Lamotrigine Desitin (lamotrigine) 10 mg/ml Oral Suspension Abbreviated Prescribing Information

Prescribers should consult the Summary of Product Characteristics before prescribing Lamotrigine Desitin 10 mg/ml Oral Suspension. Lamotrigine available as Lamotrigine Desitin 10 mg/ml Oral Suspension in 300 ml with dosing devices. **Indications:** Patients aged 13 yrs and above: Adjunctive or monotherapy treatment of partial seizures and generalised seizures, including tonic-clonic seizures. Seizures associated with Lennox-Gastaut syndrome; may be given as adjunctive or initial therapy. Patients aged 2 to 12 yrs: Adjunctive treatment of partial seizures and generalised seizures, including tonic-clonic and seizures associated with Lennox-Gastaut syndrome. Monotherapy of typical absence seizures. **Dose and administration: See SmPC for full recommended treatment regimen.** Patients aged 13 yrs and above: Monotherapy OR Adjunctive therapy without sodium valproate and without lamotrigine glucuronidation inducers: Weeks 1 & 2: 25 mg/day once daily. Weeks 3 & 4: 50 mg/day once daily. Maintenance: 100 – 200 mg/day once daily or 2 divided doses; dose may be increased by 50 – 100 mg maximum every 1 – 2 weeks until optimal response achieved. In monotherapy up to 500 mg/day may be required. Adjunctive therapy with sodium valproate: Weeks 1 & 2: 12.5 mg/day given as 25 mg on alternate days. Weeks 3 & 4: 25 mg/day once daily. Maintenance: 100 – 200 mg/day once daily or 2 divided doses; dose may be increased by 25 – 50 mg maximum every 1 – 2 weeks until optimal response achieved. Adjunctive therapy without sodium valproate and with lamotrigine glucuronidation inducers (phenytoin, carbamazepine, phenobarbitone, primidone, rifampicin, lopinavir/ritonavir): Weeks 1 & 2: 50 mg/day once daily. Weeks 3 & 4: 100 mg/day in 2 divided doses. Maintenance: 200 – 400 mg/day in 2 divided doses; dose may be increased by 100 mg maximum every 1 – 2 weeks until optimal response achieved; up to 700 mg/day may be required. Patients aged 2 to 12 yrs: Monotherapy of typical absence seizures: Weeks 1 & 2: 0.3 mg/kg/day once daily or 2 divided doses. Weeks 3 & 4: 0.6 mg/kg/day once daily or 2 divided doses. Maintenance: 1 – 15 mg/kg/day once daily or 2 divided doses; dose may be increased by 0.6 mg/kg/day maximum every 1 – 2 weeks until optimal response achieved, to a maximum of 200 mg/day. Adjunctive therapy with sodium valproate: Weeks 1 & 2: 0.15 mg/kg/day once daily. If calculated daily dose is 1 mg or more but less than 2 mg Lamotrigine 2 mg chewable tablets may be taken on alternate days. If calculated daily dose is less than 1 mg do not give Lamotrigine Desitin. Weeks 3 & 4: 0.3 mg/kg/day once daily. Maintenance: 1 – 5 mg/kg/day once daily or 2 divided doses; dose may be increased by 0.3 mg/kg/day maximum every 1 – 2 weeks until optimal response achieved, to a maximum of 200 mg/day. Adjunctive therapy without sodium valproate and with lamotrigine glucuronidation inducers: Weeks 1 & 2: 0.6 mg/kg/day in 2 divided doses. Weeks 3 & 4: 1.2 mg/kg/day in 2 divided doses. Maintenance: 5 – 15 mg/kg/day once daily or 2 divided doses; dose may be increased by 1.2 mg/kg/day maximum every 1 – 2 weeks until optimal response achieved, to a maximum of 400 mg/day. Adjunctive therapy without sodium valproate and without lamotrigine glucuronidation inducers: Weeks 1 & 2: 0.3 mg/kg/day once daily or 2 divided doses. Weeks 3 & 4: 0.6 mg/kg/day once daily or 2 divided doses. Maintenance: 1 – 10 mg/kg/day once daily or 2 divided doses; dose may be increased by 0.6 mg/kg/day maximum every 1 – 2 weeks until optimal response achieved, to a maximum of 200 mg/day. Monitor weight of children and review dose as weight changes occur. Patients aged 2 – 6 yrs are likely to require maintenance dose at higher end of recommended range. Where PK interaction of concomitant medicines with lamotrigine is unknown use regimen as recommended for adjunctive therapy with sodium valproate. Not recommended in children below 2 yrs due to limited data (no data in children aged <1 month); treatment to be based on clinical need. If epileptic control achieved with adjunctive treatment concomitant antiepileptics (AEDs) may be withdrawn and Lamotrigine Desitin continued as monotherapy. Do not exceed recommended initial dose or escalation due to risk of serious rash. Consider impact on lamotrigine pharmacokinetics when other AEDs are added/withdrawn from treatment regimen. Following discontinuation assess need for escalation to maintenance dose prior to restarting therapy dependent on time since previous dose. Do not restart in patients who have discontinued due to rash unless benefit outweighs risk. Higher lamotrigine maintenance doses may be needed in women taking hormonal contraceptives due to increased lamotrigine clearance. In patients taking lamotrigine and starting hormonal contraceptives maintenance dose may need to increase up to 2-fold at a rate of 50 – 100 mg/day every week; in patients stopping, maintenance dose may need to decrease by up to 50% at a rate of 50 – 100 mg/day every week (not exceeding 25% of total daily dose/week) over 3-week period; consider monitoring lamotrigine serum levels; dose adjustment may not be required in patients taking lamotrigine glucuronidation inducers. Lamotrigine maintenance dose may need to be increased if atazanavir/ritonavir or lopinavir/ritonavir is added and decreased if discontinued; monitor plasma lamotrigine before and during 2 weeks after starting or stopping antivirals. Caution in renal impairment; in end-stage failure base initial dose on concomitant treatment; reduced maintenance dose may be possible where significant renal impairment. Reduce dose by approx. 50% in patients with moderate/severe hepatic impairment; adjust dose based on clinical response. **Contraindications:** Hypersensitivity. **Warnings and Precautions:** Reports of adverse skin reactions occurring within 8 weeks of initiation; majority mild and self-limiting but potentially life threatening cases reported (see Undesirable Effects); risk strongly associated with high initial doses and concomitant sodium valproate and is higher in children where may be mistaken for infection; caution in patients with history of allergy or rash with other AEDs; caution in patients of Asian origin positive for HLA-B*1502 allele; promptly evaluate patients presenting with rash and withdraw treatment immediately unless clearly unrelated; do not restart treatment in patients who have previously developed lamotrigine-related Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN) or drug reaction with eosinophilia and systemic symptoms (DRESS)/hypersensitivity syndrome. Do not restart in patients discontinued due to aseptic meningitis. Photosensitivity reactions reported with high doses or rapid dose escalation/up-titration; consider discontinuation if signs of photosensitivity occur; advise patients to avoid exposure to sunlight/artificial UV and take protective measures. Haemophagocytic lymphohistiocytosis (HLH) has been reported with symptoms generally occurring within 4 weeks of initiation; advise patients to seek immediate medical attention if symptoms occur; discontinue lamotrigine unless alternative aetiology established. Risk of suicidal ideation and behaviour; monitor for signs and advise patients to seek medical advice; monitor bipolar patients for clinical worsening; consider changes to treatment regimen including discontinuation especially if symptoms severe or sudden onset. Use of hormonal contraceptives decreases levels of lamotrigine with associated loss of seizure control; increase in lamotrigine levels on cessation of hormonal contraceptive use may be associated with dose-related adverse events; consider omitting pill-free week as first line therapy; small possibility of decreased contraceptive efficacy, advise patients to report changes to menstrual pattern; HRT may similarly affect PK. Possibility of interference with folate metabolism in long-term therapy. Caution in renal failure. Do not administer alongside other lamotrigine-containing preparations. Arrhythmogenic ST-T abnormality and typical Brugada ECG reported; potential risk of serious or fatal cardiac events particularly with concomitant use of other sodium channel blockers; caution in patients with clinically important structural or functional heart disease including Brugada syndrome or other cardiac channelopathies, heart failure, ischemic heart disease, heart block or ventricular arrhythmias; consider consultation with cardiologist prior to initiation. Abrupt withdrawal may provoke rebound seizures; decrease dose over 2 weeks. Severe convulsive seizures/status epilepticus with fatal outcome have occurred in association with lamotrigine. Worsening of seizure frequency may be observed; benefit of control vs observed worsening to be considered for patients with more than one seizure type. Myoclonic seizures may be worsened by lamotrigine. Response in combination with enzyme inducers may be less than in combination with non-enzyme inducing AEDs. Efficacy may not be maintained in all children treated for typical absence seizures. Ingredients E218 & E216 may cause allergic reactions, possibly delayed. Contains sodium, propylene glycol and benzoic acid. **Interactions:** (see Dose and administration) Glucuronidation inducers/inhibitors may affect lamotrigine clearance. CYP3A4 inducers may enhance lamotrigine metabolism. Lamotrigine concentration is increased by valproate and is decreased by atazanavir/ritonavir, carbamazepine, ethinyloestradiol/levonorgestrel, lopinavir/ritonavir, phenobarbitone, phenytoin, primidone, rifampicin, paracetamol. Lamotrigine may increase plasma concentration of metformin, gabapentin, varenicline and other renally excreted OCT 2 substrates. Reports of CNS events with concomitant use of carbamazepine/oxcarbazepine, typically resolve when carbamazepine dose reduced. For concomitant oxcarbazepine use treatment regimen for lamotrigine adjunctive therapy without valproate and without inducers of lamotrigine glucuronidation. May increase topiramate concentrations. Olanzapine and aripiprazole may reduce lamotrigine concentration. **Pregnancy/Lactation:** Specialist advice should be given to all women and girls of childbearing potential. Review treatment when pregnancy is planned. Avoid sudden discontinuation due to risk of breakthrough seizures. Monotherapy preferred due to increased risk of foetal malformations with polytherapy. Data do not suggest increased risk of major congenital malformations with lamotrigine; animal studies show developmental toxicity. Use the lowest possible therapeutic dose. May reduce folic acid levels, consider

supplementation. Monitor lamotrigine serum concentration for reduction of lamotrigine levels before and during pregnancy and after birth; risk of loss of seizure control due to physiological changes. Lamotrigine is present in breast milk; monitor infant for adverse effects including sedation, rash and poor weight gain; consider benefit/risk. **Effects on ability to drive and use machines:** Risk of neurological adverse reactions; patients should assess individual impact/impairment. **Undesirable Effects (See SmPC for full details):** Very common: headache, skin rash. Common: aggression, irritability, somnolence, dizziness, tremor, insomnia, agitation, nausea, vomiting, diarrhoea, dry mouth, arthralgia, tiredness, pain, back pain. Uncommon: ataxia, diplopia, blurred vision, alopecia, photosensitivity reaction. Rare: nystagmus, aseptic meningitis, conjunctivitis, SJS. Very rare: haematological abnormalities (neutropenia, leucopenia, anaemia, thrombocytopenia, pancytopenia, aplastic anaemia, agranulocytosis), HLH, hypersensitivity syndrome, confusion, hallucinations, tics (motor/phonic), unsteadiness, movement disorders, worsening of Parkinson's, extrapyramidal effects, choreoathetosis, increase in seizure frequency, hepatic failure, hepatic dysfunction (usually associated with hypersensitivity reactions), increased liver function tests, TEN, DRESS, lupus-like reactions. Not known: lymphadenopathy, pseudolymphoma, hypogammaglobulinaemia, nightmares, tubulointerstitial nephritis and uveitis syndrome. Skin rash usually maculopapular, appears within 8 weeks of treatment initiation and resolves on withdrawal; serious life threatening rash has been reported with some irreversible scarring and rare fatalities. Hypersensitivity syndrome/DRESS associated with rash, fever, lymphadenopathy, facial oedema, blood, liver and kidney abnormalities, may rarely lead to disseminated intravascular coagulation and multiorgan failure; early signs of hypersensitivity may be present with no rash evident; discontinue lamotrigine if no other aetiology established. Haematological abnormalities and lymphadenopathy may or may not be associated with DRESS/hypersensitivity syndrome. Reports of decreased bone mineral density, osteopenia, osteoporosis and fractures in patients on long-term therapy. **Pack sizes and NHS price:** 300 ml bottle, packs of 1 [PL 14040/0040], £43.87. **Legal category:** POM. **Marketing Authorisation Holder:** Desitin Arzneimittel GmbH Weg beim Jäger 214 D-22335 Hamburg Germany. **Prepared in:** Feb 2024. For further information on Lamotrigine Desitin 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.