

Memorin®

Donepezil Hydrochloride
Tablet



Description

Donepezil hydrochloride is a reversible inhibitor of the enzyme acetylcholinesterase, known chemically as (±)-2,3-dihydro-5,6-dimethoxy-2-[[1-(phenylmethyl)-4-piperidinyl]methyl]-1H-inden-1-one hydrochloride. It has an empirical formula of C₂₄H₂₉NO₃ HCl and a molecular weight of 415.96. Donepezil hydrochloride is a white crystalline powder and is freely soluble in chloroform, soluble in water and in glacial acetic acid, slightly soluble in ethanol and in acetonitrile and practically insoluble in ethyl acetate and in n-hexane.

Indications

Donepezil hydrochloride is indicated for the treatment of mild to moderate dementia of the Alzheimer's type.

Dosage and Administration

The dosages of Donepezil hydrochloride shown to be effective in controlled clinical trials are 5 mg and 10 mg administered once per day.

The higher dose of 10 mg did not provide a statistically significantly greater clinical benefit than 5 mg. There is a suggestion, however, based upon order of group mean scores and dose trend analyses of data from these clinical trials, that a daily dose of 10 mg of Donepezil hydrochloride might provide additional benefit for some patients. Accordingly, whether or not to employ a dose of 10 mg is a matter of prescriber and patient preference.

Side Effects

The rates of discontinuation from controlled clinical trials of Donepezil hydrochloride due to adverse events for the Donepezil hydrochloride 5 mg/day treatment groups were comparable to those of placebo-treatment

groups at approximately 5%.

The most common adverse events, defined as those occurring in at least 2% of patients and at twice the incidence seen in placebo patients are nausea, vomiting & diarrhoea. Donepezil hydrochloride, as a predictable consequence of its pharmacological properties, has been shown to produce diarrhea, nausea and vomiting. These effects, when they occur, appear more frequently with the 10 mg/day dose than with the 5 mg/day dose. In most cases, these effects have been mild and transient, sometimes lasting one to three weeks, and have resolved during continued use of Donepezil hydrochloride.

Contraindications

Donepezil hydrochloride is contraindicated in patients with known hypersensitivity to donepezil hydrochloride or to piperidine derivatives.

Use in Pregnancy and Lactation

Pregnancy Category C: Teratology studies conducted in pregnant rats at doses up to 16 mg/kg/day (approximately 13 times the maximum recommended human dose on a mg/m² basis) and in pregnant rabbits at doses up to 10 mg/kg/day (approximately 16 times the maximum recommended human dose on a mg/m² basis) did not disclose any evidence for a teratogenic potential of donepezil. However, in a study in which pregnant rats were given up to 10 mg/kg/day (approximately 8 times the maximum recommended human dose on a mg/m² basis) from day 17 of gestation through day 20 postpartum, there was a slight increase in still births and a slight decrease in pup survival through day 4 postpartum at this

dose: the next lower dose tested was 3 mg/kg/day. There are no adequate or well-controlled studies in pregnant women. Donepezil hydrochloride should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

It is not known whether donepezil is excreted in human breast milk. Donepezil hydrochloride has no indication for use in nursing mothers.

Precautions

Because of their cholinomimetic actions, cholinesterase inhibitors should be prescribed with care to patients with a history of asthma or obstructive pulmonary disease.

Drug Interactions

Effect of Other Drugs on the Metabolism of Donepezil hydrochloride: Ketoconazole and quinidine, inhibitors of CYP450, 3A4 and 2D6, respectively, inhibit donepezil metabolism in vitro. Whether there is a clinical effect of these inhibitors is not known. Inducers of CYP 2D6 and CYP 3A4 (e.g., phenytoin, carbamazepine, dexamethasone, rifampin, and phenobarbital) could increase the rate of elimination of Donepezil hydrochloride.

Use with Anticholinergics: Because of their mechanism of action, cholinesterase inhibitors have the potential to interfere with the activity of anticholinergic medications.

Use with Cholinomimetics and Other Cholinesterase Inhibitors: A synergistic effect may be expected when cholinesterase inhibitors are given concurrently with succinylcholine, similar neuromuscular blocking agents or cholinergic agonists such as bethanechol.

Pharmaceuticals Precautions

Store in a cool, dry place, away from light.

Keep out of reach of children.

Commercial Pack

Each box contains 2 blister strips of 10 tablets. Each film-coated tablet contains Donepezil Hydrochloride INN 5 mg.



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