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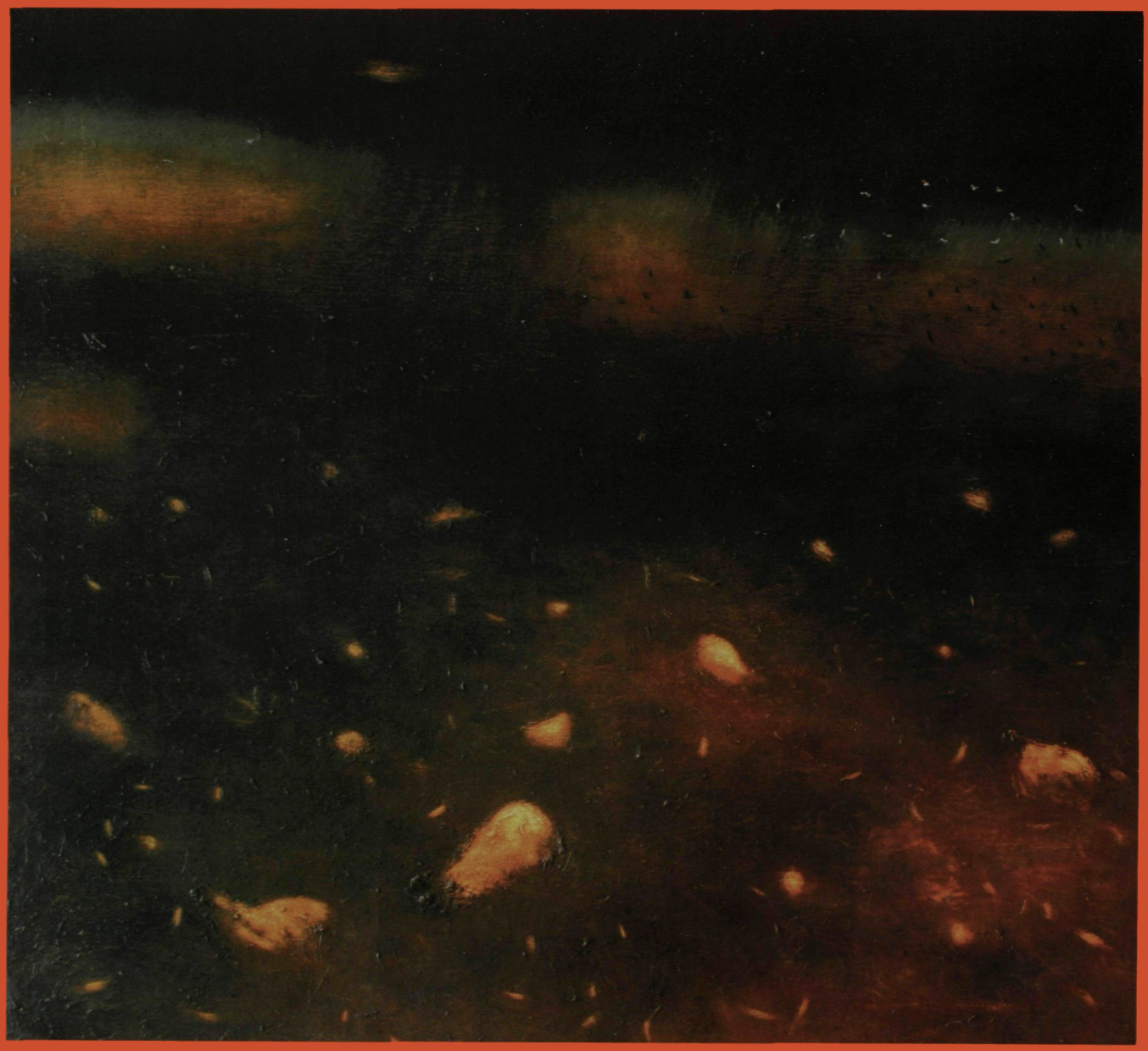

'Wintered Glen' by Jean Clyne, 2004. Oil on Linen (32 x 34").

In the treatment of schizophrenia

Positive symptom control is the start, but what brightens the picture?

