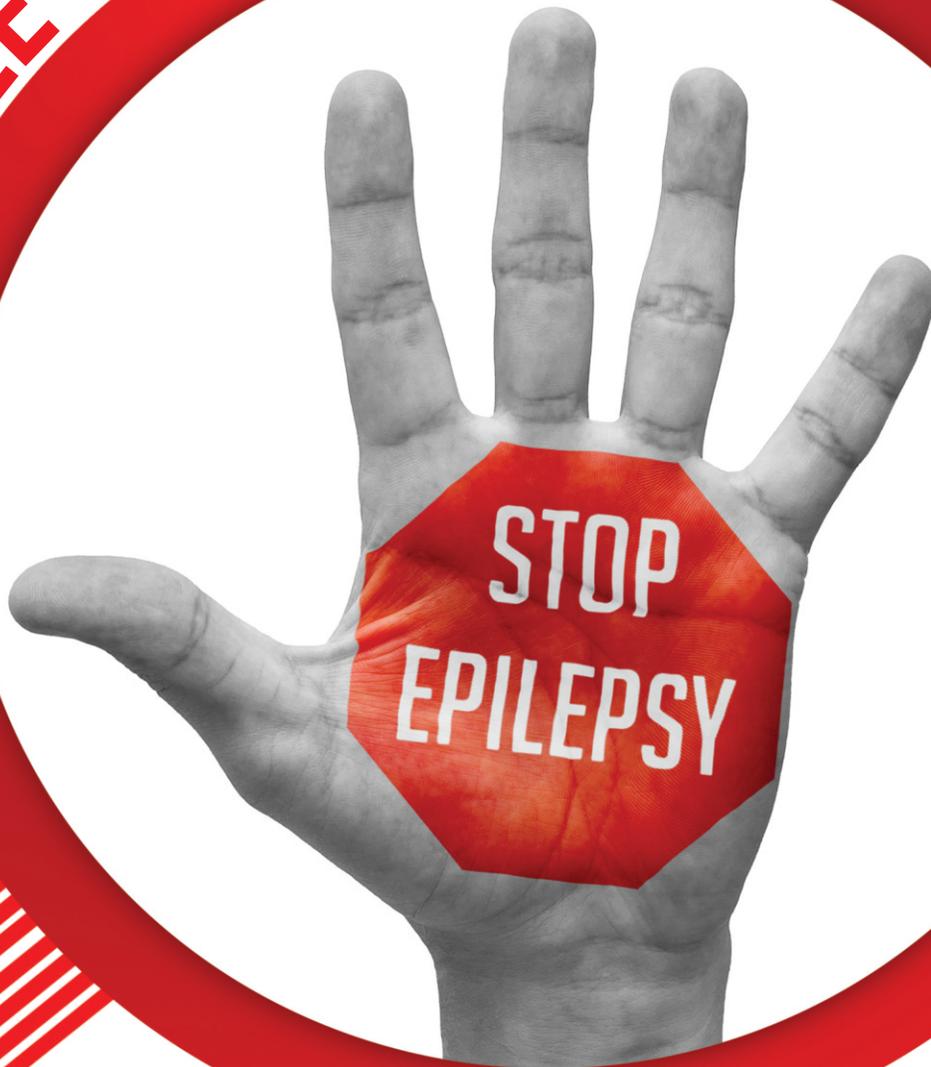


SEIZE THE SEIZURES



With...

LOBACHEKTM

Clobazam 5 mg, 10 mg Mouth Dissolving, Scored Tablets

la Renon[®]

In Epilepsy,
Recommend,
LOBACHEKTM
Clobazam 5 mg, 10 mg Mouth Dissolving, Scored Tablets

BACKGROUND:

Epileptic seizures are caused by a disturbance in the electrical activity of the brain. There are many different types of epileptic seizure. Any of us could potentially have a single epileptic seizure at some point in our lives. This is not the same as having epilepsy, which is a tendency to have seizures that start in the brain.

