Package leaflet: Information for the patient

Levetiracetam Mylan 250 mg Film-coated Tablets
Levetiracetam Mylan 500 mg Film-coated Tablets
Levetiracetam Mylan 1000 mg Film-coated Tablets
levetiracetam

Read all of this leaflet carefully before you or your child start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Levetiracetam Mylan is and what it is used for
2. What you need to know before you take Levetiracetam Mylan
3. How to take Levetiracetam Mylan
4. Possible side effects
5. How to store Levetiracetam Mylan
6. Contents of the pack and other information

1. What Levetiracetam Mylan is and what it is used for

Levetiracetam Mylan contains the active substance levetiracetam, which is an antiepileptic medicine (a medicine used to treat seizures in epilepsy).

Levetiracetam Mylan is used:
- on its own 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 Mylan is used for the epilepsy form in which the fits initially affect only one side of the brain, but could then extend to larger areas on both sides of the brain (partial onset seizures with or without secondary generalisation). Levetiracetam Mylan 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, adolescents, children and infants from one month 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. What you need to know before you take Levetiracetam Mylan

Do not take Levetiracetam Mylan:
- if you are allergic to levetiracetam, other pyrrolidone derivatives or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Talk to your doctor before taking Levetiracetam Mylan:
- If you suffer from kidney problems, follow your doctor's instructions. He/she may decide if your dose should be adjusted.

A small number of people being treated with anti-epileptics such as levetiracetam have had thoughts of harming or killing themselves. If you have any symptoms of depression and/or suicidal thoughts, please contact your doctor.

Children and adolescents
If you notice any slow down in the growth or unexpected puberty development of your child, please contact your doctor. Levetiracetam is not intended for use on its own (monotherapy) in children and adolescents below 16 years.

Other medicines and Levetiracetam Mylan
Tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines, including medicines obtained without a prescription.

It is especially important to inform your doctor if you are taking:
- methotrexate (a medicine for psoriasis, inflammation and some cancers).
- macrogol (a medicine for constipation). You should not take macrogol for one hour before and one hour after taking levetiracetam as this may decrease its effect.
- probenecid (medicine for gout).

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Levetiracetam Mylan should not be used during pregnancy unless clearly necessary, as there is a risk of harm to your unborn child.

Breast-feeding is not recommended during treatment as levetiracetam passes into breast milk.

Driving and using machines
Levetiracetam may impair your ability to drive or operate any tools or machinery, as it 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.

3. How to take Levetiracetam Mylan

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.

Levetiracetam Mylan must be taken twice a day, once in the morning and once in the evening, at about the same time each day.

Swallow Levetiracetam Mylan tablets with a sufficient quantity of liquid (e.g. a glass of water). You may take this medicine with or without food.

The score line is only there to help you break the tablet if you have difficulty swallowing it whole.

Monotherapy

Dose in adults and adolescents (from 16 years of age):
General dose: between 1000 mg and 3000 mg each day.
When you will first start taking Levetiracetam Mylan, your doctor will prescribe you a **lower dose (500 mg each day)** during 2 weeks before giving you the lowest general dose of 1000 mg.
Example: if your daily dose is 1000 mg, your reduced starting dose is 2 tablets of 250 mg in the morning and 2 tablets of 250 mg in the evening.

Add-on therapy

Dose in adults and adolescents (12 to 17 years) weighing 50 kg or more:
General dose: between 1000 mg and 3000 mg each day.
Example: if your daily dose is 1000 mg, you might take 2 tablets of 250 mg in the morning and 2 tablets of 250 mg in the evening.

Dose in infants (1 month to 23 months), children (2 to 11 years) and adolescents (12 to 17 years) weighing less than 50 kg:
Your doctor will prescribe the most appropriate pharmaceutical form of levetiracetam according to the age, weight and dose.

An oral solution may be available which is a formulation more appropriate to infants and children under the age of 6 years and to children and adolescents (from 6 to 17 years) weighing less than 50 kg and when tablets do not allow accurate dosing.

Duration of treatment:
- Levetiracetam Mylan is used as a chronic treatment. You should continue Levetiracetam Mylan 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 take more Levetiracetam Mylan than you should
The possible side effects of an overdose of Levetiracetam Mylan 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.

If you forget to take Levetiracetam Mylan
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 stop taking Levetiracetam Mylan
If stopping treatment, as with other antiepileptic medicines, Levetiracetam Mylan should be discontinued gradually to avoid an increase of seizures. Should your doctor decide to stop your treatment with this medicine, he/she will instruct you about a gradual withdrawal.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

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

The most frequently reported side effects are a sore nose or throat (nasopharyngitis), sleepiness (somnolence), headache, fatigue and dizziness. At the beginning of treatment or at dose increase, side effects like sleepiness, tiredness and dizziness may be more common at the beginning of the treatment or at dosage increase. These effects should however decrease over time.

