

Now for bipolar disorder

Mania under control.
Stability ahead.

Proven Efficacy

Trusted Tolerability



Seroquel

quetiapine

Stabilise without Compromise

Seroquel® Abridged Prescribing Information (for full details see summary of product characteristics)

Presentations: Film coated tablets containing 25mg, 100mg, 200mg and 300mg of quetiapine (as quetiapine fumarate). **Uses:** Treatment of schizophrenia and moderate to severe manic episode. **Dosage and Administration:** **Schizophrenia: Adults:** Initial titration from 50mg to 300mg over first 4 days. From day 4 onwards the dose should be titrated to the usual effective dose of 300-450 mg/day. Dose range: 150 to 750 mg/day. **Bipolar disorder: Adults:** Initial titration from 100mg to 400mg over first 4 days. Dose range: 200-800 mg/day. **Elderly:** Rate of dose titration may need to be slower and daily therapeutic dose lower than in younger patients. **Children & Adolescents:** Not evaluated. **Renal Impairment:** No dose adjustment required. **Hepatic Impairment:** Use with caution. Patients should be started on 25 mg/day and increased by 25 - 50 mg/day until an effective dosage is achieved. **Contra-indications:** Hypersensitivity to quetiapine fumarate or excipients. Concomitant administration of cytochrome P450 3A4 inhibitors, such as HIV-protease inhibitors, azole-antifungal agents, erythromycin, clarithromycin and nefazodone. **Precautions and warnings:** Known cardiovascular disease, cerebrovascular disease, or other conditions predisposing to hypotension. Possible initial orthostatic hypotension during the dose titration period. Caution is recommended in patients with a history of seizures. If signs and symptoms of tardive dyskinesia appear dose reduction or discontinuation should be considered. In the event of neuroleptic malignant syndrome discontinue treatment. Hyperglycaemia or exacerbation of pre-existing diabetes has been reported in very rare cases. **Undesirable effects:** Mild asthenia, dizziness, somnolence, peripheral oedema, syncope, dry mouth, rhinitis, dyspepsia, constipation, leucopenia and tachycardia. Elevations in gamma-GT levels, non-fasting serum triglyceride levels and total cholesterol. Seroquel was associated with dose related decreases in thyroid hormone levels, particularly total T₄ and free T₄. **Interactions:** Use with caution with other centrally acting drugs and alcohol. CYP3A4 inhibitors such as ketoconazole are contraindicated. Grapefruit juice, omeprazole, carbamazepine, thioridazine. **Pregnancy & lactation:** Safety and efficacy not established. **Effects on ability to drive:** Patients should be advised not to drive or operate machinery. **Authorisation Numbers:** Seroquel 25 PA970/18/1, Seroquel 100 PA970/18/2, Seroquel 200 PA970/18/3, Seroquel 300 PA970/18/7, 4 Day starter pack (Schizophrenia) PA 970/18/5. **Product authorisation holder:** AstraZeneca Ltd., Horizon Place, 600 Capability Green, Luton Bedfordshire, LU1 3LU. **Further information** on request from: AstraZeneca Pharmaceuticals (Ireland) Limited, Collins Park House, 20 Meehan Street, Dublin 2, Tel: 01 609 7100, Fax: 01 670 6660. **Date of Preparation:** January 2004

