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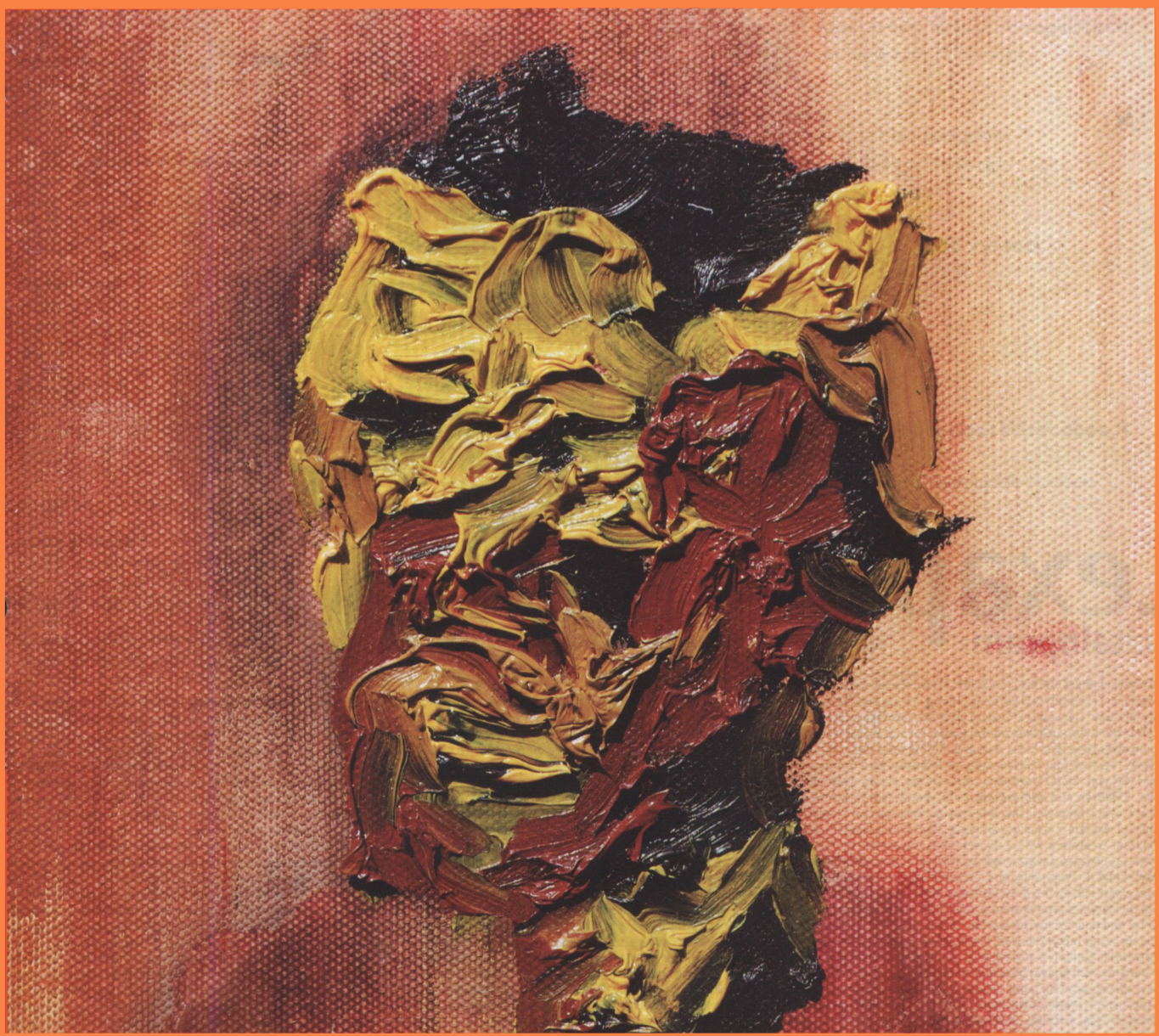

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References 1. Fawcett J, Barkin RL. J Affect Disord 1998;**51**(3):267-85. 2. Baker RA and Schutte AJ. Poster presented at American Psychiatric Association 156th Annual Meeting, May 17-22, 2003, San Francisco, USA. 3. Montejo AL *et al.* J Clin Psychiatry.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