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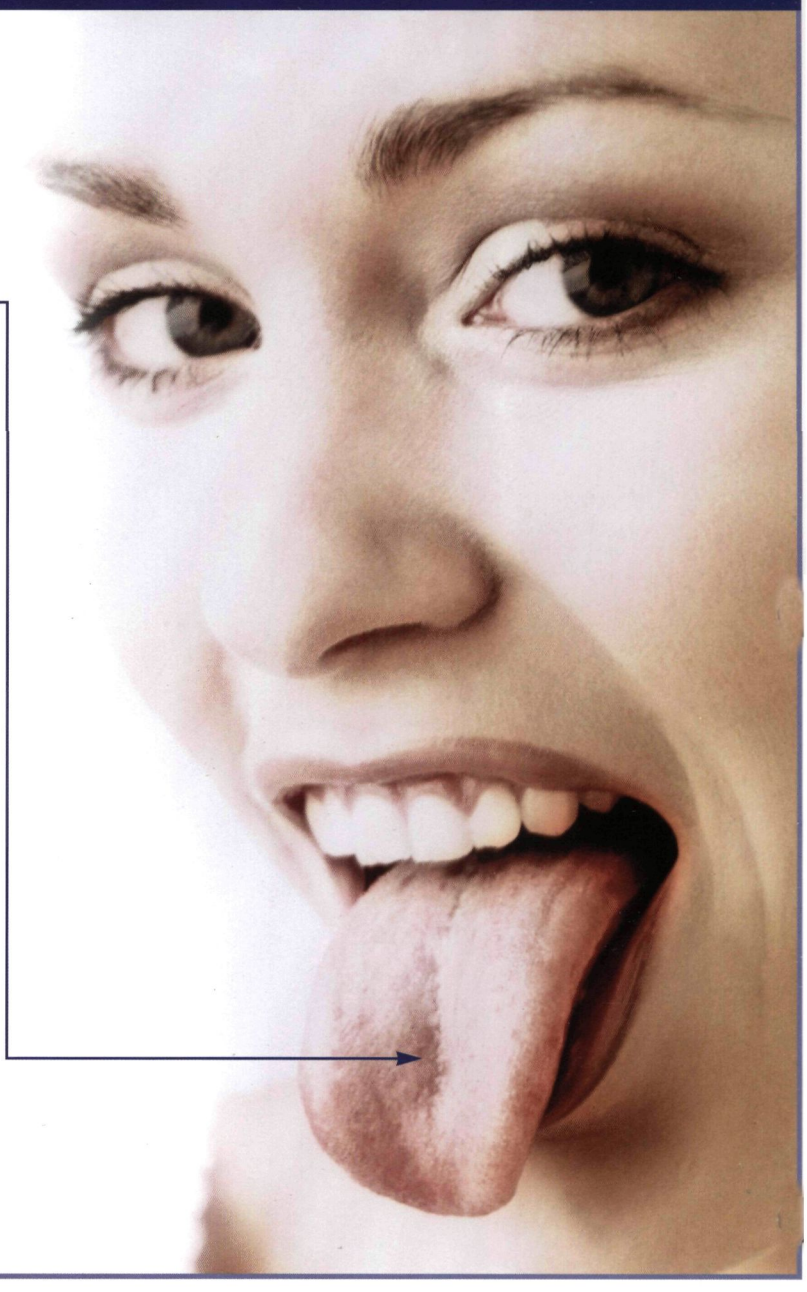
NEW DELIVERY, TRUSTED EFFICACY

ZISPIN® SolTab™

mirtazapine orodispersible tablet



- Zispin SolTab is available in 15mg, 30mg and 45mg doses
- Zispin SolTab is bioequivalent to conventional Zispin tablets,[1] and can be taken with or without water
- Zispin SolTab is easier to use than conventional Zispin tablets and has a pleasant orange taste[2]*

References 1. van den Heuvel MW, *et al.* Clin Drug Invest 2001; **21**(6): 43-432 2. Roose SP *et al.* Presented at 16th AAGP meeting, 1st – 4th March, Honolulu, Hawaii

*In a survey of patients over 50 years of age, the majority reported that Zispin SolTab was easier to use than conventional tablets

Zispin SolTab 15mg, 30mg, 45mg - Zispin 30 mg Tablets (See SPCs 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 tablets** Blister strips of 7 tablets each containing 30mg of mirtazapine, available in packs of 28 tablets. **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 disintegrate and can be swallowed with or without water. Zispin tablets should be taken orally, if necessary with fluid, and swallowed without chewing. **Dosage:** Adults and elderly: The effective daily dose is usually between 15 and 45mg. Children: Not recommended. 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. **Contraindications:** Hypersensitivity to mirtazapine or any ingredients of Zispin. **Precautions and warnings:** Reversible bone marrow suppression presenting as agranulocytosis and granulocytopenia have been reported with most antidepressants. Reversible agranulocytosis has been reported as a rare occurrence with Zispin. 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 (See SPC); hepatic or renal insufficiency; cardiac diseases; low blood pressure, diabetes mellitus (Insulin and/or oral hypoglycaemic dosage may need to be adjusted.) 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. Treatment should be discontinued if jaundice occurs. Moreover, 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 may increase in the first few weeks of treatment. Zispin has sedative properties and may impair concentration and alertness. **Interactions:** Alcohol, benzodiazepines and MAO inhibitors. **Pregnancy & Lactation:** Safety in human pregnancy has not been established. Use during pregnancy not recommended. Women of child bearing potential should employ an adequate method of contraception. Use in nursing mothers not recommended. **Adverse reactions:** The following adverse effects have been reported: Most common: 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. Rare: (Orthostatic) hypotension. Exanthema. Mania, convulsions, tremor, myoclonus. Acute bone marrow depression (refer to SPC). Elevations in serum transaminase activities. Paraesthesia. Restless legs. **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. Treat by gastric lavage with appropriate symptomatic and supportive therapy for vital functions. **Legal Category:** Prescription Medicine.

Product Authorisation Numbers:

Zispin SolTab 15mg orodispersible tablet: PA 61/26/5	Price: € 17.03
Zispin SolTab 30mg orodispersible tablet: PA 61/26/6	Price: € 34.05
Zispin SolTab 45mg orodispersible tablet: PA 61/26/7	Price: € 51.07
Zispin 30mg tablet: PA 261/43/2	Price: € 34.92

Product Authorisation holder:

Zispin SolTab 15mg, 30mg and 45mg orodispersible tablet:
Organon Ireland Limited, P.O. Box 2857, Drynam Road,
Swords, Co. Dublin, Ireland.

Organon

Zispin 30mg tablet:
Organon Laboratories Limited, Cambridge Science Park,
Milton Road, Cambridge, CB4 OFL. March 2004 ORG04472E

ZISPIN® SolTab™
mirtazapine orodispersible tablet
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