NOVARTIS

EXELON® (rivastigmine)

1.5 mg, 3.0 mg, 4.5 mg or 6.0 mg hard capsules

Basic Succinct Statement
Version 2.1

Code: BSS RD 04 Mar 2016; APPR 31 May 2016

This material is only meant for Healthcare Professionals

EXELON® hard capsules

Important note: Before prescribing, please consult full prescribing information.

Presentation: Capsules containing 1.5 mg, 3.0 mg, 4.5 mg or 6.0 mg rivastigmine (as the hydrogen tartrate salt).

Indication: Mild to moderately severe dementia associated with Alzheimer's disease or Parkinson's disease.

Dosage and administration: Treatment should always be started at a dose of 1.5 mg twice daily at initiation and re-initiation of therapy. If well tolerated, it may be increased after a minimum of 2 weeks of treatment to 3 mg twice daily, subsequently to 4.5 mg twice daily, up to a maximum of 6 mg twice daily. Adverse effects may respond to omitting one or more doses. If they persist, the daily dose should be reduced to the previous well-tolerated dose.

Contraindications: Known hypersensitivity to rivastigmine, other carbamate derivatives, or other ingredients. Previous history of application site reactions suggestive of allergic contact dermatitis with rivastigmine transdermal patch.

Warnings and precautions: If treatment is interrupted more than three days treatment should be re-initiated with the lowest daily dose to reduce the possibility of adverse reactions (e.g. severe vomiting). ♦As with other cholinomimetics, adverse effects have been observed at initiation of therapy and shortly after dose increase. ♦Caution in case of severe vomiting, or prolonged vomiting or diarrhoea (risk of dehydration): appropriate dose adjustments must be made. ♦Caution in patients with clinically significant renal or hepatic impairment or patients with body weight below 50 kg. Patient's weight should be monitored during therapy with Exelon. ♦As with other cholinomimetics, caution is recommended in patients with sick sinus syndrome, conduction defects (sino-atrial block, atrio-ventricular block), gastroduodenal ulcerative conditions, history of or current respiratory disease, urinary obstruction, and seizures in predisposed patients. ♦Extrapyramidal symptoms may be induced or exarcerbated by cholinomimetics and worsening of parkinsonian symptoms (particularly tremor) has been observed in patients with Parkinson's disease treated with rivastigmine. ♦ In case of disseminated skin hypersensitivity reactions with the use of rivastigmine, treatment should be discontinued. In case of allergic contact dermatitis with the use of rivastigmine patch, treatment should be discontinued and patients should be switched to oral rivastigmine only after negative allergy testing and under close medical supervision. Some patients sensitised by exposure to rivastigmine patch may not be able to take rivastigmine in any form. ♦The safety of Exelon is not established in pregnant and breast-feeding women. ♦Not recommended in children.

Adverse reactions: Very common and common: nausea, vomiting, diarrhoea, abdominal pain, loss of appetite, dyspepsia, dizziness, headache, somnolence, tremor, agitation, confusion, nightmares, anxiety, sweating, weight loss, malaise, fatigue and asthenia.

Uncommon: insomnia, depression, syncope, accidental fall and abnormal hepatic function tests.

Rare: angina pectoris, myocardial infarction, gastric and duodenal ulcers, seizures, rash, pruritus.

Very rare: cases of cardiac arrhythmia (e.g. bradycardia, atrio-ventricular block atrial fibrillation and tachycardia), hypertension, urinary infection, hallucinations, worsening of Parkinson's disease (worsening), gastrointestinal haemorrhage, severe vomiting associated with oesophageal rupture and mild pancreatitis have been reported.

Frequency not known: dehydration, aggression, restlessness, sick sinus syndrome, hepatitis, allergic dermatitis (disseminated), extrapyramidal symptoms.

Additional adverse reactions observed with Exelon Patch: urinary incontinence (common); cerebrovascular accident, delirium, psychomotor hyperactivity (uncommon).

The safety profile in patients with dementia associated with Parkinson's disease is similar to the one with Alzheimer's disease. Some ADR frequencies in Parkinson's disease are lower and some are higher. See full prescribing information.

Interactions: Concomitant use not recommended with, metoclopramide, cholinomimetic drugs, anticholinergic medications, succinylcholine-type muscle relaxants during anaesthesia. Interaction to be considered in case of concomitant use with beta-blockers.