LETRAM (LEVETIRACETAM)

(Levetiracetam Oral Solution)

What is in this leaflet

1. What LETRAM is used for
2. How LETRAM works
3. Before you use LETRAM
4. How to take LETRAM
5. While you are using LETRAM
6. Side effects
7. Storage and Disposal of LETRAM
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision

What LETRAM is used for

LETRAM is indicated as monotherapy in the treatment of partial onset seizures with or without secondary generalization in patients from 16 years of age with newly diagnosed epilepsy.

LETRAM is indicated as adjuctive theraphy:

• In the treatment of seizures in adults and children from 4 years of age with epilepsy.
• In the treatment of myoclonic seizures in adults and adolscents from 12 years of age with Juvenile Myoclonic Epilepsy.
• In the treatment of primary generalized tonic-clonic seizures in adults and children from 12 years of age with Idiopathic Generalized Epilepsy.

How LETRAM works

LETRAM is an anti-epileptic medicine (a medicine used to treat seizures in epilepsy).

Before you use LETRAM

When you must not use it

Do not take LETRAM**:**

- If you are allergic (hypersensitive) to LETRAM or any of the other ingredients of LETRAM.

Pregnancy and lactation

Pregnancy

Ask your doctor or pharmacist for advice before taking any medicine.

If you are pregnant or if you think you may be pregnant, please inform your doctor. LETRAM should not be used during pregnancy unless clearly necessary.

The potential risk to your unborn child is unknown. LETRAM has shown unwanted reproductive effects in animal studies at dose levels higher than you would need to control your seizures.

Breastfeeding

Breast-feeding is not recommended during treatment.

- *Before you start use it*

Take special care with LETRAM and check with your doctor or pharmacist before using this medicine if you are suffering or have ever suffered from any of the following conditions or illnesses:

• If you suffer from kidney problems, follow your doctor's instructions. He/she may decide if your dose should be adjusted.

• If you notice any slowdown in the growth or unexpected puberty development of your child, please contact your doctor.

• If you notice an increase in seizure severity (e.g. increased number), please contact your doctor.

• A small number of people being treated with anti-epileptics such as LETRAM have had thoughts of harming or killing themselves.

If you have any symptoms of depression and/or suicidal ideation, please contact your doctor.

- *Taking other medicines*

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without prescription.

How to use LETRAM

How much to use

Adults

- Monotherapy

Adults and adolescents from 16 years of age

The recommended starting dose is 250 mg twice daily which should be increased to an initial therapeutic dose of 500 mg twice daily after two weeks. The dose can be further increased by 250 mg twice daily every two weeks depending upon the clinical response. The maximum dose is 1500 mg twice daily.

- Add-on therapy Adults (≥ 18 years) and adolescents (12 to 17 years) of 50 kg or more

The initial therapeutic dose is 500 mg twice daily. This dose can be started on the first day of treatment. Depending upon the clinical response and tolerability, the daily dose can be increased up to 1500 mg twice daily. Dose changes can be made in 500 mg twice daily increments or decrements every two to four weeks.

- Children

The physician should prescribe the most appropriate pharmaceutical form, presentation and strength according to age, weight and dose.

- Monotherapy

The safety and efficacy of Levetiracetam in children and adolescents below 16 years as monotherapy treatment have not been established. There are no data available.

- Add-on therapy for children (4 to 11 years) and adolescents (12 to 17 years) weighing less than 50 kg

Levetiracetam oral solution is the preferred formulation for use in children under the age of 6 years.The initial therapeutic dose is 10 mg/kg twice daily.

Depending upon the clinical response and tolerability, the dose can be increased up to 30 mg/kg twice daily. Dose changes should not exceed increases or decreases of 10 mg/kg twice daily every two weeks.

The lowest effective dose should be used. Dose in children 50 kg or greater is the same as in adults.

Renal impairment

The daily dose must be individualized according to renal function.

For children with renal impairment, Levetiracetam dose needs to be adjusted based on the renal function as Levetiracetam clearance is related to

renal function.

