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'Untitled' by JK. Acrylics on board (24" x 24")

# Proven efficacy.<sup>1-6</sup>

Active response for effective treatment of depression.<sup>1,7</sup>



• Major Depressive Episodes • Generalised Anxiety Disorder • Social Anxiety Disorder • Panic Disorder • Obsessive Compulsive Disorder<sup>6</sup>

Lundbeck



**Lexapro**<sup>®</sup>  
escitalopram

**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 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:** 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/day 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 reduced 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. Caution is 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 (Cl<sub>cr</sub><30 ml/min). **Contraindications:** Hypersensitivity to escitalopram or excipients. Concomitant treatment with a nonselective, irreversible monoamine oxidase inhibitor (MAOI). Escitalopram may be started 14 days after discontinuing treatment with an irreversible MAOI and at least one day after discontinuing treatment with a reversible MAOI (RIMA). At least 7 days should elapse after discontinuing escitalopram treatment before starting a non-selective MAOI. **Pregnancy and Lactation:** Lexapro should not be used during pregnancy unless clearly necessary. Neonates should be observed if mater-

nal use of Lexapro continues into the later stages of pregnancy, particularly the third trimester. Abrupt discontinuation should be avoided during pregnancy. Serotonergic or discontinuation symptoms may occur in the neonate after maternal SSRI/SNRI use in later stages of pregnancy. **Precautions:** No direct impairment of psychomotor function. Patients should be cautioned about the risk to their ability to drive a car or operate machinery. No pharmacokinetic or pharmacodynamic interactions are expected with concomitant alcohol intake, however the combination is not advised. Combination with the reversible MAOI-A (RIMA) moclobemide or serotonergic compounds is not recommended. Insulin and/or oral hypoglycaemic dosage may need to be readjusted in diabetics. Hyponatraemia has been observed with SSRI use. Caution is advised in patients with a history of mania/hypomania and coadministration of ECT. Caution is recommended in patients taking medicines that will affect clotting of blood, platelet function or patients with bleeding disorders. Patients with epilepsy, especially unstable epilepsy, should be carefully monitored. Stop treatment if patient develops serotonin syndrome. Use at a low starting dose for panic disorders. Do not stop treatment abruptly. 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. Caution is advised in patients with coronary heart disease. Use of SSRIs/SNRIs has been associated with the development of akathisia, increasing the dose in these patients may be detrimental. **Drug Interactions:** MAOIs (see Contraindications/ Precautions), advise caution in use with selegiline (MAOI-B), lithium, tryptophan, serotonergic medicinal product or with products capable of lowering the seizure threshold. Avoid concomitant use with St. John's Wort (Hypericum perforatum). 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 high doses of cimetidine may require reduction of the escitalopram dose. **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. **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 escitalopram alone have been taken without any severe symptoms. Symptoms seen in reported overdose of escitalopram 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, Ottilavej 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 trademark ™ 2002 Lundbeck Ltd. Date of preparation: February 2007. **References:** 1. Gorman J, et al. CNS Spectrums 2002; 7 (Suppl 1): 40-44. 2. Goodman et al (2005). Journal of Affective Disorders 87, 161-167. 3. Lader et al., Depression and Anxiety 19 :241-248 (2004). 4. Stahl S, et al. J Clin Psychiatry 2003; 64:1322-1327. 5. Stein et al Poster Presented at the 159th Annual Meeting of the American Psychiatric Association, 20-25 May 2006, Toronto, Canada. 6. Lexapro (Escitalopram) Summary of Product Characteristics 7. Wade A, et al. (2006). Curr Med Res Opin; 22(11):2101-2110

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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 cholinesterase inhibitors, 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. Cholinesterase inhibitors 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 cholinergic 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 loss 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 overdose 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 European Limited, Wimborne Road, Horsham, West Sussex, RH12 5AB, United Kingdom. **Marketing authorisation number:** EU/1/98/661/18. **Full prescribing information is available on request from:** Novartis Ireland Ltd., Beech House, Beech Hill Office Campus, Clonskeagh, Dublin 4. Telephone: 01 280 12 55. **Date of last revision:** March 2004. **References:** 1. Fallow 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 Transm 2002; 109: 1053-1065. 3. Data on file, Novartis Pharmaceuticals. NOO404047

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