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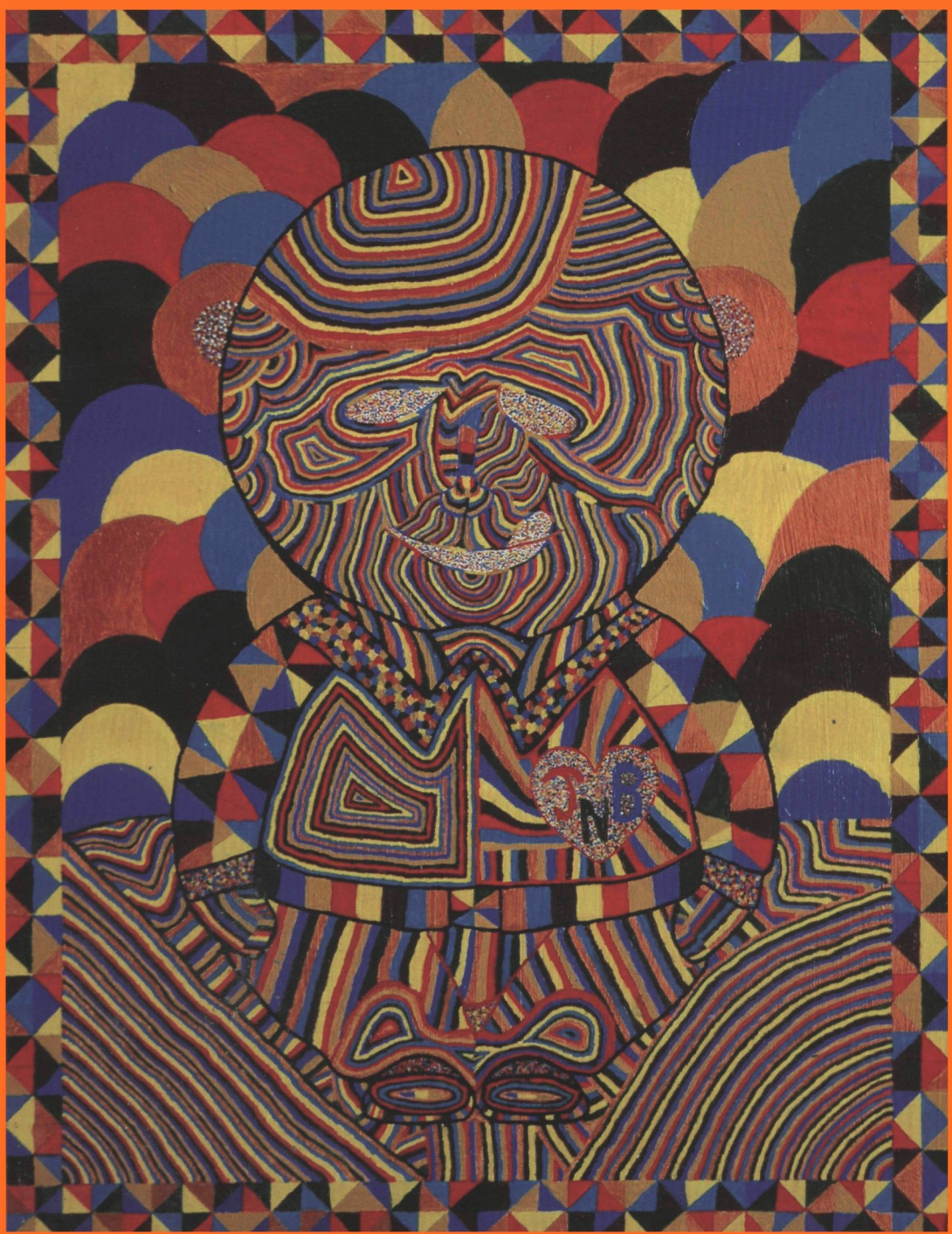

