SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Brand Name : BRAIPORIN
Generic Name: Sodium Valproate & Valproic Acid controlled release Tablets

2. QUALITATIVE AND QUANTATIVE COMPOSITIONS

Each film coated controlled release tablet contains:
Sodium Valproate BP 333 mg
Valproic Acid BP 145 mg
(Both together eq. to Sodium Valproate 500 mg)

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Film coated controlled release tablets
White to off white, oblong, plain on both sides & film coated controlled release tablets.

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

Sodium valproate is 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. Sodium valproate is also indicated for use as monotherapy and adjunctive therapy in the treatment of simple and complex absence seizures, and adjunctively in patients with multiple seizure types that include absence seizures.

Mania

Sodium valproate is indicated for the treatment of the manic episodes bipolar disorder.

Migraine

Sodium valproate is indicated for prophylaxis of migraine headaches.

4.2 Posology and method of administration

Sodium valproate tablets are administered orally.

Epilepsy

Complex Partial Seizures

For adults and children 10 years of age or older:

Monotherapy (initial therapy)

Patients should initiate therapy at 10 to 15 mg/kg/day. The dose should be increased by 5 to 10 mg/kg/week to achieve optimal clinical response.
No recommendation regarding the safety of sodium valproate for use at doses above 60 mg/kg/ day can be made.

Conversion to monotherapy

Patients should initiate therapy at 10 to 15 mg/kg/day. The dosage should be increased by 5 to 10 mg/kg/week to achieve optimal clinical response. No recommendation regarding the safety of sodium valproate for use at doses above 60 mg/kg/day can be made. If satisfactory clinical response has not been achieved, plasma levels should be measured to determine whether or not they are in the usually accepted therapeutic range (50-100 mg/mL).

Concomitant antiepileptic drug (AED) dosage can ordinarily be reduced by approximately 25% every 2 weeks. This reduction may be started at initiation of Sodium valproate therapy, or delayed by 1 to 2 weeks if there is concern that seizures are likely to occur with a reduction. The speed and duration of withdrawal of the concomitant AED can be highly variable, and patients should be monitored closely during this period for increased seizure frequency.

Adjunctive therapy

Sodium valproate may be added to the patient's regimen at a dosage of 10 to 15 mg/kg/day. The dosage may be increased by 5 to 10 mg/kg/week to achieve optimal clinical response. If the total daily dose exceeds 250 mg, it should be given in divided doses.

Simple and Complex Absence Seizures

The recommended initial dose is 15 mg/kg/day increasing at one-week intervals by 5 to 10 mg/kg/day until seizures are controlled or side effects preclude further increases. The maximum recommended dosage is 60 mg/kg/day. If the total daily dose exceeds 250 mg, it should be given in divided doses. Antiepileptic drugs should not be abruptly discontinued in patients in whom the drug is administered to prevent major seizures because of the strong possibility of precipitating

4.3 Contraindications

Status epilepticus and attendant hypoxia and threat to life. In epileptic patients previously receiving Sodium valproate therapy, Sodium valproate tablets should be initiated at the same daily dose and dosing schedule. After the patient is stabilized on Sodium valproate tablets, a dosing schedule of two or three times a day may be elected in selected patients.

Mania

The recommended initial dose is 750 mg daily in divided doses. The dose should be increased as rapidly as possible to achieve the lowest therapeutic dose, which produces desired clinical effect or the desired range of plasma concentrations. The maximum recommended dosage is 60 mg/kg/day.

Migraine

The recommended starting dose is 250 mg twice daily. Some patients may benefit from doses up to 1000 mg/day.

Dosing in elderly patients

Due to a decrease in unbound clearance of sodium valproate, the starting dose should be reduced; the ultimate therapeutic dose should be achieved on the basis of both tolerability and clinical response.

4.4 Special warnings and precautions for use

Sodium valproate should not be administered to patients with hepatic disease or significant hepatic dysfunction. Sodium valproate is contraindicated in patients with known hypersensitivity to the drug.

4.5 Interaction with other medicinal products

Blood level increased by aspirin and reduced by carbamazepine, phenobarbitone, phenytoin and primidone. Potentiate CNS depressants including alcohol.

4.6 Pregnancy and lactation

Excretion in breast milk is low, with a concentration between 1 % to 10 % of total maternal serum levels. Although there appears to be no contra-indication to breastfeeding, physicians are advised that in any individual case, consideration should be given to the safety profile of Valproates, specifically haematological disorders.

