Desitrend® (levetiracetam) Prescribing Information.
Always consult the Summary of Product Characteristics (SmPC) before prescribing Desitrend®.
Levetiracetam available as Desitrend 250 / 500 / 1000 mg coated granules in sachet. **Indications**: Monotherapy: partial seizures with or without secondary generalisation in adults/adolescents from 16 years of age with newly diagnosed epilepsy. Adjunctive therapy: Partial seizures with or without secondary generalisation in adults, adolescents, children, and infants from 1 month of age, with epilepsy. Myoclonic seizures in adults/adolescents from 12 years of age with Juvenile Myoclonic Epilepsy. Primary generalised tonic-clonic seizures in adults/adolescents from 12 years of age with Idiopathic Generalised Epilepsy. **Dosage:** Use lowest effective dose. If discontinuation required, withdraw gradually (see SmPC for guidance). The recommended dosing for monotherapy from 16 years of age and adjunctive therapy is the same; as outlined below. **Adults (≥18 years) and adolescents (12 to 17 years) weighing 50 kg or more:** The initial therapeutic dose is 500 mg twice daily. This dose can be started on the first day of treatment. However, a lower initial dose of 250 mg twice daily may be given based on physician assessment of seizure reduction versus potential side effects. This can be increased to 500 mg twice daily after two weeks.Depending upon the clinical response and tolerability, the daily dose can be increased up to 1,500 mg twice daily. 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 from 1 month of age:** The physician should prescribe the most appropriate pharmaceutical form, presentation and strength according to weight, age and dose. Refer to Paediatric population section for dosing adjustments based on weight. Elderly: Adjust dose in compromised renal function. Renal impairment: Individualise dose according to renal function (see SmPC). Hepatic impairment: In severe hepatic impairment, CLCr may underestimate renal function so reduce daily dose by 50% when CLCr <60 ml/min. Paediatric population: Prescribe the most appropriate presentation according to age, weight and dose. Granules not adapted for use in infants and children <6 years and not appropriate for initial treatment of children <25 kg, or doses <250 mg, or for doses not multiple of 250 mg when the dose is not achievable by taking multiple sachets: in all cases use levetiracetam oral solution. *Monotherapy*: No data in children or adolescents below 16 years. *Adjunctive therapy*: Infants, children and adolescents (aged 6 months to 17 years) weighing <50 kg: Starting dose for a child or adolescent weighing 25 kg: 250 mg bid. Max. dose 750 mg bid. Dose in children ≥50 kg, same as in adults. Infants from 1 month to <6 months: Use oral solution. **Administration:** Swallow granules with a sufficient quantity of liquid. Take with/without food. Bitter taste may be experienced. See SmPC for administration via a feeding tube. Each sachet is for single use only. **Contraindications**: Hypersensitivity to levetiracetam or other pyrrolidone derivatives or to any of the excipients. **Special warnings and precautions for use (see SmPC)**: Patients with renal or severe hepatic dysfunction require dose adjustment. Rare reports of acute kidney injury. Rare reports of decreased blood cell counts, generally at the start of treatment: complete blood cell counts advised in patients with relevant clinical signs. Available data in children do not suggest impact on growth and puberty, but long-term effects remain unknown. Suicide, suicide attempt, suicidal ideation and behaviour have been reported: monitor patients for signs and consider treatment. Advise patients/carers to seek medical advice if signs emerge. Abnormal and aggressive behaviours, psychotic symptoms, behavioural abnormalities including irritability and aggressiveness have been reported: monitor patients for developing psychiatric signs. If such behaviours are noticed, treatment adaptation or gradual discontinuation should be considered. Worsening of seizures. As with other types of antiepileptic drugs, levetiracetam may rarely exacerbate seizure frequency or severity. Patients should be advised to consult their physician immediately in case of aggravation of epilepsy. Lack of efficacy or seizure worsening has been reported in patients with epilepsy associated with sodium voltage-gated channel alpha subunit 8 (SCN8A) mutations. Electrocardiogram QT interval prolongation. Rare cases of ECG QT interval prolongation have been observed during the post-marketing surveillance. 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.
Interactions: Decreases methotrexate clearance resulting in potentially toxic levels: carefully monitor methotrexate and levetiracetam levels. Isolated reports of decreased efficacy when administered with macrogol: macrogol should not be taken orally for 1 hour before/after taking levetiracetam. **Effects on ability to drive and use machines**: Minor or moderate influence. **Pregnancy/lactation**: Women of childbearing potential: Specialist advice should be given. Review treatment when a woman is planning to become pregnant. Avoid sudden discontinuation. Monotherapy preferred when possible. Pregnancy: Postmarketing data do not suggest an increase in the risk for major congenital malformations. Limited evidence on neurodevelopment of children exposed to monotherapy *in utero* does not suggest an increased risk of disorders or delays. Can be used in pregnancy if clinically needed, after careful assessment. Use lowest effective dose. Levetiracetam plasma levels may decrease during pregnancy, particularly in the third trimester. Lactation: Excreted in breast milk therefore not recommended. If needed, consider benefit/risk. **Side effects (see SmPC for full list)**: *Very common*: Nasopharyngitis; somnolence, headache. *Common*: anorexia (higher risk with concomitant topiramate); depression, hostility/aggression, anxiety, insomnia, nervousness/irritability; convulsion, balance disorder, dizziness, lethargy, tremor; vertigo; cough; abdominal pain, diarrhoea, dyspepsia, vomiting, nausea; rash; asthenia/fatigue. *Uncommon*: Thrombocytopenia, leukopenia; weight decrease/increase; suicide attempt, suicidal ideation, psychotic disorder, abnormal behaviour, hallucination, anger, confusional state, panic attack, affect lability/mood swings, agitation; amnesia, memory impairment, coordination abnormal/ataxia, paraesthesia, disturbance in attention; diplopia, vision blurred; liver function test abnormal; alopecia, eczema, pruritus; muscular weakness, myalgia; injury; *Rare*: Infection; pancytopenia (in some cases with bone marrow suppression), neutropenia, agranulocytosis; DRESS, hypersensitivity; hyponatraemia; completed suicide, personality disorder, thinking abnormal; choreoathetosis, dyskinesia, hyperkinesia, gait disturbance; encephalopathy; seizures aggravated; Electrocardiogram QT prolonged; pancreatitis; hepatic failure, hepatitis; toxic epidermal necrolysis, Stevens-Johnson syndrome, erythema multiforme; rhabdomyolysis and blood creatinine phosphokinase increased (Prevalence is significantly higher in Japanese patients when compared to non-Japanese patients.
Evidence also suggests a possible predisposition of the Japanese population to neuroleptic malignant syndrome); acute kidney injury; **Pack sizes and NHS price:** Packs of 60, 250 mg sachets £22.41 [PL14040/0029]; Packs of 60, 500 mg sachets £39.46 [PL14040/0030]; Packs of 60, 1000 mg sachets £76.27 [PL14040/0032]. **Legal category:** POM. **Marketing Authorisation Holder:** Desitin Arzneimittel GmbH, Weg beim Jaeger 214, 22335 Hamburg, Germany. **Prepared:** 26 Nov 23**.** For further information on Desitrend® please contact Medical Information on MedInfo@desitin.co.uk.

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Desitin Pharma Limited on MedInfo@desitin.co.uk.