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If adverse effects are observed, these may respond to omitting one or more doses; if they persist, the dose can be temporarily reduced to the previous well tolerated dose. If treatment is interrupted for longer than several days, treatment should be re-initiated at 1.5mg twice daily. Dose titration should then be carried out as described above. For patients with renal or mild-to-moderate hepatic impairment, treatment must be individually titrated based on tolerability. See full prescribing information. The capsules should be swallowed whole. The oral solution may be swallowed directly from the dosing syringe. Exelon oral solution and capsules may be interchanged at equal doses. *Children:* not recommended. **Contra-indications:** Hypersensitivity to rivastigmine, carbamate derivatives or any excipients used in Exelon. Severe liver impairment. **Precautions and warnings:** Initiation and supervision by a physician with experience of Alzheimer's Dementia. A caregiver should be available to monitor compliance. Exelon has not been investigated in patients with severe Alzheimer's Dementia; other types of dementia or other types of memory impairment. Gastrointestinal disorders such as nausea and vomiting may occur, especially in women. During therapy patient's weight should be monitored as cholinesterase inhibitors, including Exelon, have been associated with weight loss. As with other cholinomimetics, care must be taken when using Exelon in patients with sick sinus syndrome or other conduction defects, and in patients with active or a predisposition to gastric or duodenal ulcer. Care in patients with asthma and obstructive pulmonary disease. Cholinomimetics may induce or exacerbate urinary obstruction, seizures and extrapyramidal symptoms. **Pregnancy and lactation, ability to drive/operate machinery:** See full prescribing information. **Interactions:** No pharmacokinetic interaction was observed between Exelon and digoxin, warfarin, diazepam or fluoxetine. Cholinesterase inhibitors may exaggerate the effects of succinylcholine-type muscle relaxants during anaesthesia. Exelon should not be given with other cholinomimetic drugs and may interfere with the activity of anticholinergics. See full prescribing information. **Side-effects:** The most commonly reported adverse drug reactions are gastrointestinal, including nausea (38%) and vomiting (23%), especially during titration. Female patients in clinical studies were found to be more susceptible to gastrointestinal adverse drug reactions and weight loss. The following adverse drug reactions have been accumulated both from clinical studies with Exelon and since the introduction of Exelon into the market. Very common (>1/10): dizziness, nausea, vomiting, diarrhoea and lost of appetite. Common (>1/100, <1/10): agitation, confusion, headache, somnolence, tremor, abdominal pain, dyspepsia, sweating increased, fatigue, asthenia, malaise and weight loss. Uncommon (>1/1,000, <1/100): insomnia, depression, syncope and accidental fall. Rare (>1/10,000, <1/1,000): seizures, angina pectoris, rashes, gastric and duodenal ulcers. Very rare (<1/10,000) including isolated reports: urinary infection, hallucinations, extrapyramidal symptoms, cardiac arrhythmia, hypertension, gastrointestinal haemorrhage, pancreatitis and elevated liver function test. **Overdose:** Most cases of accidental overdosage have not been associated with any clinical signs or symptoms, and almost all of the patients concerned continued Exelon treatment. In overdose accompanied by severe nausea and vomiting, the use of antiemetics should be considered. In massive overdose, atropine sulphate can be used at an initial intravenous dose of 0.03 mg/kg. Use of scopolamine as an antidote is not recommended. **Presentation:** Blister strips with 14 capsules. Marketed pack sizes 28 and 56 for capsules and 120 ml Bottle packed with oral dosing syringe. **Marketing authorisation holder:** Novartis Europharm Limited, Wimblehurst Road, Horsham, West Sussex, RH12 5AB, United Kingdom. **Marketing authorisation number:** EU/1/98/66/1-18. **Full prescribing information is available on request from:** Novartis Ireland Ltd., Beech House, Beech Hill Office Campus, Clonskeagh, Dublin 4. Telephone: 01 260 12 55. **Date of last revision:** March 2004

References. 1. Farlow MR, *et al.* Response of patients with Alzheimer Disease to rivastigmine treatment is predicted by the rate of disease progression. *Arch Neurol* 2001; 58: 417-422. **2.** Giacobini E. Inhibition of acetyl- and butyryl-cholinesterase in the cerebrospinal fluid of patients with Alzheimer's disease by rivastigmine: correlation with cognitive benefit. J Neural Trans 2002; 109: 1053-1065. **3.** Data on file, Novartis Pharmaceuticals.

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