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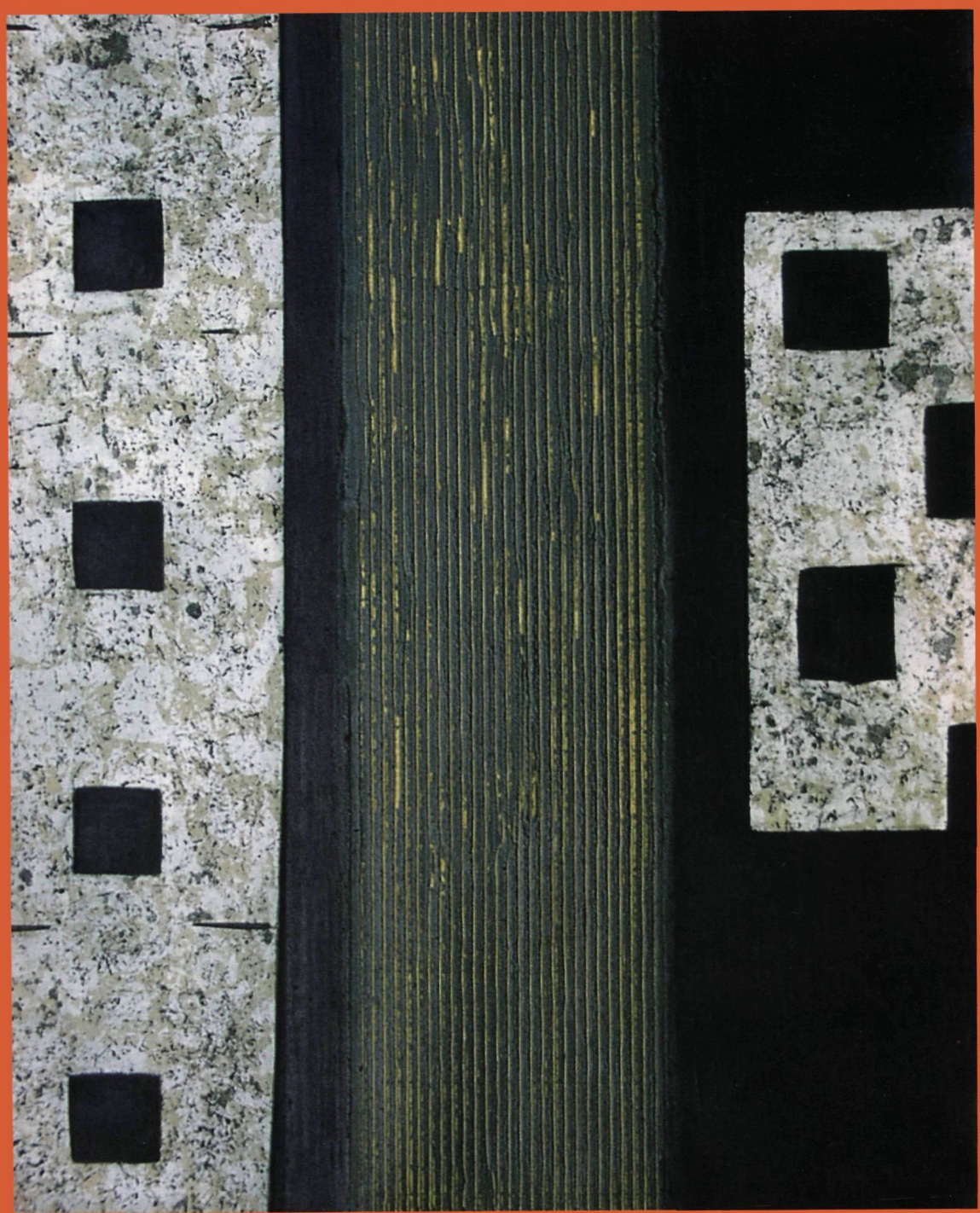

'Elevation' by Stephen Vaughan, 2003. Intaglio/screen print (70cm x 100cm)

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, Chanclizod, Dublin 20. Further information is available on request. Date of preparation: March 2005.

