

Topiramate

【OTORA】Toramate® 100mg/Tab

ATC Code : N03AX11

中文名：適癲痛膜衣錠 «永信»

適應症：用於成人及兩歲以上兒童局部癲癇或併有 Lennox-Gastaut 症候群之癲癇及原發性全身性強直陣攣癲癇的輔助治療，用於 Partial Onset Seizure 病患之單一藥物治療、預防偏頭痛。

藥理分類：Anticonvulsant, Miscellaneous.

用法用量： **Note:** Do not abruptly discontinue therapy; taper dosage gradually to prevent rebound effects. (In clinical trials, adult doses were withdrawn by decreasing in **weekly intervals of 50 to 100 mg** daily gradually over 2 to 8 weeks for seizure treatment, and by decreasing in weekly intervals by 25 to 50 mg daily for migraine prophylaxis.)

Administration: Administer without regard to meals. It is not recommended to crush, break, or chew the tablets due to bitter taste.

Indications and dosage regimens:

Adult

Epilepsy, monotherapy:

Partial-onset seizure and primary generalized tonic-clonic seizure:

Initial: 25 mg BID; may increase weekly by 50 mg daily up to 100 mg BID (week 4 dose); thereafter, may further increase weekly by 100 mg daily up to the recommended dose of 200 mg BID.

Epilepsy, adjunctive therapy:

Partial-onset seizure, primary generalized tonic-clonic seizure, or Lennox-Gastaut syndrome: Note: Doses > 1600 mg have not been studied.

Initial: 25 mg QD or BID for 1 week; may increase weekly by 25 to 50 mg daily until response;

maintenance dose: 100 to 200 mg BID (partial-onset seizures) or 200 mg BID (primary generalized tonic-clonic seizures).

Doses > 400 mg have not shown additional benefit for treatment of partial-onset seizures.

Migraine prophylaxis:

Initial: 25 mg QD (in evening); may increase weekly by 25 mg daily up to the recommended dose of 100 mg daily given in 2 divided doses. Increased intervals between dose adjustments may be considered.

Doses > 100 mg daily have shown no additional benefit.

Pediatric

Epilepsy, monotherapy:

Partial-onset seizure and primary generalized tonic-clonic seizure:

Children 2 to < 10 years:

Initial: 25 mg oQD (in evening); may increase to 25 mg BID in week 2; thereafter, may increase by 25 to 50 mg daily at weekly intervals over 5 to 7 weeks up to the following minimum recommended maintenance dose:

≤ 11 kg: 150 mg daily in 2 divided doses

12 to 22 kg: 200 mg daily in 2 divided doses

23 to 31 kg: 200 mg daily in 2 divided doses

32 to 38 kg: 250 mg daily in 2 divided doses

≥ 39 kg: 250 mg daily in 2 divided doses

Maximum maintenance dose: If additional seizure control is needed and therapy is tolerated, may further increase by 25 to 50 mg daily at weekly intervals up

to the following maximum recommended maintenance dose:

- ≤ 11 kg: 250 mg daily in 2 divided doses
- 12 to 22 kg: 300 mg daily in 2 divided doses
- 23 to 31 kg: 350 mg daily in 2 divided doses
- 32 to 38 kg: 350 mg daily in 2 divided doses
- ≥ 39 kg: 400 mg daily in 2 divided doses

Epilepsy, adjunctive therapy:

Partial-onset seizure, primary generalized tonic-clonic seizure, or Lennox-Gastaut syndrome:

Children 2 to < 6 years:

Initial: 25 mg (1 to 3 mg/kg/day) QD (in evening) for 1 week; may increase every 1 to 2 weeks in increments of 1 to 3 mg/kg/day up to the recommended dose of 5 to 9 mg/kg/day in 2 divided doses.

Children ≥ 6 years and Adolescents < 17 years:

Initial: 25 mg (1 to 3 mg/kg/day) QD (in evening) for 1 week; may increase every 1 to 2 weeks in increments of 1 to 3 mg/kg/day up to the recommended dose of 5 to 9 mg/kg/day in 2 divided doses.

不良反應：熱潮紅、頭暈、嗜睡、不安、消化不良。

交互作用：

- Nifedipine: ↓ nifedipine exposure.
- Hormonal contraceptives: ↓ plasma levels of hormonal contraceptive.
- Buprenorphine, pregabalin, gabapentin: ↑ risk of respiratory depression.
- Codeine, meperidine, morphine: ↑ risk of respiratory or CNS depression.
- Metoclopramide: ↑ risk of CNS depression.
- Midazolam: ↑ risk of hypoventilation, airway obstruction, desaturation, or apnea.

注意事項：1.飯前或飯後服用均可。

2.本品味苦，不宜嚼碎。

3.治療期間應攝取充足的水分(非碳酸飲料)，以降低發生腎結石的危險性。

懷 孕 期：可能造成胎兒傷害。只有在絕對必要時，才能於懷孕期間使用。

授 乳 期：對病人有限的觀察顯示 Toramate 會大量分泌至乳汁。因為很多藥物都會分泌到人體乳汁內，要考慮該藥對母親的重要性以決定母親是否需停止授乳或停止用藥。