Hepatic impairment

No dose adjustment is needed in patients with mild to moderate hepatic impairment. In patients with severe hepatic impairment, the creatinine clearance may underestimate the renal insufficiency. Therefore a 50% reduction of the daily maintenance dose is recommended when the creatinine clearance is < 60 ml/min/1.73m2.

- *When to use it*

Use as directed by your doctor or pharmacist.

LETRAM must be taken twice a day, once in the morning and once in the evening, at about the same time each day.Take the number of tablets following your doctor's instructions.

- *How long to use it*

- LETRAM is used as a chronic treatment. You should continue LETRAM treatment for as long as your doctor has told you.
- Do not stop your treatment without your doctor's advice as this could increase your seizures. Should your doctor decide to stop your LETRAM treatment, he/she will instruct you about the gradual withdrawal of LETRAM

- *If you forget to use it*

Consult your doctor or pharmacist on what you should do if you forget to use it.
Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- *If you use too much (overdose)*

The possible side effects of an overdose of LETRAM are sleepiness, agitation, aggression, decrease of alertness, inhibition of breathing and coma.

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using it

- *Things you must do*

You may take LETRAM with or without food. As a safety precaution, do not take LETRAM with alcohol.

Swallow LETRAM tablets with a sufficient quantity of liquid (e.g. a glass of water).

- *Things you must not do*

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Alcohol should be avoided when taking LETRAM

- *Things to be careful of*

Driving and using machines

LETRAM may impair your ability to drive or operate any tools or machinery, as LETRAM may make you feel sleepy. This is more likely at the beginning of treatment or after an increase in the dose.

You should not drive or use machines until it is established that your ability to perform such activities is not affected.

Side effects

Like all medicines, LETRAM can cause side effects, although not everybody gets them.

Tell your doctor if you have any of the following and they worry you.

The most frequently reported adverse reactions were nasopharyngitis, somnolence, headache, fatigue and dizziness. The safety profile of levetiracetam is generally similar across age groups (adult and paediatric patients) and across the approved epilepsy indications.

Adverse reactions:

Tell your doctor immediately if you notice any of the following :

- Symptoms such as low urine volume, tiredness, nausea , vomiting, confusion and swelling in the legs, ankles or feet, may be a sign of suffen decrease of kidney function.
- Sign and symptoms including muscleache, feeling of weakness and dark urine may indicate the side effect of rhabdomyolysis (breakdown of muscle tissue).
- If someone around you notices signs of confusion, somnolence (sleepiness), amnesia (loss of memory), memory impairment (forgetfulness), abnormal behavior or other neurological signs including involuntary or controlled movement , these could be symptom of an encephalopathy.

Description of selected adverse reactions
The risk of anorexia is higher when topiramate is co-administered with Levetiracetam. In several cases of alopecia, recovery was observed when Levetiracetam was discontinued. Bone marrow suppression was identified in some of the cases of pancytopenia.

You may report any side effects or adverse drug reactions directly to The National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835490, or visiting the website npra.moh.gov. (Consumers -> Reporting ->Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)).

Storage and Disposal of LETRAM

- *Storage*
Store below 30 ºC.

- *Disposal*

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description
- *What it looks like*

LETRAM Oral Solution (Levetiracetam oral solution) : LEVETIRACETAM ORAL SOLUTION 100 MG/ML filled in 200 ml glass bottle/28 mm neck amber TYPE III-DMF, capped with child resistant with expanded PE wad, 28 mm.

- *Ingredients*
  - Active ingredient

    Each ml contains :
    Levetiracetam….. 100 mg

  - Inactive ingredients

    LETRAM OS (Levetiracetam Oral Solution 100 mg/ml)
    Methyl Parahydroxy Benzoate, Propyl Parahydroxy Benzoate, Maltitol, glycerol, Citric Acid Monohydrate, Sodium Citrate Dihydrate, Ammonium Glycyrrhizinate, Acesulfame Potassium, Purified Water, Grapefruit Flavor.

- *MAL number(s):*

LETRAM OS (Levetiracetam Oral Solution) : MAL15095023AZ

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