LOGUFEN

Levetiracetam Tablets 250 mg & 500 mg

What is in this leaflet

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

1. What Logufen is used for

Logufen tablets contain a medicine called Levetiracetam. This belongs to a group of medicines called Antiepileptic medicine (a medicine used to treat seizures in epilepsy).

Logufen is used:

- in adults and adolescents from 16 years of age with newly diagnosed epilepsy, to treat a certain form of epilepsy. Epilepsy is a condition where the patients have repeated fits (seizures). Levetiracetam is used for the epilepsy form in which the fits initially affect only one side of the brain, but could thereafter extend to larger areas on both sides of the brain (partial onset seizure with or without secondary generalisation). Levetiracetam has been given to you by your doctor to reduce the number of fits.

- as an add-on to other antiepileptic medicines to treat:
  - partial onset seizures with or without generalisation in adults and children from 4 years of age
  - myoclonic seizures (short, shock-like jerks of a muscle or group of muscles) in adults and adolescents from 12 years of age with juvenile myoclonic epilepsy;
  - primary generalised tonic-clonic seizures (major fits, including loss of consciousness) in adults and adolescents from 12 years of age with idiopathic generalised epilepsy (the type of epilepsy that is thought to have a genetic cause).

2. How Logufen works

Logufen is an antiepileptic medicine (a medicine used to treat seizures in epilepsy).

3. Before you use Logufen

- *When you must not use it*

- If you are allergic (hypersensitive) to Levetiracetam or other pyrrolidone derivatives or to any of the excipients. (These are listed at the end of the leaflet).
- If you have kidney disease or kidney injury.
- If you have extreme liver problem.
- If you have low blood cell counts (neutropenia, agranulocytosis, leucopenia, thrombocytopenia and pancytopenia)
- If you are lactating mother.
- In infants or in children under 4 years of age.

Pregnancy and lactation

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Logufen should not be used during pregnancy unless clearly necessary. A risk of birth defects for your unborn child cannot be completely excluded. Levetiracetam has shown unwanted reproductive effects in animal studies at dose levels higher than you would need to control your seizures.
Breast-feeding is not recommended during treatment. Talk to your doctor before taking this product if you are pregnant or breast feeding.

- *Before you start use it*

Talk to your doctor before taking Logufen

- 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.
- A small number of people being treated with anti-epileptics such as Logufen 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*

Some medicines can interfere with your treatment. Talk to your doctor or pharmacist if you are taking any of the following:

- Probenecid (for gout)
- Methotrexate (cancer and rheumatoid arthritis)
- Osmotic laxative macrogol (to treat and/or prevent constipation.)

Always tell your doctor or pharmacist about all the medicines you are taking. This means medicines you have bought yourself as well as medicines on prescription from your doctor.

4. How to use Logufen

- *How much to use*

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
Take the number of tablets following your doctor's instructions.
Logufen must be taken twice a day, once in the morning and once in the evening, at about the same time each day. Your doctor will prescribe the most appropriate dose of Logufen according to the age and weight.

- *When to use it*

Use as directed by your doctor or pharmacist.

- *How long to use it*

Logufen is used as a chronic treatment. You should continue Logufen 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.

- *If you forget to use it*

Contact your doctor if you have missed one or more doses. Do not take a double dose to make up for a forgotten tablet.

- *If you use too much (overdose)*

The possible side effects of an overdose of Logufen are sleepiness, agitation,

aggression, decrease of alertness, inhibition of breathing and coma.
Contact your doctor if you took more tablets than you should. Your doctor will establish the best possible treatment of overdose.

5. While you are using it
- *Things you must do*

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking Logufen.

Tell your doctor immediately if you become pregnant while taking this medication.

- *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.
- Do not give Logufen to anyone else, even if they have the same symptoms or condition as you.

- *Things to be careful of*

Driving and using machines

You may feel sleepiness at the beginning of treatment. If this happens, do not drive or use any tools or machines.

