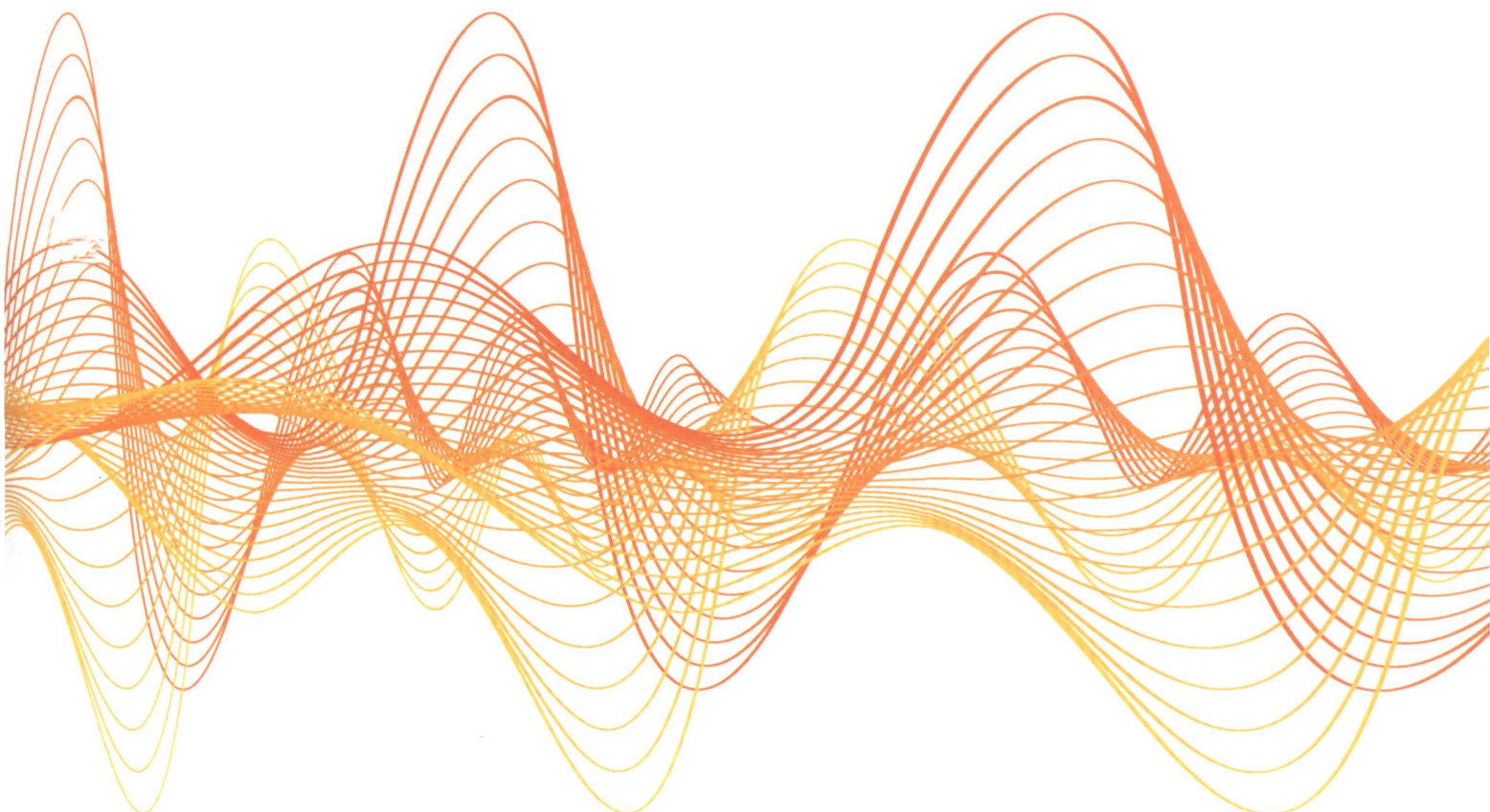


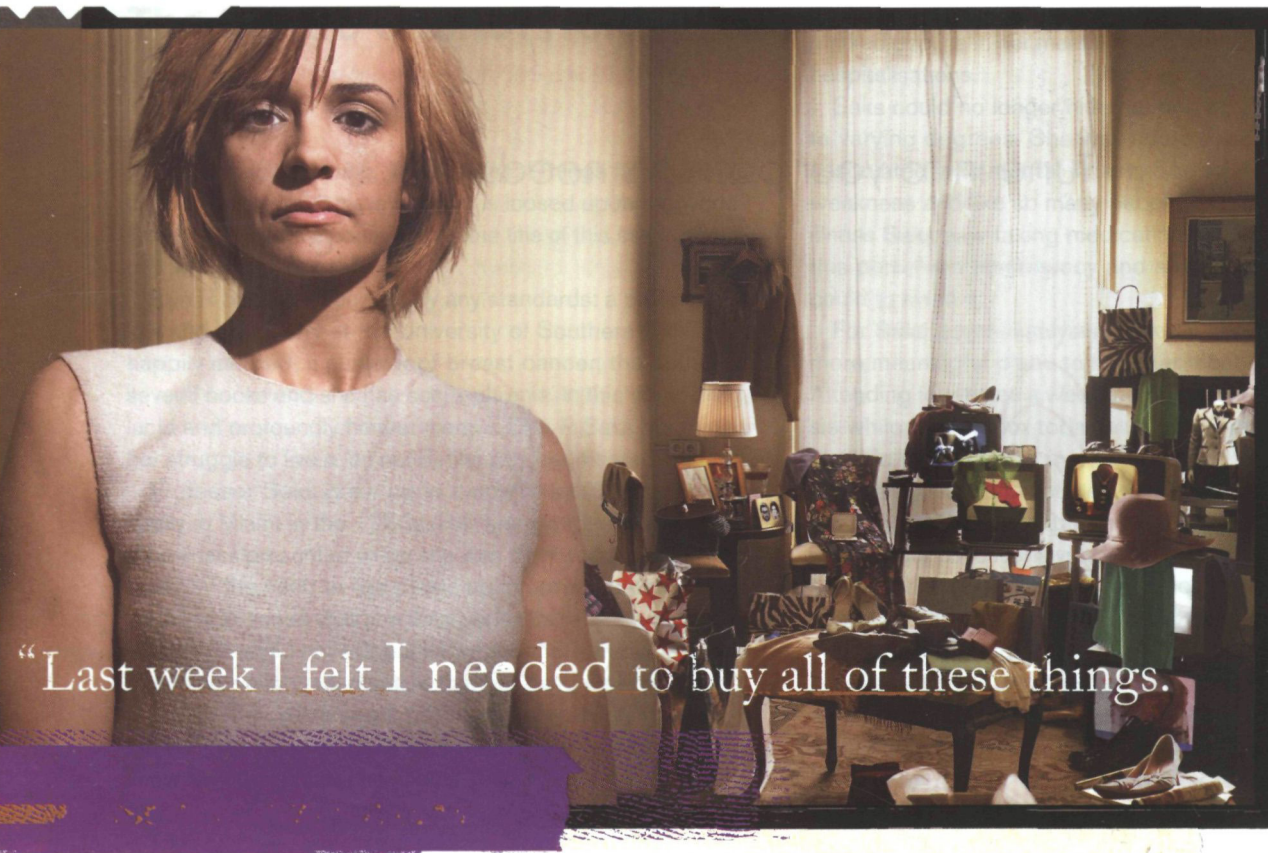
Tune in to your patients needs



Perdamel® for the treatment of **schizophrenia**.

