Taj Pharmaceuticals Ltd.

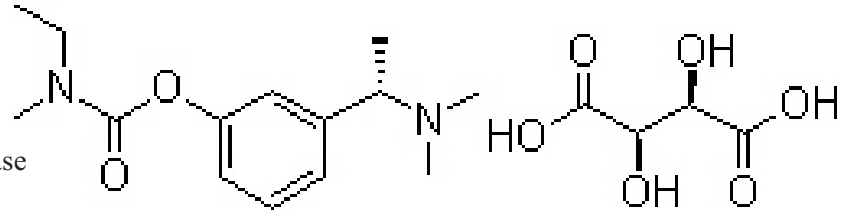
Rivastigmine Tartrate

CAS No. : 129101-54-8

Chemical data

Molecular Formula C14H22N2O2.C4H6O6
Molecular Weight 400.43
CAS Registry Number 129101-54-8

Pharmacokinetic data



Bioavailability 96%
Protein binding 40%
Metabolism Hepatic, via pseudocholinesterase
Half life 1.5 hours
Excretion Renal, 97%

Rivastigmine Tartrate often causes nausea and vomiting, especially at the beginning of treatment. The problem is more likely in women, but it can lead to significant weight loss in both women and men. Tell your doctor immediately if these side effects occur.

The chance of severe vomiting increases when Rivastigmine Tartrate is given after an interruption of several days. Do not start giving the drug again without first checking with the doctor. Dosage may need to be reduced to the lowest starting level.

Rivastigmine Tartrate may aggravate asthma and other breathing problems and can increase the risk of seizures. Other drugs of its type are also known to increase the chance of ulcers, stomach bleeding, and urinary obstruction, although these problems have not been noted with Rivastigmine Tartrate. Drugs in this category can also slow the heartbeat, possibly causing fainting in people who have a heart condition. Contact your doctor if any of these problems occur.
Rivastigmine Tartrate has not been tested in children.

USES

Rivastigmine is used to treat mild to moderate confusion (dementia) related to Alzheimer's disease. It is also used to treat mild to moderate confusion (dementia) related to Parkinson's disease. Rivastigmine does not cure either of these diseases, but it may improve memory, awareness, and the ability to perform daily functions. This medication works by restoring the balance of natural substances (neurotransmitters) in the brain. HOW TO USE: Take this medication by mouth with food, usually twice daily in the morning and evening or as directed by your doctor. In order to minimize nausea and vomiting, your dosage will be gradually increased to your target dose. Your dosage is based on your medical condition and response to therapy. Do not take more than the maximum recommended dose of 12 milligrams per day.

SIDE EFFECTS

Nausea, vomiting, stomach pain, loss of appetite, diarrhea, weakness, headache, dizziness, drowsiness, and shakiness may occur. If any of these effects persist or worsen, contact your doctor or pharmacist promptly.

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PRECAUTIONS

Before taking rivastigmine, 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: stomach/intestinal problems (e.g., ulcers, bleeding), heart problems (e.g., sick sinus syndrome, conduction disorders), breathing/lung problems (e.g., asthma, COPD-chronic obstructive pulmonary disease), seizures, problems urinating (e.g., due to enlarged prostate).

MISSED DOSE

If you miss a dose, use 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 (77 degrees F or 25 degrees C) away from light and moisture. Brief storage between 59-86 degrees F (15-30 degrees C) is permitted. Do not store in the bathroom. Keep all medicines away from children and pets.

DOSAGE

Rivastigmine Tartrate should be taken with food in the morning and in the evening.

* If you miss a dose...
Give the forgotten dose as soon as you remember. If it is almost time for the next dose, skip the one you missed and go back to the regular schedule. Never double the dose.

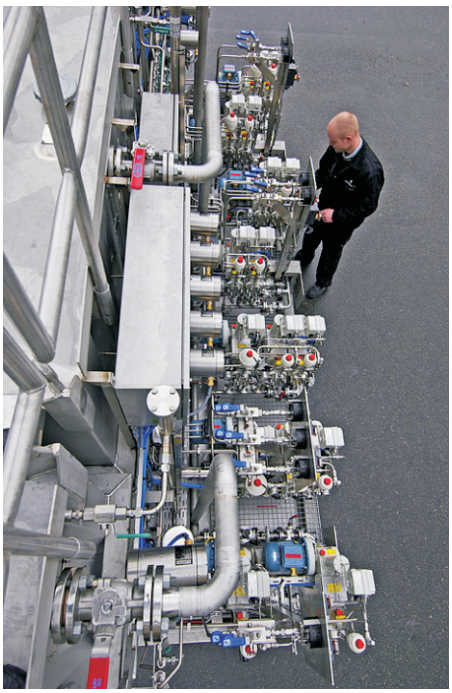
* Storage instructions...
Store at room temperature in a tightly closed container.
The dosage of Rivastigmine Tartrate (rivastigmine tartrate) shown to be effective in controlled clinical trials in Alzheimer's Disease is 6-12 mg/day, given as twice-a-day dosing (daily doses of 3 to 6 mg BID). There is evidence from the clinical trials that doses at the higher end of this range may be more beneficial.

The starting dose of Rivastigmine Tartrate is 1.5 mg twice a day (BID). If this dose is well tolerated, after a minimum of 2 weeks of treatment, the dose may be increased to 3 mg BID. Subsequent increases to 4.5 mg BID and 6 mg BID should be attempted after a minimum of 2 weeks at the previous dose. If adverse effects (e.g., nausea, vomiting, abdominal pain, loss of appetite) cause intolerance during treatment, the patient should be instructed to discontinue treatment for several doses and then restart at the same or next lower dose level. If treatment is interrupted for longer than several days, treatment should be reinitiated with the lowest daily dose and titrated as described above
The maximum dose is 6 mg BID (12 mg/day).

DRUG DESCRIPTION

Rivastigmine Tartrate (rivastigmine tartrate) is a reversible cholinesterase inhibitor and is known chemically as (S)-N-Ethyl-N-methyl-3-[1-(dimethylamino)ethyl]-phenyl carbamate hydrogen-(2R,3R)-tartrate. Rivastigmine tartrate is commonly referred to in the pharmacological literature as SDZ ENA 713 or ENA 713. It has an empirical formula of $C_{14}H_{22}N_2O_2 \cdot C_4H_6O_6$ (hydrogen tartrate salt - hta salt) and a molecular weight of 400.43 (hta salt). Rivastigmine tartrate is a white to off-white, fine crystalline powder that is very soluble in water, soluble in ethanol and acetonitrile, slightly soluble in n-octanol and very slightly soluble in ethyl acetate.

The distribution coefficient at 37°C in n- octanol/phosphate buffer solution pH 7 is 3.0.rivastigmine tartrate, equivalent to 1.5, 3, 4.5 and 6 mg of rivastigmine base for oral administration. Inactive ingredients are hydroxypropyl methylcellulose, magnesium stearate, microcrystalline cellulose, and silicon dioxide. Each hard-gelatin capsule contains gelatin, titanium dioxide and red and/or yellow iron oxides.



Rivastigmine Tartrate is used in the treatment of mild to moderate Alzheimer's disease. Alzheimer's disease causes physical changes in the brain that disrupt the flow of information and interfere with memory, thinking, and behavior. By boosting levels of the chemical messenger acetylcholine, Rivastigmine Tartrate can temporarily improve brain function in some Alzheimer's sufferers, though it does not halt the progress of the underlying disease. Rivastigmine Tartrate may become less effective as the disease progresses.

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.

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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

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