Proval

Sodium Valproate BP

Presentation :

Proval Tablet : Each enteric coated tablet contains Sodium Valproate BP 200 mg.

Proval Syrup : Each 5 ml contains Sodium Valproate BP 200 mg.

Indications :

- All forms of epilepsy
- Manic episodes associated with bipolar disorder
- Prophylaxis of migraine

Dosage & administration :

Epilepsy : ADULT - 600 mg daily given in 2 divided doses, preferably after food, increasing by 200 mg/day at 3-day intervals to a max. of 2.5 gm daily in divided doses, usual maintenance 1-2 gm daily (20-30 mg/kg daily);
CHILD (up to 20 kg) : Initially 20 mg/kg daily in divided doses, may be increased provided plasma concentrations monitored (above 40 mg/kg daily, also monitor clinical chemistry and haematological parameters).
CHILD (over 20 kg) : Initially 400 mg daily in divided doses increased until control (usually in range of 20-30 mg/kg daily); max. 35 mg/kg daily.

Manic episodes associated with bipolar disorder : Initially 750 mg daily in 2-3 divided doses, increased according to response; usual dose is 1-2 gm/day.
CHILD & ADOLESCENT (under 18 years) : Not recommended.

Prophylaxis of migraine : Starting dose - 300 mg twice daily, increased if necessary to 1.2 gm daily in divided doses.

Caution :

Liver function should be monitored before therapy and during first 6 months especially in patients most at risk, ensure no undue potential for bleeding before starting and before surgery; renal impairment; systemic lupus erythematosus; avoided sudden withdrawal.
If the dose greater than 45 mg/kg daily, close monitoring should be necessary.

Side effects :

Gastric irritation, nausea, ataxia and tremor; hyperammonaemia, increased appetite and weight gain; transient hair loss, oedema, thrombocytopenia and inhibition of platelet aggregation; impaired hepatic function leading rarely to fatal hepatic failure; rashes, sedation and also increased alertness; rarely pancreatitis, EPS, dementia, leucopenia, pancytopenia, red cell hypoplasia, fibrinogen reduction; irregular periods, amenorrhoea, gynaecomastia, hearing loss, Fanconi's syndrome, toxic epidermal necrolysis, Steven-Johnson syndrome, vasculitis, hirsutism and acne also reported.

Contraindication :

Patients with active liver disease, family history of severe hepatic dysfunction, porphyria and patients with a previous history of adverse reactions to Valproate.

Drug interactions :

Valproate reduces the metabolism of lamotrigine. It displaces phenytoin from its binding site on albumin. Serum phenobarbital concentrations may increase when Valproate is introduced concurrently and result in excessive sedation. Carbamazepine may reduce plasma Valproate concentrations by inducing its metabolism. Cimetidine may prolong the half-life and reduces the clearance of Valproate. It may enhance the effects of central nervous system depressants (including alcohol). Caution is recommended when Valproate is administered with other drugs liable to interfere with blood coagulation, such as warfarin or aspirin.

Use in pregnancy and lactation :

Safe use of Valproate during pregnancy has not been established. Valproate can cause teratognic effects in humans.
Since Valproate is distributed into milk, the drug should be used with caution in nursing women.

Commercial pack :

Proval Tablet : Each box contains 5 Alu-Alu blister strips of 10 tablets.
Proval Syrup : Each bottle contains 100 ml syrup.

general GENERAL
Pharmaceuticals Ltd.
Gazipur, Bangladesh