Lamotrigine

【OLAMO5】Lamictal® 50mg/Tab *ATC Code：N03AX09*

【OLAMO1】Lamictal® 100mg/Tab *ATC Code：N03AX09*

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適應症： 癲癇（泛發性強直陣攣性發作及簡單性或複雜性局部發作）成人與 12 歲以上兒童之單獨用藥治療；成人與 2 歲以上兒童之輔助性治療；Lennox-Gastaut Syndrome 徵候群之治療。處於明顯鬱期之雙極性疾患情感症狀之治療，有明顯鬱期或鬱－躁期循環之雙極性疾患之情感症狀之預防。

藥理分類： **Anticonvulsant, Miscellaneous.**

用法用量： **Administration** :Taken without regard to meals. Swallow whole; do not chew, crush, or cut.

Indications and dosage regimens :

Epilepsy:

If the calculated dose cannot be achieved using whole tablets, the dose should be rounded down to the nearest whole tablet.

Maintenance doses in patients weighing less than 30 kg, regardless of age or concomitant AED, may need to be increased as much as 50%, based on clinical response. Recommended dosing guidelines are summarized in Table 1.

Table 1. Escalation regimen for lamotrigine for patients with epilepsy

	For Patients Taking Valproate (see Table 2 for weight-based dosing guide)	For Patients Taking AEDs★ Other Than EIAED* or Valproate	For Patients Taking EIAED* and Not Taking Valproate
Weeks 1 & 2	**2-12 years of age** 0.15 mg/kg/day in 1-2 divided doses **> 12 years of age** 25 mg QOD	0.3 mg/kg/day in 1-2 divided doses 25 mg QD	0.6 mg/kg/day in 2 divided doses 50 mg QD
Weeks 3 & 4	**2-12 years of age** 0.3 mg/kg/day in 1-2 divided doses **> 12 years of age** 25 mg QD	0.6 mg/kg/day in 2 divided doses 50 mg QD	1.2 mg/kg/day in 2 divided doses 50 mg BID
Weeks 5 onward to maintenance	**2-12 years of age** Increase by 0.3 mg/kg/day Q1-2wk **> 12 years of age** Increase by 25-50 mg/kg/day Q1-2wk	Increase by 0.6 mg/kg/day Q1-2wk Increase by 50 mg/day Q1-2wk	Increase by 1.2 mg/kg/day Q1-2wk Increase by 100 mg/day Q1-2wk
Usual maintenance dose	**2-12 years of age** ①1-5 mg/kg/day (Max 200 mg/day in 1-2 divided doses) OR ②1-3 mg/kg/day with valproate alone **> 12 years of age** ①1-5 mg/kg/day (Max 200mg/day in 1-2 divided doses) OR ②1-3 mg/kg/day with valproate alone	4.5-7.5 mg/kg/day (Max 400 mg/day in 2 divided doses)	5-15 mg/kg/day (Max 400 mg/day in 2 divided doses)

★AEDs: Antiepileptic drugs

*EIAEDs: enzyme-inducing antiepileptic drugs (carbamazepine, phenobarbital, phenytoin, primidone)

Table 2. The initial weight-based dosing guide for patients 2 to 12 years taking valproate (weeks 1 to 4) with epilepsy

Patient's Weight (wt)	Give this daily dose, using the most appropriate combination of lamotrigine 2-mg and 5-mg tablets	
	Weeks 1 and 2	Weeks 3 and 4
6.7 kg ≦ wt ≦ 14 kg	2 mg QOD	2 mg QD
14.1 kg ≦ wt ≦ 27 kg	2 mg QD	4 mg QD
27.1 kg ≦ wt ≦ 34 kg	4 mg QD	8 mg QD
34.1 kg ≦ wt ≦ 40 kg	5 mg QD	10 mg QD

Table 3. Conversion from adjunctive therapy with valproate to monotherapy with lamotrigine in patients ≧ 16 years of age with epilepsy

	Lamotrigine	Valproate
Step 1	Achieve a dose of 200 mg/day according to guidelines in Table 1 (if not already on 200 mg/day).	Maintain previous stable dose.
Step 2	Maintain at 200 mg/day.	Decrease to 500 mg/day by decrements no greater than 500 mg/day per week and then maintain the dose of 500 mg/day for 1 week.
Step 3	Increase to 300 mg/day and maintain for 1 week.	Simultaneously decrease to 250 mg/day and maintain for 1 week.
Step 4	Increase by 100 mg/day every week to achieve maintenance dose of 500 mg/day.	Discontinue.