GEODON –

Efficacy that brightens outcomes[1]

Power to take patients beyond positive symptoms to positive outcomes[1]

Abbreviated Prescribing Information for Geodon (ziprasidone), Republic of Ireland Geodon™. **Presentation:** Capsules containing ziprasidone hydrochloride monohydrate equivalent to 20, 40, 60 and 80mg ziprasidone. **Indications:** Treatment of schizophrenia. **Dosage:** Acute treatment - 40mg twice daily with food. Maximum dosage of 80mg twice daily may be reached by day 3 of treatment. Maintenance treatment - use the lowest effective dose. ***In elderly:*** A lower starting dose should be considered for patients over 65 where clinical factors warrant. ***In children:*** Caution as no evaluation under 18 years of age. In renal impairment: No dosage adjustment required. ***In hepatic impairment:*** Consider lower doses in hepatic insufficiency. Caution in severe hepatic insufficiency. **Contra-indications:** Known hypersensitivity to any ingredient of the product. Known QT-interval prolongation. Congenital long QT syndrome. Recent acute myocardial infarction. Uncompensated heart failure. Arrhythmias treated with class IA and III antiarrhythmic drugs. Concomitant treatment with medicines known to prolong the QT interval. **Special warnings:** A medical history, family history and physical examination should be undertaken to identify patients for whom ziprasidone is not recommended. Mild to moderate dose-related QT-interval prolongation, therefore, do not give together with medicinal products known to prolong the QT interval. Caution in patients with significant bradycardia. Before treatment is started - correct electrolyte disturbances; and as with other drugs which prolong QT interval, consider ECG review in patients with stable cardiac disease. If cardiac symptoms occur, consider the possibility of a malignant cardiac arrhythmia and perform a cardiac evaluation, including an ECG. It is recommended to stop treatment if the QT interval is >500msec. No cases of Neuroleptic Malignant Syndrome (NMS) seen in clinical trials, but potential risk cannot be excluded. Management of NMS should included immediate withdrawal of all antipsychotic drugs. Potential to cause tardive dyskinesia, if signs appear consider dose reduction or discontinuation. Caution in patients with a history of seizures. Interactions: ziprasidone should not be given with medicinal products known to prolong the QT interval (see SPC for details). Caution in combination with other centrally acting drugs and alcohol. Ziprasidone is unlikely to cause clinically important drug interactions mediated by CYP3A4 or CYP2D6 (see SPC for details). **Pregnancy and lactation:** Not recommended unless the expected benefit outweighs the risk. Women of childbearing potential should use an appropriate method of contraception. Avoid breastfeeding. **Driving:** Ziprasidone may cause somnolence, therefore caution patients likely to drive or operate machines. **Undesirable effects:** In short term placebo controlled trials: >1/10 somnolence; >1/100,<1/10 asthenia, headache, constipation, dry mouth, dyspepsia, increased salivation, nausea, vomiting, agitation, akathisia, dizziness, dystonia, extrapyramidal syndrome, hypertonia, tremor, abnormal vision; >1/1000,<1/100 pain, postural hypotension, tachycardia, flatulence, thirst, joint disorder, leg cramps, cogwheel rigidity, paresthesia, speech disorder, tardive dyskinesia, rhinitis, rash, urticaria. In long term maintenance trials: elevated prolactin levels, returning to normal without cessation of treatment and rare reports of clinical manifestation (gynaecomastia and breast enlargement). **Legal Category:** POM. **Package quantities:** blister packs containing 56 capsules. **Further information on request:** Pfizer Healthcare Ireland, Parkway House, Ballymount Road Lower, Dublin 12, Republic of Ireland. **Marketing Authorisation numbers:** PA 19/52/1-5. Date of first authorisation/renewal of the authorisation: February 2002. **Date of revision of the text:** February 2002.

References: 1. Data on file. Pfizer Inc., New York, NY.

GEO/2004/016

GEODON®

Oral Capsules (ziprasidone HCl)
and ***Injection*** (ziprasidone mesylate)

Power to restore potential™

Pfizer NEUROSCIENCE

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In Depression & Anxiety...