AstraZeneca 
NEUROSCIENCE

ZYPREXA® (OLANZAPINE) ABBREVIATED PRESCRIBING INFORMATION INFORMATION REPUBLIC OF IRELAND Presentations: 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. Powder for Solution for injection, containing 10mg olanzapine. Uses: **Tablets and Velotabs:** Schizophrenia, both as initial therapy and for maintenance. Moderate to severe manic episode and prevention of recurrence in bipolar disorder. **Injection:** Rapid control of agitation and disturbed behaviours in patients with schizophrenia or manic episode, when oral therapy is not appropriate. **Dosage and Administration** **Tablets and Velotabs:** Schizophrenia: 10mg/day orally. **Manic episode:** 15mg/day in monotherapy; 10mg/day in combination therapy. **Preventing recurrence in bipolar disorder:** 10mg/day or, for patients who have been receiving olanzapine for treatment of manic episode, continue therapy for preventing recurrence at the same dose. May subsequently be adjusted to 5-20mg daily. **Injection:** Intramuscular use only for up to a maximum of three consecutive days. Initial dose is 10mg. A second injection, 5-10 mg, may be administered 2 hours after. Maximum daily dose is 20mg, with not more than 3 injections in any 24-hour period. Treatment with Zyprexa Intramuscular Injection should be discontinued, and the use of oral Zyprexa should be initiated, as soon as clinically appropriate. Do not administer intravenously or subcutaneously. **Children:** Not recommended (under 18 years). **Elderly patients:** Oral therapy - a lower starting dose (5mg/day) is not routinely indicated but should be considered when clinical factors warrant. **Injection -** recommended starting dose is 2.5-5mg. **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** **Injection:** Efficacy not established in patients with agitation and disturbed behaviours related to conditions other than schizophrenia or manic episode. Should not be administered to patients with unstable medical conditions (see Summary of Product Characteristics (SPC)). Safety and efficacy have not been evaluated in patients with alcohol or drug intoxication. Patients should be closely observed for hypotension, including postural hypotension, bradyarrhythmia, and/or hypotension (see SPC). Simultaneous injection with parenteral benzodiazepine is not recommended. Special caution in patients who receive other medicinal products having haemodynamic properties similar to those of Zyprexa Intramuscular Injection (see SPC). Clinical monitoring advisable in diabetic patients and those with risk factors for diabetes. Caution with prostatic hypertrophy, or paralytic ileus and related conditions. With oral Zyprexa, 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, in patients receiving medicines known to cause neutropenia, and in patients with hypersensitivity conditions or with myeloproliferative disease. Discontinue if signs and symptoms indicative of MMS, 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, Zyprexa was not associated with a persistent increase in absolute QT intervals. Gradual dose reduction should be considered when discontinuing olanzapine. Use of olanzapine to treat drug-induced psychosis in patients with Parkinson's disease is not recommended. **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. Zyprexa Intramuscular Injection 5mg, administered 1 hour before lorazepam 2mg, added to the somnolence observed with either drug alone. **Pregnancy and Lactation** There are very rare reports of foetal hypotonia, lethargy, and sleepiness in infants born to mothers who used olanzapine during the 3rd trimester. 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 or dizziness. Patients should be cautioned about operating hazardous machinery, including motor vehicles. **Undesirable Effects** **Clinical trial adverse event reporting and investigations with oral Zyprexa:** 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 nutrition.** Very common (>10%): weight gain. Common (1-10%): increased appetite, elevated glucose levels (incidence 1.0% for Zyprexa versus 0.9% for placebo for non-fasting levels ≥ 11 mmol/l), elevated triglyceride levels. **Nervous.** Very common (>10%): somnolence, abnormal gait in Alzheimer's disease patients. Worsening of Parkinsonian symptomatology and hallucinations were reported in patients with Parkinson's disease. Common (1-10%): dizziness, akathisia, parkinsonism, dyskinesia. (Zyprexa-treated patients had a lower incidence of parkinsonism, akathisia, and dystonia compared with titrated doses of haloperidol.) **Cardiac.** Uncommon (0.1-1%): bradycardia, with or without hypotension or syncope. **Vascular.** Common (1-10%): orthostatic hypotension. **Gastro-intestinal.** Common (1-10%): constipation, 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 with oral Zyprexa:** Blood and lymphatics. Rare (0.01-0.1%): leucopenia. Very rare (<0.01%): thrombocytopenia, neutropenia. **Immune system disorder.** Very rare (<0.01%): allergic reaction. **Metabolism and nutrition.** Very rare (<0.01%): hyperglycaemia and/or development or exacerbation of 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 MMS. Parkinsonism, dystonia, and tardive dyskinesia. 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. **Renal and urinary disorders:** Very rare (<0.01%): urinary hesitation. **Additional clinical trial adverse event reporting and investigations with Zyprexa Intramuscular Injection:** Cardiac. Common (1-10%): bradycardia, with or without hypotension or syncope, tachycardia. Uncommon (0.1-1%): sinus pause. **Vascular.** Common (1-10%): postural hypotension, hypotension. **Respiratory.** Uncommon (0.1-1%): hypoventilation. **General.** Common (1-10%): injection site discomfort. **For further information** see SPCs. **Legal Category** POM. **Marketing Authorisation Numbers and Holder** 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; EU/1/96/022/016. **Elis Lilly, Nederland BV, Grootslag 1-5, 3991 RA Houten, The Netherlands. Date of Preparation or Last Review** November 2003. **Full Prescribing Information is Available From** Eli Lilly and Company Limited, Lilly House, Priestley Road, Basingstoke, Hampshire, RG24 9NL. Telephone: Basingstoke (01256) 315 999 or Eli Lilly and Company (Ireland) Limited, Hyde House, 65 Adelaide Road, Dublin 2, Republic of Ireland. Telephone: Dublin (01) 661 4377. **ZYPREXA (olanzapine) and VELOTAB are trademarks of Eli Lilly and Company. References:** 1. Adapted from Zyprexa Summary of Product Characteristics.

NEW

Now indicated for prevention of recurrence in Bipolar Disorder*



Zyprexa is an antipsychotic and a mood stabiliser¹

ZYPREXA®
Olanzapine
HELPING MOVE LIVES FORWARD

*in patients whose manic episode has responded to olanzapine treatment.

Zyprexa is manufactured in Cork.

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