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/S079096670000690X Published online by Cambridge University Press

IRELAND ABBREVIATED PRESCRIBING INFORMATION: Presentation: Coated tablets containing 2.5mg, 5mg, 7.5mg or 10mg of olanzapine. The tablets also contain lactose. Velotab 5mg and 10mg orodispersible tablets. Velotab orodispersible tablet is a freeze-dried, rapid-dispersing preparation to be placed in the mouth or alternatively to be dispersed in water or other suitable beverage for administration. Velotabs also contain gelatin, aspartame (see below), mannitol and parahydroxybenzoates (see below). Velotab orodispersible tablets are bioequivalent to olanzapine coated tablets, with a similar rate and extent of absorption. They have the same dosage and frequency of administration as olanzapine coated tablets. Olanzapine orodispersible tablets may be used as an alternative to olanzapine coated tablets. **Uses:** Schizophrenia, both as initial therapy and for maintenance of response. **Further Information:** In studies of patients with schizophrenia and associated depressive symptoms, mood score improved significantly more with olanzapine than with haloperidol. **Pharmacodynamics:** Olanzapine was associated with significantly greater improvements in both negative and positive symptoms of schizophrenia than placebo or comparator in most studies. **Dosage and Administration:** 10mg/day orally, as a single dose, without regard to meals. Dosage may subsequently be adjusted within the range of 5-20mg daily. An increase to a dose greater than the routine therapeutic dose of 10mg/day is recommended only after clinical assessment. *Children:* Not recommended under 18 years of age. *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:* A lower starting dose (5mg) should be considered. In *moderate hepatic insufficiency, the starting dose* should be 5mg, and only increased with caution. When more than one factor is present which might result in slower metabolism (female gender, elderly age, non-smoking status), consideration should be given to decreasing the starting dose. Dose escalation should be conservative in such patients. **Contra-indications:** Known hypersensitivity to any ingredient of the product. Known risk of narrow-angle glaucoma. **Warnings and Special Precautions:** Hyperglycaemia or exacerbation of pre-existing diabetes occasionally associated with ketoacidosis or coma has been reported very rarely, including some fatal cases. In some cases, a prior increase in body weight has been reported, which may be a predisposing factor. Appropriate clinical monitoring is advisable in diabetic patients and in patients with risk factors for the development of diabetes mellitus. Caution in patients with prostatic hypertrophy, or paralytic ileus and related conditions. During antipsychotic treatment, improvement in the patient's clinical condition may take several days to some weeks. Patients should *be closely monitored during this period. Phenylalanine:* Zyprexa Velotabs contain aspartame, which is a source of phenylalanine. Sodium methyl parahydroxybenzoate and sodium propyl parahydroxybenzoate: Zyprexa Velotabs contain these preservatives, which are known to cause urticaria. Generally, delayed type reactions such as contact dermatitis may occur, but rarely immediate reactions with bronchospasm may occur. Caution in patients with elevated ALT and/or AST, signs and symptoms of hepatic impairment, pre-existing conditions associated with limited hepatic functional reserve, and in patients who are being treated with potentially hepatotoxic drugs. In cases where hepatitis has been diagnosed, olanzapine treatment should be discontinued. As with other neuroleptic drugs, caution in patients with low leucocyte and/or neutrophil counts for any reason, a history of drug-induced bone marrow depression/toxicity, bone marrow depression caused by concomitant illness, radiation therapy or chemotherapy, and in patients with hypereosinophilic conditions or with myeloproliferative disease. Thirty-two patients *with clozapine-related neutropenia or agranulocytosis* histories received olanzapine without decreases in baseline neutrophil counts. Rare cases reported as NMS have been received in association with olanzapine. If a patient develops signs and symptoms indicative of NMS, or presents with unexplained high fever without additional clinical manifestations of