NEW

Risperdal Consta

The first long-acting atypical that provides constant coverage for long-term stability

RISPERDAL CONSTA ADDRESSES FACTORS THAT CAUSE DISRUPTION IN THERAPY.

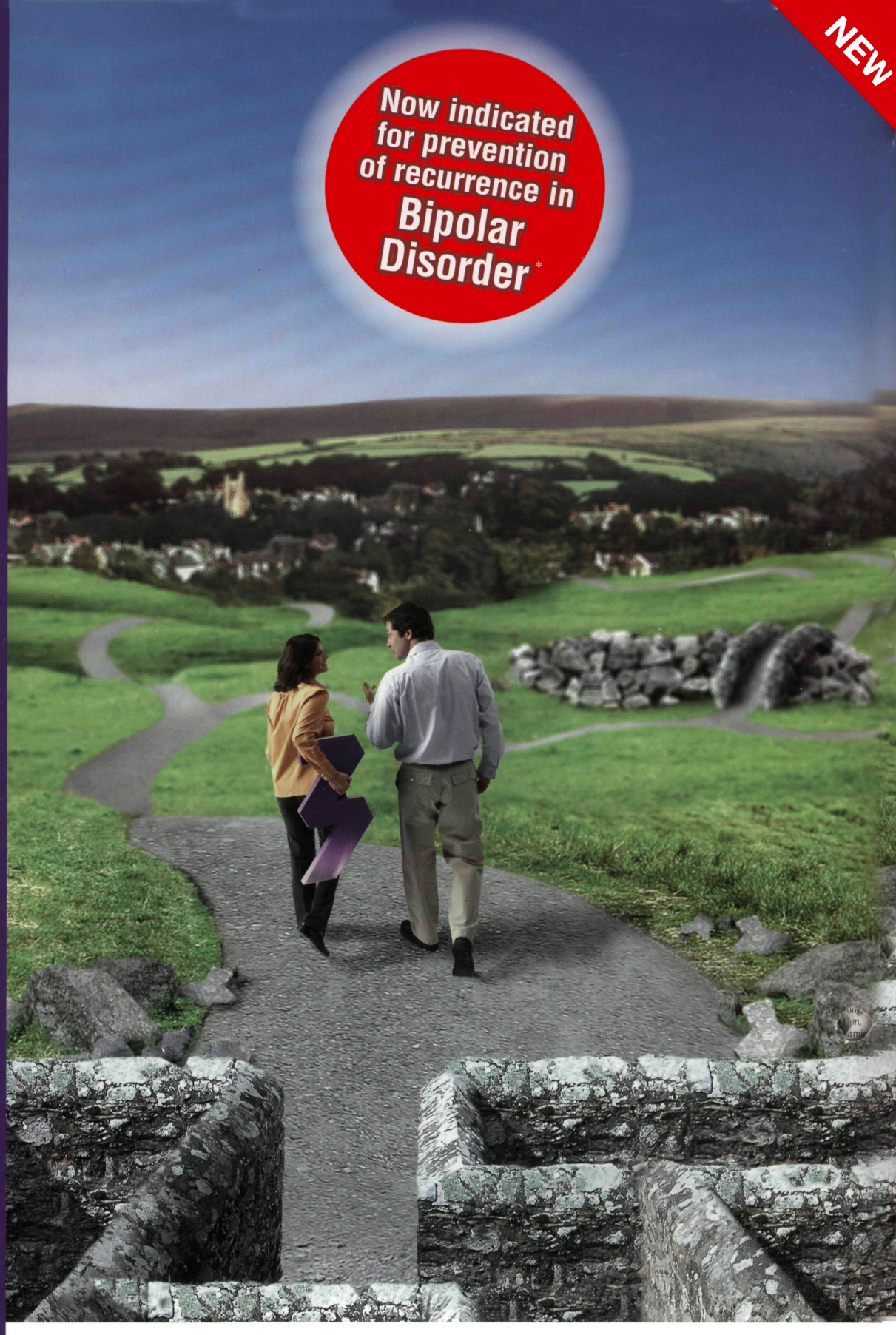
- Long-acting formulations improve compliance (3) with non-compliance becoming immediately detectable (4,5).
- Powerful PANSS score reductions after twelve weeks (6) and continuous significant improvement over 1 year (7).
- Well tolerated – with a low percentage of discontinuations due to adverse events (8).

NEW RisperdalCONSTA™

RISPERIDONE LONG-ACTING INJECTION

At long last

References: 1.Oehl M,Hummer M, Fleischhacker WW.ACTA psychiatr Scand 2000;102(suppl 407):83-86 2.Weiden P,Glazer W.Psych Quarterly.1997;68:377-392 3.Remington GJ, Adams ME.Can J Psychiatry 1995;40(suppl 1):S5-S12.4.Kane JM, Aguglia E, Altamura AC, et al.Eur Neuropsychopharmacol.1998:8:55-66.5.Barnes TRE,Curson DA.Drug Safety. 1994;10:464-479. 6. Kane J,Eerdekens M,Keith S, et al.poster 2002;Davos Switzerland 7.Data on file, JJPRD. 8.Data on file,JJPRD (Integrated Summary of Safety).



ZYPREXA* (OLANZAPINE) ABBREVIATED PRESCRIBING 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 hypoventilation (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 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, 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 tremor, hypertonia, 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 nutritional.* 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 ≥11mmol/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%): 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 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 nutritional.* 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 NMS. 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. Eli 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.

*In patients whose manic episode has responded to olanzapine treatment, olanzapine is indicated for prevention of recurrence in patients with bipolar disorder.

Zyprexa is an **antipsychotic** and a **mood stabiliser**[1]

ZYPREXA® Olanzapine

HELPING MOVE LIVES FORWARD

Zyprexa is manufactured in Cork

Lilly