APPROVED PATIENT INFORMATION LEAFLET

S3

ZESITON 5 mg TABLETS (Dispersible tablet)

ZESITON 25 mg TABLETS (Dispersible tablet)

ZESITON 50 mg TABLETS (Dispersible tablet)

ZESITON 100 mg TABLETS (Dispersible tablet)

ZESITON 200 mg TABLETS (Dispersible tablet)

Lamotrigine

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

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

- If you have further questions, please ask your doctor or your pharmacist.

- **ZESITON** have 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 ZESITON CONTAIN

The active substance is lamotrigine.

ZESITON 5 mg TABLETS: Each uncoated tablet contains lamotrigine 5 mg.

ZESITON 25 mg TABLETS: Each uncoated tablet contains lamotrigine 25 mg.

ZESITON 50 mg TABLETS: Each uncoated tablet contains lamotrigine 50 mg.

ZESITON 100 mg TABLETS: Each uncoated tablet contains lamotrigine 100 mg.

ZESITON 200 mg TABLETS: Each uncoated tablet contains lamotrigine 200 mg.

The other ingredients are black currant flavour; cellulose, microcrystalline; magnesium carbonate; magnesium stearate; polacrilin potassium, povidone and sucralose.

2. WHAT ZESITON ARE USED FOR

ZESITON belong to a group of medicines called antiepileptics. They are used to treat two conditions – epilepsy and bipolar disorder.

EPILEPSY

- **For adults and children aged 12 years and over**

  ZESITON can be used on their own or with other medicines, to treat certain types of seizures in patients with epilepsy.

- **For children aged between 2 and 12 years**

  ZESITON can be used with other medicines, to treat certain types of seizures in patients with epilepsy. It is recommended that **ZESITON** are not used on their own to treat epilepsy in children under 12 years of age.

- **ZESITON** can also be used with other medicines to treat the seizures that occur with a condition called Lennox-Gastaut Syndrome.

BIPOLAR DISORDER

- **For adults 18 years of age and over**

  ZESITON are used to help prevent the mood episodes that occur in patients with bipolar disorder, mainly by preventing the depressive phases.

3. BEFORE YOU TAKE MUNATREPTABLETS

Do not take ZESITON:

- If you are hypersensitive (allergic) to lamotrigine, or any of the other ingredients of **ZESITON**.
- If you are pregnant or breast-feeding.
- If you have kidney or liver problems.
- If you are over the age of 65 years.

Take special care with ZESITON:

- Some patients may experience severe seizures, which may lead to serious health problems, usually causing death.

  If you experience a severe seizure while you are taking **ZESITON**, see a doctor as soon as possible. Your doctor may consider withdrawing **ZESITON** therapy if worsening of seizure control occurs.

- You may develop a rash while taking **ZESITON**. These skin reactions are most likely to happen within the first 8 weeks of starting treatment. Although most patients who develop

a rash have mild symptoms, some individuals may develop a serious (sometimes fatal i.e. causing death) skin reaction that requires hospitalisation. Scarring and deaths have been reported. Serious skin reactions occur more often in children than in adults.

- Rashes may be more likely to occur if you:
    - take **ZESITON** in combination with another medicine called valproate
    - start on too high a dose
    - increase your dose too quickly
- It is not possible to predict whether a mild rash will develop into a more serious reaction. **Therefore, if you develop any of these symptoms after you start taking ZESITON, get a doctor's help straight away: skin rash, a high temperature (fever), swollen lymph glands, itching, swelling around your face, blood and liver problems, unexpected bleeding or bruising, flu-like symptoms or drowsiness.** A doctor should evaluate your condition and decide if you should continue taking **ZESITON** .
- Patients with bipolar disorder can sometimes have thoughts of harming themselves or committing suicide. Call your doctor at once if you have any thoughts about suicide or hurting yourself.
- While you are taking **ZESITON**, your doctor may decide to carry out tests on your liver, kidneys or blood.
- Never take more **ZESITON** than your doctor tells you to.
- To stop taking **ZESITON** , it is important that your dose is reduced gradually, over a period of 2 weeks. If you suddenly stop taking **ZESITON** your epilepsy may come back or get worse.
- Since the effective dose for children depends on their body weight, the weight of a child must be monitored and the dose reviewed as weight changes occur.
- **ZESITON** should be used cautiously in patients taking folate antagonists (medicines which interfere with folic acid metabolism).

Taking ZESITON with food and drink:

- **ZESITON** can be taken with or without food.

