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Valepsy-200 Insert
Date : 07-12-2017

SIZE : 75 X 155 MM FRONT

SIZE : 75 x 155 MM BACK

PATIENT INFORMATION LEAFLET

Valepsy-200

GASTRO-RESISTANT SODIUM VALPROATE TABLETS BP

Valepsy-200
SCHEDULING STATUS : S3

PROPRIETARY NAME
(and dosage form): **Valepsy-200**

Composition :
Each Enteric coated tablet Contains
Sodium Valproate BP 200 mg

PHARMACOLOGICAL CLASSIFICATION: A 2.5 Anticonvulsants, including anti-epileptics.

PHARMACOLOGICAL ACTION:
Pharmacodynamic properties: Sodium valproate has anticonvulsant properties. The exact mode of action is unknown. However, the most likely mode of action for valproate is potentiation of the inhibitory action of gamma amino butyric acid (GABA) through an action on the further synthesis or further metabolism of GABA
Pharmacokinetic properties: Peak plasma concentrations are observed in 1 to 4 hours after sodium valproate liquid, but this can be delayed for several hours if valproic acid is administered in enteric-coated tablets, in prolonged release formulation, or is ingested with meals. Sodium valproate bioavailability is close to 100 % following oral or IV administration. Valproic acid concentration in cerebrospinal fluid is close to free plasma concentration. Steady state plasma concentration is reached after 3 to 4 days, following oral administration. Valproate is highly bound to plasma proteins; protein binding is dose dependent and saturable. When given in therapeutic doses, most of the medicine is converted to the conjugate ester of glucuronic acid, while mitochondrial metabolism, principally by means of beta-oxidation, accounts for the remainder. Some of the metabolites have anticonvulsant activity. Sodium valproate is mainly excreted in urine following metabolism via glucuro-conjugation and beta-oxidation. Sodium valproate does not increase its own degradation, neither that of other agents such as oestrogen and progestogen containing medicines. The elimination half-life of sodium valproate varies from approximately 8 to 20 hours. It is usually shorter in children. In patients with severe renal insufficiency it may be necessary to alter dosage in accordance with free plasma valproic acid levels. The reported effective therapeutic range for plasma valproic acid levels in epilepsy is considered to be between 30 and 100 μg/ml. This reported range may depend on time of sampling andpresence of co-medication. The percentage of free (unbound) drug is usually between 6 % and 15 % of total plasma levels. The pharmacological (or therapeutic) effects of Valepsy-200 are not clearly correlated with the total or free (unbound) plasma valproic acid levels. In cases where measurement of plasma levels is considered necessary, trough plasma levels should be used for therapeutic monitoring.

INDICATIONS:
In the treatment of generalised epilepsy, particularly with the following patterns of seizures: o absence o myoclonic o tonic-clonic o atonic o mixed as well as,
for partial epilepsy: o simple or complex seizures o secondary generalised seizures

CONTRA-INDICATIONS:
Hypersensitivity to sodium valproate. o Use of Valepsy-200 in pregnancy should be avoided. o Active liver disease, including the following:
- Acute hepatitis.
- Chronic hepatitis.
- Personal or family history of hepatic dysfunction especially drug related.
- Hepatic porphyria.

WARNINGS:
- ***Liver dysfunction:*** Conditions of occurrence: Cases of severe liver damage resulting sometimes in fatalities have been reported. Experience in epilepsy has indicated that patients most at risk especially in cases of multiple anticonvulsant therapy are infants and young children under the age of 3 with severe seizure disorders, particularly those with brain damage, mental retardation and (or) congenital metabolic or degenerative disease. After the age of 3, the incidence of occurrence is reduced and decreases with age. In most cases, such liver damage occurred during the first 6 months of therapy.
- ***Pancreatitis:*** Severe pancreatitis, which may result in fatalities, has been rarely reported. Young children are at particular risk. This risk decreased with increasing age. Severe seizures, neurological impairment or anticonvulsant therapy may be risk factors. Hepatic failure with pancreatitis increases the risk of fatal outcome

INTERACTIONS:
Neuroleptics, MAO inhibitors, antidepressants and benzodiazepines
Phenobarbital
Primidone, Phenytoin, Carbamazepine, Lamotrigine, Zidovudine

