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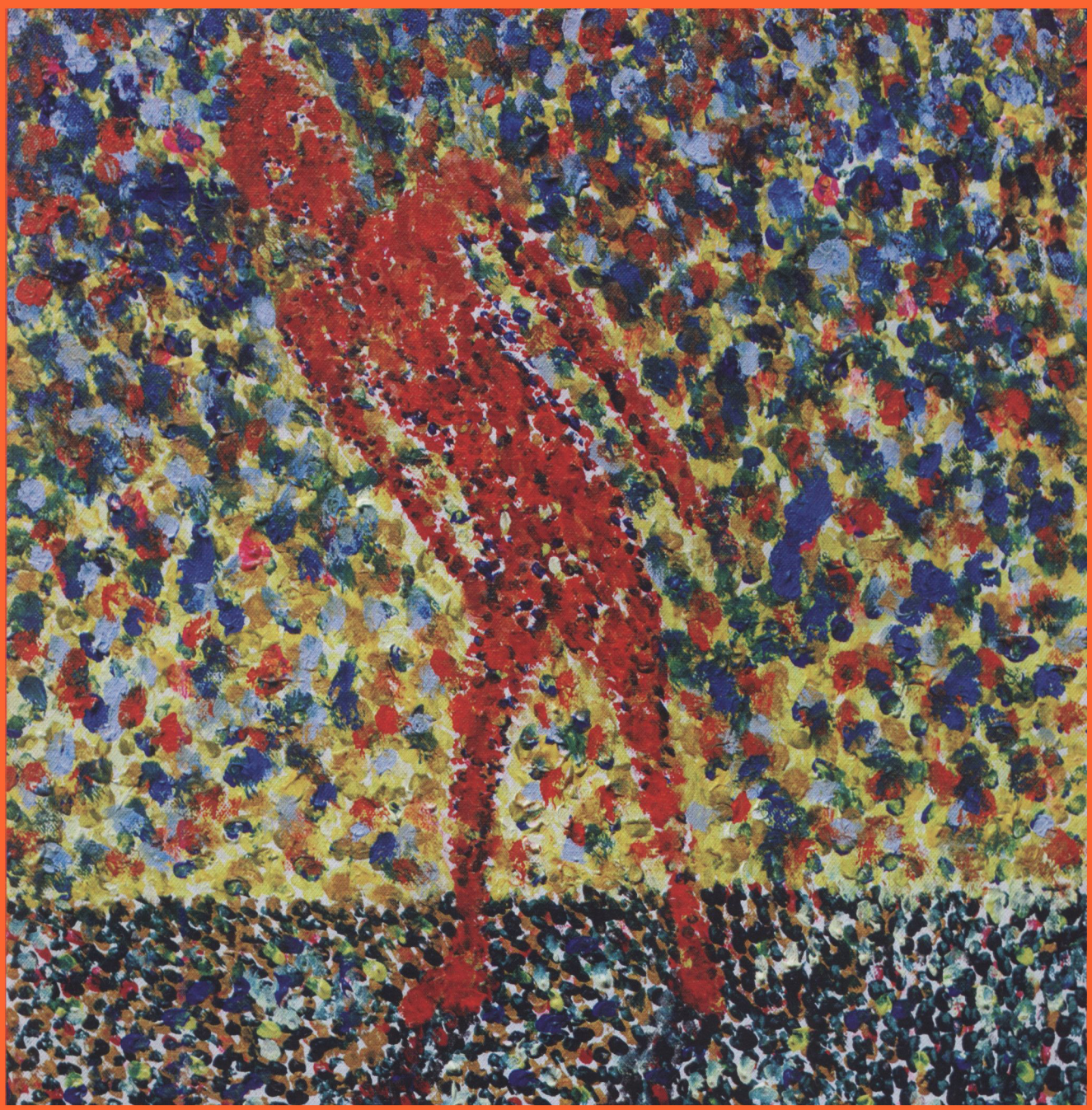

