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. 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; 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:** 19 Oct 2021**.** 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.

Desizon® (zonisamide) Prescribing Information.
Always consult the Summary of Product Characteristics (SmPC) before prescribing Desizon®.

Zonisamide available as Desizon® 20 mg/ml oral suspension. **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. 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 to 100 mg (5 ml) per day in 2 divided doses at 2 weeks. 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 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 with 20 kg to 55 kg body weight*: 1 mg (0.05 ml)/kg/day od with increase at weekly intervals to up to 8 mg/kg/day (0.4 ml/kg/day) od. *Adjunctive therapy with CYP3A4 inducing agents >55 kg body weight*: 300 to 500 mg/day (15 ml to 25 ml/day) od *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 to a maintenance dose of 500 mg/day (25 ml/day) od. 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. See SmPC for administration via a feeding tube. Contraindications: Hypersensitivity to active substance, sodium methyl p-hydroxybenzoate (E219), sodium propyl p-hydroxybenzoate (E217), sulphonamides or to any of the excipients. **Special warnings and precautions for use (see SmPC**). The warnings and precautions mentioned are also applicable to adolescent and paediatric patients. 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, metabolic acidosis with or without hyperammonaemia, dehydration, heat stroke, increased levels of hepatobiliary parameters, suicidal ideation and behaviour have been reported: monitor patients for signs and consider treatment. Discontinuation to be considered in cases of pancreatitis, rhabdomyolysis. Advise patients/carers to seek medical advice if signs emerge; weight loss might be experienced.

Preventing overheating and dehydration in children: Desizon 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. When taking Desizon, 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.

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. **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: 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. 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, 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, oedema peripheral, weight decreased. *Uncommon*: Pneumonia, urinary tract infection, hypokalaemia, anger, aggression, suicidal ideation, suicide attempt, convulsion, vomiting, cholecystitis, Cholithiasis, calcus urinary. *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, pneumonia, aspiration 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, blood urea increased, liver function tests abnormal, heat stroke. **Pack sizes and NHS price:** 20 mg/ml oral suspension. Pack size 250 ml £181.90 [PL14040/0036]; **Legal category:** POM. **Marketing Authorisation Holder:** Desitin Arzneimittel GmbH, Weg beim Jaeger 214, 22335 Hamburg, Germany. **Prepared:** 22 Mar 2021**.** For further information on Desizon® 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.

