

**SHUT DOWN** the  
**DISPLEASING**  
**KINETICS**

# LEPTOMATE

Topiramate Tablets 25 mg / 50 mg / 100 mg

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## BACKGROUND

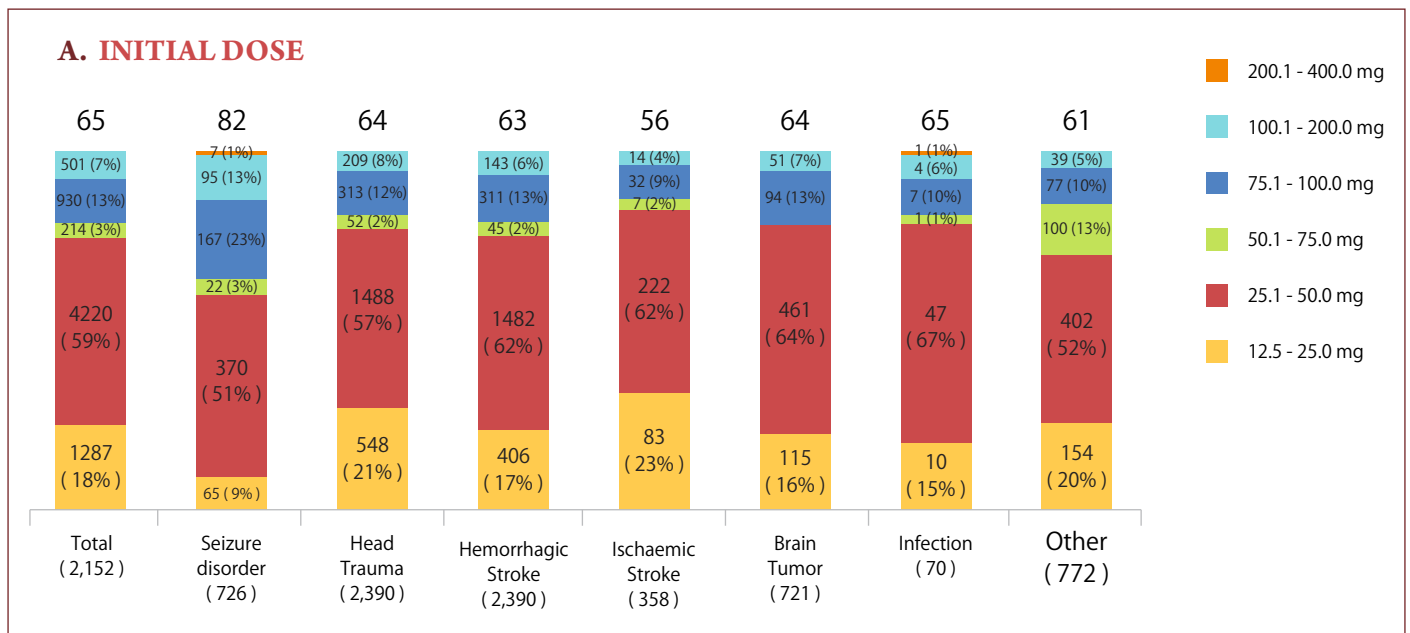
**Epilepsy** is a neurological condition - which means it affects the brain. A seizure happens when there is a sudden burst of intense electrical activity in the brain.<sup>1</sup> This is often referred to as epileptic activity. The epileptic activity causes a temporary disruption to the way the brain normally works, so the brain's messages become mixed up. The result is an epileptic seizure.

**Migraine** is a common, chronic, incapacitating neurovascular disorder, characterized by attacks of severe headache, autonomic nervous system dysfunction, and in some patients, an aura involving neurologic symptoms.<sup>2</sup>