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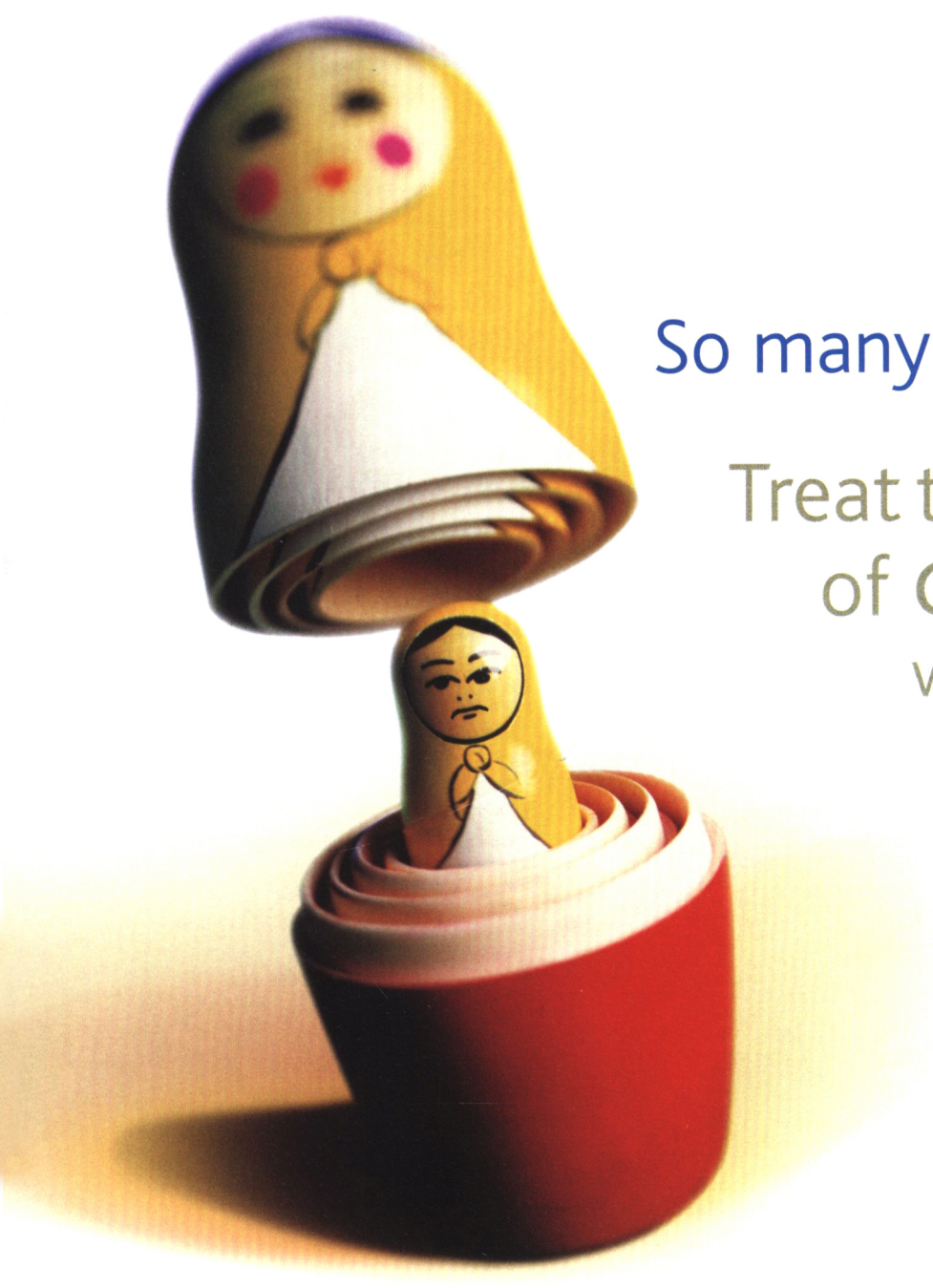

So many symptoms...