6. Side effects
Like all medicines, this medicine can cause side effects, although not everybody gets them.
Consult your doctor / pharmacist for further information.
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 sudden decrease of kidney function.
- Signs or 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 behaviour or other neurological signs including involuntary or uncontrolled movements, these could be symptoms of an encephalopathy.
- The most frequently reported side effects are nasopharyngitis, somnolence (sleepiness), headache, fatigue and dizziness. At the beginning of the treatment or at dose increase side effects like sleepiness, tiredness and dizziness may be more common. These effects should however decrease over time.

Very common:
- nasopharyngitis;
- somnolence (sleepiness), headache.

Common:
- anorexia (loss of appetite);
- depression, hostility or aggression, anxiety, insomnia, nervousness or irritability;
- convulsion, balance disorder (equilibrium disorder), dizziness (sensation of unsteadiness), lethargy (lack of energy and enthusiasm), tremor (involuntary trembling);
- vertigo (sensation of rotation);
- cough;
- abdominal pain, diarrhoea, dyspepsia (indigestion), vomiting, nausea;
- rash;
- asthenia/fatigue (tiredness).

Uncommon:
- decreased number of blood platelets, decreased number of white blood cells;
- weight decrease, weight increase;
- suicide attempt and suicidal ideation, mental disorder, abnormal behaviour, hallucination, anger, confusion, panic attack, emotional instability/mood swings, agitation;
- amnesia (loss of memory), memory impairment (forgetfulness), abnormal coordination/ataxia (impaired coordinated movements), paraesthesia (tingling), disturbance in attention (loss of concentration);
- diplopia (double vision), vision blurred;
- elevated/abnormal values in a liver function test;
- hair loss, eczema, pruritus;
- muscle weakness, myalgia (muscle pain);
- injury.

Rare:
- infection;
- decreased number of all blood cell types;
- severe allergic reactions (DRESS, anaphylactic reaction [severe and important allergic reaction], Quincke's oedema [swelling of the face, lips, tongue and throat]);
- decreased blood sodium concentration;
- suicide, personality disorders (behavioural problems), thinking abnormal (slow thinking, unable to concentrate);
- uncontrollable muscle spasms affecting the head, torso and limbs, difficulty in controlling movements, hyperkinesia (hyperactivity);
- pancreatitis;
- liver failure, hepatitis;
- sudden decrease in kidney function
- skin rash, which may form blisters and looks like small targets (central dark spots surrounded by a paler area, with a dark ring around the edge) (*erythema multiforme*), a widespread rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals (*Stevens–Johnson syndrome)*, and a more severe form causing skin peeling in more than 30% of the body surface (*toxic epidermal necrolysis*).
- rhabdomyolysis (breakdown of muscle tissue) and associated blood creatine phosphokinase increase. Prevalence is significantly higher in Japanese patients when compared to non-Japanese patients.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

7. Storage and Disposal of Logufen
- *Storage*

Keep this medicine below 30ºC, out of the sight and reach of children.

Do not use this medicine after the expiry date stated on the carton box and blister after EXP.

- *Disposal*

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

8. Product Description

- *What it looks like*

Logufen Tablets 250 mg: White to off white color, oval shape, film coated tablets, with break line on one side.

Logufen Tablets 500 mg: Yellow color, oval shape, film coated tablets, with break line on one side.

* The break line is non-functional and the scored tablet is not meant to be cut / split in half.

- *Ingredients*

Logufen Tablets 250 mg: Maize starch, povidone, croscarmellose sodium, colloidal anhydrous silica, magnesium stearate, Opadry (II) 85G68918 white.

Logufen Tablets 500 mg: Maize starch, povidone, croscarmellose sodium, colloidal anhydrous silica, magnesium stearate, opadry (II) 85G52482 yellow.

- *MAL number(s):*

Logufen Tablets 250 mg
MALXXXXXXXX

Logufen Tablets 500 mg
MALXXXXXXXX

Manufacturer
Kusum Healthcare Private Limited
SP-289 (A), RIICO Industrial Area, Chopanki, Bhiwadi, Dist. Alwar, (Rajasthan), India

Product Registration Holder
Pahang Pharmacy Sdn. Bhd.,
Lot 5979 Jalan Teratai, 5 1/2 Miles Off Jalan Meru, 41050 Klang, Selangor, Malaysia

Date of revision
16/02/2021

Serial Number
NPRA (R2) 21/001