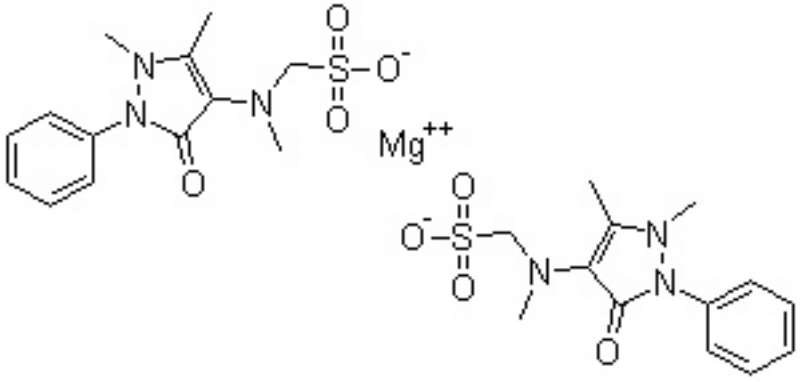
Taj Pharmaceuticals Ltd.

Magnesium Valproate

CAS No. : 62959-43-7

Molecular Formula C26H32MgN6O8S2
Molecular Weight 645.00
CAS Registry Number 62959-43-7



Element category alkaline earth metal
Group, period, block 2, 3, s
Appearance silvery white solid at room temp
Standard atomic weight 24.3050(6) g·mol- 1
Electron configuration [Ne] 3s2
Electrons per shell 2, 8, 2 (Image)
Physical properties
Phase solid
Density (near r.t.) 1.738 g·cm- 3
Liquid density at m.p. 1.584 g·cm- 3
Melting point 923 K
(650 °C, 1202 °F)
Boiling point 1363 K
(1091 °C, 1994 °F)
Heat of fusion 8.48 kJ·mol- 1
Heat of vaporization 128 kJ·mol- 1
Specific heat capacity (25 °C) 24.869 J·mol- 1·K- 1

DOSAGE

Magnesium Valproate is indicated as adjunctive therapy for partial seizures, the generalized seizures of Lennox-Gastaut syndrome, and primary generalized tonic-clonic seizures in adult and pediatric patients

Magnesium Valproate is indicated for conversion to monotherapy in adults with partial seizures who are receiving treatment with carbamazepine, phenytoin, phenobarbital, primidone, or valproate as the single AED.

General Dosing Considerations for Epilepsy and Bipolar Disorder Patients

The risk of nonserious rash is increased when the recommended initial dose and/or the rate of dose escalation of Magnesium Valproate is exceeded. There are suggestions, yet to be proven, that the risk of severe, potentially life-threatening rash may be increased by coadministration of Magnesium Valproate with valproate, exceeding the recommended initial dose of Magnesium Valproate, or exceeding the recommended dose escalation for Magnesium Valproate. However, cases have been reported in the absence of these factors Therefore, it is important that the dosing recommendations be followed closely.

It is recommended that Magnesium Valproate not be restarted in patients who discontinued due to rash associated with prior treatment with Magnesium Valproate, unless the potential benefits clearly outweigh the risks. If the decision is made to restart a patient who has discontinued Magnesium Valproate, the need to restart with the initial dosing recommendations should be assessed. The greater the interval of time since the previous dose, the greater consideration should be given to restarting with the initial dosing recommendations. If a patient has discontinued Magnesium Valproate for a period of more than 5 half-lives, it is recommended that initial dosing recommendations and guidelines be followed.

Taj Pharmaceuticals Ltd..
Magnesium
Valproate
CAS NO- 62959-43-7

SIDE EFFECTS

General: Fever, neck pain.
Cardiovascular: Migraine.

Digestive: Flatulence.
Metabolic and Nutritional: Weight gain, edema.

Musculoskeletal: Arthralgia, myalgia.
Nervous System: Amnesia, depression, agitation, emotional lability, dyspraxia, abnormal thoughts, dream abnormality, hypoesthesia.

Respiratory: Sinusitis.
Urogenital: Urinary frequency.

Body as a Whole: Infrequent: Allergic reaction, chills, halitosis, and malaise.
Rare: Abdomen enlarged, abscess, and suicide/suicide attempt.

Cardiovascular System: Infrequent: Flushing, hot flashes, hypertension, palpitations, postural hypotension, syncope, tachycardia, and vasodilation.

Rare: Angina pectoris, atrial fibrillation, deep thrombophlebitis, ECG abnormality, and myocardial infarction.

Dermatological: Infrequent: Acne, alopecia, hirsutism, maculopapular rash, skin discoloration, and urticaria.

Rare: Angioedema, erythema, exfoliative dermatitis, fungal dermatitis, herpes zoster, leukoderma, multiforme erythema, petechial rash, pustular rash, seborrhea, Stevens-Johnson syndrome, and vesiculobullous rash.

Digestive System: Infrequent: Dysphagia, eructation, gastritis, gingivitis, increased appetite, increased salivation, liver function tests abnormal, and mouth ulceration.

Rare: Gastrointestinal hemorrhage, glossitis, gum hemorrhage, gum hyperplasia, hematemesis, hemorrhagic colitis, hepatitis, melena, stomach ulcer, stomatitis, thirst, and tongue edema.

