

Destroy
the
Invasion



DIVALGRESS

Divalproex Sodium Extended Release Tablets 250 mg / 500 mg / 750 mg / 1000 mg

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. 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.

The area of the brain that is affected by a seizure will determine the symptoms and sensations the seizure causes :

1. Focal Seizures with subtypes : A) simple focal seizures B) dyscognitive focal seizures
2. Generalized Seizures the subtype of generalized seizures include : tonic, clonic, myoclonic tonic clonic atonic and absence seizures..

Reference : 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

KEY FACTS

- Approximately 50 million people worldwide have epilepsy, making it one of the most common neurological diseases globally.
- Globally, each year an estimated 2.4 million people are diagnosed with epilepsy.
- Nearly 80% of the people with epilepsy live in low- and middle-income countries.
- About three fourths of people with epilepsy living in low- and middle- income countries do not get the treatment they need.
- In 2012, epilepsy was responsible for approximately 20.6 million disability-adjusted life years (DALYs) lost.

Reference : WHO; 2016

CLINICAL EFFECTIVENESS

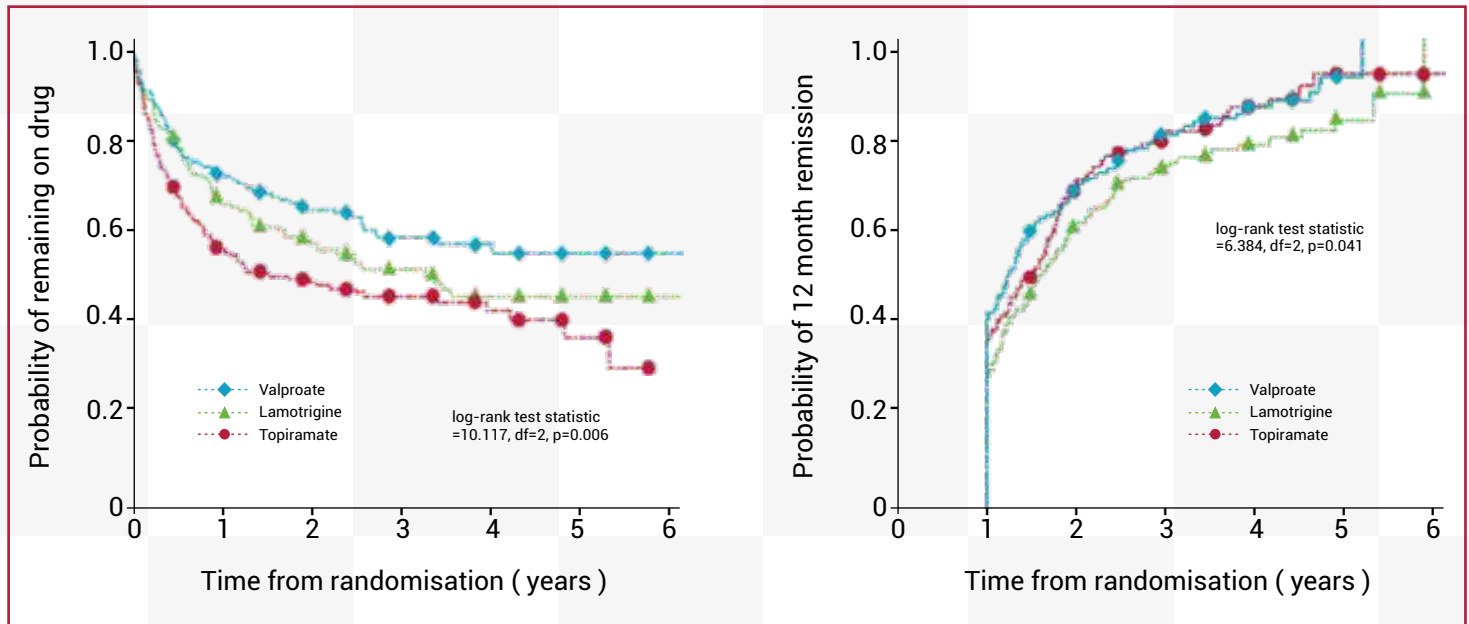
Lancet; 2007

1. "The SANAD study of effectiveness of valproate, lamotrigine, or topiramate for generalised and unclassifiable epilepsy: an unblinded randomised controlled trial."