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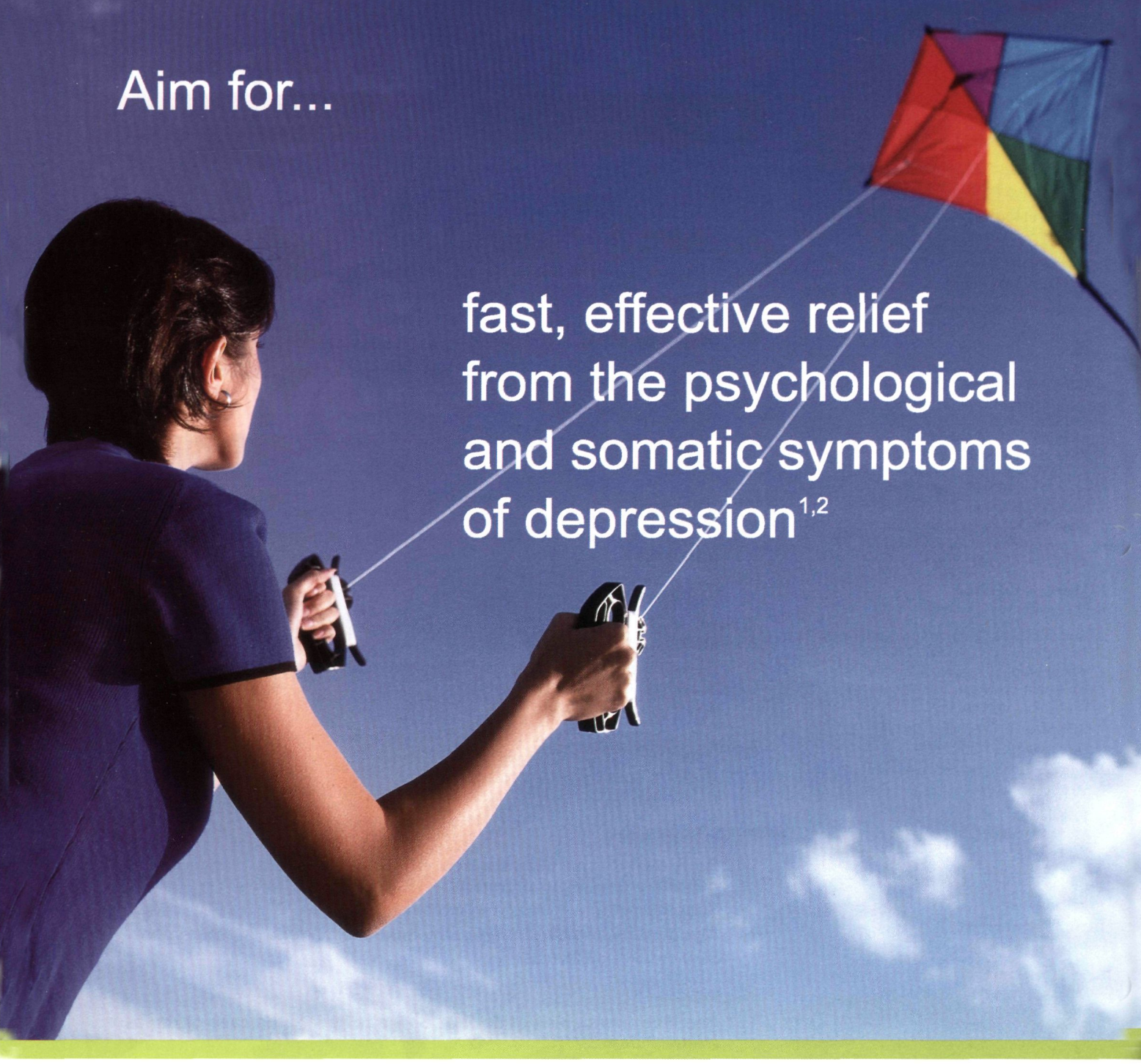

Introducing Cymbalta 60mg once daily.