PRECAUTIONS

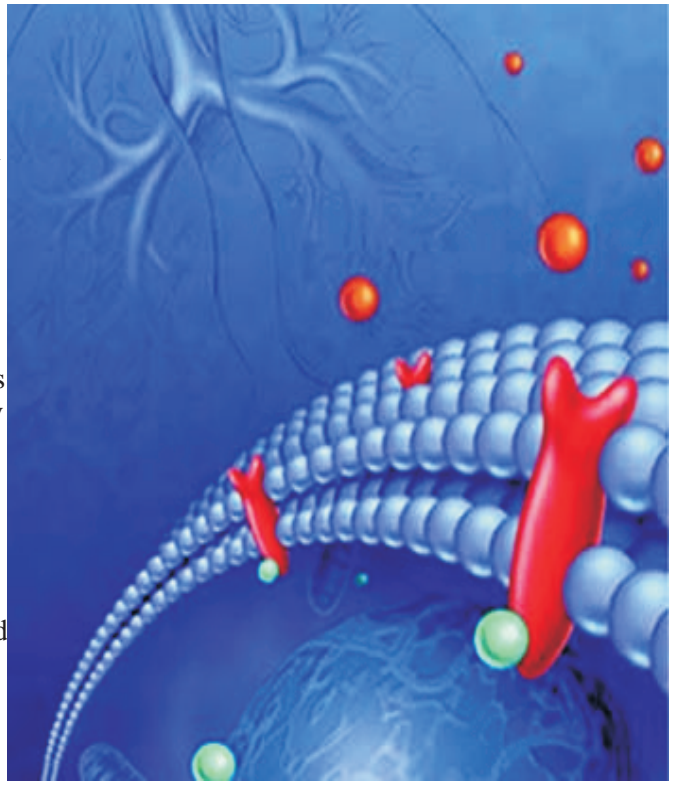
Before using this medication, tell your doctor or pharmacist your medical history, especially of: kidney disease, liver disease, heart disease, rash while taking Magnesium Valproate.

This drug may make you dizzy or drowsy; use caution while engaging in activities requiring alertness such as driving or using machinery. Limit alcoholic beverages.

Though not proven, Magnesium Valproate may cause harm to an unborn baby if used during the first three months of pregnancy (cleft palate). Therefore, this medication should be used only when clearly needed during pregnancy. Promptly discuss the risks and benefits with your doctor if you are pregnant, think you are pregnant, or are planning to become pregnant. Do not stop using this medication before talking with your doctor.

This drug may pass into breast milk and could have undesirable effects on a nursing infant. Therefore, breast-feeding is not recommended while using this drug. Consult your doctor before breast-feeding.

DRUG DESCRIPTION



The magnesium salt of valproic acid (2-propylpentanoic acid) with antiepileptic and potential antineoplastic activities. Magnesium valproate dissociates in the gastrointestinal tract and is absorbed into the circulation as magnesium ions and valproic acid ions; valproic acid may inhibit histone deacetylases, inducing tumor cell differentiation, apoptosis, and growth arrest. In addition, valproic acid exerts an antiepileptic effect, likely by inhibiting enzymes that catabolize the inhibitory neurotransmitter gamma-aminobutyric acid (GABA) catabolism and so increasing concentrations of GABA in the central nervous system (CNS). The presence of the magnesium in this agent may contribute to its anticonvulsant activity and sedative properties.

Salicylates, particularly aspirin, may displace valproate from protein binding sites and inhibit its clearance. Four-fold increases in the free fraction of valproate have been reported in children. Increased therapeutic and toxic effects may be expected to occur. This interaction is more likely with large or prolonged doses of salicylates.

Note /Government Notification: These chemicals are designated as those that are used in the manufacture of the controlled substances and are important to themanufacture of the substances. For any (Control Substance) products Import and Export *** subjected to your country government laws /control substance ACT.

Information: The information on this web page is provided to help you to work safely, but it is intended to be an overview of hazards, not a replacement for a full Material Safety Data Sheet (MSDS). MSDS forms can be downloaded from the web sites of many chemical suppliers. ,also that the information on the PTCL Safety web site, where this page was hosted, has been copied onto many other sites, often without permission. If you have any doubts about the veracity of the information that you are viewing, or have any queries, please check the URL that your web browser displays for this page. If the URL begins "www.tajapi.com/www/Denatonium Benzoate.htm/" the page is maintained by the Safety Officer in Physical Chemistry at Oxford University. If not, this page is a copy made by some other person and we have no responsibility for it.

The Controlled Substances Act (CSA) was enacted into law by the Congress of the United States as Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970.[1] The CSA is the federal U.S. drug policy under which the manufacture, importation, possession, use and distribution of certain substances is regulated. The Act also served as the national implementing legislation for the Single Convention on Narcotic Drugs

This document plus the full buyer/ prescribing information, prepared for health professionals can be found at:
http://www.tajapi.com
or by contacting the sponsor, Taj Pharmaceuticals Limited., at:
91 022 30601000.
This leaflet was prepared by
Taj Pharmaceuticals Limited,
Mumbai (India).
MPSTJ278
Last revised: 29 August 2009