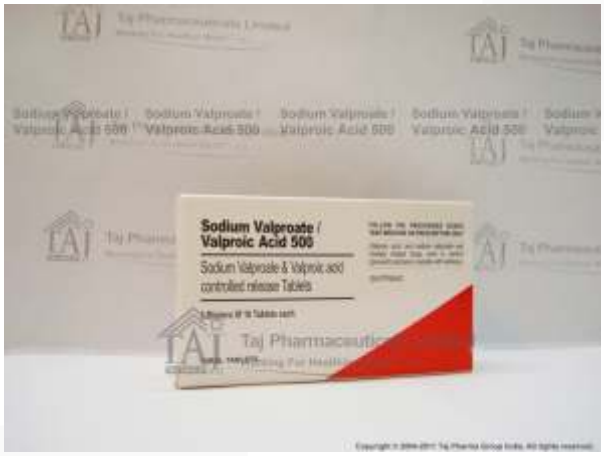
Sodium Valproate +Valproic Acid tablets film-coated

Each retard 500 tablet film-coated tablet contains:
Valproic acid.....145 mg
Sodium valproate.....333 mg

Excipients contained in the tablets film-coated tablets include: hipromelose 4000 (3000 mPas); silicone-dioxide, colloid, hydrate; ethyl cellulose 20 mPas; saccharine sodium; silicone-dioxide, colloid, anhydrate. Excipients in the film coating of tablets include: hipromelose
(6 mPas); macrogel 6000; polyacrylate, dispersion 30%; talcum and titanium-dioxide (E 171)

Each Tablet contains:
Sodium valproate.....333/145mg



COMPOSITION :

Sodium valproate-200
Each film coated tablet contains
Sodium valproate I.P.....200 mg

Sodium valproate-300
Each film coated tablet contains
Sodium valproate I.P.....300 mg

Sodium valproate-500
Each film coated tablet contains
Sodium valproate I.P.....500 mg

Sodium valproate CR-200
Each film coated tablet contains
Sodium valproate I.P.....133.5 mg + Valproic acid
USP 58 mg (Both together correspond to Sodium Valproate 200 mg)

Sodium valproate CR-300
Each film coated tablet contains
Sodium valproate I.P.....200 mg + Valproic acid
USP 87 mg (Both together correspond to Sodium Valproate 300 mg)

Sodium valproate CR-500
Each film coated tablet contains
Sodium valproate I.P.....333 mg + Valproic acid
USP 145 mg (Both together correspond to Sodium Valproate 500 mg)

DESCRIPTION :
Sodium valproate is the sodium salt of valproic acid and mechanisms by which valproate exerts its therapeutic effects have not been established. It has been suggested that its activity in epilepsy is related to increased brain concentrations of gamma-aminobutyric acid (GABA).

INDICATIONS :
Epilepsy
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 sole 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 associated with bipolar disorder.

Migraine
Sodium valproate is indicated for prophylaxis of migraine headaches.

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DOSAGE AND ADMINISTRATION :
Sodium valproate tablets are administered orally.

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 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

CONTRAINDICATIONS :
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

PRECAUTIONS :
Hepatic failure resulting in fatalaties has occurred in patients receiving sodium valproate. These incidents usually have occurred during the first six months of treatment. Serious or fatal hepatotoxicity may be preceded by non-specific symptoms such as malaise, weakness, lethargy, facial oedema, anorexia and vomiting. In patients with epilepsy, a loss of seizure control may also occur.

The benefits of the therapy should be weighed against the risks. Above this age group, experience in epilepsy has indicated that the incidence of fatal hepatotoxicity decreases considerably in progressively older patient groups. The drug should be discontinued immediately, in the presence of significant hepatic dysfunction suspected or apparent. In some cases, hepatic dysfunction has progressed in spite of discontinuation of drug.

SIDE EFFECT :
The common adverse events reported during sodium valproate therapy include nausea, somnolence, dizziness, vomiting, asthenia, abdominal pain, dyspepsia, rash and mania.

PACKAGING INFORMATION :
Sodium valproate-200 Blister strip of 10's
Sodium valproate-300 Blister strip of 10's
Sodium valproate-500 Blister strip of 10's

Sodium valproate CR-200 Blister strip of 10's
Sodium valproate CR-300 Blister strip of 10's
Sodium valproate CR-500 Blister strip of 10's
Adverse Reactions :

For Information about Generic Medicines : **genericmedicines@tajpharma.com**

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Information for Health Care Professionals

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Taj Pharmaceuticals Limited is a pharmaceutical company founded and based in India. The company manufacturers pharmaceutical formulations and API for India and other countries of world. The company was established in 1995 as an enterprise and in 2004 became a public limited company. As per Mumbai pharmaxil and Chemixil association the company manufacturers and exports to countries like Albania, Argentina, Austria, Chile and Iraq. In 1995 pharmaceuticals wing only has a schedule M certification for pharmaceuticals products manufacturing in India. Taj Pharmaceuticals established its manufacturing unit in Gujarat because of government policies in 1999 with WHO / GMP licence. The company in 2003 revived all the old manufacturing units and approached the FDA Gujarat for 4000 new pharmaceuticals drug permissions for the first time in India.

According to the Indian Trade Mark the company owns about 450 brands and 4600 generic manufacturing permissions in India. According to the export data analysis the company was the largest exporter of generic medicines to the Europe and Middle East countries.
www.tajpharma.com

The company medicines are present in France, Georgia, Egypt and CIF countries.

Taj Pharmaceuticals Limited
Working For Healthier World™ INDIA

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