APPROVED PATIENT INFORMATION LEAFLET FOR SERINEM

SCHEDULING STATUS:

S3

PROPRIETARY NAMES, STRENGTH AND PHARMACEUTICAL FORM

SERINEM 25 tablets

SERINEM 50 tablets

SERINEM 100 tablets

SERINEM 200 tablets

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

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- SERINEM 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.

1. WHAT SERINEM CONTAINS

Active ingredient:

Each SERINEM 25 tablet contains 25 mg lamotrigine.

Each SERINEM 50 tablet contains 50 mg lamotrigine.

Each SERINEM 100 tablet contains 100 mg lamotrigine.

Each SERINEM 200 tablet contains 200 mg lamotrigine.

Inactive ingredients:

Lactose monohydrate, magnesium stearate, microcrystalline cellulose, povidone and sodium starch glycolate.

Contains sugar:

SERINEM 25 contains 12,5 mg lactose monohydrate per tablet.

SERINEM 50 contains 25 mg lactose monohydrate per tablet.

SERINEM 100 contains 50 mg lactose monohydrate per tablet.

SERINEM 200 contains 64,37 mg lactose monohydrate per tablet.

SERINEM 200 also contains FD&C Blue No. 2 s a colourant.

2. WHAT SERINEM IS USED FOR

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

3. BEFORE YOU TAKE SERINEM

Do not take SERINEM:

- If you are allergic (hypersensitive) to lamotrigine or any of the other ingredients of SERINEM (see **WHAT SERINEM CONTAINS**).

Take special care with SERINEM:

- **If you have thoughts of harming yourself or suicide. SERINEM 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 SERINEM. 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 SERINEM immediately. The risk of skin reactions increases if a high initial dose of SERINEM is taken, or if SERINEM is taken with valproate.
- If you are taking antiepileptic medicine.

  The addition of SERINEM 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 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 SERINEM 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 SERINEM is affecting the way your contraceptive is working.
- If you have any kidney problems. Your doctor will decide if SERINEM 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 SERINEM. Symptoms may include fever, nausea, vomiting, headache, stiff neck and extreme sensitivity to bright light. Talk to your doctor.

Taking SERINEM with food and drink:

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

Pregnancy and breastfeeding:

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking SERINEM.

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

Driving and using machinery:

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

Important information about some of the ingredients of SERINEM:

SERINEM contains lactose, which may have an effect on the glycaemic control of patients with diabetes mellitus. Patients with rare hereditary conditions of lactose or galactose intolerance should not take SERINEM.

Taking other medicines with SERINEM:

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

Tell your doctor or pharmacist if you are currently using:

- Carbamazepine, phenytoin, phenobarbitone, primidone, gabapentin or valproate (used to treat epilepsy (seizures)).
- Rifampicin (used to treat tuberculosis (TB)).
- Oral contraceptives (e.g. ethinyloestradiol or levonorgestrel).
- 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).

HOW TO TAKE SERINEM

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

Always take SERINEM 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 SERINEM for you. The dose you take will depend on:

- your age
- whether you are taking SERINEM 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 SERINEM than your doctor tells you to.

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

SERINEM is not recommended for children aged under 2 years.

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

If you take more SERINEM 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.

Take this leaflet and the rest of the remaining SERINEM with you so the doctor will know what you have taken.

If you forget to take SERINEM:

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 SERINEM at the next regularly scheduled time.

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

Effects when treatment with SERINEM is stopped:

Contact your doctor, if you stop taking SERINEM 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 SERINEM without consulting your doctor.

5. POSSIBLE SIDE EFFECTS

SERINEM may have side effects.

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

Should your general health worsen or if you experience any untoward effects while taking SERINEM, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking SERINEM 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 SERINEM. 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:

Less frequent:

- 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)
- 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 as soon as possible if you notice any of the following:

Frequent:

- feeling irritated

- 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
- 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 (leucopoenia, 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
- aggression, 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), motor speech disorder (dysarthria)
- itchy eyes, with discharge and crusty eyelids (conjunctivitis)
- constipation, dry mouth, heartburn
- increased liver function test, liver abnormalities, liver failure
- 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)
- inflammation of your pancreas (pancreatitis)
- inflammation of your blood vessels (vasculitis)
- 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.

6. STORING AND DISPOSING OF SERINEM

- 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).

7. PRESENTATION OF SERINEM

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

6 blister strips are packed in an outer carton.

8. IDENTIFICATION OF SERINEM

SERINEM 25: 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.

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

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

SERINEM 200: 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.

9. REGISTRATION NUMBERS

SERINEM 25: 46/2.5/0412

SERINEM 50: 46/2.5/0413

SERINEM 100: 46/2.5/0414

SERINEM 200: 46/2.5/0415

10. NAME AND ADDRESS OF REGISTRATION HOLDER

Unicorn Pharmaceuticals (Pty) Ltd

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11. DATE OF PUBLICATION

11 June 2018