Treat the core of depression with Lexapro®

Lexapro®
escitalopram

The No.1 prescribed anti-depressant in Ireland

ABBREVIATED PRESCRIBING INFORMATION: Please refer to the Summary of Product Characteristics before prescribing.
Presentation: Lexapro™ tablets 5 mg, 10 mg, 15 mg and 20 mg containing escitalopram as the oxalate. **Indications:** Treatment of major depressive episodes. Panic disorder with or without agoraphobia. Social Anxiety Disorder. Generalised Anxiety Disorder. Obsessive Compulsive Disorder. **Dosage:** Treating depression: Adults: Usual dosage is 10 mg once daily. The dose may be increased to a maximum of 20 mg/day. **Panic Disorder *with or without agoraphobia*:** An initial dose of 5 mg is recommended for the first week before increasing the dose to 10 mg/day. The dose may be further increased, up to a maximum of 20 mg/day. **Social Anxiety Disorder:** Usual dosage is 10 mg once daily. The dose may subsequently be decreased to 5 mg or increased to a maximum of 20 mg/day. **Generalised Anxiety Disorder:** Initial dosage is 10 mg once daily. The dose may subsequently be increased to a maximum of 20 mg/day. **Obsessive Compulsive Disorder:** Initial dosage is 10 mg once daily. The dose may be increased to a maximum of 20 mg daily. **Elderly (>65 yrs):** Initial treatment with half the usually recommended dose and a lower maximum dose should be considered. The efficacy of Lexapro in social anxiety disorder has not been studied in elderly patients. **Children and adolescents (<18 years):** Not recommended. **Reduced hepatic/renal function:** In mild/moderately impaired hepatic function an initial dose of 5 mg/day for the first two weeks of treatment is recommended, the dose may be increased to 10 mg/day. Caution and careful dose titration advised in patients with severely reduced hepatic function. Dosage adjustment is not necessary in patients with mild or moderate renal impairment. Caution is advised in patients with severely reduced renal function (CLcr<30 ml/min). **Contraindications:** Hypersensitivity to escitalopram or to any of the excipients. Concomitant treatment with a nonselective, irreversible monoamine oxidase inhibitor (MAOI). Concomitant treatment with a reversible MAO-A inhibitor e.g. moclobemide or reversible non-selective MAO-inhibitors e.g. linezolid. Lexapro may be started 14 days after discontinuing treatment with an irreversible MAOI. At least 7 days should elapse after discontinuing Lexapro treatment, before starting a non-selective irreversible MAOI. **Pregnancy and Lactation:** Lexapro should not be used during pregnancy unless clearly necessary. Neonates should be observed if maternal use of Lexapro continues into the later stages of pregnancy, particularly the third trimester. Abrupt discontinuation should be avoided during pregnancy. Refer to the full prescribing information for a list of serotonergic or discontinuation symptoms, which may occur in the neonate after maternal SSRI/SNRI use in later stages of pregnancy. Breast-feeding is not recommended during treatment. **Precautions:** Patients should be cautioned about the risk to their ability to drive a car and operate machinery. No pharmacokinetic or pharmacodynamic interactions are expected with concomitant alcohol intake, however the combination is not advised. Combination with serotonergic compounds is not recommended. Insulin and/or oral hypoglycaemic dosage may need to be readjusted in diabetics. Hyponatraemia has been observed rarely with SSRI use, caution required in patients at risk of hyponatraemia. Caution is advised with coadministration of ECT and in patients with a history of mania/hypomania. Caution advised with concomitant use of oral anticoagulants, products affecting platelet function and in patients with known bleeding tendencies. Avoid in patients with unstable epilepsy and monitor patients with controlled epilepsy. Stop treatment immediately if patient develops serotonin syndrome. Use at a low starting dose for panic disorders. Avoid abrupt discontinuation. Gradual discontinuation by dose tapering is advised. As with all SSRIs it is advisable to closely monitor patients for suicide and self-harm risk in the first few weeks of treatment and until significant remission occurs. Caution is advised in patients with coronary heart disease. The use of SSRIs/SNRIs has been associated with the development of akathisia, increasing the dose in these patients may be detrimental. **Drug Interactions:** MAO inhibitors (see Contraindications/ Precautions), advise caution in use with irreversible selective MAO-B inhibitors (selegiline). Caution in use with lithium, tryptophan, serotonergic medicinal products or with products capable of lowering the seizure threshold. Avoid concomitant use with St. John's Wort. In known poor metabolisers, with respect to CYP2C19, an initial 5 mg/day dose should be used, which can be increased to 10 mg after assessment. Caution is advised with co-administration of drugs metabolised by enzymes CYP2C19 and CYP2D6. Co-administration with CYP2C19 inhibitors, and general enzyme inhibitors e.g. cimetidine may require reduction of the Lexapro dose. Caution recommended with concomitant use of products metabolised by CYP2D6 with a narrow therapeutic index and those metabolised by CYP2C19. **Adverse Events:** Adverse reactions are most frequent during the first or second week of treatment and usually decrease in intensity and frequency with continued treatment. Very Common (≥1/10) & common (≥1/100 to <1/10) adverse drug reactions are listed below. Frequencies are not placebo-corrected.
Very Common: Nausea; Common: Decreased & increased appetite, anxiety, restlessness, abnormal dreams, libido decreased, female anorgasmia, insomnia, somnolence, dizziness, paraesthesia, tremor, sinusitis, yawning, diarrhoea, constipation, vomiting, dry mouth, sweating increased, arthralgia, myalgia, ejaculation disorder, impotence, fatigue, pyrexia, weight increased. **Overdosage:** Clinical data on escitalopram overdose is limited and many cases involve concomitant overdoses with other drugs. Doses between 400-800 mg of Lexapro alone have been taken without any severe symptoms. Symptoms seen in reported overdose of Lexapro mainly relate to the central nervous system, the gastrointestinal system, the cardiovascular system and electrolyte/fluid balance conditions. There is no specific antidote. Treatment is symptomatic and supportive with monitoring of cardiac and vital signs. Gastric lavage and the use of activated charcoal should be considered. **Legal Category:** POM. **Product Licence Holder:** H. Lundbeck A/S, Ottiliavej 9, DK-2500, Copenhagen – Valby, Denmark. **PA Numbers:** 5 mg PA805/2/1; 10 mg PA805/2/2; 15 mg PA805/2/3; 20 mg PA805/2/4. Further information is available upon request from Lundbeck (Ireland) Ltd., 7 Riverwalk, Citywest Business Campus, Citywest, Dublin 24. 'Lexapro' is a registered trademark® 2002 Lundbeck Ltd. **Date of preparation:** May 2008. Reference 1. Combined IMS Hospital & Retail Data (Unit Sales) YTD June 2010.

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