60 tablets.

LAMICTIN P50:

White to off-white with odour of blackcurrant. Multifaceted, superelliptical, unscored. Branded 'GS CX7' on one side and '50' on the reverse. The tablets may be slightly mottled.

LAMICTIN P50 dispersible tablets are packed in amber glass bottles containing 60 tablets.

Holder of Certificate of Registration:

GlaxoSmithKline South Africa (Pty) Ltd

39 Hawkins Avenue

Epping Industria 1, 7460

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LAMICTIN 25: Z/2.5/280

LAMICTIN 50: Z/2.5/281

LAMICTIN 100: Z/2.5/282

LAMICTIN 200: 29/2.5/0472

LAMICTIN P2: 36/2.5/0407

LAMICTIN P5: 29/2.5/0303

LAMICTIN P25: 29/2.5/0304

LAMICTIN P50: 32/2.5/0459

GDS-50

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