When **sleep** matters in **depression**

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 rapidly 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. Treatment should begin with 15mg daily and dosage should be reviewed and adjusted if necessary within 2 to 4 weeks of initiation of therapy. Children: Do not use in children or adolescents under 18 years. 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 [illegible] 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. 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, and diabetes mellitus. 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, suicidal thoughts and self harm may increase in the first few weeks of treatment, see SmPC for full details. Zispin has sedative properties and may impair concentration and alertness. The use of Zispin has been associated with psychomotor restlessness. Withdrawal symptoms when treatment is discontinued are common, particularly if discontinuation is abrupt, see SmPC for full details. **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.
Zispin 30mg tablet: Organon Laboratories Limited, Cambridge Science Park, Milton Road, Cambridge, CB4 OFL, UK.

Distributed by: Organon Laboratories, c/o United Drug House, Magna Drive, Magna Business Park, Citywest Road, Dublin 24, Ireland.
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Help safeguard public health and support medicine vigilance by reporting [illegible] www.IMB.ie
Alternatively, adverse events can be reported to Organon Laboratories, by calling (+44) 01223 432740.

ZISPIN® SolTab™

mirtazapine orodispersible tablet

The ***melt-in-the-mouth*** antidepressant with the **orange taste**

Organon

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