DOSAGE AND DIRECTIONS FOR USE:
Adults: Dosage should start at 600 mg/day, where applicable in divided doses, increasing by 200 mg/day at three day intervals until control is achieved; this is generally within the range of 1 000 to 2 000 mg/day (i.e. 20 - 30 mg/kg body mass). If adequate control has not been achieved after two weeks, the dose may be further increased, in stages, to a maximum of 2 500 mg/day, or one other anti-epileptic agent may be added at a low dosage. In patients already receiving other therapy, the same pattern should be followed. If increased sedation is observed, dosage of barbiturates or benzodiazepines (e.g. lorazepam) should be reduced as that of Valepsy-200 is increased; dosage of both Valepsy-200 and other agents should be adjusted, during the stabilization period, to give optimum control at the lowest possible combined dosage level, and it may be found possible to maintain optimum control with Valepsy-200 alone.
Children over 20 kg: Initial dosage should be 400 mg/day irrespective of mass, where applicable in divided doses, with spaced increases until control is achieved. This is usually within the range of 20 to 30 mg/kg of body mass per day. Where adequate control is not achieved within this range, the dose may be increased to 35 mg/kg body mass per day.
Children under 20 kg: 20 mg/kg of body mass per day; in severe cases, this may be increased but only in patients in whom plasma valproic acid levels can be monitored. Above 40 mg/kg/day, clinical chemistry and haematological parameters should be monitored

SIDE EFFECTS AND SPECIAL PRECAUTIONS:
Side-effects: Where applicable, the following frequency rating has been used: Very common (> 1/10); common (> 1/100; < 1/10); uncommon (> 1/1000; < 1/100); rare (> 1/10000; < 1/1000); very rare (< 1/10000), including "isolated reports".
Congenital and familial/genetic disorders: (See "Pregnancy and Lactation"). Hepato-biliary disorders: Rare cases of liver dysfunction (see "Warnings").
Gastrointestinal disorders: Nausea, gastralgia, diarrhoea frequently occurs in some patients at the start of treatment, but they usually disappear after a few days without discontinuing the treatment. Very rare cases of pancreatitis, sometimes lethal, have been reported.
Nervous system disorders: Confusion; a few cases of stupor or lethargy sometimes leading to transient coma (encephalopathy) have been described during sodium valproate therapy; they were isolated or associated with an increase in the occurrence of convulsions whilst on therapy, and they decreased on withdrawal of treatment or reduction of dosage. These cases have most often been reported during combined therapy (in particular with phenobarbital) or after a sudden increase in valproate doses
Very rare cases of reversible dementia associated with reversible cerebral atrophy have been reported. Isolated reversible Parkinsonism has been reported. Transient and (or) dose related fine postural tremor and somnolence have often been reported.
Metabolic disorders: Cases of isolated and moderate hyperammonemia without change in liver function tests may frequently occur and should not cause treatment discontinuation. Hyperammonemia associated with neurological symptoms have also been reported. In such cases further investigations should be considered (see "Special precautions").
Blood and lymphatic system disorders: Frequent occurrences of thrombocytopenia, rare cases of anaemia, leucopenia or pancytopenia have been reported. Isolated reduction of fibrinogen or increase in bleeding time has been reported, usually without associated clinical signs and particularly with high doses (sodium valproate has an inhibitory effect on the second phase of platelet aggregation) (see also "Pregnancy"). Skin and subcutaneous tissue disorders: The following side-effects have been reported and the frequencies are unknown: Cutaneous reactions may occur with valproate such as exanthematous rash. In exceptional cases, toxic epidermal necrolysis, Stevens-Johnson syndrome and erythema multiforme have been reported

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:
Clinical signs of acute massive overdose usually include a coma, with muscular hypotonia, hyporeflexia, miosis and impaired respiratory function. Symptoms may however be variable and seizures have been reported in the presence of very high plasma levels. Cases of intracranial hypertension related to cerebral oedema have been reported. Hospital management of overdose should be symptomatic: gastric lavage (which is useful up to 10 to 12 hours following ingestion), cardio-respiratory monitoring, assisted ventilation and other supportive measures are recommended. Haemodialysis and haemoperfusion have been used successfully. Naloxone has been successfully used in a few isolated cases. Deaths have occurred following massive overdose

STORAGE INSTRUCTIONS: Store below 30° C & Protect from light & moisture.

KEEP THE MEDICINE OUT OF REACH OF CHILDREN

PRESENTATION: 10X10's Tablets in Alu-Alu packs

Manufactured in India By :
MAXTAR BIO-GENICS
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Malku Majra ,Baddi-173205(H.P)