Levetiracetam Neuraxpharm 250 mg, 500 mg, 750 mg, 1000 mg, 1500 mg granules for oral solution in sachet Prescribing Information

Please consult the full Summary of Product Characteristics (SmPC) before prescribing

Presentation: Each sachet contains either 250 mg, 500 mg, 750 mg, 1000 mg, or 1500 mg levetiracetam (in 1 g, 2 g, 3 g, 4 g, or 5 g of oral solution, respectively). **Indication:** Monotherapy in the treatment of partial onset seizures with or without secondary generalisation in adults and adolescents from 16 years of age with newly diagnosed epilepsy. *As adjunctive therapy:* in the treatment of partial onset seizures with or without secondary generalisation in adults,adolescents , children and infants from 1 month of age with epilepsy; in the treatment of myoclonic seizures in adults and adolescents from 12 years of age with Juvenile Myoclonic Epilepsy; in the treatment of primary generalised tonic-clonic seizures in adults and adolescents from 12 years of age with Idiopathic Generalised Epilepsy. **Dosage and administration:** *Partial onset seizures:* Recommended dosing for monotherapy (from 16 years of age) and adjunctive therapy is the same. *Adults (≥18 years) and adolescents (12 to 17 years) weighing 50 kg or more*: The initial therapeutic dose is 500 mg twice daily, starting from the first day of treatment. A lower initial dose of 250 mg twice daily may be given based on physician assessment of seizure reduction versus potential side effects, which can be increased to 500 mg twice daily after two weeks. The daily dose can be increased to 1500 mg twice daily depending upon the clinical response and tolerability. Dose changes can be made in 250 mg or 500 mg twice daily increases or decreases every two to four weeks. *Adolescents (12 to 17 years) weighing below 50 kg and children children from 1 month of age*: The physician should prescribe the most appropriate pharmaceutical form, presentation and strength according to weight, age and dose. *Discontinuation:* It is recommended to withdraw levetiracetam gradually. *Elderly (65 years and older):* Dose adjustment is recommended in elderly patients with compromised renal function. *Renal impairment:* The daily dose must be individualised according to renal function. Please refer to the full SmPC for further details. *Hepatic impairment:* No dose adjustment is needed in patients with mild to moderate hepatic impairment. In patients with severe hepatic impairment a 50% reduction of the daily maintenance dose is recommended when the creatinine clearance is <60 ml/min/1.73 m^2. *Paediatric population:* The most appropriate pharmaceutical form, presentation and strength according to age, weight and dose should be prescribed. Levetiracetam oral solution is the preferred formulation for use in infants and children under the age of 6 years. *Add on therapy for infants aged from 6 to 23 months, children (2 to 11 years) and adolescents (12 to 17 years) weighing less than 50 kg:* The initial therapeutic dose is 10 mg/kg twice daily. Depending upon the clinical response and tolerability, the dose can be increased by 10 mg/kg twice daily every 2 weeks 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 for all indications. Please refer to the full SmPC for further details. The granules should be dissolved in a glass of water, and the resulting solution ingested immediately after reconstitution. The solution may be taken with or without food. The daily dose is administered in two equally divided doses. **Contraindications:** Hypersensitivity to the active substance or other pyrrolidone derivatives or to any of the excipients. **Special warnings and precautions:** *Renal impairment:* Dose adjustment may be required for patients with renal impairment. *Acute kidney injury:* Use of levetiracetam has been very rarely associated with acute kidney injury. *Blood cell counts:* Rare cases of decreased blood cell counts have been described in association with levetiracetam administration, generally at the beginning of treatment. *Suicide:* Patients should be monitored for signs of depression and/or suicidal ideation and behaviours and appropriate treatment should be considered. Patients (and caregivers of patients) should be advised to seek medical advice should signs of depression and/or suicidal ideation or behaviour emerge. *Abnormal and aggressive behavours:* Patients treated with levetiracetam should be monitored for developing psychiatric signs suggesting important mood and/or personality changes. If such behaviours are noticed, treatment adaptation or gradual discontinuation should be considered. *Worsening of seizures:* Patients should be advised to consult their physician immediately in case of aggravation of epilepsy. *Electrocardiogram QT interval prolongation:* Levetiracetam should be used with caution in patients with QTc-interval prolongation, in patients concomitantly treated with drugs affecting the QTc-interval, or in patients with relevant pre-existing cardiac disease or electrolyte disturbances. *Paediatric population:* Available data in children did not suggest impact on growth and puberty. However, long term effects on learning, intelligence, growth, endocrine function, puberty and childbearing potential in children remain unknown. *Excipients:* Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine. **For further information please refer to SmPC**. **Pregnancy and lactation**: Treatment with levetiracetam should be reviewed when a woman is planning to become pregnant. Levetiracetam can be used during pregnancy, if after careful assessment it is considered clinically needed. In such case, the lowest effective dose is recommended. Breast-feeding is not recommended whilst taking levetiraccetam. **Effects on ability to drive and use machines:** Caution is recommended in those patients when performing skilled tasks, e.g. driving vehicles or operating machinery. Patients are advised not to drive or use machines until it is established that their ability to perform such activities is not affected. **Undesirable effects:** *Very common (≥1/10):* nasopharyngitis, somnolence, headache; *Common (≥1/100 to <1/10):* anorexia, depression, hostility/aggression, anxiety, insomnia, nervousness/irritability, convulsion, balance disorder, dizziness, lethargy, tremor, vertigo, cough, abdominal pain, diarrhoea, dyspepsia, vomiting, nausea, rash, asthenia/fatigue. **Refer to SmPC for full details**. **Legal category:** POM. **Presentation & cost:** (60 sachets) 250 mg £22.41; 500 mg £39.46; 750 mg £57.87; 1000 mg £76.27; 1500 mg £110.73. **Marketing authorisation holder and numbers:** Neuraxpharm UK Limited. Unit 12, Farnborough Business Centre, Eelmoor Road, Farnborough GU14 7XA, UK. (250 mg) PL 49718/0073, (500 mg) PL 49718/0074, (750 mg) PL 49718/0075, (1000 mg) PL 49718/0076, (1500 mg) PL 49718/0077. **Date of revision of text:** August 2022.

Adverse events should be reported. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to Neuraxpharm UK Ltd by email to pv-uk@neuraxpharm.com