Episenta®-(sodium valproate) Abbreviated Prescribing Information

Prescribers should consult the SmPC before prescribing Episenta. Sodium valproate available as Episenta 150mg or 300mg prolonged-release capsules, Episenta sachets containing 500mg or 1000mg prolonged-release granules and Episenta 100mg/ml solution for injection (IV). **Indications**: Oral: All forms of epilepsy. Manic episode in bipolar disorder when lithium is contraindicated or not tolerated. Consider continuation of treatment after acute manic episode for those who have responded. IV: Epilepsy in patients normally maintained on oral sodium valproate but temporarily not possible. **Dose and Administration**: Female children and women of childbearing potential: Must be initiated and supervised by a specialist in epilepsy or bipolar disorder. Do not use unless other treatments are ineffective or not tolerated. Prescribe and dispense according to Valproate Pregnancy Prevention Programme. Preferably prescribe as monotherapy and at lowest effective dose; divide daily dose into at least two single doses. *Epilepsy*: Oral: Daily dosage given in 1-2 single doses. Monotherapy: Adults: 600mg daily increasing by 150-300mg at 3-day intervals until controlled; usual dose range 1000-2000mg/day. Max dose 2500mg/day. Children >20kg: 300mg/day increasing until controlled; usual dose range 20-30mg/kg/day. Max dose 35mg/kg/day. Children <20kg: 20mg/kg per day; in severe cases up to 40mg/kg/day. Doses >40mg/kg/day, monitor clinical chemistry and haematological parameters. Elderly: Care when adjusting dosage. Dosage should be determined by seizure control. Renal insufficiency: It may be necessary in patients with renal insufficiency to decrease the dosage, or to increase the dosage in patients on haemodialysis. Valproate is dialysable. Dosing should be modified according to clinical monitoring of the patient. Hepatic insufficiency: see Contraindications, Warnings and Undesirable effects. Salicylates should not be used concomitantly. Combined Therapy: Start Episenta in patients already on anticonvulsants gradually to reach target dose after about 2 weeks. In combination with barbiturates, reduce barbiturate dose, particularly if sedation observed. IV: Use current daily dosage for patients adequately controlled on oral therapy but divide into 3-4 single slow IV injections or give by continuous or repeated infusion. Adults: 400-800mg daily increasing by 150-300mg at 3-day intervals until controlled; usual dose range 1000-2000mg/day. Max dose 2500mg/day. Children: 300mg/day increasing until controlled; usual dose range 20-30mg/kg/day. Max dose 40mg/kg/day, only if plasma levels can be monitored. *Manic episodes*: Adults: initial daily dose 750mg or 20mg/kg, increase dose rapidly, mean daily dose 1000-2000mg. Monitor patients if dosage higher than 45mg/kg/day. Children/adolescents: Safety and efficacy not established in patients <18 years. Method of administration: Oral: Swallow capsules whole without chewing, with plenty of liquid. Contents of the capsule/sachet may be sprinkled or stirred into soft food or drinks (cold/room temperature) and swallowed immediately without chewing or crushing the granules. Changing from valproate enteric coated tablets to Episenta, keep the same daily dose. IV: Give by slow IV injection over 3-5 mins or by infusion in 0.9% saline or 5% dextrose. Do not administer via same line with other IV additives. Replace with oral therapy as soon as practicable. Monitor plasma levels during therapy and when changing to/back from parenteral therapy. **Contraindications**: Hypersensitivity to valproate or excipients. Active liver disease; Personal or family history of severe hepatic dysfunction, especially drug related; Porphyria; Known urea cycle disorders; Bipolar disorder in pregnancy. Epilepsy in pregnancy unless there is no suitable alternative. Epilepsy or bipolar disorder in women of childbearing potential unless the conditions of the pregnancy prevention programme are met. Known or suspected mitochondrial disease. **Warnings and Precautions**: Monitor for signs of suicidal ideation/behaviour. Discontinue gradually, under specialist supervision. Generic switching of valproate preparations not recommended. Use with carbapenem not recommended. Risk of aggravated convulsions. Monitor for early signs of liver damage. Risk of severe liver damage, including fatal hepatic failure; children <3 years most at risk especially with multiple anticonvulsants, severe seizure disorders, organic brain disease, diseases associated with mental retardation. Avoid concomitant salicylates in children <16 years. Measure liver function before treatment and during first 6 months. Risk of severe or fatal pancreatitis, particularly young children; risk decreases with increasing age. Blood cell count, platelet count, bleeding time and coagulation tests recommended prior to starting therapy or before surgery, or if spontaneous bruising/bleeding. Caution in patients with systemic lupus erythematosus. Risk of hyperammonaemia in patients with urea cycle enzymatic deficiency. Risk of marked weight gain. Valproate may trigger or worsen clinical signs of underlying mitochondrial diseases. Patients with an underlying carnitine palmitoyltransferase (CPT) type II deficiency should be warned of the greater risk of rhabdomyolysis. Alcohol intake not recommended. Contains sodium.

Pregnancy Prevention Programme

Valproate is highly teratogenic, and children exposed in utero to valproate have a high risk for congenital malformations: neurodevelopmental disorders, hearing impairment or deafness, due to ear and/or nose malformations, or eye malformations. See Contraindications. See SmPC for full conditions of the Pregnancy Prevention Programme. The potential for pregnancy must be assessed for all female patients. Pregnancy must be excluded before start of treatment with valproate. Women of childbearing potential must use effective contraception without interruption and be provided with comprehensive information on pregnancy prevention. A specialist should review the patient at least annually and additionally if a woman is planning a pregnancy. If a woman using valproate becomes pregnant she must be immediately referred to a specialist to re-evaluate treatment. Women of childbearing potential must be provided with a patient guide and patient card. A risk acknowledgement form must be completed at treatment initiation and annual review.

