Permission has been granted to use and reference the NEWT Guidelines.

Prescribing information can be found on back cover.

Desitrend®

Levetiracetam

The only formulation of levetiracetam licensed for and suited to administration by feeding tube

The NEWT Guidelines, for administration of medication to patients with enteral feeding tubes or swallowing difficulties, recommend levetiracetam granules licensed for administration via enteral feeding tube as a second choice in patients with enteral tubes, if it is not possible to administer levetiracetam intravenously.[1,2]

Desitrend® minitablets for adjunctive therapy of partial seizures in children ≥6 years[2]

DESITREND® ADVANCED MINITABLETS: USE IN FEEDING TUBES

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. *Monotherapy:* Adults and adolescents ≥16 years: Starting dose 250 mg bid increasing to 500 mg bid after 2 weeks. Dose can be increased by 250 mg bid every 2 weeks to a maximum of 1500 mg bid. *Adjunctive therapy:* Adults and adolescents (12-17 years) weighing ≥50 kg: Initial dose 500 mg bid. Dose can be increased up to 1500 mg bid (changes made in 500 mg bid increases or decreases every 2-4 weeks). 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. Children: 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. **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; pancreatitis; hepatic failure, hepatitis; toxic epidermal necrolysis, Stevens-Johnson syndrome, erythema multiforme; rhabdomyolysis, blood creatinine phosphokinase increased; acute kidney injury; encephalopathy. **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:** 14 Aug 2019. 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

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UK/DD/0055 Date of preparation: August 2019.

Desitrend® AGE-APPROPRIATE ADVANCED MINITABLET FORMULATION
Levetiracetam

Use in feeding tubes

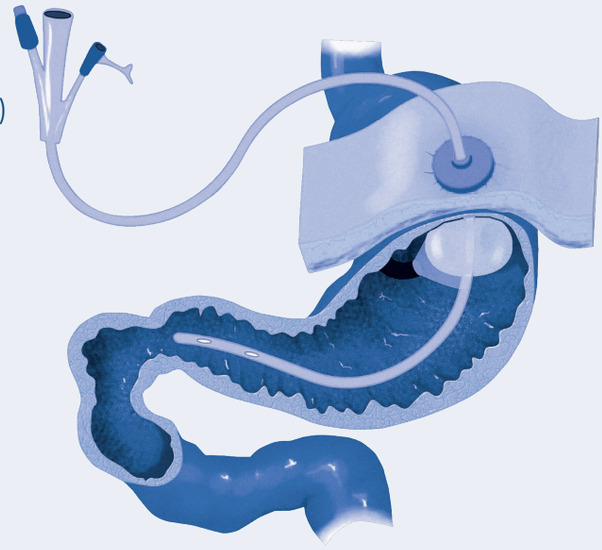
Internal tests to investigate the use of Desitrend® in feeding tubes were conducted by Desitin with 1000mg levetiracetam and 1500mg levetiracetam.

Test procedure

- The Desitrend® minitablets were placed in a conventional 10ml syringe cylinder
- Thereafter, the plunger was reinserted and 10ml of tepid water was drawn up with the syringe
- The filled syringe was then rotated for 2 minutes until the minitablets were dissolved and could be administered into the feeding tube
- Afterwards, the tube was flushed twice with water (see below) to remove any residues from syringe and tube

The following feeding tube diameters were tested:

Tube diameter
F8
F12
F16



Summary

Desitrend® minitablets can be administered via a feeding tube. Due to the solubility of the formulation, a **total of only 30ml of water** is needed for the administration (in addition to the volume required for flushes before and after drug administration):[1]

10ml for the preparation of the suspension, and 2 x 10ml for flushing the syringe and tube.

- Desitrend® minitablets are carbohydrate-free, sugar-free and maltitol-free therefore suitable for ketogenic diets[2]

Instructions for administration of Desitrend® minitablets via a feeding tube:[2]

- The minitablets should be suspended by shaking for a minimum of 2 minutes in at least 10ml of water
- The suspension should be prepared immediately before administration
- Immediately after administration the tube should be flushed twice, using 10ml of water for each flush
- Suitable for paediatric and adult use

References:
1. NEWT Guidelines. Available at: http://www.newtguidelines.com (last accessed November 2018).
2. Desitrend® Summary of Product Characteristics.

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