Perdamel®
Risperidone

ABBREVIATED PRESCRIBING INFORMATION Perdamel 0.5, 1, 2, 3, 4 & 6 mg Tablets Presentation: The 0.5 mg tablet is brownish-red, oblong, scored on one side with R on the scored side and 0.5 on the other side. The 1 mg tablet is white, oblong, scored on one side with R 1 on the scored side and plain on the other side. The 2 mg tablet is salmon, oblong, scored on one side with R 2 on the scored side and plain on the other side. The 3 mg tablet is yellow, oblong, scored on one side with R 3 on the scored side and plain on the other side. The 4 mg tablet is light green, oblong, scored on one side with R 4 on the scored side and plain on the other side. The 6 mg tablet is yellow, round with R on one side and 6 on the other side. Each tablet contains 0.5 mg, 1 mg, 2 mg, 3 mg, 4 mg or 6 mg risperidone. Indications: Treatment of schizophrenia. Maintenance treatment to prevent relapse in chronic schizophrenia in patients having shown a response to initial treatment. Treatment of aggression and pronounced psychotic symptoms in patients with dementia in whom such disorders can cause suffering, potential danger or risk of self-harm in the patient. Treatment of manic episodes in association with bipolar disorder. Serious acting out conduct disorders such as behavioural disorder and oppositional defiant disorder according to DSM IV in children (> 5 years of age), adolescents and adults with psychological development disorders (mental retardation). Serious conduct disorders in children (> 5 years of age) and adolescents with autism. Dosage: Schizophrenia (adults and adolescents ≥ 15 years): Start on 2 mg/day, taken once or twice daily. On the second day, dose may be increased to 4 mg/day. For most patients, the optimal daily dose ranges between 4 and 6 mg/day. Elderly: Start on 0.5 mg twice daily, increased as required by 0.5 mg twice daily to 1–2 mg twice daily. Children and adolescents under 15 years: Not recommended. For other dosage regimens refer to the SPC. Hepatic and renal disease: The starting dose and subsequent doses should be halved and dose titration should be slower. No dose adjustment is required in mild hepatic impairment. Caution should be exercised when treating patients with moderate-severe hepatic impairment. Contraindications: Hypersensitivity to risperidone or to any of the excipients. Warnings and precautions: Orthostatic hypotension, cardiovascular disorders, tardive dyskinesia, neuroleptic malignant syndrome, exacerbation of symptoms such as excitation, agitation and aggression, caution in patients with Lewy body dementia or Parkinson's disease, epilepsy, increased mortality and cerebrovascular events in elderly patients with dementia, combination with furosemide or other potent diuretics. As risperidone can prolong the QT interval, caution is advised when treating patients with pronounced bradycardia, cardiovascular disease and hereditary long QT syndrome. Dehydration should be avoided in elderly patients with dementia. Hyperprolactinaemia, caution in patients with prolactin-dependent tumours. Hyperglycaemia or deterioration in existing diabetes may occur. Gradual withdrawal is recommended to avoid withdrawal symptoms. Perdamel contains lactose. Interactions: Other substances that act on the CNS, alcohol, other antipsychotics, lithium, antidepressants, antiparkinson agents, drugs with a central anticholinergic effect, phenoxybenzamine, labetalol, alpha-blocking sympatholytics, methylidopa, reserpine and other centrally acting antihypertensives, guanethidine, levodopa and other dopaminergic agonists, carbamazepine, quinidine, fluoxetine, paroxetine, terbinafine, other potent CYP2D6 inhibitors, beta-blockers, ranitidine, cimetidine, class IA and III antiarrhythmics, moxifloxacin, erythromycin, methadone, mefloquine, cispride, thiazide diuretics. Undesirable effects: Most common: Agitation, anxiety, insomnia, headache, sedation, weight gain. For other undesirable effects see Summary of Product Characteristics. Pack sizes: 0.5 mg – 20 tablets, 1 mg – 20 and 60 tablets, 2, 3 and 4 mg – 60 tablets, 6 mg – 30 tablets. Marketing authorisation holder: Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary. Marketing authorisation numbers: PA 126/169/2-7. Full prescribing information is available on request. Date last revised: November 2007.



"Last week I felt I needed to buy all of these things."

Now I want to gain control again."



This is the story of Anna* and a lifetime of excessive buying and collecting. When she couldn't sleep, she shopped. Today, with the support of her doctor, treatment team and family, Anna is managing her relapses in bipolar disorder with Zyprexa, and can add a university degree to her collecting.¹

Knowing where you have been is one measure of how far you have come. Together you can find another way to stay on the road to improvement.

ZYPREXA TABLETS REPUBLIC OF IRELAND (OLANZAPINE) ABBREVIATED PRESCRIBING INFORMATION ZYPREXA VELOTABS ZYPREXA INTRAMUSCULAR INJECTION Presentations** Tablets 2.5mg, 5mg, 7.5mg, 10mg, 15mg, or 20mg of olanzapine. Also contain lactose. Velotab** 5mg, 10mg, 15mg, or 20mg olanzapine. 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, prevention of recurrence in bipolar disorder in patients whose manic episode has responded to olanzapine treatment. **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 a maximum of three consecutive days. Initial dose 10mg. A second injection, 5-10mg, 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 oral Zyprexa 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, consider a decreased starting dose. **Contra-indications** Known hypersensitivity to any ingredient. Known risk of narrow-angle glaucoma. **Warnings and Special Precautions** Olanzapine is not approved for the treatment of dementia-related psychosis and/or behavioural disturbances because of an increase in mortality and the risk of CVAE. **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, bradycardia, and/or hypovolaemia (see SPC). Simultaneous injection with parenteral benzodiazepine is not recommended. Use to treat drug-induced psychosis with Parkinson's disease is not recommended. **Caution in patients:** • who receive other medicinal products having haemodynamic properties similar to those of Zyprexa Intramuscular Injection. • with prostatic hypertrophy, or paralytic ileus and related conditions. • with elevated ALT and/or AST, hepatic