- Unblinded randomized controlled trial to compare the longer-term effects of Valproate Lamotrigine and Topiramate drugs in patients with generalized onset seizures or seizures that are difficult to classify.
- 716 patients recruited for whom valproate was considered to be standard treatment.
- Patients were randomly assigned to valproate, lamotrigine, or topiramate between 1999, and 2004, and follow-up data were obtained up to 2006.

Results :

- For time to treatment failure : Valproate is significantly better than topiramate (hazard ratio 1.57 [95% CI 1.19–2.08]), but there is no significant difference between valproate and lamotrigine (1.25 [0.94–1.68]).
- For patients with an idiopathic generalized epilepsy: Valproate is significantly better than both lamotrigine (1.55 [1.07–2.24] and topiramate (1.89 [1.32–2.70])).
- For time to 12-month remission: Valproate is significantly better than lamotrigine overall (0.76 [0.62–0.94]), and for the subgroup with an idiopathic generalized epilepsy 0.68 (0.53–0.89).



Conclusion :

- Valproate is better tolerated than topiramate and more efficacious than lamotrigine, and drug of first choice for the patients with generalised and unclassified epilepsies.

2. Divalproex Sodium in Migraine Prophylaxis

Headache; 2001

Divalproex in the Long-term Treatment of Chronic Daily Headache

Study on 138 patients to assess the safety and efficacy of divalproex sodium in the long-term treatment of chronic daily headache suggest that.

- Divalproex sodium can be used for a prolonged period as a sole agent for the successful treatment of chronic daily headache.¹
- Nearly 75% of the patients had at least a 50% reduction in headache frequency.¹
- **The American Academy of Neurology** and the **American Society of Headache** classify divalproex sodium (DVP) as Level-A medications for **migraine prophylaxis**.²

Reference : 1. The Headache; 41(3) : 271-278 : 2001 | 2. The Headache; 56(3) : 603-615 : 2016

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DESCRIPTION

DIVALGRESS contains Divalproex sodium Extended Release Tablets. Divalproex sodium extended release tablets are indicated as monotherapy and adjunctive therapy in the treatment of patients with complex partial seizures that occur either in isolation or in association with other types of seizures. Divalproex sodium extended release tablets are indicated for prophylaxis of migraine headaches.

MECHANISM OF ACTION

Divalproex sodium has anticonvulsant properties, and is chemically related to valproic acid. Divalproex sodium dissociates to the valproate ion in the gastrointestinal tract. Although its mechanism of action has not yet been established, it has been suggested that its activity in epilepsy is related to increased brain concentrations of gamma-aminobutyric acid (GABA). The effect on the neuronal membrane is unknown.

INDICATION

- Use as sole or adjunctive therapy in the treatment of simple or complex absence seizures, including petit mal, and is useful in primary generalized seizures with tonic-clonic manifestations.
- Use adjunctively in patients with multiple seizure types which include either absence or tonic clonic seizures.
- For treatment and management of seizure disorders, mania, & prophylactic treatment of migraine headache.

DOSAGE

Usual Adult Dose for Epilepsy: Extended-release tablets

■ **Complex partial seizures :**

Initial Therapy : 10 to 15 mg/kg/day orally

Titration : Increase by 5 to 10 mg/kg/week to achieve optimal clinical response

Maintenance : Usually below 60 mg/kg/day

Maximum dose : No recommendation regarding safety at doses above 60 mg/kg/day can be made

■ **Simple and complex absence seizures :**

Initial Therapy : 15 mg/kg/day orally

Titration : Increase at one week intervals by 5 to 10 mg/kg/day until seizures are controlled or side effects preclude further increase

Maximum Recommended Dose : 60 mg/kg/day

Usual Adult Dose for Migraine Prophylaxis : Extended-release tablets:

Initial dose : 500 mg orally once a day for 1 week

Maintenance dose : May increase to 1000 mg orally once a day

Administration : It comes as extended release tablets and to be taken by mouth with or without food.

Presentation : Available as strip of 10 tablets.

Storage : Store in dry and dark place, temperature not exceeding 30°C.

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