Zonisamide Desitin 20 mg/ml Oral Suspension Prescribing Information.

Always consult the Summary of Product Characteristics (SmPC) before prescribing Zonisamide Desitin.

Indications: Monotherapy: Partial seizures with or without secondary generalisation in adults with newly diagnosed epilepsy. Adjunctive therapy: Partial seizures with or without secondary generalisation in adults, adolescents and children aged 6 years and above. **Dosage:** Dosage escalation and maintenance required. May be taken as monotherapy or added to existing therapy in adults. Titrate dose on basis of clinical effect. Some patients may respond to lower doses. If discontinuation required, withdraw gradually. *Monotherapy*: Adults: Starting dose 100 mg (5 ml) od increasing to 200 mg (10 ml) od after 2 weeks and 300 mg (15 ml) after 4 weeks. Dose can be increased at 2 weekly intervals in increments of 100 mg (5 ml) to a maximum of 500 mg (25 ml) once a day. *Adjunctive therapy with CYP3A4 inducing agents*: Initial dose 50 mg (2.5 ml) per day in 2 divided doses for first week, increasing to 100 mg (5 ml) per day in 2 divided doses in week 2. Dose can be increased at weekly intervals in increments of 100 mg (5 ml) to up to 500 mg (25 ml) per day, once daily or in 2 divided doses. *Adjunctive therapy with renal or hepatic impairment*: Initial dose 50 mg (2.5 ml) per day in 2 divided doses for first 2 weeks, increasing to 100 mg (5 ml) per day in 2 divided doses at 4 weeks. Dose can be increased at 2 weekly intervals in increments of 100 mg (5 ml) to up to 500 mg (25 ml) per day, once a day or in 2 divided doses. *Paediatric Population >6 years*: Must be added to the existing therapy. *Adjunctive therapy with CYP3A4 inducing agents*: 1 mg (0.05 ml)/kg/day od with increase at weekly intervals of 1 mg (0.05 ml)/kg/day up to 8 mg/kg/day (0.4 ml/kg/day) od for patients 20 kg to 55 kg bodyweight and up to 300 to 500 mg/day (15 ml to 25 ml/day) od for patients >55kg. *Adjunctive therapy without CYP3A4 inducing agents*: 1 mg (0.05 ml)/kg/day od with increase at 2 weekly intervals to up to 8 mg/kg/day (0.4 ml/kg/day) od for patients 20 kg to 55 kg bodyweight and up to 300 to 500 mg/day (15 ml to 25 ml/day) od for patients >55kg. Elderly: Caution should be exercised at initiation in elderly patients as there is limited information on the use in these patients. Renal impairment: Caution must be exercised in renal impairment, limited information on use in such patients and a slower titration might be required (see SmPC). Hepatic impairment: Use in patients with hepatic impairment has not been studied, use in patients with severe hepatic impairment is not recommended. **Administration:** Shake the bottle well before use. Oral suspension may be swallowed directly from oral syringe followed by glass of water or may be diluted in water or juice, or mixed with yoghurt. See SmPC for administration via a feeding tube. **Contraindications:** Hypersensitivity to active substance, sulphonamides or to any of the excipients. **Special warnings and precautions for use (see SmPC**). Serious rashes including Stevens-Johnson syndrome. Gradual dose reduction required to reduce possibility of withdrawal seizures. Sulphonamide reactions. Acute myopia and secondary angle closure glaucoma: caution should be used when treating patients with history of eye disorders. Suicidal ideation and behaviour have been reported: monitor patients for signs and consider treatment. Kidney stones, especially where existing predisposition. Metabolic acidosis with or without hyperammonaemia. Dehydration and heat stroke. Discontinuation to be considered in cases of pancreatitis, rhabdomyolysis. Increased levels of hepatobiliary parameters. Cognitive impairment. Advise patients/carers to seek medical advice if signs emerge; weight loss might be experienced. **Interactions**: Caution in using carbonic anhydrase inhibitors in adults and should not be used as co-medication in paediatric population. Caution is advised in patients on P-gp substrate medications.

