

PATIENT INFORMATION LEAFLET FOR LAMOTRIGINE KIARA

SCHEDULING STATUS

S3

LAMOTRIGINE 25 KIARA tablets

LAMOTRIGINE 50 KIARA tablets

LAMOTRIGINE 100 KIARA tablets

LAMOTRIGINE 200 KIARA tablets

Lamotrigine.

Contains sugar:

LAMOTRIGINE 25 KIARA contains 12,5 mg lactose monohydrate per tablet.

LAMOTRIGINE 50 KIARA contains 25 mg lactose monohydrate per tablet.

LAMOTRIGINE 100 KIARA contains 50 mg lactose monohydrate per tablet.

LAMOTRIGINE 200 KIARA contains 64,37 mg lactose monohydrate per tablet.

Read all of this leaflet carefully before you start taking LAMOTRIGINE KIARA.

- 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.
- LAMOTRIGINE KIARA 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 LAMOTRIGINE KIARA is and what it is used for.
2. What you need to know before you take LAMOTRIGINE KIARA.

3. How to take LAMOTRIGINE KIARA.
4. Possible side effects.
5. How to store LAMOTRIGINE KIARA.
6. Contents of the pack and other information.

1. What LAMOTRIGINE KIARA is and what it is used for

LAMOTRIGINE KIARA belongs to a group of medicines called antiepileptics. It is used to treat epilepsy and bipolar disorder.

2. What you need to know before you take LAMOTRIGINE KIARA

Do not take LAMOTRIGINE KIARA:

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

Warnings and precautions

Take special care with LAMOTRIGINE KIARA:

- 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 LAMOTRIGINE KIARA.
- Contact your health care provider right away if you experience any symptom of haemophagocytic lymphohistiocytosis (HLH), a condition which causes inflammation throughout your body, while taking LAMOTRIGINE KIARA. 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.**

LAMOTRIGINE KIARA 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 LAMOTRIGINE KIARA. 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 develop skin reactions (such as rash), that can be severe (see **Possible side effects**).**

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 LAMOTRIGINE KIARA immediately. The risk of skin reactions increases if a high initial dose of LAMOTRIGINE KIARA is taken, or if LAMOTRIGINE KIARA is taken with valproate.

- **If you are taking antiepileptic medicine.**

The addition of LAMOTRIGINE KIARA 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.

- If you experience an increased sensitivity of your skin to the sun (easily gets sunburn) or other light sources, you should contact your doctor.
- 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 LAMOTRIGINE KIARA 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 LAMOTRIGINE KIARA is affecting the way your contraceptive is working.
- If you have any kidney problems. Your doctor will decide if LAMOTRIGINE KIARA is suitable for you, or whether your dose may need to be adjusted.
- If you have ever developed meningitis (an inflammation of the membranes that cover the brain and spinal cord) after taking LAMOTRIGINE KIARA. Symptoms may include fever, nausea, vomiting, headache, stiff neck and extreme sensitivity to bright light. Talk to your doctor.

Other medicines and LAMOTRIGINE KIARA

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

Tell your doctor or pharmacist if you are currently using:

- Carbamazepine, phenytoin, phenobarbital, primidone, gabapentin or valproate (used to treat epilepsy [seizures]).
- Rifampicin (used to treat tuberculosis [TB]).
- Oral contraceptives (e.g. ethinylestradiol or levonorgestrel, such as “the pill”).
- 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).
- Paracetamol (used to treat pain and fever).
- A combination of lopinavir and ritonavir or atazanavir and ritonavir (used to treat human immunodeficiency virus [HIV] infection).

LAMOTRIGINE KIARA with food and drink

See section 3.

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 health care provider for advice before taking LAMOTRIGINE KIARA.

If you are already taking LAMOTRIGINE KIARA and then fall pregnant, you should not stop treatment without discussing this with your doctor. Your doctor may alter your dose of LAMOTRIGINE KIARA, or advise you to take extra folic acid, while you are pregnant.

Driving and using machines

Use LAMOTRIGINE KIARA with caution when driving a vehicle, operating machinery or performing other hazardous activities as LAMOTRIGINE KIARA may cause drowsiness and dizziness. If you are experiencing these side effects or are having seizures, avoid these activities and talk to your doctor.

LAMOTRIGINE KIARA contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking LAMOTRIGINE KIARA.

3. How to take LAMOTRIGINE KIARA

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

Always take LAMOTRIGINE KIARA 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 LAMOTRIGINE KIARA for you. The dose you take will depend on:

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

Your doctor will start you on a low dose, and gradually increase the dose over a few weeks until you reach a dose that works for you. Never take more LAMOTRIGINE KIARA than your doctor tells you to.

The usual effective dose of LAMOTRIGINE KIARA for adults and children aged over 12 years is between 100 mg and 400 mg each day.

LAMOTRIGINE KIARA is not recommended for children aged under 2 years.

LAMOTRIGINE KIARA should be taken at the same time every day, with or without food. Try to take it the same way, since taking LAMOTRIGINE KIARA with food may change the time it takes to be absorbed.

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

If you take more LAMOTRIGINE KIARA than you should

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

Take this leaflet and the remaining LAMOTRIGINE KIARA with you so the doctor will know what you have taken.

If you forget to take LAMOTRIGINE KIARA

If you have missed your dose by only a few hours, take the missed dose as soon as you remember. If it is almost time for your next dose, skip the missed dose and take LAMOTRIGINE KIARA at the next regularly scheduled time.

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

If you stop taking LAMOTRIGINE KIARA

Contact your doctor, if you stop taking LAMOTRIGINE KIARA for any reason.

