This medication is used in combination with other medications to treat seizure disorders (epilepsy). Levetiracetam has been shown to decrease the number of seizures in adults and children with a certain type of seizure (partial onset). It is not known how it works to prevent seizures.

Active Pharmaceuticals Ingredients Manufacturers





Chemical Name Levetiracetam

(α S)-α-Ethyl-2-oxo-1-pyrrolidineαcetamide 2(S)-(2-oxopyrrolidin-1-yl)butyramide Ethyl Oxo Pyrrolidine Acetamide, Oxopyrrolidin Butyramide UCB-L059 SIB-S1

Molecular Formula C8H14N2O2 / C8H14N2O2 / C8 H14 N2 O2

Molecular Weight 170.21

Molecular Structure

C8H14N2O2, Levetiracetam, 102767-28-2, Ethyl Pyrrolidine Acetamide, Oxopyrrolidin Butyramide, C8 H14 N2 O2,

USES

This medication is used in combination with other medications to treat seizure disorders (epilepsy). Levetiracetam has been shown to decrease the number of seizures in adults and children with a certain type of seizure (partial onset). It is not known how it works to prevent seizures.

HOW TO USE

Take this medication by mouth with or without food, usually twice daily or as directed by your doctor. Take this medication regularly in order to get the most benefit from it. To help you remember, take it at the same times each day, about 12 hours apart. Your doctor may slowly increase the dose to lessen the chance of side effects, especially dizziness and drowsiness. If you are using the liquid form of this medication, carefully measure your dose using a special measuring spoon or device. Do not use a household spoon because you may not get the correct dose. Dosage is based on your condition and response to therapy. The dosage in children is also based on weight. Do not take this drug more often or increase your dose without consulting your doctor.

SIDE EFFECTS

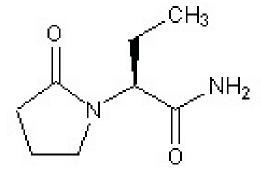
Side effects include: hair loss; pins and needles sensation in the extremities; anxiety and psychiatric symptoms ranging from irritability to depression; and other common side effects like headache and nausea. Recent literature[5] suggests that the addition of pyridoxine (vitamin B6) may curtail some of the psychiatric symptoms.

Levetiracetam is generally well tolerated

but may cause sleepiness, weakness, dizziness, and infection. In children, the most common side effects are sleepiness, accidental injury, hostility, irritability, and weakness.

Many medications can cause side effects. A side effect is an unwanted response to a medication when it is taken in normal doses. Side effects can be mild or severe, temporary or permanent. The side effects listed below are not experienced by everyone who takes this medication. If you are concerned about side effects, discuss the risks and benefits of this medication with your doctor.

The following side effects have been reported by at least 1% of people taking this medication. Many of these side effects can be managed, and some may go away on their own over time.







Taj Pharmaceuticals Ltd.

Levetiracetam



Contact your doctor if you experience these side effects and they are severe or bothersome. Your pharmacist may be able to advise you on managing side effects.

- * bruising
- * cough
- * dizziness
- * drowsiness
- * feeling weαk
- * infection such as the common cold
- * loss of strength or energy
- * muscle pain or weakness
- * weight loss

PRECAUTIONS

Before using this medication, tell your doctor or pharmacist if you are allergic to it; or if you have any other allergies.

Before using this medication, tell your doctor or pharmacist your medical history, especially of: blood disorders (e.g., anemia), kidney disease (including dialysis treatment), mental/mood disorders (e.g., depression).

This drug may make you dizzy or drowsy, especially during the first month of treatment. Use caution engaging in activities requiring alertness such as driving, riding a bicycle, or using machinery. Limit alcoholic beverages.

Kidney function declines as you grow older. This medication is removed by the kidneys. Therefore, elderly people may be ot a greater risk for side effects such as dizziness while using this drug.

MISSED DOSE

If you miss α dose, take it as soon as you remember. If it is near the time of the next dose, skip the missed dose and resume your usual dosing schedule. Do not double the dose to catch up.

STORAGE

Store at room temperature at 77 degrees F (25 degrees C) away from light and moisture. Brief storage between 59-86 degrees F (15-30 degrees C) is permitted. Keep all medicines away from children

DOSAGE2

The usual recommended starting dose of levetiracetam for an adult is 500 mg twice daily, with or without food according to your doctor's instructions. This dose may be increased to a maximum of 3,000 mg per day, according to need and as prescribed by your doctor. People with poor kidney function may need α lower dose.

Many things can affect the dose of medication that a person needs, such as body weight, other medical conditions, and other medications. If your doctor has recommended a dose different from the ones listed here, do not change the way that you are taking the medication without consulting your doctor.

It is important to use this medication exactly as prescribed by your doctor. If you miss a dose, take it as soon as possible and continue with your regular schedule. However, if it is almost time for your next dose, skip the missed dose and continue with your regular dosing schedule. Do not take a double dose to make up for a missed one. If you are not sure what to do after missing a dose, contact your doctor or pharmacist for advice.



Store this medication at room temperature and keep it out of the reach of children.

DRUG DESCRIPTION

Levetiracetam is an anticonvulsant medication used to treat epilepsylt is S- enantiomer of etiracetam, structurally similar to the prototypical nootropic drug piracetam.

Properties
Molecular formula C8H14N2O2
Molar mass 170.21 g mol- 1
Appearance Fine white crystalline powder
Pharmacology
Bioavailability 100%
Routes of
administration Oral, Intravenous
Elimination
half-life 6 - 8 hr
Excretion Urinary

- The chemical name of levetiracetam, α single enantiomer, is (-)-(S)-α-ethyl-2-oxo-1-pyrrolidine acetamide, its molecular formula is C8H14N2O2 and its molecular weight is 170.21.Levetiracetam is α white to off-white crystalline powder with α faint odor and α bitter taste. It is very soluble in water (104.0 g/100 mL). It is freely soluble in chloroform (65.3 g/100 mL) and in methanol (53.6 g/100 mL), soluble in ethanol (16.5 g/100 mL), sparingly soluble in acetonitrile (5.7 g/100 mL) and practically insoluble in n-hexane. (Solubility limits are expressed as g/100 mL solvent.)
- Levetiracetam tablets contain the labeled amount of levetiracetam. Inactive ingredients: colloidal silicon dioxide, croscarmellose sodium, magnesium stearate, polyethylene glycol 3350, polyethylene glycol 6000, polyvinyl alcohol, talc, titanium dioxide, and additional agentsLevetiracetam oral solution contains 100 mg of levetiracetam per mL. Inactive ingredients: ammonium glycyrrhizinate, citric acid monohydrate, glycerin, maltitol solution, methylparaben, potassium acesulfame, propylparaben, purified water, sodium citrate dihydrate and natural and artificial flavor.

Note /Government Notification: These chemicals are designated as those that are used in the manufacture of the controlled substances and are important to the manufacture 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,

Mumbαi (Indiα).

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