Lennox–Gastaut Syndrome:

Lennox-Gastaut syndrome (LGS) is a severe form of epilepsy that typically becomes apparent during infancy or early childhood. LGS is a severe childhood epileptic encephalopathy characterized by:

- (1) Multiple seizure types, mainly generalized seizures such as tonic, atonic and atypical absence, although partial, myoclonic and generalized tonic–clonic seizures are also observed;
- (2) An electroencephalogram (EEG) pattern with diffuse, slow spike-and-wave complexes (<3 Hz) with characteristic paroxysmal fast rhythms of 10–12 Hz in sleep;
- (3) Cognitive dysfunction with psychomotor delay and neuropsychiatric problems [Commission on Classification and Terminology of the International League Against Epilepsy, 1989].

The International League Against Epilepsy (ILAE) Task Force most recently classified the disorder as an epileptic encephalopathy. Epileptic encephalopathies are a group of disorders in which seizure activity leads to progressive cognitive dysfunction.

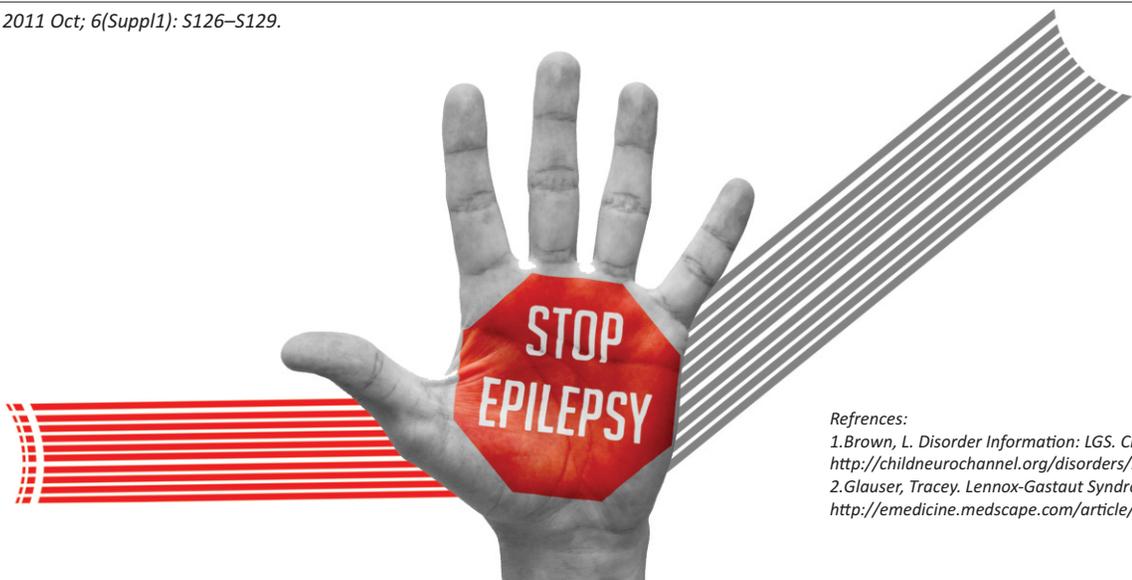
FACTS & PREVALENCE:

- Lennox-Gastaut Syndrome is named after Drs. William Lennox and Henri Gastaut. Lennox (1945) along with his colleague Davis (1950) described the triad of cognitive impairment, multiple seizures and slow spike and wave discharges in the EEG; Dr. Gastaut described the syndrome in 1966.¹
- November 1 annually is International LGS Day, the official awareness day for Lennox-Gastaut Syndrome around the world.¹
- LGS constitutes between 1-4% of pediatric epilepsies. This translates to a prevalence of 14,500 - 18,500 children under the age of 18 in the U.S. and more than 30,000 children and adults in the U.S.²

INDIAN SCENARIO OF EPILEPSY:

Location	Incidence/ Prevalence
Kolkata's urban population	Annual Incidence Rate 27.27 per 100,000 per year
Uttarakhand Rural Population	Prevalence rate of two or more unprovoked seizures 7.5 per 1000
Kerala	4.9/1000
Kashmir valley	3.74/1000 in males and 3.13/1000 in females

Source: *J Pediatr Neurosci.* 2011 Oct; 6(Suppl1): S126–S129.



