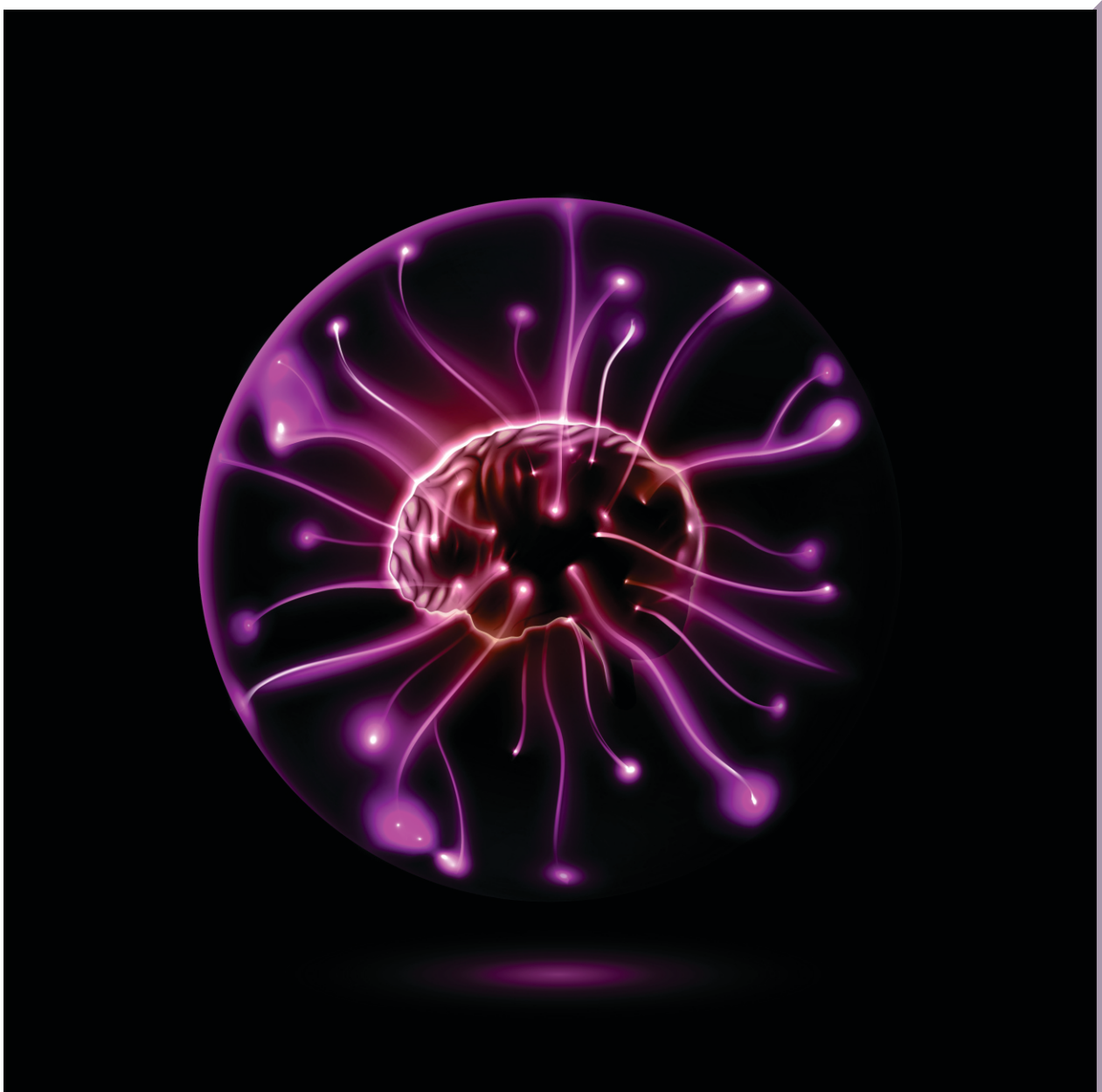
La Renon

Power the motion with

VALGRESS



SODIUM VALPROATE AND VALPROIC ACID CONTROLLED RELEASE 200, 300 AND 500 MG TABLETS

BACKGROUND :

Electrical activity is happening in our brain all the time. A seizure happens when there is a sudden burst of intense electrical activity in the brain.[1] 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. How seizures affect you depends on the area of your brain affected by the epileptic activity. For example, some people lose consciousness during a seizure but other people don't. Some people have strange sensations, or parts of their body might twitch or jerk. Other people fall to the floor and convulse. This is when they jerk violently as their muscles tighten and relax repeatedly. Seizures usually last between a few seconds and several minutes. After a seizure, the person's brain and body will usually return to normal. Some people only ever have seizures when they are awake. Other people only ever have them when they are asleep. Some people have a mixture of both.[2]

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. NICE;Diagnosis and management of the epilepsies; 2013

PREVALENCE :

Epilepsy is a chronic non-communicable disorder of the brain that affects people of all ages.

Approximately 50 million people worldwide have epilepsy, making it one of the most common neurological diseases globally.

Nearly 80% of the people with epilepsy live in low- and middle-income countries.

People with epilepsy respond to treatment approximately 70% of the time.

About three fourths of people with epilepsy living in low- and middle-income countries do not get the treatment they need.

Reference :
WHO, February 2016

WHAT VALGRESS CR OFFERS??

Valproic acid (VPA) is a first line antiepileptic drug for generalized and absence seizures and one of the most widely prescribed anti-epileptic drugs.

The use of VPA may be limited due to the side effects such as weight gain and postural tremor.

