



## ZISPIN WORKS IN A WAY OTHER ANTIDEPRESSANTS CAN'T

### Zispin 30 mg (See SPC before Prescribing)

**Presentation:** Blister strips of 28 tablets each containing 30 mg of mirtazapine. **Uses:** Episode of major depression. **Administration:** The tablets should be taken orally, if necessary with fluid, and swallowed without chewing. Adults and elderly: The effective daily dose is usually between 15 and 45 mg. 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 white blood cell disorders including agranulocytosis, leukopenia and granulocytopenia have been reported 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; 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. Zispin has sedative properties and may impair concentration and alertness. **Interactions:** Mirtazapine may potentiate the central nervous dampening action of alcohol; patients should therefore be advised to avoid alcohol during treatment with Zispin; Zispin should not be administered concomitantly with MAO inhibitors or within two weeks of cessation of therapy with these agents; Mirtazapine may potentiate the sedative effects of benzodiazepines; in vitro data suggest that clinically significant

interactions are unlikely with mirtazapine. **Pregnancy & Lactation:** The safety of Zispin in human pregnancy has not been established. Use during pregnancy is not recommended. Women of child bearing potential should employ an adequate method of contraception. Use in nursing mothers is not recommended. **Adverse reactions:** The following adverse effects have been reported: Common (>1/100): Increase in appetite and weight gain. 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). Less common: Increases in liver enzyme levels. Rare (<1/1000): Oedema and accompanying weight gain. Reversible agranulocytosis has been reported as a rare occurrence. (Orthostatic) hypotension. Exanthema. Mania, convulsions, tremor, myoclonus. **Overdosage:** Toxicity studies in animals suggest that clinically relevant cardiotoxic effects will not occur after overdosing with Zispin. Experience in clinical trials and from the market has shown that no serious adverse effects have been associated with Zispin in overdose. Symptoms of acute overdosage are confined to prolonged sedation. Cases of overdose should be treated by gastric lavage with appropriate symptomatic and supportive therapy for vital functions. **Legal Category:** Prescription medicine **Product Licence Numbers:** 261/43/2 **Basic Cost:** € 34.92 (pack size 28) **Product Authorisation Holder:** Organon Laboratories Ltd, Cambridge Science Park, Milton Road, Cambridge, UK CB4 0FL. Telephone: + 44 1223 432700 **Distributed by:** United Drugs plc, Belgard Rd, Tallaght, Dublin 24. Telephone: 01 4041524 Full Prescribing information is available on request. March 2002 **Date of preparation:** April 2002 ORG 03343J



MIRTAZAPINE

**ZISPIN**<sup>®</sup> 30 mg nocte