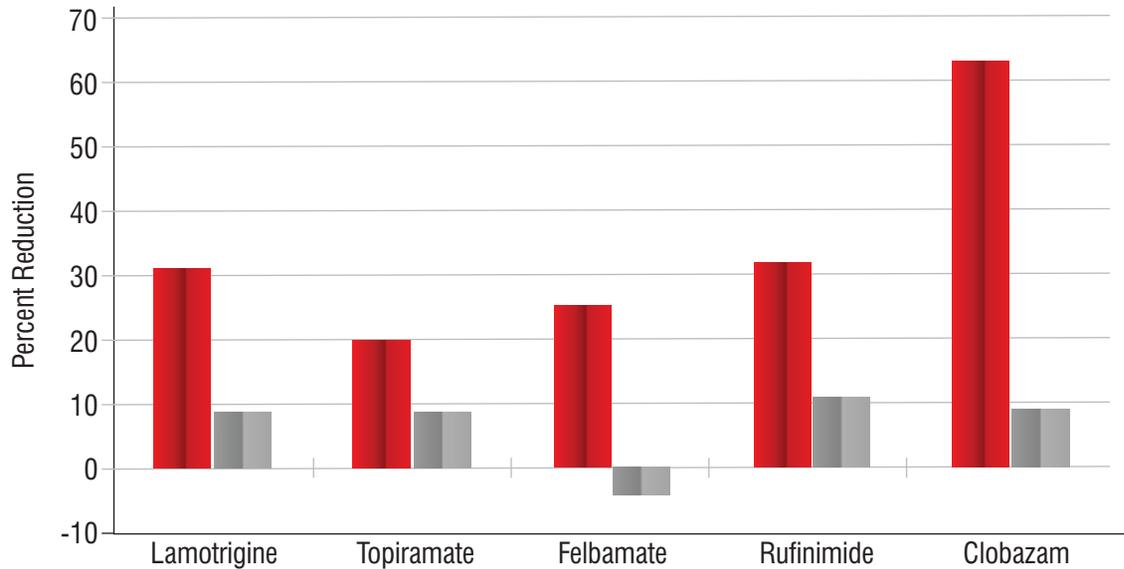
References:

1. Brown, L. Disorder Information: LGS. *Child Neuro Net.* <http://childneurochannel.org/disorders/lgs/>.
2. Glauser, Tracey. Lennox-Gastaut Syndrome. *Medscape.* 2011. <http://emedicine.medscape.com/article/1176735-overview>.

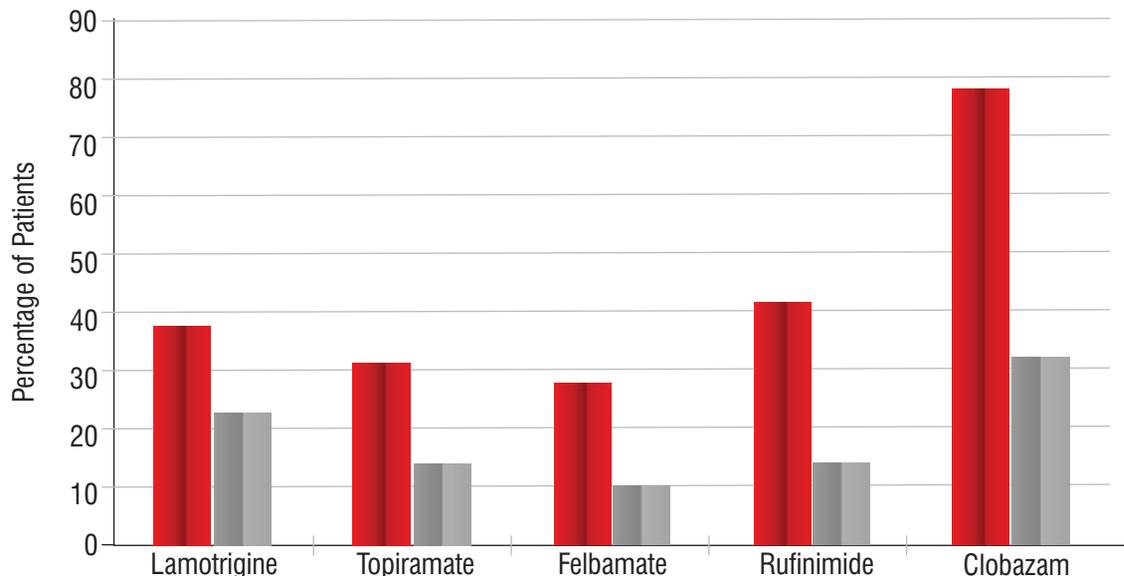
CLINICAL EFFECTIVENESS OF CLOBAZAM IN LSG:

As per *Therapeutic Advances in Neurological Disorders*; 2014 Journal:

- There are six molecules approved by the US FDA for treatment of LGS: lamotrigine, topiramate, felbamate, rufinamide, clonazepam and clobazam.
- Below figures represent a summary of placebo controlled studies with these medications and their efficacy compared with clobazam



Median reduction in total seizure frequency with antiepileptic drugs approved for Lennox–Gastaut syndrome (dark gray columns) compared with placebo (light gray columns) [The Felbamate Study Group in Lennox–Gastaut Syndrome, 1993; Glauser et al. 2008; Jensen, 1994; Sachdeo et al. 1999; Ng et al. 2011].



Percentage of patients with more than 50% reduction in drop seizures with antiepileptic drugs approved for Lennox–Gastaut syndrome compared with placebo [VanStraten and Ng, 2012].

Conclusion:

Clobazam is a safe profile and have sustained effectiveness over at least the first 3 years of use in LGS and other epilepsy syndrome with intractable seizures, which makes it a viable long-term treatment option.

In Epilepsy,
Recommend.
LOBACHEK™
Clobazam 5 mg, 10 mg Mouth Dissolving, Scored Tablets

Description:

LOBACHEK contains Clobazam mouth dissolving scored tablets in the strength of 5 mg and 10 mg. Clobazam belongs to the class of organic compounds known as benzodiazepines. Similar to other benzodiazepines, clobazam binds to the interface of the α and γ 2-subunit of the GABA-A receptor. However, it is considered a partial agonist to GABA-A receptors which sets clobazam apart from 1,4-benzodiazepines which are full agonist. The significance of this difference is that one may experience less sedation with clobazam than with other benzodiazepines.

Mechanism of Action:

Clobazam is a 1, 5-benzodiazepine with anticonvulsant properties. The exact mechanism of action for clobazam, a 1, 5-benzodiazepine, is not fully understood but is thought to involve potentiation of GABAergic neurotransmission resulting from greater binding at the benzodiazepine site of the GABA-A α 2 receptor.

In general, the mode of antiepileptic action of clobazam is probably largely analogous to that of the 1, 4-benzodiazepines. The differences between clobazam (a 1,5-benzodiazepine) and the 1,4-benzodiazepines in terms of therapeutic efficacy and neurotoxicity are possibly due to the variation in degree of the agonist action at the high affinity benzodiazepine receptor or to differing relative action at the high and low affinity benzodiazepine receptors.

Indications:

- For treatment and management of epilepsy and seizures associated with Lennox-Gastaut syndrome, a difficult-to-treat form of childhood epilepsy.
- Refractory epilepsy in adults

Dosage:

Tablets for oral use.

Adults: Small doses, 5-15 mg/day, should be used initially, gradually increasing to a maximum daily dose of 80 mg as necessary.

Children from 2 to 16 years: The initial dose in children should be 5 mg/day, which may be increased at 5-day intervals to a maximum of 40 mg/day.

Elderly: Due to decreased organ function in elderly patients, lower initial doses and gradual dose increments are recommended and patients should be monitored for responsiveness and adverse events.

Administration:

To be taken by mouth with or without food.

Presentation:

Available as strip of 10 tablets.



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I am: _____
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