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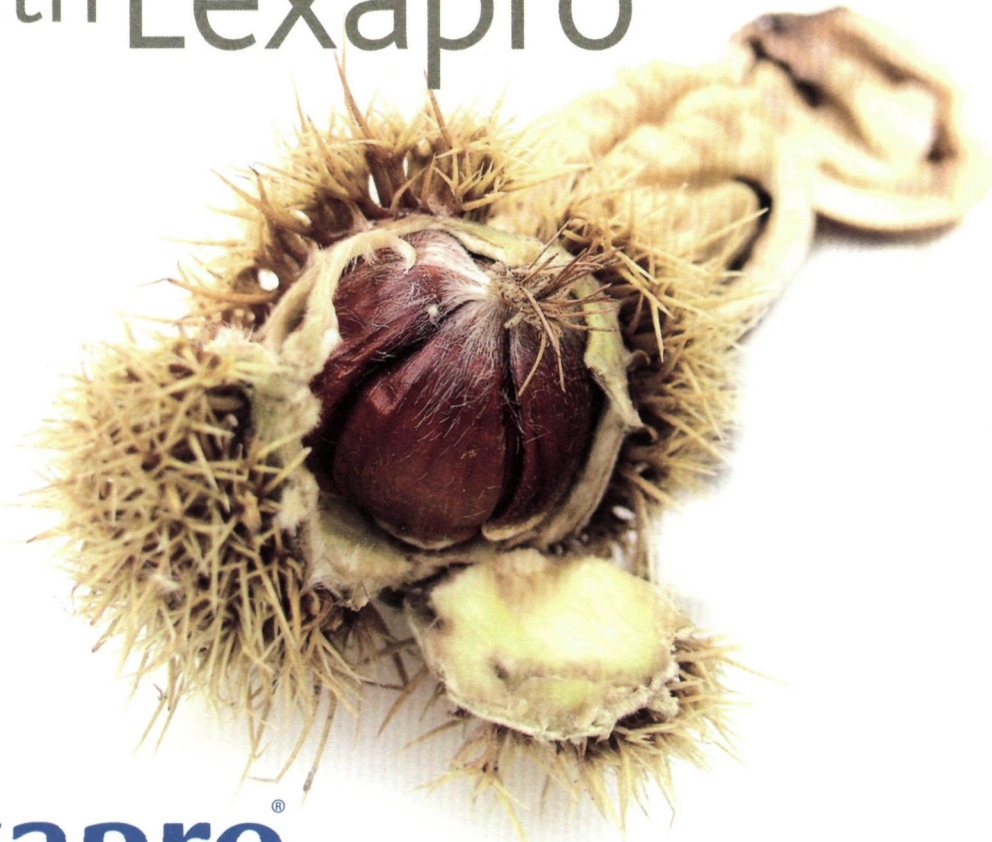
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**'Untitled' by MD.** Reproduced with kind permission from the Art Therapy Group at the Central Mental Hospital, Dublin, Ireland

So many symptoms...

# Treat the CORE of depression with Lexapro<sup>®</sup>



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

The No.1 prescribed anti-depressant in Ireland<sup>1</sup>

**ABBREVIATED PRESCRIBING INFORMATION:** Please refer to the Summary of Product Characteristics before prescribing.

**Presentation:** Lexapro<sup>™</sup> 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 (CL<sub>cr</sub><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 August 2009.