Pregnancy and Breast-feeding:

- The safe use of **ZESITON** during pregnancy and breast-feeding has not been determined.

If you are pregnant or breast-feeding your baby, please consult your doctor, pharmacist or other health care professional for advice before taking this medicine.

Driving and using machinery:

- **ZESITON** can cause dizziness, drowsiness and blurred or double vision. Do not drive or operate machines if you are affected.

Taking other medicines with ZESITON:

Always tell your healthcare professional if you are taking any other medicine

(This include complementary or traditional medicine)

Before taking **ZESITON**, tell your doctor if you are using any of the following medicines:

- Phenytoin
- Carbamazepine
- Phenobarbitone
- Primidone
- Valproic acid
- Oral contraceptives (birth control pills) – If you are using an oral contraceptive and you notice any changes in your menstrual pattern, such as breakthrough bleeding or spotting between periods, tell your doctor.
- Rifampicin
- Lopinivir
- Ritonavir

If you are using any of the above medicines, you may not be able to take **ZESITON** , or you may need dosage adjustments or your doctor may need to monitor you carefully for side-effects.

4. HOW TO TAKE ZESITON

Always take **ZESITON** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. If you have the impression that the effect of **ZESITON** is too strong or too weak, tell your doctor or pharmacist.

- Use **ZESITON** as directed by your doctor.
- Do not increase your dose of **ZESITON** or take more frequent doses than those indicated by your doctor.
- 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 (called the effective dose).
- The dose you take will depend on your age and whether you are taking **ZESITON** with other medicines.
- The usual effective dose of **ZESITON** for adults and children aged over 12 years is between 100 mg and 400 mg each day.
- For children aged 2 to 12 years, the effective dose depends on their body weight – usually its between 1 mg and 15 mg for each kilogram of the child's weight, up to a maximum of 400 mg daily.
- **ZESITON** should not be given to patients aged under 18 years to treat bipolar disorder.

If you take more ZESITON than you should:

- Symptoms of overdose may include sedation (having a soothing, calming or tranquilizing effect), clumsiness and lack of co-ordination, double vision, nausea and vomiting.
- If you have taken more **ZESITON** than you should, you should be admitted to hospital and given appropriate treatment.

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 ZESITON:

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

5. POSSIBLE SIDE-EFFECTS

ZESITON can have side-effects.

Allergic reaction or potentially serious skin reaction, get a doctor's help straight away.

You may experience an allergic reaction or potentially serious skin reaction, which may develop into more serious, and even life-threatening problems if not treated.

Symptoms of these reactions include:

- skin rashes or redness
- angioedema (trouble in breathing, swelling of face, mouth, hands or feet)
- high temperature (fever), flu-like symptoms or drowsiness
- swelling around your face or swollen glands in your neck, armpit or groin
- unusual bleeding or bruising
- a sore throat or more infections than usual
- rare skin condition, with severe blisters, and bleeding from the lips, eyes, mouth, nose and genital area (Stevens-Johnson syndrome)
- severe skin reaction, starting with a painful red area, developing into large blisters then peeling of layers of skin (toxic epidermal necrolysis)

In many cases these symptoms will be signs of less serious side effects. However, you must be aware that they are potentially serious – so, if you notice any of these symptoms see a doctor as soon as possible.

Call your doctor at once if you have any of these serious side-effects:

- seizures that happen more often
- trouble in breathing, swelling of face, mouth, hands or feet
- depression
- hallucinations ("seeing" or "hearing" things that aren't really there)

Other side-effects include:

- changes which may show up in blood tests
  - including reduced numbers of red blood cells (anaemia), reduced number of white blood cells, reduced numbers of platelets which can cause bleeding or bruising.

- headache
- changes in liver function
- feeling dizzy or drowsy
- clumsiness and lack of co-ordination
- feeling “wobbly” or unsteady when you move about
- rapid, uncontrollable eye movements
- anxiety
- confusion
- irritability
- difficulty in sleeping
- shaking or tremors
- double or blurred vision
- feeling tired
- nausea (feeling sick) or vomiting (being sick)
- sensitivity of the skin to light
- aggression
- pain in your back or joints, or elsewhere
- numbness, tingling, pins and needles
- sensation of spinning or whirling (vertigo)
- worsening of Parkinson’s disease

If any of the side-effects become severe or troublesome, please tell your doctor or pharmacist.

Not all side-effects reported for **ZESITON** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **ZESITON**, please consult your doctor, pharmacist or other health care professional for advice.

