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

Organon

MIRTAZAPINE
ZISPIN® 30 mg nocte

https://doi.org/10.1017/S0790966700007084 Published online by Cambridge University Press

ZYPREXA® REPUBLIC OF IRELAND (OLANZAPINE) ABBREVIATED PRESCRIBING INFORMATION. **Presentation:** Tablets, 2.5mg, 5mg, 7.5mg, 10mg or 15mg of olanzapine. Also contain lactose. Velotab® 5mg, 10mg or 15mg orodispersible tablets. Also contain gelatin, aspartame, mannitol and parahydroxybenzoates. **Uses:** Schizophrenia, both as initial therapy and for maintenance; also moderate to severe manic episode. **Dosage and Administration:** *Schizophrenia:* 10mg/day orally. *Manic episode:* 15mg/day in monotherapy; 10mg/day in combination therapy. May subsequently be adjusted to 5-20mg daily. *Children:* Not recommended (under 18 years). *The elderly:* A lower starting dose (5mg/day) is not routinely indicated but should be considered when clinical factors warrant. *Renal and/or hepatic impairment:* 5mg starting dose in moderate hepatic insufficiency. When more than one factor which might cause slower metabolism (*female gender, elderly age, non-smoking* status), consider a decreased starting dose. **Contra-indications:** Known hypersensitivity to any ingredient. Known risk of narrow-angle glaucoma. **Warnings and Special Precautions:** Clinical monitoring advisable in diabetic patients and those with risk factors for diabetes. Caution with prostatic hypertrophy, or paralytic ileus and related conditions. Improvement in clinical condition may take several days to some weeks. *Phenylalanine:* Velotabs contain aspartame - a source of phenylalanine. *Sodium methyl parahydroxybenzoate and sodium propyl parahydroxybenzoate:* Velotabs contain these preservatives, known to cause urticaria, contact dermatitis and, rarely, immediate reactions with bronchospasm. Caution in patients with elevated ALT and/or AST, hepatic impairment, limited hepatic functional reserve, and in patients being treated with hepatotoxic drugs. Where hepatitis has been diagnosed, discontinue Zyprexa. Caution in patients with low leucocyte and/or neutrophil counts, bone marrow depression, and in patients with hypereosinophilic conditions or with myeloproliferative disease. Discontinue if signs and symptoms indicative of NMS, or unexplained high fever. Caution in patients who have a history of seizures or are subject to factors which may lower the seizure threshold. If tardive dyskinesia appears, consider dose reduction or discontinuation. Caution when taken with other centrally acting drugs and alcohol. May antagonise effects of dopamine agonists. Blood pressure should be measured periodically in patients over 65 years. As with other antipsychotics, caution when prescribed with drugs known to increase QTc interval, especially in the elderly, in patients with congenital long QT syndrome, congestive heart failure, heart hypertrophy, hypokalaemia or hypomagnesaemia. In clinical trials, olanzapine was not associated with a persistent increase in absolute QT intervals. **Interactions:** Metabolism may be affected by substances that can specifically induce (eg, concomitant smoking or carbamazepine) or inhibit (eg, fluvoxamine) the isoenzyme P450-CYP1A2 which metabolises olanzapine. Activated charcoal reduces the bioavailability of oral olanzapine. Olanzapine may antagonise the effects of direct and indirect dopamine agonists. Olanzapine showed no interaction when co-administered with lithium or biperiden. **Pregnancy and Lactation:** Should be used in pregnancy only if the potential benefit justifies the potential risk to the foetus. Patients should be advised not to breast-feed an infant if they are taking Zyprexa. **Driving, etc:** May cause somnolence. Patients should be cautioned about operating hazardous machinery, including motor vehicles. **Undesirable Effects:** *Clinical trial adverse event reporting and investigations: Blood and lymphatics.* Common (1-10%): eosinophilia. Neutropenia was seen in a valproate combination therapy trial in bipolar mania patients; a potential contributing factor could be high plasma valproate levels. *Metabolism and nutritional.* Very common (>10%): weight gain. Common (1-10%): increased appetite, elevated glucose levels (incidence 1.0% for olanzapine versus 0.9% for placebo for non-fasting levels ≥11mmol/l), elevated triglyceride levels. *Nervous.* Very common (>10%): somnolence, abnormal gait in Alzheimer's disease patients. Common (1-10%): dizziness, akathisia (olanzapine-treated patients had a lower incidence of parkinsonism, akathisia and dystonia compared with titrated doses of haloperidol). Worsening of Parkinsonian symptomatology and hallucinations were reported more frequently in patients with Parkinson's disease. *Cardiac.* Uncommon (0.1-1%): bradycardia, with or without hypotension or syncope. *Vascular.* Common (1-10%): orthostatic hypotension. *Gastro-intestinal.* Common (1-10%): mild, transient, anticholinergic effects, including constipation and dry mouth. *Hepato-biliary.* Common (1-10%): transient, asymptomatic elevations of ALT, AST. *Skin and subcutaneous tissue.* Uncommon (0.1-1%): photosensitivity reaction. *General.* Common (1-10%): asthenia, oedema. *Investigations.* Very common (>10%): elevated plasma prolactin levels, but associated clinical manifestations (eg, gynaecomastia, galactorrhoea, breast enlargement) were rare. Uncommon (0.1-1%): high creatine phosphokinase. *Post-marketing spontaneous reporting: Blood and lymphatics.* Rare (0.01-0.1%): leucopenia. Very rare (<0.01%): thrombocytopenia. *Immune system disorder.* Very rare (<0.01%): allergic reaction. *Metabolism and nutritional.* Very rare (<0.01%): hyperglycaemia or exacerbation of pre-existing diabetes occasionally associated with ketoacidosis or coma, including some fatal cases. Hypertriglyceridaemia. *Nervous.* Rare (0.01-0.1%): seizures, mostly when there was a history of seizures or risk factors. Very rare (<0.01%): cases reported as NMS. Discontinuation reactions have been reported; gradual tapering of the dose should be considered. *Gastro-intestinal.* Very rare (<0.01%): pancreatitis. *Hepato-biliary.* Very rare (<0.01%): hepatitis. *Skin and subcutaneous tissue.* Rare (0.01-0.1%): rash. *Reproductive.* Very rare (<0.01%): priapism. *For further information see Summary of Product Characteristics.* **Marketing Authorisation Numbers:** EU/1/96/022/002 EU/1/96/022/004 EU/1/96/022/006 EU/1/96/022/009 EU/1/96/022/010 EU/1/96/022/012 EU/1/99/125/001 EU/1/99/125/002 EU/1/99/125/003. **Date of Preparation or Last Review:** July 2002. **Full Prescribing Information is Available From:** Eli Lilly and Company Limited Dextra Court, Chapel Hill Basingstoke, Hampshire, RG21 5SY Tel: Basingstoke (01256) 315000 or Eli Lilly and Company (Ireland) Limited, Hyde House, 65 Adelaide Road, Dublin 2, Republic of Ireland Tel: Dublin 6614377. *ZYPREXA (olanzapine) and VELOTAB are trademarks of Eli Lilly and Company. **References:** 1. Jones B et al. Schizophrenia Research 1999; 36(1-3): 183. **website:** www.elililly.ie

Zyprexa is manufactured in Cork

Indicated in schizophrenia and now in Mania

going

Orally dispersible tablet

going

placed in the mouth, starts dispersing in about 15 seconds[1]

gone

disperses completely within one minute[1]

ZYPREXA® VeloTab™

Orodispersible Tablets, Olanzapine

Available as 5mg, 10mg and NEW 15mg Velotab™

Lilly