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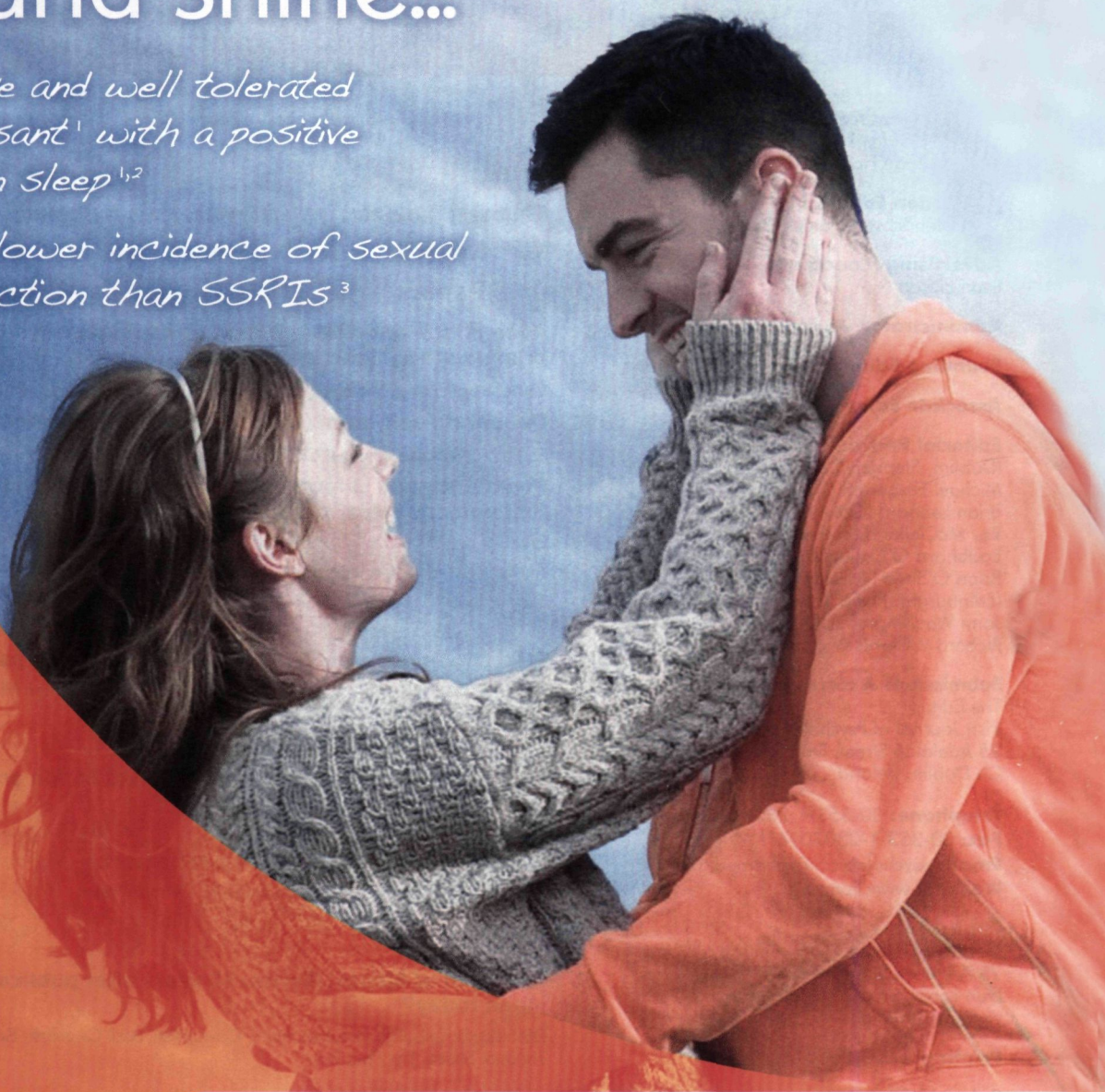
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# Rise and shine...

- An effective and well tolerated antidepressant<sup>1</sup> with a positive impact on sleep<sup>1,2</sup>
- With a lower incidence of sexual dysfunction than SSRIs<sup>3</sup>



**ZISPIN<sup>®</sup> SolTab<sup>™</sup>**  
mirtazapine orodispersible tablet


References 1. Fawcett J, Barkin RL. *J Affect Disord* 1998;**51**(3):267-85.  
2. Baker RA and Schutte AJ. Poster presented at American Psychiatric Association 156th Annual Meeting, May 17-22, 2003, San Francisco, USA.  
3. Montejo AL *et al.* *J Clin Psychiatry*. 2001;**62**(Suppl 3):10-21.

**Zispin SolTab 15mg, 30mg, 45mg (See SmPCs before Prescribing)**  
**Presentation:** Zispin SolTab 15mg, 30mg, 45mg Peel-to-open strips of 6 orodispersible tablets each containing 15, 30 or 45mg of mirtazapine, available in packs of 30 tablets. Zispin SolTabs also contain both sucrose and aspartame. **Uses:** Episode of major depression **Administration:** Zispin SolTab should be taken out of the strip with dry hands and should be placed on the tongue. The SolTab will rapidly disintegrate and can be swallowed with or without water. **Dosage:** Adults and elderly: The effective daily dose is usually between 15 and 45mg; the starting dose is 15 or 30 mg (the higher dose should be taken at night). Effects are usually seen after 1-2 weeks and, with an adequate dose, a positive response should result within 2-4 weeks. Children: Do not use in children or adolescents under 18 years (See Precautions and Warnings). The clearance of mirtazapine may be decreased in patients with renal or hepatic insufficiency. Zispin is suitable for once-a-day administration, preferably as a single night-time dose. Treatment should be continued until the patient has been completely symptom-free for 4-6 months after which treatment can be gradually discontinued. **Contraindications:** Hypersensitivity to mirtazapine or any ingredients of Zispin. **Precautions and warnings:** Bone marrow depression, usually presenting as agranulocytosis or granulocytopenia has been reported with Zispin. This mostly appears after 4-6 weeks and is generally reversible once treatment stops although, in very rare cases, agranulocytosis can be fatal. Reversible agranulocytosis has also been reported as a rare occurrence in clinical studies with Zispin. During post marketing with Zispin, very rare cases of agranulocytosis were reported, mostly reversible, but in some cases fatal. All fatal cases were over age 65. The physician should be alert to symptoms such as fever, sore throat, stomatitis or other signs of infection; if these occur, treatment should be stopped and blood counts taken. Patients should also be advised of the importance of these symptoms. Careful dosing, as well as regular and close monitoring, is necessary in patients with: epilepsy and organic brain syndrome, hepatic or renal insufficiency, cardiac diseases; low blood pressure. As with other antidepressants, care should be taken in

