

Lamotrigine 50mg / 100mg Tablets

Each Uncoated scored tablet contains: Lamotrigine...............................50 mg Excipients..................Q.S.

Lamotrigine-25 Tablets
Lamotrigine-50 Tablets
Lamotrigine-100 Tablets
Lamotrigine-5 DT

Composition

Lamotrigine-25 Tablets

Each uncoated scored tablet contains Lamotrigine 25 mg

Lamotrigine-50 Tablets

Each uncoated scored tablet contains Lamotrigine 50 mg

Lamotrigine-100 Tablets

Each uncoated scored tablet contains Lamotrigine 100 mg

Lamotrigine-5DT

Each dispersible tablet contains Lamotrigine 5 mg

Indications

Lamotrigine is indicated as monotherapy as well as an adjunctive therapy in the treatment of partial seizures in adults with epilepsy.

Lamotrigine is also indicated as adjunctive therapy in the generalized seizures of Lennox-Gestaut syndrome in paediatric and adult patients.

Dosage and Administration

Monotherapy with Lamotrigine in patients 316 years of age:

 $Lamotrigine is to be titrated to the targeted dose of 50\,mg/day while maintaining the dose of the EIAEDs at a fixed level. The EIAEDs is then gradually withdrawn over a period of 4 weeks.$

 $Recommended \, maintenance \, dose \, of \, Lamotrigine \, as \, Monotherapy \, is \, 500 \, mg/day \, given \, in \, two \, divided \, doses.$

Dose recommendation for Lamotrigine (mg/day) for adults (over 12 year).				
	W eek 1&2	W eek 1&2	Usual Maintenance dose	
With enzyme-inducing antiepileptic drugs (EIAEDS*) & No valproic acid (VPA)	50 mg/day (once a day)	100 mg/day (two divided doses)	300-500 mg/day (two divided doses). To achieve maintenance, doses may be increased by 100 mg/day every 1 to 2 weeks.	
EIAEDS* & valproic acid (VPA)	25 mg every other day.	25 mg (once a day)	100-400 mg/day (two divided doses). To achieve maintenance, doses may be increased by 25-50 mg/day every 1 to 2 weeks.	

^{*} e.g. phenytoin, carbamazepine, phenobarbitone and primidone

Note: In patients taking AEDs where the pharmacokinetic interaction with lamotrigine is currently not known, the dose escalation as recommended for lamotrigine with concurrent valproate should be used, thereafter, the dose should be increased until optimal response is achieved.

Because of a risk of rash the initial dose and subsequent dose escalation should not be exceeded.



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Lamotrigine 50mg / 100mg Tablets

RECOMMENDED DOSE ESCALATION FOR LAMOTRIGINE (Lamotrigine) FOR CHILDREN AGED 2-12 YEARS (TOTAL DAILY DOSE IN MG/KG BODY WEIGHT/DAY) ON COMBINED DRUG THERAPY					
	Week 1&2	Week 1&2	U sual Maintenance dose		
With AED regimen containing VPA	0.15 mg/kg/day (1 or 2 divided doses)	0.3 mg/kg/day (1 or 2 divided doses)	1-5 mg/kg/day (maximum 200 mg/day in 1 or 2 divided doses). To achieve maintenance, doses may be increased by 0.5-1 mg every 1 to 2 weeks.		
Added to EIAEDs and without VPA	0.6 mg/ kg/day (two divided doses)	1.2 mg/kg/day (two divided doses)	5-15 mg/kg (in two divided doses). To achieve maintenance, doses may be increased by 2-3 mg/kg 1 to 2 weeks to a maximum of 400 mg/day.		

Lamotrigine as adjunctive therapy

Lamotrigine therapy should be initiated slowly to avoid the occurrence of rash and should be gradually decreased when it is to be discontinued to prevent rebound seizures. Lamotrigine tablets should be swallowed with water.

Discontinuation Strategy:

For patients receiving lamotrigine in combination with other AEDs, a re-evaluation of all AEDs in the regimen should be considered if a change in seizure control or an appearance of worsening of adverse experiences is observed.

If a decision is made to discontinue therapy with lamotrigine, a step-wise reduction of dose over at least 2 weeks (approximately 50% per week) is recommended unless safety concerns require a more rapid withdrawal.

Discontinuing an EIAED should prolong the half-life of lamotrigine; discontinuing VPA should shorten the half-life of lamotrigine.

Contraindications

- 1. In children below 2 years of age
- 2. Hypersensitivity to lamotrigine.

Presentation

Lamotrigine- 25 Blister pack of 10 tablets Lamotrigine- 50 Blister pack of 10 tablets Lamotrigine- 100 Blister pack of 10 tablets Lamotrigine- 5 DT Blister pack of 10 tablets

For Information about Generic Medicines: genericmedicines@tajpharma.com

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According to the Indian Trade Mark the company owns about 450 brands and 4600 generic manufacturing permissions in India. According to the export data analysis the company was the largest exporter of generic medicines to the Europe and Middle East countries.

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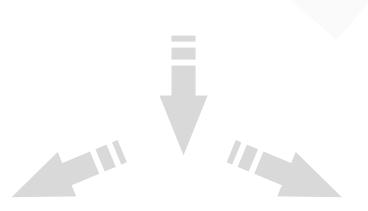
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