Only for the use of Medical Professionals

# Lamitrin®

Lamotrigine

**Description**

Lamitrin® is a preparation of Lamotrigine which is a use- and voltage-dependent blocker of voltage gated sodium channels. It inhibits sustained repetitive firing of neurons and inhibits release of glutamate (the neurotransmitter which plays a key role in the generation of epileptic seizures).

**Indication and usage**

Lamitrin® is indicated for-

- monotherapy and adjunctive treatment of partial seizures and primary and secondarily generalized tonic-clonic seizures; seizures associated with Lennox-Gastaut syndrome
- prevention of depressive episodes associated with bipolar disorder

**Dose and administration**

***Monotherapy of seizures (adult and child over 12 years):***

Initially 25 mg once daily for 14 days, increased to 50 mg once daily for further 14 days, then increased by maximum 50–100 mg daily every 7–14 days; usual maintenance 100–200 mg daily in 1–2 divided doses (up to 500 mg daily has been required)

***Adjunctive therapy of seizures with Valproate***

*Adult and child over 12 years*

Initially 25 mg on alternate days for 14 days then 25 mg once daily for further 14 days, thereafter increased by maximum 25–50 mg daily every 7–14 days; usual maintenance, 100–200 mg daily in 1–2 divided doses

*Child 2–12 years*

Initially 150 micrograms/kg once daily for 14 days (those weighing under 13 kg may receive 2 mg on alternate days for first 14 days) then 300 micrograms/kg once daily for further 14 days, thereafter increased by maximum 300 micrograms/kg daily every 7–14 days; usual maintenance 1–5 mg/kg daily in 1–2 divided doses (maximum single dose 100 mg)

***Adjunctive therapy of seizures (with enzyme inducing drugs) without Valproate***

*Adult and child over 12 years*
Initially 50 mg once daily for 14 days then 50 mg twice daily for further 14 days, thereafter increased by maximum 100 mg daily every 7–14 days; usual maintenance 200–400 mg daily in 2 divided doses (up to 700 mg daily has been required)

*Child 2–12 years*
Initially 600 micrograms/kg daily in 2 divided doses for 14 days then 1.2 mg/kg daily in 2 divided doses for further 14 days, thereafter increased by maximum 1.2 mg/kg daily every 7–14 days; usual maintenance 5–15 mg/kg daily in 2 divided doses (maximum single dose 200 mg)

***Adjunctive therapy of seizures (without enzyme inducing drugs) without Valproate***

*Adult and child over 12 years*
Initially 25 mg once daily for 14 days, increased to 50 mg once daily for further 14 days, then increased by 50–100 mg daily every 7–14 days; usual maintenance 100–200 mg daily in 1–2 divided doses

*Child 2–12 years*
Initially 300 micrograms/kg daily in 1–2 divided doses for 14 days then 600 micrograms/kg daily in 1–2 divided doses for further 14 days, thereafter increased by maximum 600 micrograms/kg daily every 7–14 days; usual maintenance 1–10 mg/kg daily in 1–2 divided doses; maximum 200 mg daily

***Monotherapy or adjunctive therapy of bipolar disorder (without enzyme inducing drugs) without valproate (adult over 18 years):***
Initially 25 mg once daily for 14 days, then 50 mg daily in 1–2 divided doses for further 14 days, then 100 mg daily in 1–2 divided doses for further 7 days; usual maintenance 200 mg daily in 1–2 divided doses; maximum 400 mg daily

***Adjunctive therapy of bipolar disorder with valproate (adult over 18 years):***
Initially 25 mg on alternate days for 14 days, then 25 mg once daily for further 14 days, then 50 mg daily in 1–2 divided doses for further 7 days; usual maintenance 100 mg daily in 1–2 divided doses; maximum 200 mg daily

***Adjunctive therapy of bipolar disorder (with enzyme inducing drugs) without valproate (adult over 18 years):***

Initially 50 mg once daily for 14 days, then 50 mg twice daily for further 14 days, then 100 mg twice daily for further 7 days, then 150 mg twice daily for further 7 days; usual maintenance 200 mg twice daily

***Elderly (above 65 years)***

No dosage adjustment is required.

***Hepatic impaired patients***

Halve dose in moderate impairment & quarter dose in severe impairment should be exercised

***Renally impaired patients***

Caution in renal failure; metabolite may accumulate; reduced maintenance dose should be considered in significant impairment

**Use in pregnancy and lactation**

If therapy with Lamotrigine is considered necessary during pregnancy, the lowest possible therapeutic dose is recommended. If Lamotrigine treatment is needed during breastfeeding, risk/benefit ratio of the treatment should be weighed considering the importance of breastfeeding.

**Side effects**

The side effects of Lamotrigine are rash, hypersensitivity syndrome (possibly including rash, fever, facial edema, lymphadenopathy, hepatic dysfunction, blood disorders, disseminated intravascular coagulation and multi-organ dysfunction), nausea, vomiting, diarrhoea, hepatic dysfunction; headache, fatigue, dizziness, sleep disturbances, tremor, movement disorders, agitation, confusion, hallucinations, occasional increase in seizure frequency, blood disorders (including leucopenia, thrombocytopenia, pancytopenia), arthralgia, lupus erythematosus-like effect, photosensitivity, nystagmus, diplopia, blurred vision, conjunctivitis and suicidal ideation.

**Precautions**

Adverse skin reactions may occur, usually within the first 8 weeks after initiation of lamotrigine treatment. All patients (adults and children) who develop a rash should be promptly evaluated and Lamotrigine should be withdrawn immediately unless the rash is clearly not related to lamotrigine treatment.

**Drug interactions**

Antiepileptic agents (such as phenytoin, carbamazepine, phenobarbitone and primidone) which induce hepatic drug metabolizing enzymes enhance the metabolism of lamotrigine. Valporate, which competes with lamotrigine for hepatic drug metabolizing enzymes, reduces the metabolism of lamotrigine.

**Contraindications**

Lamotrigine is contraindicated in patients with known hypersensitivity to the active substance or to any of the excipients.

**Overdose**

The symptoms of overdose are nystagmus, ataxia, impaired consciousness and coma. Therapy aimed at decreasing absorption (activated charcoal, laxative or gastric lavage) should be performed if indicated.

**Pharmaceutical precautions**

Store in a cool and dry place. Protect from light.

**Presentation**

**Lamitrin**® 25 tablet: Each tablet contains Lamotrigine INN 25 mg
**Lamitrin**® 50 tablet: Each tablet contains Lamotrigine INN 50 mg

**Packaging**

**Lamitrin**® 25 tablet: Carton of 30 tablets in blister pack
**Lamitrin**® 50 tablet: Carton of 30 tablets in blister pack

® Registered Trade Mark

**ACI Limited**