# Package Leaflet: Information for the patient

**Levetiracetam Neuraxpharm 250** mg granules for oral solution in sachet
**Levetiracetam Neuraxpharm 500** mg granules for oral solution in sachet
**Levetiracetam Neuraxpharm 750** mg granules for oral solution in sachet
**Levetiracetam Neuraxpharm 1000** mg granules for oral solution in sachet
**Levetiracetam Neuraxpharm 1500** mg granules for oral solution in sachet
**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 granules are and what they are used for
2. What you need to know before you take Levetiracetam granules
3. How to take Levetiracetam granules
4. Possible side effects
5. How to store Levetiracetam granules
6. Contents of the pack and other information

## 1. What Levetiracetam granules are and what they are used for

The name of the medicinal product is Levetiracetam Neuraxpharm granules for oral solution, referred to as Levetiracetam granules throughout this leaflet.

The active substance in Levetiracetam granules is levetiracetam.

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

Levetiracetam granules are used:

- on their 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 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, adolescents and children

- 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 granules

**Do not take Levetiracetam granules:**

- if you are allergic to levetiracetam, 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 granules

- 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 levetiracetam have had thoughts of harming or killing themselves. If you have any symptoms of depression and/or suicidal ideation, please contact your doctor.
- Tell your doctor 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 granules, see a doctor as soon as possible.

**Children and adolescents**

- Levetiracetam granules are not indicated in children and adolescents below 16 years on its own (monotherapy).

**Other medicines and Levetiracetam granules:**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Do not take macrogol (a drug used as laxative) for one hour before and one hour after taking levetiracetam as this may result in a loss of its effect.

**Pregnancy and breast-feeding:**

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.
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. Two studies do not suggest an increased risk of autism or intellectual disability in children born to mothers treated with levetiracetam during pregnancy. However, the available data regarding the impact of levetiracetam on neurodevelopment in children is limited.

Breast-feeding is not recommended during treatment.

**Driving and using machines:**

Levetiracetam granules 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 granules contain isomalt (E 953) and sucrose.**

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.
Sucrose may be harmful to the teeth.

## 3. How to take Levetiracetam granules

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 amount of granules following your doctor's instructions.
Levetiracetam granules must be taken twice a day, once in the morning and once in the evening, at about the same time each day.

***Adjunctive therapy and monotherapy (from 16 years of age)***

- **Adults (≥18 years) and adolescents (12 to 17 years) weighing 50 kg or more:**
  General dose: between 1000 mg and 3000 mg each day.
  When you first start taking Levetiracetam granules, your doctor may prescribe you a **lower dose** for 2 weeks before giving you the lowest general dose.
  *Example: if your daily dose is intended to be 1000 mg, your starting dose may be 1 sachet of 250 mg in the morning and 1 sachet of 250 mg in the evening, and the dose then gradually increased 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 (1 month to 23 months) and children (2 to 11 years) weighing less than 50 kg:**
  Your doctor will prescribe the most appropriate pharmaceutical form of levetiracetam according to the age, weight and dose.
  Levetiracetam oral solution is a formulation more appropriate for infants and children under the age of 6 years, for children and adolescents (from 6 to 17 years) weighing less than 50 kg and for when granules for oral solution don't allow accurate dosage.

**Method of administration:**

Empty the entire contents of the sachet into a glass of water. Stir well until the granules have dissolved, then drink the solution immediately.
After drinking the solution, you may experience the bitter taste of levetiracetam.
You may take this medicine with or without food.

**Duration of treatment:**

- Levetiracetam is used as a chronic treatment. You should continue Levetiracetam granules 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 granules than you should:**

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

**If you forget to take Levetiracetam granules:**

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

**If you stop taking Levetiracetam granules:**

If stopping treatment, Levetiracetam granules should be discontinued gradually to avoid an increase of seizures. Should your doctor decide to stop your Levetiracetam granules treatment, he/she will instruct you about the gradual withdrawal of Levetiracetam granules.

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.

**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

The most frequently reported adverse reactions were 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 (**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 (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 (**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
- elevated/abnormal values in a liver function test
- 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 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)
- 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
- 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
- limp or difficulty walking

**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 Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the 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 granules

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

Do not use this medicine after the expiry date stated on the carton and sachets after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

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 to protect the environment.

## 6. Contents of the pack and other information

**What Levetiracetam granules contain**

The active substance is levetiracetam.

*Levetiracetam Neuraxpharm 250 mg granules for oral solution:* each sachet contains 250 mg of levetiracetam
*Levetiracetam Neuraxpharm 500 mg granules for oral solution:* each sachet contains 500 mg of levetiracetam
*Levetiracetam Neuraxpharm 750 mg granules for oral solution:* each sachet contains 750 mg of levetiracetam
*Levetiracetam Neuraxpharm 1000 mg granules for oral solution:* each sachet contains 1000 mg of levetiracetam
*Levetiracetam Neuraxpharm 1500 mg granules for oral solution:* each sachet contains 1500 mg of levetiracetam
The other ingredients are: isomalt, acesulfame potassium, fantasy flavour (contains sucrose and propylene glycol (E 1520), masking flavour, ammonium glycyrrhizate.

**What Levetiracetam granules look like and contents of the pack**

Levetiracetam Neuraxpharm granules for oral solution is a white to slight brownish powder contained in a sachet.

*Levetiracetam Neuraxpharm 250 mg granules for oral solution:* each sachet contains 1 g of granules

*Levetiracetam Neuraxpharm 500 mg granules for oral solution:* each sachet contains 2 g of granules

*Levetiracetam Neuraxpharm 750 mg granules for oral solution:* each sachet contains 3 g of granules

*Levetiracetam Neuraxpharm 1000 mg granules for oral solution:* each sachet contains 4 g of granules

*Levetiracetam Neuraxpharm 1500 mg granules for oral solution:* each sachet contains 6 g of granules

The sachets are supplied in cardboard cartons.
Each carton contains 60 sachets.

**Marketing Authorisation Holder**
Neuraxpharm UK Limited
First Floor, Building 1410,
Arlington Business Park,
Theale, Reading,
Berkshire, RG7 4SA
United Kingdom

**Manufacturer**
neuraxpharm Arzneimittel GmbH
Elisabeth-Selbert-Straße 23
40764 Langenfeld
Germany

**This leaflet was last revised in 12/2025**