NOVARTIS

EXELON® Patch (rivastigmine)

4.6 mg/24 h transdermal patch (Exelon® Patch 5)
9.5 mg/24 h transdermal patch (Exelon® Patch 10)
13.3 mg/24 hours transdermal patch (Exelon® Patch 15)

Basic Succinct Statement

(with severe dementia of the Alzheimer's type)

Version 2.1

Code: BSS RD 04 MAR 16; APPR 14 APR 16

This material is only meant for Healthcare Professionals

EXELON® Patch 5

EXELON® Patch 10

EXELON® Patch 15

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

Presentation: Exelon Patch 5 contains 9 mg rivastigmine. The release rate is 4.6 mg/24 h.

Exelon Patch 10 contains 18 mg rivastigmine. The release rate is 9.5 mg/24 h.

Exelon Patch 15 contains 27 mg rivastigmine. The release rate is 13.3 mg/24 h.

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

Dosage and administration: In patients with mild to moderately severe dementia associated with Alzheimer's disease, or associated with Parkinson's disease: Initiation and re-initiation of therapy should start with one Exelon Patch 5 each day. If well tolerated, it may be increased after a minimum of 4 weeks of treatment to one Exelon Patch 10 each day which is the recommended effective dose. Patients treated by Exelon capsules or oral suspension with a maintenance dose of 6 to 12 mg may be switched to Exelon Patch 10. Some patients may benefit from higher dose, in this case the dose can be titrated up to Exelon Patch 15. A minimum of 4 weeks of treatment and good tolerability with the previous dose should be observed before titrating up to higher doses.
In patients with severe dementia associated with Alzheimer's disease: Treatment is started with Exelon Patch 5 once a day. Subsequently the dose should be increased to Exelon Patch 10 and then to Exelon Patch 15 which is the demonstrated effective dose. These dose increases should always be based on good tolerability of the current dose and may be considered only after a minimum of four weeks of treatment at each dose level.

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

Warnings and precautions: Medication misuse and dosing errors with Exelon transdermal patch (e.g. not removing the old patch when putting on a new one and the use of multiple patches at one time) have resulted in serious adverse reactions; some cases have required hospitalization, and rarely led to death. Patients and their caregivers must be instructed on important administration instructions for Exelon transdermal patch. ♦If treatment is interrupted for longer than three days, treatment should be re-initiated with Exelon Patch 5. Gastrointestinal adverse effects have been observed at initiation of therapy and shortly after dose increase. ♦Caution in case of prolonged vomiting or diarrhoea (risk of dehydration). ♦Extrapyramidal symptoms may be induced or exacerbated by cholinomimetics and worsening of parkinsonian symptoms (particularly tremor) has been observed in patients with Parkinson's disease treated with rivastigmine. Adverse effects may respond to removing the patch. If they persist, the daily dose should be temporarily reduced to the previous well-tolerated dose. ♦Patient's weight should be monitored during therapy with Exelon Patch. ♦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. ♦In case of disseminated skin hypersensitivity reactions with the use of rivastigmine, treatment should be discontinued. Use of rivastigmine patch may lead to allergic contact dermatitis, in this case 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. ♦Caution in patients with clinically significant hepatic impairment ♦Caution in patients with body weight below 50 kg: carefully titrate and monitor these patients for adverse reactions (e.g. excessive nausea or vomiting) and consider reducing the dose if such adverse reactions develop. ♦The safety of Exelon Patch is not established in pregnant and breast-feeding women. ♦Not recommended in children.

Adverse reactions: Very common: nausea.

Common: vomiting, anorexia, decreased appetite, anxiety, depression, insomnia, dizziness, headache, diarrhoea, dyspepsia, abdominal pain, urinary incontinence, application site reactions (erythema*, pruritus*, oedema*), fatigue, asthenia, weight decrease, urinary tract infection. *very common in Japanese patients.

Uncommon: dehydration, agitation, delirium, hallucinations, aggression, cerebrovascular accident, syncope, somnolence**, psychomotor hyperactivity, cardiac arrhythmia (e.g. bradycardia, supraventricular extrasystole), gastric ulcers, gastrointestinal haemorrhage, hyperhidrosis, contact dermatitis*, malaise. *very common in Japanese patients. **common in Chinese patients.

Rare: hypertension, application site hypersensitivity, pruritus, rash, erythema, urticaria, blister, dermatitis allergic, fall.

Very rare: tachycardia, atrioventricular block, atrial fibrillation, pancreatitis, seizure, Parkinson's disease (worsening).

Frequency not known: restlessness, sick sinus syndrome, hepatitis, abnormal liver function tests, allergic dermatitis (disseminated), extrapyramidal symptoms, tremor, nightmares.

Additional adverse reactions observed with Exelon capsules/oral solution: severe vomiting associated with oesophageal rupture (very rare); angina pectoris, myocardial infarction, duodenal ulcers (rare); confusion (common).

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 and in patients with severe Alzheimer's disease 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.