Bipolar Disorder:

The target dose of lamotrigine is 200 mg/day (100 mg/day in patients taking valproate, which decreases the apparent clearance of lamotrigine, and 400 mg/day in patients not taking valproate and taking either carbamazepine, phenobarbital, phenytoin, primidone or rifampin, which increases the apparent clearance of lamotrigine).

To avoid an increased risk of rash, the recommended initial dose and subsequent dose escalations of lamotrigine should not be exceeded.

Table 4. Escalation regimen for lamotrigine for patients with bipolar disorder

	For Patients Taking Valproate	For Patients Not Taking EIAED* and Not taking Valproate	For Patients Not Taking EIAED* and Not taking Valproate
Weeks 1&2	25 mg QOD	25 mg QD	50 mg QD
Weeks 3&4	25 mg QD	50 mg QD	100 mg/day, in divided doses QD
Weeks 5	50 mg QD	100 mg QD	200 mg/day, in divided doses QD
Weeks 6	100 mg QD	200 mg QD	300 mg/day, in divided doses QD
Weeks 7	100 mg QD	200 mg QD	up to 400 mg/day, in divided doses QD

*EIAEDs: enzyme-inducing antiepileptic drugs (carbamazepine, phenobarbital, phenytoin, primidone)

Table 5. Adjustments to lamotrigine dosing for patients with bipolar disorder following discontinuation of Psychotropic medications

	Discontinuation of Psychotropic Drugs (Excluding EIAEDs*, Rifampin, or Valproate	After Discontinuation of Valproate/ Current lamotrigine dose: **100** mg/kg	After Discontinuation of EIAEDs* or Rifampin/ Current lamotrigine dose: **400** mg/kg
Weeks 1	Maintain current lamotrigine dose	150	400
Weeks 2	Maintain current lamotrigine dose	200	300
Weeks 3 onward	Maintain current lamotrigine dose	200	200

*EIAEDs: enzyme-inducing antiepileptic drugs (carbamazepine, phenobarbital, phenytoin, primidone)

不良反應：噁心、頭暈、失眠、頭痛、嗜睡等，若有皮膚疹、皮膚起泡或脫皮應立即就醫。

交互作用：

- Valproic acid: ↑ lamotrigine exposure.
- Carbamazepine、phenytoin、phenobarbital: ↓ Lamotrigine exposure.
- Rifampin: ↓ lamotrigine exposure.
- Desmopressin: ↑ risk of hyponatremia.

注意事項：1.癲癇病患突然停藥可能會導致重積性癲癇。雙極性疾患患者在突然停用 lamotrigine 之後，並不會增加副作用的發生率、嚴重度或型態，因此病患可以不需要以逐漸停用的方式停用 lamotrigine。

2.應定期做血液學檢查。

3.本品味苦，請整粒吞服，不要嚼碎。

4. Lamotrigine 初用時會有頭暈、睏倦、視線模糊等不良反應，應叮囑病患服藥期間勿從事具潛在危險之活動，如開車或操作危險機械。

懷 孕 期： 1.當益處高於可能風險高時才使用本品。

2. Lamotrigine crosses the human placenta and can be measured in the plasma of exposed newborns (Harden and Pennell 2009; Ohman 2000).

3. An increased risk of malformations following maternal lamotrigine use may be associated with larger doses (Cunnington 2007; Tomson 2011).

4.Polytherapy may increase the risk of congenital malformations; **monotherapy with the lowest effective dose is recommended** (Harden and Meader 2009).

授 乳 期： 1.安全性尚未確立。 須衡量哺育母乳的益處及可能風險。

2. Lamotrigine is present in breast milk.

3. Adverse events observed in breastfed infants include apnea, drowsiness, poor sucking, thrombocytosis, and rash (Newport 2008; Nordmo 2009; Soussan 2014). Symptoms of withdrawal may occur if breastfeeding is abruptly discontinued.