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Detail from **'Truth Hole'** by Anthony Kelly, 2005. Giclee print (100cm x 87cm)

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Now Once a Day. Championing the treatment of mild to moderate Alzheimer's disease

*Dosage has moved from BD to Once a Day

Prescribing Information (Please refer to full Summaries of Product Characteristics before prescribing)
Reminyl® XL 8mg, 16mg and 24mg prolonged release capsules

Presentation: Capsules containing 8mg, 16mg and 24mg galantamine (as hydrobromide). Uses: Symptomatic treatment of mild to moderately severe Alzheimer's Dementia. Dosage and administration: Oral. Adults/Elderly: Once daily in the morning. Ensure adequate fluid intake during treatment. Capsules to be swallowed whole not chewed or crushed. Starting dose: 8mg/day (8mg od) for 4 weeks. Initial maintenance dose: 16 mg/day (16mg od) for at least 4 weeks. Maintenance dose: 24 mg/day (24mg od). Evaluate patients regularly. Consider reducing dose to 16mg/day if patient cannot tolerate higher dose or no increased benefit shown. Moderate hepatic impairment: reduce dose – see SmPCs. Children: Not recommended. Contraindications: Hypersensitivity, severe hepatic/severe renal impairment, patients with both significant renal and hepatic dysfunction. Special Warnings and Precautions: Cardiovascular conditions, predisposition or history of gastrointestinal ulcers, gastrointestinal obstruction/surgery, convulsions, severe asthma or obstructive pulmonary disease, urinary obstruction, bladder surgery, fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency. Interactions: Other cholinomimetics, betablockers, digoxin, certain calcium-channel blocking agents, amiodarone, anaesthetics, CYP2D6 or CYP3A4 inhibitors. Pregnancy and Lactation: Not recommended. Undesirable Effects: Very common (>1/10): Nausea, vomiting. Common (>1/100, <1/10): diarrhoea, abdominal pain, dyspepsia, anorexia, fatigue, headache, dizziness and somnolence (if affected, do not drive), weight decrease, confusion, depression, fall, injury, insomnia, rhinitis, urinary tract infection. Rare (>1/10,000, <1/1,000): hypokalaemia, hallucinations, agitation, aggression, syncope, convulsions, severe bradycardia, rash. Very rare (<1/10,000): tremor, worsening of Parkinsonism, hypotension, AV block, gastrointestinal bleeding, dysphagia, increased sweating, dehydration. Overdose: General supportive measures. Atropine in severe cases. Legal category: POM. Product Authorisation numbers: PA 535/6/5-7. Product Authorisation holder: Shire Pharmaceuticals Limited, Hampshire International Business Park, Chineham, Basingstoke, Hampshire, RG24 8EP, UK.
Distributed by Cahill May Roberts, Pharmapark, Chapelizod, Dublin 20. Further information is available on request. Date of preparation: March 2005.

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Fax: +44 (0)1767 601640
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- Long-term efficacy proven over 5 years[3]

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PRESCRIBING INFORMATION EXELON® (rivastigmine) CAPSULES. Presentation: 1.5mg, 3mg, 4.5mg & 6mg. **EXELON® ORAL SOLUTION (rivastigmine). Presentation:** 2mg/ml oral solution. **Indications:** Symptomatic treatment of mild to moderately severe Alzheimer's Dementia. **Dosage and administration:** *Adults/Elderly:* Initially 1.5mg twice a day with morning and evening meals. If well tolerated after at least two weeks of treatment, the dose should be increased to 3mg twice a day. Further increases to 4.5mg and then 6mg twice a day, should be based on good tolerability after at least two weeks treatment at each dose level. The effective dose is 3 to 6mg twice a day; patients should be maintained on their highest well tolerated dose for as long as therapeutic benefit exists. The recommended maximum daily dose is 6mg twice a day. 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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