impairment, limited hepatic functional reserve, and in patients treated with hepatotoxic drugs. If hepatitis is diagnosed, discontinue Zyprexa. • with low leucocyte and/or neutrophil counts, bone marrow depression, in patients receiving medicines known to cause neutropenia, and in patients with hyper eosinophilic conditions or with myeloproliferative disease. • who have a history of seizures or are subject to factors which may lower the seizure threshold. • using other centrally acting drugs and alcohol. As with other antipsychotics, caution should be exercised when olanzapine is prescribed with medicines known to increase QTc interval. Discontinue if signs and symptoms indicative of NMS, or unexplained high fever, if tardive dyskinesia appears, consider dose reduction or discontinuation. Clinical monitoring advisable in diabetic patients and those with risk factors for diabetes. Blood pressure should be measured periodically in patients over 65 years. Undesirable alterations in lipids have been observed in olanzapine-treated patients in placebo-controlled clinical trials. Lipid alterations should be managed as clinically appropriate. May antagonise effects of dopamine agonists. **Gradual dose reduction** should be considered when discontinuing olanzapine. **Phenylethylamine:** Velotabs contain aspartame - a source of phenylethylamine. **Sodium methyl parahydroxybenzoate and sodium propyl parahydroxybenzoate:** Contained in Velotabs; known to cause urticaria, contact dermatitis, and, rarely, immediate reactions with bronchospasm. **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** 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** Those observed from spontaneous reporting and in placebo-controlled clinical trials at a rate of $\geq 1\%$, or where the event is clinically relevant, are: **Clinical Trial Adverse Event Reporting and Investigations With Oral Zyprexa** Very common ($>10\%$): Weight gain, somnolence, elevated plasma prolactin levels. **Common (1-10%):** Eosinophilia, increased appetite, elevated glucose levels, elevated triglyceride levels, elevated cholesterol levels, glycosuria, dizziness, akathisia, parkinsonism, dyskinesia. Orthostatic hypotension, mild, transient anticholinergic effects, including constipation and dry mouth, transient, asymptomatic elevations of ALT, AST, ashtenia, fatigue, oedema. **Uncommon (0.1-1%):** Bradycardia, with or without hypotension or syncope. In clinical trials of elderly patients with dementia, olanzapine was associated with a higher incidence of death and cerebrovascular adverse

events compared to placebo. Very common ($>10\%$) undesirable effects in this patient group were abnormal gait and falls. Pneumonia, increased body temperature, lethargy, erythema, visual hallucinations, and urinary incontinence were observed commonly (1-10%). **Post-Marketing Spontaneous Reporting With Oral Zyprexa:** Rare (0.01-0.1%): Leucopenia, seizures, hepatitis, hyperglycaemia, and/or development or exacerbation of diabetes (occasionally associated with ketoacidosis or coma, including some fatal cases). **Very rare ($<0.01\%$):** Thrombocytopenia, neutropenia, allergic reaction, neuroleptic malignant syndrome, parkinsonism, dystonia (including oculogyration), and tardive dyskinesia. **Hypertriglyceridaemia, hypercholesterolaemia, QTc prolongation, ventricular tachycardia/fibrillation and sudden death, thrombocytopenia, pancreatitis, thalidomidylis, and priapism.** **Additional Clinical Trial Adverse Event Reporting and Investigations With Zyprexa Intramuscular Injection:** Common (1-10%): Bradycardia, with or without hypotension or syncope, tachycardia. Injection site discomfort, somnolence, postural hypotension, hypotension. **Uncommon (0.1-1%):** Sinus pause. **Post-Marketing Spontaneous Events With Zyprexa Intramuscular Injection** Temporal association in cases of respiratory depression, hypotension, or bradycardia, and death reported very rarely, mostly with concomitant use of benzodiazepines and/or other antipsychotic drugs, or use of olanzapine in excess of recommended dose. **For full details of these and other side-effects, please see the Summary of Product Characteristics, which is available at <http://www.medicines.ie/>** **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/1/96/022/014 EU/1/96/022/016 EU/1/99/125/001 EU/1/99/125/002 EU/1/99/125/003 EU/1/99/125/004. Eli Lilly Nederland BV, Grootslag 1-5, 3981 PA Houliën, The Netherlands. **Date of Preparation or Last Review** January 2008. **Full Prescribing Information is Available From** Eli Lilly and Company Limited, Lilly House, Priestley Road, Basingstoke, Hampshire, RG24 8NL, 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. Reference:** 1. Tohen M et al. Olanzapine versus lithium in the maintenance treatment of bipolar disorder. A 12 month, randomized, double-blind controlled clinical trial. *Am J Psychiatry* 2005;162:1281-1290.

*Case study based on fictional characters

■ Zyprexa is manufactured in Cork.

ZY/27/09/08/058

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