4.7 Effects on ability to drive and use machines

Use of Epilim may provide seizure control such that the patient may be eligible to hold a driving licence. Patients should be warned of the risk of transient drowsiness, especially in cases of anticonvulsant polytherapy or association with benzodiazepines.

4.8 Undesirable effects

Side Effects

Weight gain, edema, fulminate hepatitis, Anorexia, vomiting, drowsiness, ataxia, and tremor. Curling & loss of hair, increased blood ammonia, rashes, thrombocytopenia.

Healthcare professionals are requested to report any suspected adverse reactions via pharmacy and poisons board, Pharmacovigilance Electronic Reporting System (PvERS) https://pv.pharmacyboardkenya.org ’

4.9 Overdose

Cases of accidental and deliberate Epilim overdosage have been reported. At plasma concentrations of up to 5 to 6 times the maximum therapeutic levels, there are unlikely to be any symptoms other than nausea, vomiting and dizziness. Signs of massive overdose, i.e. plasma concentration 10 to 20 times maximum therapeutic levels, usually include CNS depression or coma with muscular hypotonia, hyporeflexia, miosis, impaired respiratory function, metabolic acidosis. A favourable outcome is usual, however some deaths have

occurred following massive overdose. Symptoms may however be variable and seizures have been reported in the presence of very high plasma levels.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamics

Sodium valproate increases levels of gamma-aminobutyric acid and prolongs the recovery of inactivated sodium channels. These properties may be responsible for its action as a CNS depressant. Sodium valproate interacts with voltage-sensitive sodium channels. Its presence inhibits repetitive firing of neurons and is frequency dependent. In this way, its action is similar to those of phenytoin and carbamazepine. Sodium valproate affects the action of gamma-aminobutyric acid (GABA). Unlike sedative- hypnotics that enhance the postsynaptic action of GABA (eg, phenobarbital, benzodiazepines), Sodium valproate appears to indirectly increase the amount of GABA available to the CNS. In vitro studies have shown that Sodium valproate increases GABA levels by increasing the activity of glutamic acid decarboxylase and by inhibiting GABA transaminase.

5.2 Pharmacokinetic properties

Sodium valproate is usually absorbed rapidly from the GI tract. The absolute bioavailability of Sodium valproate tablets administered as a single dose after a meal was approximately 90% relative to intravenous infusion. The plasma protein binding of valproate is concentration dependent and the free fraction increases from approximately 10% at 40 mcg/mL to 18.5% at 130 mcg/mL. Valproate is metabolized almost entirely by the liver. In adult patients on monotherapy, 30-50% of an administered dose appears in urine as a glucuronide conjugate. Mean plasma clearance and volume of distribution for total valproate are 0.56 L/hr/1.73 m2 and 11 L/1.73 m2, respectively. Mean plasma clearance and volume of distribution for free valproate are 4.6 L/hr/1.73 m2 and 92 L/1.73 m^2.

5.3 Preclinical safety data

There are no preclinical data of relevance to the prescriber which are additional to that
already included in other sections of the SPC.

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

Core Tablet

Ammonio Methacrylate Copolymer (Type B)
Ethylcellulose (20 cps)
Colloidal Anhydrous Silica

Film Coating

Polyacrylate Dispersion 30%
Hypromellose (E 15)
Glycerol
Isopropyl Alcohol Dichloromethane
Polyethylene Glycol 1500
Purified Talc

6.2 Incompatibilities

No effect noted to date.

6.3 Shelf Life

36 months

6.4 Special Precautions for Storage

Store below 30°C. Protected from light & moisture.
Keep medicine out of reach of children.

6.5 Nature and Contents of Container

1 x 10 tablets are packed into Alu/Alu Strips.

6.6 Special Precautions for Disposal

There are no special instructions.

7. MARKETING AUTHORIZATION HOLDER:
UNOSOURCE PHARMA LTD.
503-504, 5th Floor,
Hubtown Solaris, N.S. Phadke Marg,
Andheri (East), Mumbai 400069, India.

Manufacturing Site
Akums Drugs & Pharmaceuticals Limited
Plot No. 19, 20 & 21 Sector 6A, IIE, SIDCUL, Ranipur,
Haridwar-249403, Uttarakhand, India

8. MARKETING AUTHORIZATION NUMBERS

H2015/CTD2820/397

9. DATE OF FIRST REGISTRATION

23/01/2026

10. DATE OF THE REVISION OF THE TEXT

23/01/2026