patients with: micturition disturbances, like prostate hypertrophy; acute narrow-angle glaucoma and increased intra-ocular pressure; diabetes mellitus. Treatment should be discontinued if jaundice occurs. As with other antidepressants, the following should be taken into account: worsening of psychotic symptoms can occur when antidepressants are administered to patients with schizophrenia or other psychotic disturbances; when the depressive phase of manic-depressive psychosis is being treated, it can transform into the manic phase. As for all therapies for depression, risk of suicide, suicidal thoughts and self harm may increase in the first few weeks of treatment. Zispin is not addictive, but abruptly stopping treatment may sometimes cause withdrawal symptoms such as dizziness, agitation, anxiety, nausea and headache. It is recommended that mirtazapine is stopped gradually. Elderly patients may be more sensitive to the undesirable effects of anti-depressants. Serotonin syndrome occurs very rarely. See SmPC for full details. Zispin may impair concentration and alertness. **Zispin should not be used in the treatment of children and adolescents under 18 years.** Suicide-related behaviours (suicide attempt and suicidal thoughts), and hostility (predominantly aggression, oppositional behaviour and anger) were more frequently observed in clinical trials among children and adolescents treated with antidepressants compared to those treated with placebo. If, based on clinical need, a decision to treat is nevertheless taken, the patient should be carefully monitored for the appearance of suicidal symptoms. In addition, long-term safety data in children and adolescents concerning growth, maturation and cognitive and behavioural development are lacking. **Interactions:** Caution is advised with potent CYP3A4 inhibitors, HIV protease inhibitors, azole antifungals, erythromycin or nefazodone. Higher doses may be needed with carbamazepine (or other inducers of hepatic metabolism (such as rifampicin)) and lower doses with cimetidine. Interactions may also occur with alcohol, benzodiazepines, other serotonergic drugs, warfarin and MAO inhibitors. **Pregnancy & Lactation:** Safety in human pregnancy has not been established. Use during pregnancy only if clearly needed. Use in nursing mothers, not recommended. **Adverse reactions:** The following

common adverse effects have been reported: Increase in appetite and weight gain. Oedema. Drowsiness/sedation, generally occurring during the first few weeks of treatment. (N.B. dose reduction generally does not lead to less sedation but can jeopardize antidepressant efficacy). Dizziness. Headache. Other less common and rarely reported side effects are listed in the SmPC. **Overdosage:** Present experience with Zispin alone indicates that symptoms are usually mild. Depression of the CNS with disorientation and prolonged sedation together with tachycardia and mild hyper- or hypotension have been reported. There is a possibility of more serious outcomes (including fatalities) at dosages much higher than the therapeutic dose, especially with mixed overdoses. Treat overdose with appropriate symptomatic and supportive therapy for vital functions. Consider activated charcoal or gastric lavage. **Legal Category:** Prescription Medicine. **Product Authorisation Numbers:** Zispin SolTab 15mg orodispersible tablet: PA 61/26/5, Zispin SolTab 30mg orodispersible tablet: PA 61/26/6, Zispin SolTab 45mg orodispersible tablet: PA 61/26/7. **Product Authorisation holder:** Zispin SolTab 15mg, 30mg and 45mg orodispersible tablet: Organon Ireland Limited, a part of Schering-Plough, P.O. Box 2857, Drynain Road, Swords, Co. Dublin, Ireland. **Further information is available from:** Schering-Plough Ltd, Shire Park, Welwyn Garden City, Hertfordshire, AL7 1TW, UK. Telephone +44 (0)1707 363636. Date of revision of API: November 2008 Zispin API/IRL/11-08/1

Please refer to the full SPC text before prescribing this product. Adverse events should be reported. Reporting forms and information can be found at [www.yellowcard.gov.uk](http://www.yellowcard.gov.uk) (UK) and [www.imb.ie](http://www.imb.ie) (Ireland). Adverse events with this product should also be reported to Schering-Plough Drug Safety Department on +44 (0)1707 363773

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