Tell your doctor immediately, or go to your nearest emergency department, if you experience:
- weakness, feel light-headed or dizzy or have difficulty breathing, as these may be signs of a serious allergic (anaphylactic) reaction
- swelling of the face, lips, tongue and throat (Quincke's oedema)
- flu-like symptoms and a rash on the face followed by an extended rash with a high temperature, increased levels of liver enzymes seen in blood tests and an increase in a type of white blood cell

(eosinophilia) and enlarged lymph nodes (Drug Reaction with Eosinophilia and Systemic Symptoms [DRESS])
- symptoms such as low urine volume, tiredness, nausea, vomiting, confusion and swelling in the legs, ankles or feet, as this may be a sign of sudden decrease of kidney function
- a skin rash which may form blisters and look 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*)
- a more severe form of rash causing skin peeling in more than 30% of the body surface (*toxic epidermal necrolysis*)
- signs of serious mental changes or 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
- thinking about suicide or attempting suicide
- severe abdominal pain that spreads to the back, which may be signs of a swollen pancreas.

Tell your doctor straight away if you notice any of the following, as you may need medical attention

Uncommon (may affect up to 1 in 100 people):
- increased signs of infection such as sore throat, fever, mouth ulcers, which may be caused by a reduction in white blood cells.

Rare (may affect up to 1 in 1,000 people):
- signs of liver problems such as abdominal pain, fever, pale stools or dark urine, yellowing of the skin and eyes
- rhabdomyolysis (breakdown of muscle tissue) and associated blood creatine phosphokinase increase. Prevalence is significantly higher in Japanese patients when compared to non-Japanese patients.

Other side effects include:

Very common: may affect more than 1 in 10 people
- nasopharyngitis (sore nose or throat)
- somnolence (sleepiness), headache.

Common: may affect up to 1 in 10 people
- 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 (weakness/tiredness).

Uncommon: may affect up to 1 in 100 people
- decreased number of blood platelets, causing you to bruise or bleed more easily or for longer than usual
- weight decrease, weight increase
- 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
- liver function test abnormal

- hair loss, eczema, pruritus
- muscle weakness, myalgia (muscle pain)
- injury.

Rare: may affect up to 1 in 1,000 people
- decreased number of all blood cell types
- infection
- 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)
- decreased blood sodium concentration.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.
You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517; website: http://www.hpra.ie; e-mail: medsafety@hpra.ie..

By reporting side effects, you can help provide more information on the safety of this medicine**.**

5. How to store Levetiracetam Mylan

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date, which is stated on the carton, bottle and blister after EXP. The expiry date refers to the last day of that month.
This medicinal product does not require any special storage conditions.

Bottles: Use within 3 months of opening. Once open keep bottle tightly closed.

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

6. Contents of the pack and other information

What Levetiracetam Mylan contains
- The active substance is levetiracetam. Each film-coated tablet contains either 250 mg, 500 mg, or 1000 mg levetiracetam.
- The other ingredients are: Tablet core: Povidone; microcrystalline cellulose; croscarmellose sodium; magnesium stearate; sodium laurilsulfate; colloidal anhydrous silica. Film coat: titanium dioxide (E171); polydextrose; hypromellose; triacetin; macrogol 8000, macrogol 400.

What Levetiracetam Mylan looks like and contents of the pack
Film-coated Tablet
250 mg tablet: A white film-coated, round, biconvex, beveled-edge tablet marked with “M” above the score and “613” below the score on one side of the tablet and blank on the other side.
500 mg tablet: A white film-coated, oblong shaped, biconvex, beveled-edge tablet marked with “M” on the left of the score and “615” on the right of the score on one side of the tablet and blank on the other side.
1000 mg tablet: A white film-coated, oblong shaped, biconvex, beveled-edge tablet marked with “M” on the left of the score and “619” on the right of the score on one side of the tablet and blank on the other side.

Levetiracetam Mylan Tablets are packed in blister packs containing 20, 30, 50, 60, 90, 100, 120 and 200 film-coated tablets and perforated unit-dose blisters of 30 x 1 and 60 x 1 film-coated tablets.
Levetiracetam Mylan Tablets are packed in bottles containing 60, 100, 120, 200 and 500 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder
McDermott Laboratories Limited t/a Gerard Laboratories, 35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13 Ireland.

Manufacturer
Generics [UK] Ltd, Station Close, Potters Bar, Hertfordshire, EN6 1TL, United Kingdom.
McDermott Laboratories Limited t/a Gerard Laboratories, 35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland.

This medicinal product is authorised in the Member States of the EEA under the following names:

Denmark	Levetiracetam Mylan
France	Lévétiracétam Mylan 250 mg, 500 mg, 750 mg, 1000 mg comprimé pelliculé
Germany	Levetiracetam Mylan 250 mg, 500 mg, 750 mg, 1000 mg Filmtabletten
Greece	Levetiracetam/Mylan Film-coated Tablets 250 mg, 500 mg, 750 mg, 1000 mg/TAB
Ireland	Levetiracetam Mylan 250 mg, 500 mg, 1000 mg Film-coated Tablets
Portugal	Levetiracetam Mylan
Romania	Levetiracetam Mylan 250 mg, 500 mg, 750 mg, 1000 mg comprimate filmate
Slovakia	Levetiracetam Mylan
Slovenia	Levetiracetama Mylan 250 mg, 500 mg, 1000 mg filmsko obložene tablete
Spain	Levetiracetam MYLAN 250 mg, 500 mg, 1000 mg comprimidos recubiertos con película EFG
The Netherlands	Levetiracetam Mylan 250 mg, 500 mg, 750 mg, 1000 mg filmomhulde tabletten
United Kingdom	Levetiracetam Mylan 250 mg, 500 mg, 750 mg, 1000 mg Film-coated Tablets

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