Interactions (see SmPC):.Effects of Episenta on other drugs: Episenta® may potentiate the effect of other psychotropics, such as antipsychotics, MAOIs, antidepressants, benzodiazepines. Episenta may increase plasma levels/toxicity of other drugs: phenobarbital, primidone, lamotrigine, carbamazepine, felbamate, rufinamide, propofol, zidovudine, nimodipine warfarin and other coumarin anticoagulants. Episenta may decrease plasma levels of other drugs: olanzapine and phenytoin. Effects of other drugs on Episenta: Valproate plasma levels may be decreased with phenytoin, phenobarbital, carbamazepine, carbapenem agents, cholestyramine, rifampicin, lopinavir, ritonavir, protease inhibitors, oestrogen containing products, mefloquine, chloroquine and metamizole. Valproate levels may be increased with acetylsalicylic acid (and other highly protein bound agents) and cimetidine or erythromycin (as a result of reduced hepatic metabolism). Other interactions: Caution with newer antiepileptics; increased risk of neutropenia/leucopenia with quetiapine. **Pregnancy/Lactation**: See Contraindications and Warnings and Precautions. Refer patients with a valproate-exposed pregnancy to a specialist in prenatal medicine for evaluation and counselling. Neonate risks: haemorrhagic syndrome, hypoglycaemia, hypothyroidism, withdrawal syndrome. Valproate is excreted in human milk. Haematological disorders have been shown in breastfed infants of treated women. Consider benefit:risk. **Effects on ability to drive and use machines**: Reaction time may be altered; risk of transient drowsiness. **Undesirable effects (See SmPC for full details)**: Congenital malformations, developmental disorders and hearing impairment or deafness due to ear and/or nose malformations or malformations. Risk of developing attention deficit/hyperactivity disorder. Very common: nausea; tremor. Common: liver injury; increased liver enzymes; vomiting; gingival disorder; stomatitis; gastralgia; diarrhoea; urinary incontinence; confusional state; hallucinations; aggression; agitation; disturbance in attention; extrapyramidal disorder; stupor; somnolence (sedation occasionally reported, usually in combination with other anticonvulsants); convulsion; memory impairment; headache; nystagmus; hyponatraemia; weight increased: anaemia; thrombocytopenia; hypersensitivity; transient/or dose related hair loss; nail and nail bed disorders; dysmenorrhea; haemorrhage; deafness; weight increased (monitor since a factor for polycystic ovary syndrome). Uncommon: pancreatitis, sometimes lethal; renal failure: hypothermia: coma; encephalopathy, lethargy, reversible parkinsonism, ataxia, paresthesia; aggravated convulsions SIADH; hyperandrogenism; pancytopenia; leucopenia; angioedema; hair disorder rash; amenorrhea; non-severe peripheral oedema; vasculitis; bone mineral density decreased, osteopenia, osteoporosis and fractures in patients on long-term therapy; pleural effusion. Rare: myelodysplastic syndrome; abnormal behaviour; diplopia psychomotor hyperactivity; learning disorder; reversible dementia with reversible cerebral atrophy; cognitive disorder; hypothyroidism; hyperammonaemia; bone marrow failure, including pure red cell aplasia; agranulocytosis; macrocytic anaemia; macrocytosis; toxic epidermal necrolysis, Stevens-Johnson syndrome; erythema multiforme; DRESS syndrome; male infertility; polycystic ovaries; enuresis; tubulointerstitial nephritis; reversible Fanconi syndrome; systemic lupus erythematosus; rhabdomyolysis; coagulation factors decreased; abnormal coagulation tests. Very rare: gynaecomastia. Not known: Severe liver damage, including hepatic failure, sometimes fatal. **Pack sizes and NHS price**: 150mg capsules: packs of 30, £2.76; packs of 100, £7.00 [PL14040/0024]; 300mg capsules: packs of 30, £4.56; packs of 100, £13.00 [PL14040/0025]; 500mg sachets: packs of 30, £6.30; packs of 100, £21.00 [PL14040/0026]; 1000mg sachets: packs of 30, £12.30; packs of 100, £41.00 [PL14040/0027]. Packs of 5, 3ml ampoules 100mg/ml solution for injection £35.00 [PL14040/0028]. **Legal category**: POM. **Marketing Authorisation Holder**: Desitin Arzneimittel GmbH Weg beim Jäger 214 D-22335 Hamburg Germany. **Prepared in**: Jan 2022. For further information on Episenta please contact Medical Information on MedInfo@desitin.co.uk.

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Episenta is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reaction. 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.