new Cymbalta® duloxetine

because depression hurts

CYMBALTA® REPUBLIC OF IRELAND (DULOXETINE) ABBREVIATED PRESCRIBING INFORMATION Presentation Hard gastro-resistant capsules, 30mg or 60mg of duloxetine. Also contains sucrose. **Uses** Treatment of major depressive episodes. **Dosage and Administration** Starting and maintenance dose is 60mg once daily, with or without food. Dosages up to a maximum dose of 120mg per day, administered in evenly divided doses, have been evaluated from a safety perspective in clinical trials. However, there is no clinical evidence suggesting that patients not responding to the initial recommended dose may benefit from dose up-titrations. Therapeutic response is usually seen after 2-4 weeks. After establishing response, it is recommended to continue treatment for several months, in order to avoid relapse. When discontinuing after more than 1 week of therapy, the dose should be tapered over no less than 2 weeks before discontinuation, generally reducing the treatment to half-dose or alternate day dosing, and accounting for individual patient circumstances, such as duration of treatment and final dose. **Contra-indications** Hypersensitivity to any of the components. Combination with MAOIs. Liver disease resulting in hepatic impairment. Use with potent inhibitors of CYP1A2, eg, fluvoxamine, ciprofloxacin, enoxacine. Severe renal impairment (creatinine clearance <30ml/min). Should be used in pregnancy only if the potential benefit justifies the potential risk to the foetus. Breast-feeding is not recommended. **Precautions** Use in children or adolescents is not recommended. The safety and efficacy of duloxetine in these age groups have not been studied. No dosage adjustment is recommended for elderly patients solely on the basis of age. However, as with any medicine, caution should be exercised. Use with caution in patients with a history of mania, bipolar disorder, or seizures. Caution in patients with increased intra-ocular pressure or those at risk of acute narrow-angle glaucoma. In patients with known hypertension and/or other cardiac disease, blood pressure monitoring is recommended as appropriate. Caution in patients taking anticoagulants or products known to affect platelet function, and those with bleeding tendencies. Hyponatraemia has been reported rarely, predominantly in the elderly. Depression is associated with an increased risk of suicidal thoughts, self-harm, and suicide. As with other drugs with similar pharmacological action, isolated cases of suicidal ideation or behaviours have been reported during therapy or early after treatment discontinuation. Close supervision of high-risk patients should accompany drug therapy. Patients (and caregivers) should be alerted about the need to monitor for the emergence of suicidal ideation/behaviour or thoughts of harming themselves and to seek medical advice immediately if these symptoms present. Since treatment may be associated with sedation, patients should be cautioned about their ability to drive a car or operate hazardous machinery. Duloxetine is used under different trademarks in several indications (major depressive episodes, as well as stress urinary incontinence and diabetic neuropathic pain). The use of more than one of these products concomitantly should be avoided. **Interactions** Caution is advised when taken in combination with other centrally acting medicinal products and substances, including alcohol and sedative medicinal products; exercise caution when using in combination with antidepressants. In rare cases, serotonin syndrome has been reported in patients using SSRIs concomitantly with serotonergic products. Caution is advisable if duloxetine is used concomitantly with serotonergic antidepressants like SSRIs, tricyclics, St John's Wort, venlafaxine, or triptans, tramadol, pethidine, and tryptophan. Undesirable effects may be more common during use with herbal preparations containing St John's Wort. *Effects on other drugs:* Caution is advised if co-administered with products that are predominantly metabolised by CYP2D6 if they have a narrow therapeutic index. **Undesirable Effects** The majority of common adverse reactions were mild to moderate, usually starting early in therapy, and most tended to subside as therapy continued. Those occurring in placebo-controlled clinical trials in depression and diabetic neuropathic pain at a rate of >1% and significantly different to the placebo rate, or where the event is clinically relevant, are: *Very common (≥10%):* Insomnia, dizziness, somnolence, nausea, dry mouth, and constipation. *Common (≥1% and <10%):* Appetite decreased, weight decreased, anorexia, middle insomnia, sedation, hypersomnia, yawning, libido decreased, anorgasmia, tremor, blurred vision, hot flushes, diarrhoea, vomiting, sweating increased, night sweats, muscle tightness, lethargy, feeling jittery, erectile dysfunction, ejaculation delay or disorder, fatigue. Common symptoms, particularly on abrupt discontinuation, include dizziness, nausea, insomnia, headache, and anxiety. In trials, treatment was associated with numerically significant, but not clinically related, increases in ALT, AST, alkaline phosphatase, and creatinine phosphokinase. These transient, abnormal values were infrequently observed compared with placebo-treated patients. Duloxetine is known to affect urethral resistance. In placebo-controlled trials, urinary hesitation was reported rarely (<1%) in male patients. If symptoms develop during treatment, consideration should be given that they might be drug-related. Cases of suicidal ideation and suicidal behaviours have been reported during duloxetine therapy or early after treatment discontinuation. ECGs evaluated during the clinical trials demonstrated no difference in QTc intervals in duloxetine-treated patients compared with those on placebo. No clinically significant differences were observed for QT, PR, QRS, or QTcB measurements between duloxetine-treated and placebo-treated patients. There is limited clinical experience of overdose with duloxetine. No fatal overdose was demonstrated, including doses up to 1400mg either alone or in combination with other medicinal products. No specific antidote is known but routine monitoring and appropriate symptomatic supportive measures should be used, including, if appropriate, early gastric lavage or activated charcoal. For further information see Summary of Product Characteristics, which is available at http://www.medicines.ie/. **Legal Category** POM. **Marketing Authorisation Numbers and Holder** EU/1/04/296/001, EU/1/04/296/002, EU/1/04/296/003, EU/1/04/296/004, Eli Lilly Nederland BV, Grootslag 1-5, NL-3991 RA Houten, The Netherlands. **Date of Preparation or Last Review** July 2005. **Full Prescribing Information is Available From** Eli Lilly and Company Limited Lilly House, Priestley Road Basingstoke, Hampshire, RG24 9NL, Telephone: Basingstoke (01256) 315 999 or Eli Lilly and Company (Ireland) Limited, Hyde House, 65 Adelaide Road, Dublin 2, Republic of Ireland, Telephone: Dublin (01) 661 4377. *CYMBALTA (duloxetine) is a trademark of Eli Lilly and Company. **References: 1.** Brannan SK, Mallinckrodt CH, et al. Journal of Psychiatric Research 2005; 39: 161–172. **2.** Hirschfeld RMS, Mallinckrodt CH et al. Early Symptom Response During Treatment With Duloxetine 60 mg QD: HAMD-17 Items. 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