Standard immediate oral VPA treatment induces postural tremor in 6-45% of patients.

As per the study published in Epilepsia; 2005 suggest that:
Controlled release valproate (CR-VPA) cause less tremorigenic activity as compared with standard valproate.

Table: Clinical characteristic of patient receiving either VPA or CR-VPA

	CR - VPA (n=8)	VPA (n =10)
Age, Yr (SD)	31 (15)	32 (16)
Gender (F / M)	4/4	3/7
Epilepsy type	IGE (8; 4 JME)	IGE (8; 3 JME) FE (2)
Median Daily Dosage (mg)	1000 (600-1000)	950 (600 - 1500)
Median Follow up (week)	11 (8-21)	14 (8-24)
Median Plasma Conc (µg/ml)	45.5 (27.5 - 65.4)	48.3 (16.8 - 94.6)
Median Tremor Amplitude at base line [(mm/s2)2]	1.2 x 10-3	1.3 x 10-3
Median Tremor Amplitude at follow-up [(mm/s2)2]	1.1 x 10-3	2.4 x 10-3

Source: Epilepsia, 46(2):320-323; 2005)

IGE-Idiopathic Generalized Epilepsy, FE-Focal Epilepsy, JME-Juvenile Myoclonic Epilepsy

VALGRESS & MIGRAINE :

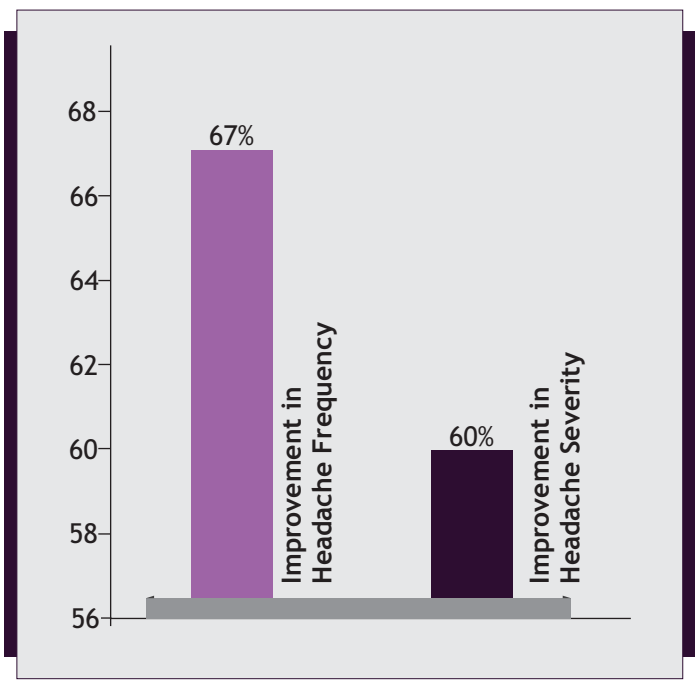
Acta Neurologica Scandinavica; 2000 Journal

Objective : To evaluate the efficacy and safety of valproic acid as a prophylactic agent in migraine patients who previously derived no significant benefit from conventional prophylactic medications for migraine.

Evaluation Parameter : Reduction of 50% or greater in the frequency or severity of headache.

Number of Patients: 120 patients

Results : Improvement was observed in headache frequency within 67% of patients. Headache severity had been improved in 60% of patients.



VALGRESS

SODIUM VALPROATE AND VALPROIC ACID
CONTROLLED RELEASE 200, 300 AND 500 MG TABLETS

DESCRIPTION :

VALGRESS is a controlled release tablets of Sodium Valproate and Valproic acid. Valproic acid, supplied as the sodium salt valproate semisodium or divalproex sodium, is a fatty acid with anticonvulsant properties used in the treatment of epilepsy.

MECHANISM OF ACTION :

Valproic Acid dissociates to the valproate ion in the gastrointestinal tract and then binds to and inhibits GABA transaminase. The drug's anticonvulsant activity may be related to increased brain concentrations of gamma-aminobutyric acid (GABA), an inhibitory neurotransmitter in the CNS, by inhibiting enzymes that catabolize GABA or block the reuptake of GABA into glia and nerve endings. Valproic Acid may also work by suppressing repetitive neuronal firing through inhibition of voltage-sensitive sodium channels. It is also a histone deacetylase inhibitor. Valproic acid has also been shown to be an inhibitor of an enzyme called histone deacetylase 1 (HDAC1). HDAC1 is needed for HIV to remain in infected cells. A study published in August 2005 revealed that patients treated with valproic acid in addition to highly active antiretroviral therapy (HAART) showed a 75% reduction in latent HIV infection.

INDICATION :

For treatment and management of seizure disorders, mania, and prophylactic treatment of migraine headache. In epileptics, valproic acid is used to control absence seizures, tonic-clonic seizures (grand mal), complex partial seizures, and the seizures associated with Lennox-Gastaut syndrome.

DOSAGE : Usual Adult Dose for Epilepsy

Complex partial seizures:

Initial dose: 10 to 15 mg/kg orally or intravenously per day as an IV infusion in divided doses, increased by 5 to 10 mg/kg per week if necessary according to clinical response

Maintenance dose: 10 to 60 mg/kg per day in divided doses | Maximum dose: 60 mg/kg per day

Simple and complex absence seizures:

Initial dose : 15 mg/kg orally or intravenously per day as an IV infusion in divided doses, increased at one week intervals by 5 to 10 mg/kg per day according to seizure control and tolerability

Maximum dose: 60 mg/kg per day

ADMINISTRATION : It comes as controlled 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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