Benzenod™

Rivastigmine

Composition
Benzenod™ 1.5 Capsule: Each capsule contains Rivastigmine 1.5 mg (as Rivastigmine Tartrate USP)

Benzenod™ 3 Capsule: Each capsule contains Rivastigmine 3 mg (as Rivastigmine Tartrate USP)

Pharmacodynamics Properties
Rivastigmine is an acetyl and butyrylcholinesterase inhibitor of the carbamate type, thought to facilitate cholinergic neurotransmission by slowing the degradation of acetylcholine released by functionally intact cholinergic neurons. Thus, Rivastigmine may have an ameliorative effect on cholinergic-mediated cognitive deficits in dementia associated with Alzheimer's disease and Parkinson's disease.

Pharmacokinetics Properties
Rivastigmine shows linear pharmacokinetics up to 3 mg twice a day but is nonlinear at higher doses. Doubling the dose from 3 mg to 6 mg twice a day results in a 3-fold increase in area under the curve (AUC). The elimination half-life is about 1.5 hours, with most elimination as metabolites via the urine.

Indications
Rivastigmine is indicated for the treatment of mild to moderate dementia of the Alzheimer's disease (AD). Rivastigmine is indicated for the treatment of mild to moderate dementia associated with Parkinson's disease (PD).

Dosage & Administration
Mild to moderate dementia in Alzheimer's disease: By mouth: Adult: Initially 1.5 mg twice daily, increased in steps of 1.5 mg twice daily, dose to be increased at intervals at least 2 weeks according to response and tolerance; usual dose 3-6 mg twice daily (max. per dose 6 mg twice daily), if treatment interrupted for more than several days, retitrate from 1.5 mg twice daily.

Mild to moderate dementia in Parkinson's disease: By mouth: Adult: Initially 1.5 mg twice daily, increased in steps of 1.5 mg twice daily, dose to be increased at intervals of at least 2 weeks according to response and tolerance; usual dose 3-6 mg twice daily (max. per dose 6 mg twice daily), if treatment interrupted for more than several days, retitrate from 1.5 mg twice daily.

Contraindication & warning
Rivastigmine is contraindicated in patients with known hypersensitivity to Rivastigmine, other carbamate derivatives or other components of the formulation.

Side Effects
The most commonly reported adverse effects with Rivastigmine are nausea, vomiting, diarrhea, loss of appetite, abdominal pain and dyspepsia, increased sweating, dizziness, headache, tremor, confusion, weight loss, fatigue/asthenia.

Drug Interactions
As a cholinesterase inhibitor, Rivastigmine may exaggerate the effects of succinylcholine-type muscle relaxants during anaesthesia. Caution is recommended when selecting anaesthetic agents. Possible dose adjustments or temporarily stopping treatment can be considered if needed. In view of its pharmacodynamic effects and possible additive effects, Rivastigmine should not be given concomitantly with other cholinomimetic substances. Rivastigmine might interfere with the activity of anticholinergic medicinal products. No pharmacokinetic interaction was observed between Rivastigmine and digoxin, warfarin, diazepam or fluoxetine in studies in healthy volunteers. The increase in prothrombin time induced by warfarin is not affected by administration of Rivastigmine. No untoward effects on cardiac conduction were observed following concomitant administration of digoxin and Rivastigmine.

Use in Pregnancy & Lactation
There are no adequate data on the developmental risks associated with the use of Rivastigmine in pregnant women. There are no data on the presence of Rivastigmine in human milk, the effects on the breastfed infant, or the effects of Rivastigmine on milk production.

Overdose
Rivastigmine has a short plasma half-life of about 1 hour and a moderate duration of acetylcholinesterase inhibition of 8 to 10 hours, it is recommended that in cases of asymptomatic overdoses, no further dose of Rivastigmine should be administered for the next 24 hours.

As in any case of overdose, general supportive measures should be utilized.

Overdose with cholinesterase inhibitors can result in cholinergic crisis characterized by severe nausea, vomiting, salivation, sweating, bradycardia, hypotension, respiratory depression, collapse and convulsions. Increasing muscle weakness is a possibility and may result in death if respiratory muscles are involved. Atypical responses in blood pressure and heart rate have been reported with other drugs that increase cholinergic activity when co-administered with quaternary anticholinergics such as glycopyrrolate. Additional symptoms associated with Rivastigmine overdose are diarrhea, abdominal pain, dizziness, headache, somnolence, confusional state, hyperhidrosis, hypertension, hallucinations and malaise. Due to the short half-life of Rivastigmine, dialysis (hemodialysis, peritoneal dialysis, or hemofiltration) would not be clinically indicated in the event of an overdose.

In overdoses accompanied by severe nausea and vomiting, the use of antiemetics should be considered.

Storage
Store in a cool (below 30ºC) and dry place, away from light. Keep out of the reach of children.

Packing
Benzenod™ 1.5 Capsule: Each box contains 2 blister packs with each blister of 14 Capsules.

Benzenod™ 3 Capsule: Each box contains 2 blister packs with each blister of 14 Capsules.

Manufactured by:
general GENERAL Pharmaceuticals Ltd.
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