6. STORING AND DISPOSING OF ZESITON

Store at or below 30 °C (room temperature). Keep blisters in the original carton until required for use.

Keep the containers tightly closed.

Store all medicines out of the reach and sight of children.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

7. PRESENTATION OF ZESITON

ZESITON 5 mg TABLETS:

1) Blister Pack:

Tablets are packed in clear PVC laminated with aclar and printed aluminium foil.

Each blister contains 10 tablets.

Pack size: 100's – Each carton contains 10 blisters of 10 tablets each.

2) HDPE Container Pack:

Tablets are packed in 75 ml white opaque HDPE containers with white opaque polypropylene closures with induction sealing wad, containing cotton coil.

Each container contains 100 tablets.

Pack size: 100's **-** One HDPE container contains 100 tablets.

ZESITON 25 mg TABLETS:

1) Blister Pack:

Tablets are packed in clear PVC laminated with aclar and printed aluminium foil.

Each blister contains 10 tablets.

Pack size: 60's – Each carton contains 6 blisters of 10 tablets each.

2) HDPE Container Pack:

Tablets are packed in 40 ml white opaque HDPE containers with white opaque polypropylene closures with induction sealing wad, containing cotton coil.

Each container contains 60 tablets.

Pack size: 60's **-** One HDPE container contains 60 tablets.

ZESITON 50 mg TABLETS:

1) Blister Pack:

Tablets are packed in clear PVC laminated with aclar and printed aluminium foil.

Each blister contains 10 tablets.

Pack size: 60's – Each carton contains 6 blisters of 10 tablets each.

2) HDPE Container Pack:

Tablets are packed in 40 ml white opaque HDPE containers with white opaque polypropylene closures with induction sealing wad, containing cotton coil.

Each container contains 60 tablets.

Pack size: 60's **-** One HDPE container contains 60 tablets.

ZESITON 100 mg TABLETS:

1) Blister Pack:

Tablets are packed in clear PVC laminated with aclar and printed aluminium foil. Each blister contains 10 tablets.

Pack size: 60's – Each carton contains 6 blisters of 10 tablets each.

2) HDPE Container Pack:

Tablets are packed in 60 ml white opaque HDPE containers with white opaque polypropylene closures with induction sealing wad, containing cotton coil.

Each container contains 60 tablets.

Pack size: 60's **-** One HDPE container contains 60 tablets

ZESITON 200 mg TABLETS:

1) Blister Pack:

Tablets are packed in clear PVC laminated with aclar and printed aluminium foil.

Each blister contains 10 tablets.

Pack size: 60's – Each carton contains 6 blisters of 10 tablets each.

2) HDPE Container Pack:

Tablets are packed in 120 ml white opaque HDPE containers with white opaque polypropylene closures with induction sealing wad, containing cotton coil.

Each container contains 60 tablets.

Pack size: 60's **-** One HDPE container contains 60 tablets.

8. IDENTIFICATION OF ZESITON

ZESITON 5 mg: White to off–white capsule shaped uncoated tablets debossed with 'H' on one side and '81' on the other side.

ZESITON 25 mg: White to off–white, rounded square shaped uncoated tablets debossed with 'H' on multifaceted side and '80' on flat side.

ZESITON 50 mg: White to off–white, rounded square shaped uncoated tablets debossed with 'H' on multifaceted side and '79' on flat side.

ZESITON 100 mg: White to off–white, rounded square shaped uncoated tablets debossed with 'H' on multifaceted side and '78' on flat side.

ZESITON 200 mg: White to off–white, rounded square shaped uncoated tablets debossed with 'H' on multifaceted side and '77' on flat side.

9. REGISTRATION NUMBER/REFERENCE NUMBER

ZESITON 5 mg TABLETS: 45/2.5/0632

ZESITON 25 mg TABLETS: 45/2.5/0633

ZESITON 50 mg TABLETS: 45/2.5/0634

ZESITON 100 mg TABLETS: 45/2.5/0635

ZESITON 200 mg TABLETS: 45/2.5/0636

10. NAME AND ADDRESS OF REGISTRATION HOLDER

Aurogen South Africa (Pty) Ltd

Woodhill Office Park, Building 1, 53 Phillip Engelbrecht Avenue

Meyersdal, Ext. 12, 1448

Johannesburg

South Africa

11. DATE OF PUBLICATION

Date of registration:

26 November 2015

Date of revision:

02 March 2023