PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

LAMOROLA 25: (25 mg tablet)

LAMOROLA 50: (50 mg tablet)

LAMOROLA 100: (100 mg tablet)

LAMOROLA 200: (200 mg tablet)

Each 25 mg tablet contains 52,50 mg lactose monohydrate.

Each 50 mg tablet contains 105,50 mg lactose monohydrate.

Each 100 mg tablet contains 211,00 mg lactose monohydrate.

Each 200 mg tablet contains 420,00 mg lactose monohydrate.

Read all of this leaflet carefully before you start taking LAMOROLA

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- **LAMOROLA** 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

6. Contents of the pack and other information

1. What LAMOROLA is and what it is used for

LAMOROLA belongs to a group of medicines called anti-epileptics. It is used to treat epilepsy by blocking the signals in the brain that produce epileptic seizures / fits.

For adults and children over the age of 12, **LAMOROLA** can be used with other medicines or on its own. It can also be used with other medicines to treat the seizures that occur with a condition called Lennox-Gastaut syndrome.

For children aged between 2 and 12 years, **LAMOROLA** can be used with other medicines, to treat partial epilepsy with or without secondary generalised tonic-clonic seizures.

2. What you need to know before you take LAMOROLA

Do not take LAMOROLA:

- If you are hypersensitive (allergic) to lamotrigine or any of the other ingredients of **LAMOROLA** (listed in section 6).
- If you have liver or kidney impairment
- If you are older than 65

Warnings and precautions

Special care should be taken with **LAMOROLA**:

- If you have ever developed a rash. Skin reactions, which have generally occurred within the first 8 weeks after initiation of lamotrigine treatment. The majority of rashes are mild and go away, however serious, potentially life-threatening skin rashes, including Stevens-Johnson syndrome and toxic

epidermal necrolysis, have been reported especially in children and in patients (adults and children) who also used valproate.

- When the seizures in some types of epilepsy may happen more often or occasionally become worse while you're taking **LAMOROLA**. 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're taking **LAMOROLA** you should see a doctor as soon as possible.
- Haemophagocytic lymphohistiocytosis (HLH)

  There have been incidents of a rare but very serious immune system reaction, in patients taking lamotrigine. If you experience any of these symptoms while taking lamotrigine: rash, fever, neurological symptoms (e.g., confusional state, tremor or shaking, disturbances of brain function); contact your doctor immediately.
- Tell your doctor if you experience a rash or exaggerated sunburn after taking lamotrigine and have been exposed to sun or artificial light. Your doctor may advise you to avoid sunlight or protect yourself against the sun (e.g. use of a sunscreen and/or to wear protective clothing)
- Tell your doctor if you have ever developed meningitis after taking lamotrigine
- If you have a condition called Brugada syndrome, tell your doctor. As Brugada syndrome is a genetic disease that results in abnormal electrical activity within the heart and Lamotrigine can trigger ECG abnormalities which may lead to abnormal heart rhythm.

Other medicines and LAMOROLA

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

These may include:

- valproate, used to treat epilepsy and mental health problems
- carbamazepine, phenytoin, primidone or phenobarbitone, used to treat epilepsy

Pregnancy and breastfeeding

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.

Driving and using machines

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

LAMOROLA contains lactose monohydrate

Patients with the rare hereditary conditions of lactose/fructose or galactose intolerance should not take **LAMOROLA**.

3. How to take LAMOROLA

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

Always take **LAMOROLA** 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 long your treatment with **LAMOROLA** will last. Do not stop treatment early because this will affect your seizures. If you have the

impression that the effect of **LAMOROLA** is too strong or too weak, tell your doctor or pharmacist.

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 (called the effective dose). Never take more **LAMOROLA** tablets than your doctor tells you to.

The usual effective dose of **LAMOROLA** for adults and children aged 12 years or over is between 100 mg and 500 mg each day.

For children aged 2 to 12 years, the effective dose depends on their body weight - usually, it's between 1 mg and 15 mg for each kilogram of the child's weight, up to a maximum of 200 mg daily.