NMS, all antipsychotic drugs, including olanzapine, must be discontinued. Caution in patients who have a history of seizures or are subject to factors which may lower the seizure threshold. If signs or symptoms of tardive dyskinesia appear, a dose reduction or drug discontinuation should be considered. Caution when taken in combination with other centrally acting drugs and alcohol. Olanzapine may antagonise the effects of direct and indirect dopamine agonists. Postural hypotension has been infrequently observed in the elderly. Blood pressure should be measured periodically in patients over 65 years, as with other antipsychotics. As with other antipsychotics, caution when prescribed with drugs known to increase QTc interval, especially in the *elderly. In clinical trials, olanzapine was not associ*ated with a persistent increase in absolute QT intervals. **Interactions:** Metabolism may be induced by concomitant smoking or carbamazepine therapy. Metabolism may be inhibited by fluvoxamine or other P450-1A2 inhibitors, and so a lower dose of olanzapine should be considered. **Pregnancy and Lactation:** Olanzapine had no teratogenic effects in animal studies. Because human experience is limited, olanzapine should be used in pregnancy only if the potential benefit justifies the potential risk to the fetus. Olanzapine was excreted in the milk of treated rats but it is not known if it is excreted in human milk. Patients should be advised not to breast-feed an infant if they are taking olanzapine. **Driving, etc:** Because olanzapine may cause somnolence, patients should be cautioned about operating hazardous machinery, including motor vehicles. **Undesirable Effects:** The only very common (>10%) undesirable effects associated with the use of olanzapine in clinical trials were somnolence, weight gain and, in Alzheimer's disease patients, abnormal gait. Common (1-10%) *undesirable effects included dizziness, increased* appetite, oedema, orthostatic hypotension and mild, transient anticholinergic effects, including constipation and dry mouth. Transient, asymptomatic elevations of hepatic transaminases, ALT, AST have been seen, especially in early treatment. Olanzapine-treated patients had a lower incidence of parkinsonism, akathisia and dystonia in trials compared with titrated doses of haloperidol. Non-fasting plasma glucose levels ≥11mmol/l (suggestive of diabetes) as well as non-fasting levels ≥8.9mmol/l but <11mmol/l (suggestive of hyperglycaemia) in patients with baseline non-fasting glucose levels ≤7.8 mmol/l have been seen occasionally in clinical trials. Photosensitivity reaction and bradycardia, with or without hypotension or syncope, have been reported uncommonly (0.1-1.0%). Rash, hepatitis and priapism have been reported rarely (<0.1%). Seizures have been reported to occur rarely in patients treated with olanzapine. In most of these cases, a history of seizures or risk factors for seizures were reported. Plasma prolactin levels were sometimes elevated, but associ*ated clinical manifestations were rare. In most* patients, levels returned to normal ranges without cessation of treatment. Cases reported as NMS and cases of high creatinine phosphokinase levels have been reported rarely. Haematological variations, such as leucopenia and thrombocytopenia, have been reported occasionally. *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/1/99/125/001 EU/1/99/125/002. **Date of Preparation or Last Review:** January 2001. **Full Prescribing Information is Available From:** Eli Lilly and Company Limited, Dextra Court, Chapel Hill, Basingstoke, Hampshire, RG21 5SY. Telephone: Basingstoke (01256) 315000 or Eli Lilly and Company (Ireland) Limited, 44 Fitzwilliam Place, Dublin 2, Republic of Ireland. Tel: Dublin 6614377. 'ZYPREXA' and 'VELOTAB' are Eli Lilly and Company Limited trademarks. **References: 1.** Jones B et al. Schizophrenia Research 1999; 36(1-3): 183.
website: www.elililly.ie

Zyprexa is manufactured in Cork.

Lilly

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

Zyprexa VeloTab is a new oral rapidly dispersing formulation of Zyprexa which offers greater ease of use and aims to enhance compliance.

Zyprexa VeloTab is especially suitable for patients with schizophrenia unable to take oral tablets.

Zyprexa VeloTab is available in 5mg and 10mg tablets.

https://doi.org/10.1017/S079096670000690X Published online by Cambridge University Press