... Patients Get Better and Stay Better with LUSTRAL™ sertraline

Abbreviated Prescribing Information: LUSTRAL™ (sertraline) **Presentation:** Tablets containing 50mg or 100mg sertraline. **Indications:** Treatment of symptoms of depressive illness, including accompanying symptoms of anxiety. Prevention of relapse or recurrence of depressive episodes, including accompanying symptoms of anxiety. Obsessive compulsive disorder (OCD) in adults and children. Panic disorder, with or without agoraphobia. Post-traumatic stress disorder (PTSD). **Dosage:** Lustral should be given as a single daily dose. The initial dose in depression and OCD is 50mg and the usual antidepressant dose is 50mg. The initial dose in panic disorder and PTSD is 25mg, increasing to 50mg after one week. Dosage can be further increased, if appropriate, to a maximum of 200mg daily. Changes in dose should not be made more frequently than once per week given the 24 hour elimination half life of sertraline. *Children (OCD only): Ages 6-12:* the initial dose is 25 mg/day increasing to 50 mg/day after 1 week. *Ages 13-17:* Usual adult dose. Consider generally lower body weights of children to avoid overdosing. Do not increase doses at intervals of less than 1 week. *Use in the elderly:* Usual adult dose. **Contra-indications:** Hypersensitivity to this group of drugs. Hepatic insufficiency, unstable epilepsy and convulsant disorders, pregnancy and lactation. Do not use with, or within two weeks of ending treatment with, MAOIs. At least 14 days should elapse before starting any MAOI following discontinuation of Lustral. Do not use with pimozide. **Precautions, warnings:** Renal insufficiency, ECT, epilepsy, driving. Lustral should be discontinued in a patient who develops seizures. Lustral should not be administered with benzodiazepines or other tranquillizers in patients who drive or operate machinery. Serotonergic drugs such as tryptophan or fenfluramine should be used with caution. Patients should be closely supervised for the possibility of suicide attempt or activation of mania/hypomania. The use of Lustral in children and adolescents under 18 with major depressive disorder is not recommended, as *benefit/risk has not been established.* ***Drug Interactions:*** *Caution* with other centrally acting medication. Lithium levels should be monitored. Increased pimozide levels have been demonstrated when co-administered with Lustral, therefore Lustral should not be taken together with pimozide. Although Lustral has been shown to have no adverse interaction with alcohol, concomitant use with alcohol is not recommended. The potential for Lustral to interact with other highly protein bound drugs should be borne in mind. Interactions with e.g. warfarin, diazepam, tolbutamide and cimetidine have not been fully assessed. With warfarin prothrombin time should be monitored when Lustral is initiated or stopped. **Side-Effects:** Dry mouth, nausea, diarrhoea/loose stools, ejaculatory delay, tremor, increased sweating, dizziness, insomnia, somnolence, headache, anorexia and dyspepsia. Rarely, abnormal LFTs, hyponatraemia. Additionally, the following adverse events were observed in clinical trials in paediatric OCD patients: anorexia, weight decrease, fatigue, chest pain, fever, malaise, hyperkinesia, tremor, urinary incontinence, nausea, insomnia, nervousness, agitation, impaired concentration, manic reaction, anxiety, emotional lability, abnormal thinking, breast pain, dysmenorrhea, menstrual disorder, epistaxis, rash, skin disorder, purpura *and headache.. The following have been reported with Lustral but* may have no causal relationship: vomiting, abdominal pain, movement disorders, convulsions, menstrual irregularities, hyperprolactinaemia, galactorrhoea, rash and alopecia. Rarely, pancreatitis, serious liver events, altered platelet function, abnormal bleeding and purpura. As with other serotonin re-uptake inhibitors rare reports of agitation, confusion, depersonalisation, hallucinations, nervousness, postural hypotension, hypo/hypertension, tachycardia and arrhythmias. Withdrawal reactions have been reported with Lustral. Common symptoms include dizziness, paraesthesia, headache, anxiety and nausea. Abrupt discontinuation of treatment with Lustral should be avoided. The majority of symptoms experienced on withdrawal of Lustral are non-serious and self-limiting. **Legal Category:** S1A. **Package Quantities:** 50mg tablet (PA 822/1/4) Calendar pack of 28; 100mg tablet (PA 822/1/5) Calendar pack of 28. **Product Authorisation Holder:** Pfizer Healthcare Ireland, Parkway House, Ballymount Road Lower, Dublin 12, Republic of Ireland. **Further information on request:** Pfizer Healthcare Ireland. **Date last revised:** January 2004