## CLINICAL EFFECTIVENESS

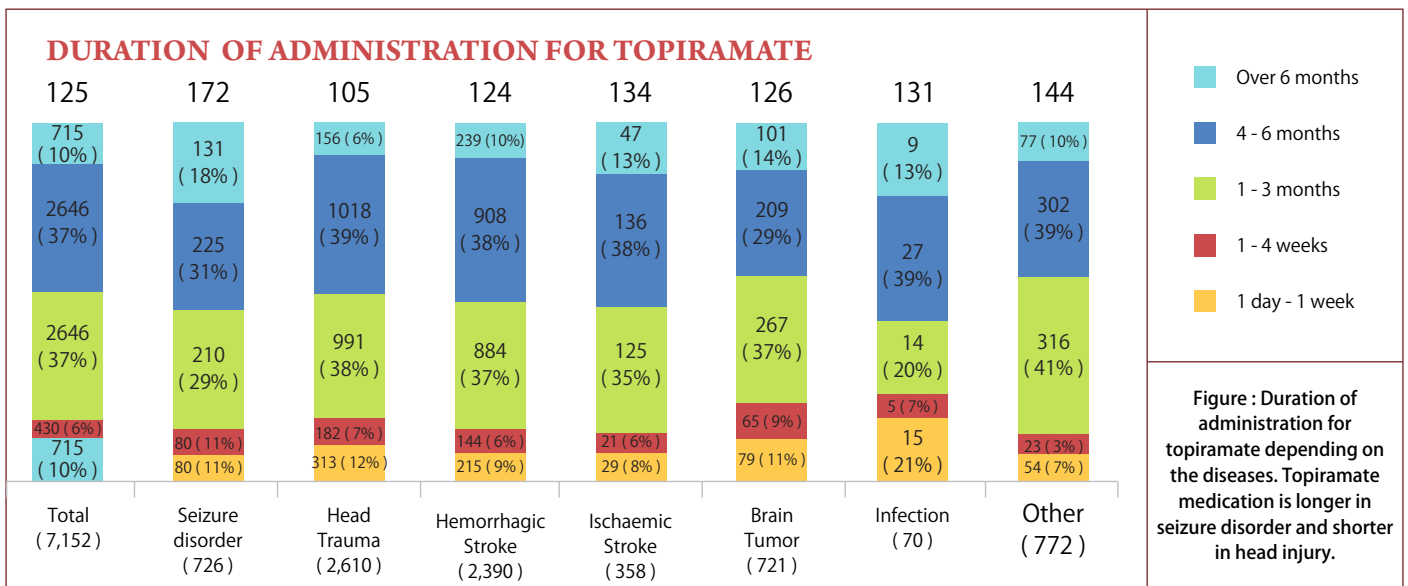
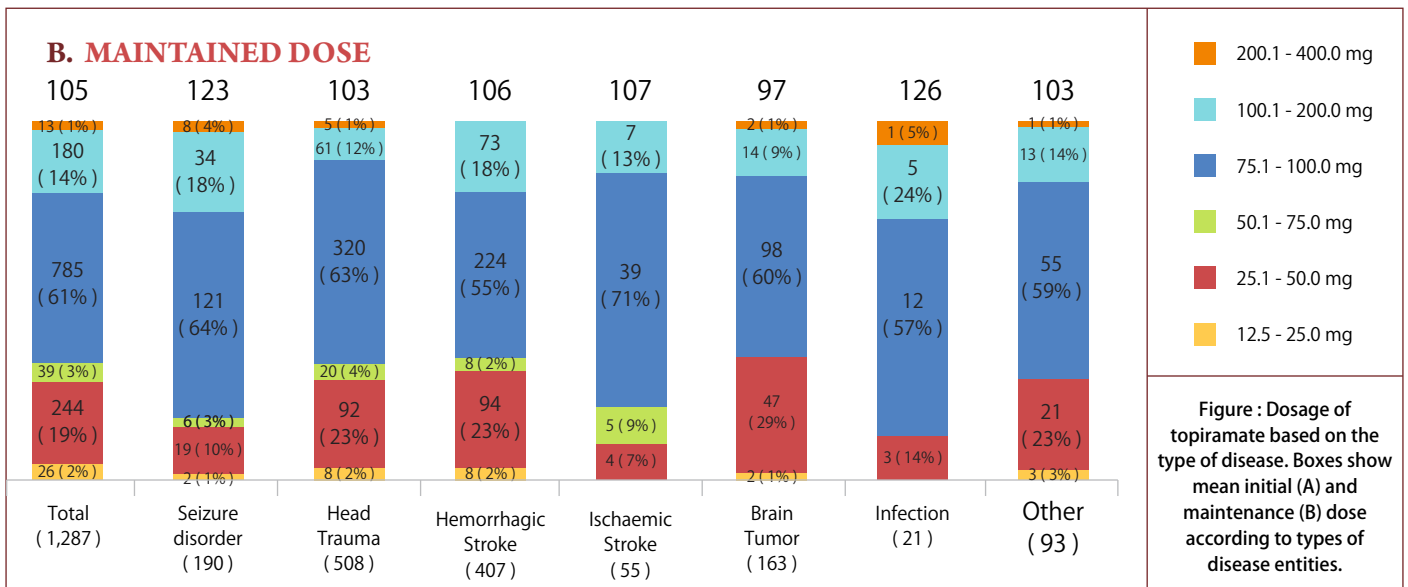
### 1. "A Multicenter Retrospective Study of the Actual Using Patterns and Clinical Effects of Topiramate in Patients with Neurosurgical Disease."

