PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

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Levetiracetam 250 mg Film-coated Tablets

Levetiracetam

Read all of this leaflet carefully before you 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:

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1 What Levetiracetam is and what it is used for

Levetiracetam is an antiepileptic medicine (a medicine used to treat seizures in epilepsy).
This medicine is used:
- on its own in adults and adolescents from 16 years of age with newly diagnosed epilepsy, to treat partial onset seizures with or without secondary generalisation.
- as an add-on to other antiepileptic medicines to treat:
  - partial onset seizures with or without generalisation in adults, adolescents, children and infants from 1 month age.
  - myoclonic seizures in adults and adolescents from 12 years of age with juvenile myoclonic epilepsy.
  - primary generalised tonic-clonic seizures in adults and adolescents from 12 years of age with idiopathic generalised epilepsy.

2 What you need to know before you take Levetiracetam

Do NOT take Levetiracetam:
- if you are allergic (hypersensitive) to levetiracetam or any of the other ingredients of this medicine (listed in Section 6).

Warnings and precautions
Talk to your doctor before taking Levetiracetam if you:
- have kidney problems, follow your doctor's instructions, your dose may need to be adjusted.
- notice any slow down in the growth or unexpected puberty development of your child, please contact your doctor.
- notice an increase in seizure severity (e.g. increased number), please contact your doctor.
- have any symptoms of depression and / or suicidal ideation, please contact your doctor. A small number of people being treated with antiepileptics such as Levetiracetam have had thoughts of harming or killing themselves.
- If you have a family or medical history of irregular heart rhythm (visible on an electrocardiogram), or if you have a disease and/or take a treatment that make(s) you prone to heartbeat irregularities or salt imbalances.

Tell your doctor or pharmacist if any of the following side effects gets serious or last longer than a few days:
- Abnormal thoughts, feeling irritable or reacting more aggressively than usually, or if you or your family and friends notice important changes in mood or behaviour.
- Aggravation of epilepsy
  Your seizures may rarely become worse or happen more often, mainly during the first month after the start of the treatment or increase of the dose. If you experience any of these new symptoms while taking Levetiracetam, see a doctor as soon as possible.

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

Levetiracetam with food, drink and alcohol
You can take Levetiracetam with or without food. As a safety precaution, do not take Levetiracetam with alcohol.

Pregnancy and breast-feeding
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.
Levetiracetam can be used during pregnancy, only if after careful assessment it is considered necessary by your doctor. You should not stop your treatment without discussing this with your doctor.
A risk of birth defects for your unborn child cannot be completely excluded.
Breast-feeding is not recommended during treatment.

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.

Levetiracetam contains sodium.
Levetiracetam contains less than 1 mmol sodium (23mg) per film-coated tablet, that is to say essentially 'sodium free'.

3 How to take Levetiracetam

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
Levetiracetam 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.

Adjunctive Therapy and monotherapy (from 16 years of age)

- **Adults (≥18 years) and adolescents (12 to 17 years) weighing 50 kg or more:**

Recommended dose: between 1,000 mg and 3,000 mg each day.
When you first start taking Levetiracetam, your doctor will prescribe you a **lower dose** for 2 weeks before giving you the lowest daily dose.

Example: if your daily dose is intended to be 1,000 mg, your reduced starting dose is 1 tablets of 250 mg in the morning and 1 tablets of 250 mg in the evening, and the dose will be gradually incremented to reach 1000 mg daily after 2 weeks.

- **Adolescents (12 to 17 years) weighing 50 kg or less:**

Your doctor will prescribe the most appropriate pharmaceutical form of Levetiracetam according to weight and dose.

Dose in infants (6 to 23 months), and children (2 to 11 years) and adolescents weighing less than 50 kg:

Your doctor will prescribe the most appropriate pharmaceutical form of levetiracetam according to age, weight and dose.

Levetiracetam 100 mg/ml oral solution is a presentation more appropriate to infants and children under the age of 6 years.

General dose: between 20 mg per kg bodyweight and 60 mg per kg bodyweight each day.

Example: a general dose of 20 mg per kg bodyweight each day, you might give your 25 kg child 1 tablet of 250 mg in the morning and 1 tablet of 250 mg in the evening.

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Dose in infants (1 month to less than 6 months):
Levetiracetam 100 mg/ml oral solution is a presentation more appropriate to infants.

Method of administration:
Swallow Levetiracetam Tablets with a sufficient quantity of liquid (e.g. a glass of water). After oral administration the bitter taste of levetiracetam may be experienced.
The tablet can be divided into equal doses.

Duration of treatment:
- Levetiracetam is used as a chronic treatment. You should continue the 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 your doctor decides to stop your treatment, he/she will instruct you to gradually withdraw the treatment.