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 LAMOTRIGINE KIARA without consulting your doctor.

4. Possible side effects

LAMOTRIGINE KIARA may have side effects.

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

Should your general health worsen or if you experience any untoward effects while taking LAMOTRIGINE KIARA, please consult your doctor, pharmacist or other health care provider for advice.

If any of the following happens, stop taking LAMOTRIGINE KIARA and tell your doctor 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 LAMOTRIGINE KIARA. 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 if you notice any of the following:

Frequent:

- feeling irritated, aggression

- headache, drowsiness, sleeplessness, dizziness, involuntary shaking or tremors, “pins and needles”, rapid, uncontrollable eye movements (nystagmus), poor coordination
- joint pain, generalised pain, back pain
- double vision or blurred vision
- a sensation of whirling and loss of balance (vertigo)
- feeling sick (nausea), stomach upset, being sick (vomiting), diarrhoea, dry mouth
- tiredness.

Less frequent:

- infection
- changes which may show up in blood tests – including reduced numbers of red blood cells (anaemia), reduced numbers of white blood cells (leukopenia, neutropenia, agranulocytosis), reduced numbers of platelets (thrombocytopenia), reduced numbers of all of these types of cells (pancytopenia), and a disorder of the bone marrow called aplastic anaemia
- uncontrollable body movements (tics), hallucinations (seeing or hearing things that do not exist), confusion, anxiety, feeling depressed, memory loss
- lack of muscle coordination which may affect speech, eye movements, the ability to swallow, walking, picking up objects and other voluntary movements (ataxia), restlessness (agitation), unsteadiness, worsening of symptoms of Parkinson’s disease, extrapyramidal effects (including tremor, slurred speech, movement disorder or abnormal muscle tone), uncontrollable muscle spasms affecting the eyes, head and torso (choreoathetosis), speech disorder (dysarthria)
- meningitis (group of symptoms together, including fever, nausea, vomiting, headache, stiff neck and extreme sensitivity to bright light)
- itchy eyes, with discharge and crusty eyelids (conjunctivitis)
- constipation, heartburn
- increased liver function test, liver abnormalities, liver failure

- hair loss or thinning (temporarily)
- increased sensitivity of your skin to the sun or other light sources
- lupus-like reactions (autoimmune disorder)
- abnormal physical weakness or lack of energy.

Frequency unknown:

- a disorder of blood clotting, which can cause unexpected bleeding or bruising (disseminated intravascular coagulation)
- swollen lymph nodes (lymphadenopathy)
- lower immunity because of lower levels of antibodies called immunoglobulins in the blood which help protect against infection (hypogammaglobulinaemia)
- inflammation of your pancreas (pancreatitis)
- inflammation of your blood vessels (vasculitis)
- nightmares
- temporary cessation of breathing (apnoea), runny nose (rhinitis)
- inflammation of the oesophagus (food tube)
- rhabdomyolysis (a serious syndrome due to a muscle injury)
- multi-organ failure (altered organ function, involving two or more organ systems).

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. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reactions Reporting Form**”, found online under SAHPRA’s publications: <http://www.sahpra.org.za/Publications/Index/8>

By reporting side effects, you can help provide more information on the safety of LAMOTRIGINE KIARA.

5. How to store LAMOTRIGINE KIARA

- Store at or below 25 °C, in a dry place.
- Keep blister strips in the outer carton until required for use.
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Do not use after the expiry date printed on the outer carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What LAMOTRIGINE KIARA contains

The active substance is lamotrigine.

Each LAMOTRIGINE 25 KIARA tablet contains 25 mg lamotrigine.

Each LAMOTRIGINE 50 KIARA tablet contains 50 mg lamotrigine.

Each LAMOTRIGINE 100 KIARA tablet contains 100 mg lamotrigine.

Each LAMOTRIGINE 200 KIARA tablet contains 200 mg lamotrigine.

The other ingredients are lactose monohydrate, magnesium stearate (E572), microcrystalline cellulose [E460(i)], povidone and sodium starch glycolate.

LAMOTRIGINE 200 KIARA also contains FD&C Blue No. 2 as a colourant.

What LAMOTRIGINE KIARA looks like and contents of the pack

LAMOTRIGINE 25 KIARA: White, round, flat faced, bevel edged tablets plain on both sides, with a diameter of 6,0 mm and a thickness of 2,2 mm.

LAMOTRIGINE 50 KIARA: White, round shaped, biconvex tablets plain on both sides, with a diameter of 7,0 mm and a thickness of 3,9 mm.

LAMOTRIGINE 100 KIARA: White, round shaped, biconvex tablets plain on both sides, with a diameter of 9,0 mm and a thickness of 5,2 mm.

LAMOTRIGINE 200 KIARA: Light blue coloured, round shaped, biconvex tablets plain on both sides, with a diameter of 11,0 mm and a thickness of 5,2 mm.

Transparent PVC/PVDC/silver aluminium foil blister strips, containing 10 tablets each.

6 blister strips are packed in an outer carton.

Holder of certificate of registration

Unichem SA (Pty) Ltd

San Domenico

Ground Floor, Unit G4

10 Church Street

Durbanville

7551 Cape Town

Tel: 021 531 0436

This leaflet was last revised in

22 September 2021.

Registration numbers

LAMOTRIGINE 25 KIARA: 46/2.5/0408

LAMOTRIGINE 50 KIARA: 46/2.5/0409

LAMOTRIGINE 100 KIARA: 46/2.5/0410

LAMOTRIGINE 200 KIARA: 46/2.5/0411