- A total of 7,152 patients ( 4,303 males, 2,849 females ) were included in the study.
- The patient's age was  $53.0 \pm 16.56$  years.
- Ninety-four major hospitals in Korea were involved in the study.



#### Reference:

1. SHORVON S, The clinical forms and causes of epilepsy. In: shorvon s, Handbook of Epilepsy Treatment, 2nd edition. Oxford: Blackwell Publishing Ltd, p. 1; 2005
2. New England Journal of Medicine; 346:257-270, 2002



**CONCLUSION** - Topiramate prescribe widely in diverse neurosurgical disorders, and effective in reduction of seizure frequency and does not cause serious adverse effects comparable with old AEDs.

## 2. "The Effects of Topiramate Therapy on Cerebral Metabolism in Migraine with Aura Patients"

*Turk Neurosurg, 2014*

- 20 migraine (with aura) patients (group 1) and 20 healthy controls (group 2) in the study.
- Group 1 initially received 25 mg/d of topiramate orally, and then the dose was increased 25 mg every week.
- At the fourth week; the optimal dose was increased to 50 mg b.i.d. and the treatment was continued at this dose.

**CONCLUSION** - Topiramate is an effective prophylactic treatment in migraine with aura patients and appeared to play a positive role in the regulation of cerebrovascular autonomic control.

**Topiramate for the treatment of Migraine is an US Food and Drug Administration ( FDA ) approved.**

**Table : American Headach Society**

Week	Week 1	Week 2	Week 3	Week 4 (& thereafter)
Morning	0	25 mg	25 mg	50 mg
Bedtime	25+ mg	25 mg	50 mg	50 mg

+1 tablet = 25 mg.

**DESCRIPTION**

LEPTOMATE contains topiramate Tablets. This compound belongs to the class of organic compounds known as dioxolopyrans. It is used to treat epilepsy in both children and adults. It is also Food and Drug Administration ( FDA ) approved for and now most frequently prescribed for the prevention of migraines.

**MECHANISM OF ACTION**

Topiramate is a novel agent classified as a sulfamate substituted monosaccharide. Three pharmacological properties of topiramate are believed to contribute to its anticonvulsant activity. First, topiramate reduces the frequency at which action potentials are generated when neurons are subjected to a sustained depolarization indicative of a state-dependent blockade of voltage-sensitive sodium channels. Second, topiramate markedly enhances the activity of GABA at some types of GABA receptors. Because the antiepileptic profile of topiramate differs markedly from that of the benzodiazepines, it may modulate a benzodiazepine-insensitive subtype of GABAA receptor. Third, topiramate antagonizes the ability of kainate to activate the kainate /AMPA subtype of excitatory amino acid ( glutamate ) receptors but has no apparent effect on the activity of N-methyl-D-aspartate ( NMDA ) at the NMDA receptor subtype.

**INDICATION**

**EPILEPSY** - Topiramate is indicated as monotherapy for the management of patients ( adults and children six years and older) with newly diagnosed epilepsy.

**MIGRAINE PROPHYLAXIS** - Topiramate is indicated in adults for the prophylaxis of migraine headache.

**DOSAGE**

**Epilepsy-Monotherapy**-Adults and Children (Age 6 years and older)

The recommended titration rate for topiramate monotherapy to 100 mg/day is:

Week	Week 1	Week 2	Week 3
Morning Dose	None	25 mg	50 mg
Evening Dose	25 mg	25 mg	50 mg

**Adjunctive therapy**-Adults (Age 17years and older)

It is recommended that topiramate as adjunctive therapy be initiated at 50 mg/day, followed by titration as needed and tolerated to an effective dose. At weekly intervals, the dose may be increased by 50 mg/day and taken in two divided doses. Some patients may benefit from lower initial doses, e.g. 25 mg and/or a slower titration schedule.

**Migraine Prophylaxis -**

Adults : The usual total daily dose of topiramate as treatment for prophylaxis of migraine headache is 100 mg/day administered in two divided doses.

Week	Week 1	Week 2	Week 3	Week 4
Morning Dose	None	25 mg	25 mg	50 mg
Evening Dose	25 mg	25 mg	50 mg	50 mg

**Administration**-It comes as Film Coated tablets and to be taken by mouth with or without food.

**Presentation**- Available as strip of 10 tablets.

**Storage**-Store in dry place, protected from moisture at a temperature not exceeding 30°C.