If you take more Levetiracetam than you should
The possible side effects of an overdose of Levetiracetam are sleepiness, agitation, aggression, decrease of alertness, inhibition of breathing and coma. Contact your doctor if you have taken more tablets than you should. Your doctor will establish the best possible treatment of overdose.

If you forget to take Levetiracetam
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
If you are stopping treatment, as with other antiepileptic medicines, Levetiracetam should be discontinued gradually to avoid an increase in seizures.

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.

Some side effects such as sleepiness, tiredness and dizziness may be more common at the beginning of the treatment or at dose increase. These effects should however decrease over time.

Very common: may affect more than 1 in 10 people
- nasopharyngitis;
- 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, tremor (involuntary trembling);
- vertigo (sensation of rotation);
- cough;
- abdominal pain, diarrhoea, dyspepsia (indigestion), vomiting, nausea;
- rash;
- asthenia/fatigue (tiredness).

Uncommon: may affect up to 1 in 100 people
- 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;
- liver function test abnormal;
- hair loss, eczema, pruritus;
- muscle weakness, myalgia (muscle pain);
- injury.

Rare: may affect up to 1 in 1,000 people
- infection;
- decreased number of all blood cell types;
- severe hypersensitivity reactions (DRESS);
- decreased blood sodium concentration;
- suicide, personality disorders (behavioural problems), thinking abnormal (slow thinking, unable to concentrate);
- delirium;
- encephalopathy (see sub-section "Tell your doctor immediately" for a detailed description of symptoms);
- seizures may become worse or happen more often;
- uncontrollable muscle spasms affecting the head, torso and limbs, difficulty in controlling movements, hyperkinesia (hyperactivity);
- change of the heart rhythm (Electrocardiogram);
- pancreatitis;
- hepatic failure, hepatitis;
- 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);
- limp or difficulty walking;
- combination of fever, muscle stiffness, unstable blood pressure and heart rate, confusion, low level of consciousness (may be signs of a disorder called neuroleptic malignant syndrome). Prevalence is significantly higher in Japanese patients when compared to non-Japanese patients.

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 the Yellow Card Scheme: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in Google play or Apple App store. By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Levetiracetam

Keep this medicine 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.
The expiry date refers to the last day of the month. The shelf life after first opening of the bottle is 100 days.

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.

Store in the original package in order to protect from moisture.

6 Contents of the pack and other information

What Levetiracetam Film-coated Tablets contain
The active substance is called levetiracetam.

Each film-coated tablet contains 250 mg levetiracetam

The other ingredients are:
povidone K25, microcrystalline cellulose, croscarmellose sodium, crospovidone (type A), silica colloidal anhydrous, talc, magnesium stearate. hypromellose, hydroxypropylcellulose, macrogol type 6000, titanium dioxide (E171), talc, indigo carmine (E132) (contains sodium).

What Levetiracetam looks like and contents of the pack
Light blue, oval, biconvex film-coated tablets, scored on both sides, debossed with 'LVT / 250' on one side.

The film-coated tablets are packed in OPA/Alu/PVC - Alu blisters or HDPE bottles with polypropylene screw cap and silica gel capsule and inserted in a carton.

Pack sizes:
Blister: 10, 20, 28, 30, 50, 50 x 1, 60, 100, 120 and 200 film-coated tablets
Bottle: 10, 20, 30, 50, 60, 100, 120 and 200 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
Marketing Authorisation Holder:
Sandoz Limited
Park View, Riverside Way
Watchmoor Park
Camberley, Surrey
GU15 3YL
United Kingdom

Manufacturer:
Lek Pharmaceuticals d.d.Verovškova 57, 1526, Ljubljana, Slovenia ***or*** LEK S.A., ul. Podlipie 16, 95-010 Stryków, Poland ***or*** LEK S.A., ul. Domaniewska 50 C, 02-672 Warszawa, Poland ***or*** Salutas Pharma GmbH, Otto-von-Guericke-Allee 1, 39179 Barleben, Germany ***or*** S.C. Sandoz, S.R.L., Str. Livezeni nr. 7A, RO-540472 Targu-Mures, Romania.

This leaflet was last revised in 08/2022.

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Artwork Proof Box:

Variation:	V039 - Adaption of PI to reference product - SPC, PL
Proof no:	012.0
Date prepared:	30/08/2022
Font size:	7pt
Fonts:	Helvetica
Dimensions:	165 x 310 mm
Technical data:	
SKUs:	0000000
SZ codes:	0000000
Item codes:	0000000
Pharma codes:	0000000
Novartis data if applicable:	
Version:	0000000
Print Proof date:	0000000
AQWA#:	0000000
Production site:	0000000
Technical num:	0000000
Old Comp num:	0000000

Technical Colours:

	Legend:
	Cutting:

Colours:

	Black

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Signature Panel: