Enodama®.

Always consult the Summary of Product Characteristics (SmPC) before prescribing Enodama®.

Primidone available as Enodama 50/125/250 mg tablets in a bottle. **Indications**: management of grand mal and psychomotor (temporal lobe) epilepsy, focal or Jacksonian seizures, myoclonic jerks and akinetic attacks, essential tremor. **Dosage:** start at the lowest possible dose in the evening and increase in a stepwise manner to minimise adverse reactions. May be given as monotherapy and can be combined with other anticonvulsants or with supporting therapy. **Epilepsy. Adults (≥18 years):** initiate 125mg in a single intake in the evening. Every 3 days, the daily dose is increased in a stepwise approach by 125mg until the patient is receiving 500mg daily. Then every 3 days, the daily dose (given in 2 divided doses) is increased by 250mg, until control is obtained or until maximum tolerated dose. Max dose 1500mg. **Children (< 18 years):** usually 125mg in a single intake in the evening. Then every 3 days, the daily dose is increased in a stepwise by 125mg until the patient is receiving 500mg daily. Then, every 3 days, the daily dose (given in 2 divided doses) is increased by 250mg in children over > 9 years and by 125mg in children < 9 years until control is obtained or until maximum tolerated dose. Maintenance dose typically <9 years 750-1500mg, 6-9 years 750-1000mg, 2-5 years 500-750mg, <2 years 250-500mg. Primidone may be used to increase the efficacy of the existing/underlying treatment of other epilepsy therapies, by using dosing above. When an appreciable/acceptable therapeutic effect is reached (primidone is at least 1/2 of the previous dose) the discontinuation of the other therapy can be attempted. This dose adjustment is to be performed progressively for a period of 2 weeks. Withdrawal of previous treatment should not be too rapid, or status epilepticus may occur. Take caution with phenobarbital as other therapy, withdraw it sooner, to prevent excessive drowsiness. **Essential tremor. Dosage**: initially 50mg daily in late afternoon. Gradual increase over a 2 to 3-week period until tolerable (max 750mg OD). **Special Population.** *Patients with renal impairment*: adjust dose according to clinical response and biological monitoring. *Patients with hepatic impairment:* adjust dose according to clinical response and biological monitoring. *Elderly patients:* Increase monitoring for those with reduced renal function. **Administration:** Oral use. Swallow whole with a glass of water. **Contraindications**: Hypersensitivity to the active substance primidone, to phenobarbital or to any of the excipients. Acute intermittent porphyria. Concomitant use with certain classes of medicinal products. **Special warnings and precautions for use (see SmPC)**: Primidone is not efficient for the treatment of absences and myoclonic fits which may be sometimes aggravated. Primidone should be given with caution and may be required in reduced dosage in children, the elderly, debilitated patients or those with impaired renal, hepatic or respiratory function. *Crisis aggravation:* Introduction may be rarely followed by a crisis for the patient, independently of the fluctuations observed in some epilepsy. Consider: changing dose, a change of the concomitant anti-epileptic treatment, an interaction, a toxicity or overdose. *Treatment Cessation*: Sudden withdrawal may induce convulsive fits and epilepticus status. There is a potential for tolerance, dependence and a withdrawal reaction on abrupt cessation. *Vitamin Deficiency*: CYP450 inducer which may increase the catabolism of vitamin D increasing the risk of osteomalacia. Consider vitamin D supplementation. Megaloblastic anaemia may develop requiring discontinuation of primidone. Consider treatment with folic acid and/or vitamin B_{12}. *Suicidal Ideation/Behaviour:* a small increased risk of suicidal ideation and behaviour. Patients should be monitored for signs of suicidal ideation and behaviours. *Severe skin reactions*: Stevens-Johnson Syndrome (SJS) and toxic epidermal necrolysis (TEN) have been reported. If the patient has developed SJS or TEN, primidone must not be re-started in this patient at any time. *Precautions for use:* Primidone, as phenobarbital, is an enzymatic inducer and is thus susceptible to reduce efficacy of some medicinal products via progressive increase of their metabolism. Intake of this medicinal product with alcoholic beverages or with medicinal products containing alcohol is not recommended. **Interactions:** Primidone is a strong inducer of cytochrome P450 (See SmPC for further information). **Effects on ability to drive and use machines**: Due to the risk of somnolence, visual disturbances and impaired reaction time, primidone has a major impact on the ability to drive and use machines. **Pregnancy/lactation**: Women of childbearing potential: Primidone is suspected to have caused serious birth defects when administered during pregnancy. Contraception is therefore advised however women should be advised that primidone may cause the contraceptive pill to be ineffective. Studies in animals have shown reproductive toxicity, including teratogenicity and effects on memory and learning (see section 5.3). Women planning a pregnancy and pregnant women: patient should be informed about the risks of treatment and treatment cessation during pregnancy. The minimal effective dose should be used; consider supplementation with folic acid before and during pregnancy. The effectiveness of this supplementation is not confirmed. Neonate: Withdrawal symptoms may occur in the newly born. Anticonvulsant therapy in pregnancy has occasionally been associated with coagulation disorders in the neonates. Treatment with Vitamin K needs to be considered. *Breast-feeding:* Due to the risk of sedation, breast-feeding is not recommended. *Fertility:* No human data on the effect of primidone on fertility are available. In animals, effects on fertility have been observed. **Side effects (see SmPC for full list)**: *Common*: visual disturbances, apathy, ataxia, nystagmus, Nausea. *Uncommon*: headache, dizziness, vomiting, allergic reactions particularly rashes. *Rare*: megaloblastic anaemia, leucopenia, thrombocytopenia, lymphadenopathy, psychotic reactions, arthralgia, osteomalacia, Dupuytren's contracture, exfoliative dermatitis, lupus erythematosus, elevation in hepatic enzymes. Very rare: severe cutaneous adverse reactions: SJS and TEN (see section 4.4). Unknown: hypersensitivity syndrome (multisystemic reactions often with fever, rash, hypereosinophilia and liver injury), decreased bone density, osteopenia, osteoporosis and fractures in patients on long term therapy. **Overdose:** Primidone is metabolised extensively to phenobarbitone and overdosage leads to varying degrees of CNS depression: ataxia, loss of consciousness, respiratory depression and coma. Crystalluria may occur in overdosage and could be used as a helpful diagnostic aid. **Pack sizes and NHS price:** Bottle containing 100 tablets, 50mg £90.00 [PL 14040/0037], Bottle containing 100 tablets, 125mg £90.00 [PL 14040/0038], Bottle containing 100 tablets, 250mg £90.00 [PL 14040/0039]. **Legal category:** POM. **Marketing Authorisation Holder:** Desitin Arzneimittel GmbH, Weg beim Jaeger 214, 22335 Hamburg, Germany. **Prepared:** Jan 2023**.** For further information on Enodama® 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.