LAMOROLA tablets are not recommended for children aged under 2 years.

Take your dose of **LAMOROLA** once or twice a day, as your doctor advises. It can be taken with or without food. Your doctor may also advise you to start or stop taking other medicines, depending on what condition you're being treated for and the way you respond to treatment.

Swallow your tablets whole. Don't break, chew or crush them.

If you take more LAMOROLA than you should

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 LAMOROLA

Do not take a double dose to make up for forgotten individual doses.

If you forget to take a dose, take it as soon as you remember. However, if it is almost time for the next dose, skip the missed dose and go back to the regular dosing schedule.

If you stop taking LAMOROLA

LAMOROLA should be taken for as long as your doctor has told you, it should not be stopped unless advised by your doctor.

4. Possible side effects

LAMOROLA can have side effects.

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

If any of the following happens, stop taking / using **LAMOROLA** and tell your doctor immediately or go to the casualty department at your nearest hospital:

- 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)
- High temperatures
- Swollen glands or sweeling around your face
- Enlarged lymph nodes
- Unexpected bruising or bleeding
- Getting more sick than usual

- Change in blood tests for liver enzymes or white blood cells

These are very serious side effects. If you have them, you may have had a serious reaction to **LAMOROLA**. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent

- Headache
- Skin rash
- Feeling dizzy
- Feeling sleepy or drowsy
- Feeling sick (nausea) or being sick (vomiting)
- Feeling agitated
- Aggression or irritability
- Shaking or tremors
- Difficulty in sleeping (insomnia)
- Diarrhoea
- Dry mouth
- Feeling tired
- Abnormal or uncoordinated movements
- Joint stiffness
- Pain or back pain

Less frequent

- Double vision or blurred vision
- Skin rash or exaggerated sunburn
- Clumsiness and lack of co-ordination

Unknown frequency:

- Hypersensitivity syndrome
- Hypogammaglobulinaemia
- Confusion, hallucinations, tics or nightmares
- Aseptic meningitis with symptoms like nausea, fever, headache, vomiting, extreme sensitivity to bright light and stiff neck
- Worsening of Parkinson's disease
- Difficulty in movement
- Increase in the amount of seizures
- Pain when urinating

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 **LAMOROLA**.

5. How to store LAMOROLA

Store all medicines out of reach of children.

- Store at or below 25 °C
- Do not refrigerate/ freeze
- Store in the original package/ container

- Keep the blisters in the outer carton
- Protect from light / moisture
- Do not store in a bathroom
- Do not use after the expiry date stated on the label or 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 LAMOROLA contains

- The active substance is lamotrigine.

The other ingredients are lactose monohydrate, microcrystalline cellulose, sodium starch glycolate, maize starch, magnesium stearate.

LAMOROLA 25, contains iron yellow oxide.

What LAMOROLA looks like and contents of the pack

LAMOROLA 25:	Yellow, round circular tablets with 25 embossed on one side and breakline on the other side.
LAMOROLA 50:	White, round, circular tablets with 50 embossed on one side and breakline on the other side.
LAMOROLA 100:	White, round, circular tablets with 100 embossed on one side and breakline on the other side**.**
LAMOROLA 200:	Yellow, capsule-shaped, biconvex tablets with 200 embossed on one side and plain on the other side.

Tablets are packaged in colourless PVC and aluminium foil blister strips of 7, 10, 14 or 15 tablets, packed in 56's or 60's in a cartons (this applies to all 4 strengths).

Holder of Certificate of Registration

Strides Pharma SA (Pty) Ltd.

106 16th Road

Building 2

Midrand

1865

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LAMOROLA 25: A38/2.5/0567

LAMOROLA 50: A38/2.5/0568

LAMOROLA 100: A38/2.5/0569

LAMOROLA 200: A38/2.5/0570

Access to the corresponding Professional Information

The Professional Information is contained in the packaging if this medicine