Preventing overheating and dehydration in children: Zonisamide Desitin can cause children to sweat less and overheat and if not treated this can lead to brain damage and death. Most at risk in hot weather. Children should stay cool and avoid heavy exercise in hot weather, drink plenty of cold water. Following medicines must not be taken: carbonic anhydrase inhibitors (like topiramate and acetazolamide), and anticholinergic agents (like clomipramine, hydroxyzine, diphenhydramine, haloperidol, imipramine and oxybutynin). If skin feels very hot with little or no sweating, or the child becomes confused or has muscle cramps, or the child's heartbeat or breathing become rapid, take the child to a cool place, cool skin with water, give cold water to drink and seek immediate medical attention.

Dose modification may be required with co-administration of CYP3A4 inducers. **Effects on ability to drive and use machines**: No studies have been performed, however caution must be exercised during activities requiring high degree of alertness. **Pregnancy/lactation**: Women of childbearing potential: Specialist medical advice should be given to women treated with zonisamide who are of childbearing potential with fully informed consent. Women must use effective contraception during treatment and for one month after discontinuation. Avoid sudden discontinuation. Pregnancy: Must not be used during pregnancy unless clearly necessary and if potential benefit is considered to justify risk to the foetus. In humans the potential risk of major congenital malformations and neurodevelopmental disorders is unknown. Lactation: Excreted in breast milk therefore not recommended and breast feeding must not be resumed until one month after therapy completion. **Side effects (see SmPC for full list)**: *Very common*: Anorexia, agitation, irritability, confusional state, depression, ataxia, dizziness, memory impairment, somnolence, diplopia, decreased bicarbonate. *Common*: Ecchymosis, hypersensitivity, affect lability, anxiety, insomnia, psychotic disorder, bradyphrenia, disturbance in attention, nystagmus, paraesthesia, speech disorder, tremor, abdominal pain, constipation, diarrhoea, dyspepsia, nausea, rash, pruritis, alopecia, nephrolithiasis, fatigue, influenza-like illness, pyrexia, peripheral oedema, weight decreased. *Uncommon*: Pneumonia, urinary tract infection, hypokalaemia, anger, aggression, suicidal ideation, suicide attempt, convulsion, vomiting, cholecystitis, cholelithiasis, urinary calculus. *Very rare:* Agranulocytosis, aplastic anaemia, leucocytosis, leucopoenia, lymphadenopathy, pancytopenia, thrombocytopenia, drug induced hypersensitivity syndrome, drug rash with eosinophilia and systemic symptoms, metabolic acidosis, renal tubular acidosis, hallucination, amnesia, coma, grand mal seizure, myasthenic syndrome, neuroleptic malignant syndrome, status epilepticus, angle closure glaucoma, eye pain, myopia, vision blurred, visual acuity reduced, dyspnoea, aspiration pneumonia, respiratory disorder, hypersensitivity-type pneumonitis, pancreatitis, hepatocellular damage, anhidrosis, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis, rhabdomyolysis, hydronephrosis, renal failure, urine abnormality, blood creatine phosphokinase, blood creatinine increased, blood urea increased, liver function tests abnormal, heat stroke. **Pack sizes and price:** 20 mg/ml oral suspension. Pack size 250 ml €208.78 [PA815/7/1]; **Legal category:** POM. **Marketing Authorisation Holder:** Desitin Arzneimittel GmbH, Weg beim Jaeger 214, 22335 Hamburg, Germany. **Prepared:** 10 Mar 25**.** For further information on Zonisamide Desitin please contact Medical Information on MedInfo@desitin.ie.

Adverse events should be reported. Reporting forms and information can be found at www.hpra.ie. Adverse events should also be reported to Desitin Pharma Limited on MedInfo@desitin.ie.