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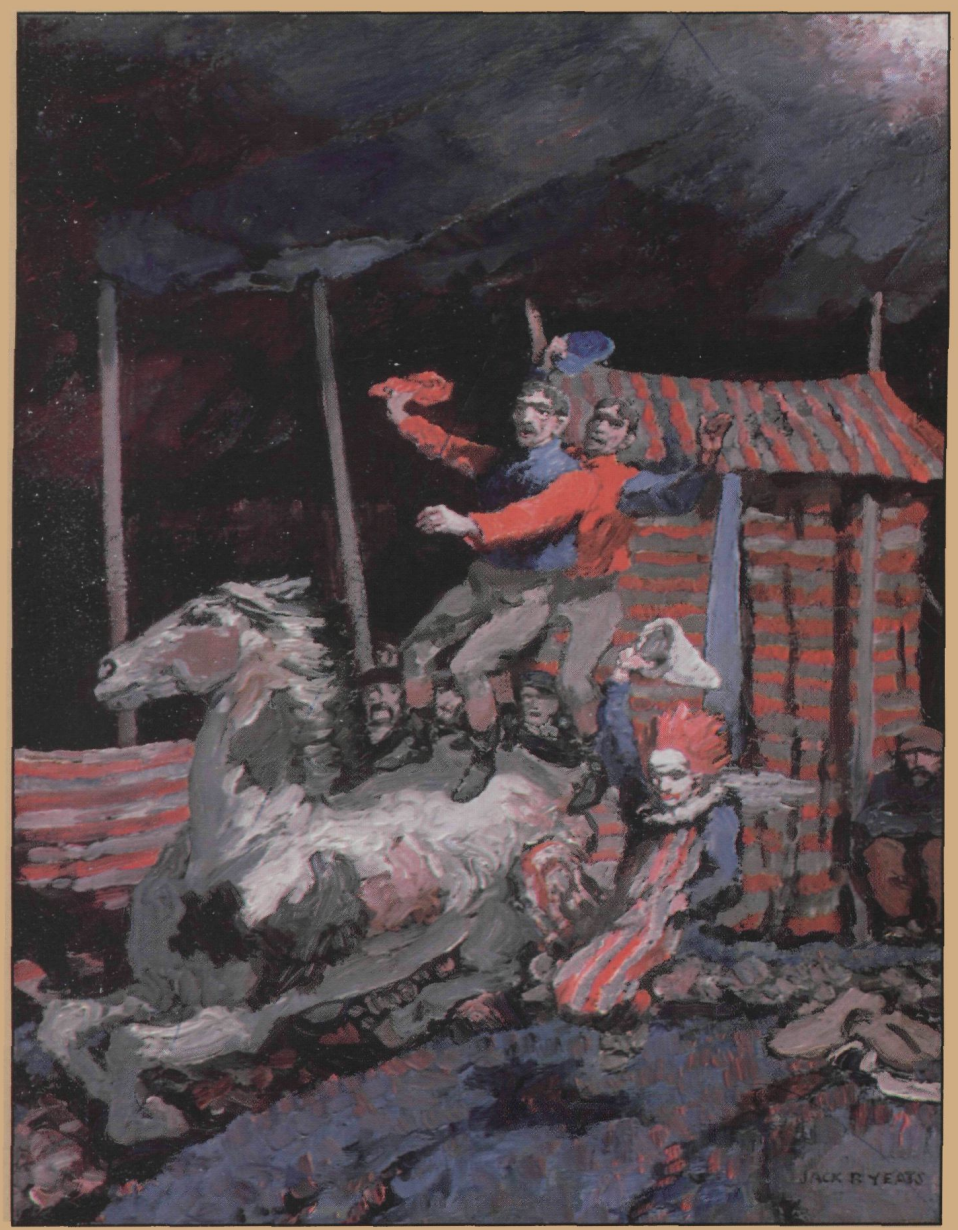

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With a record of clinical use of up to 7 years and over 19 million patients world-wide[1], Prozac has the experience you can trust.

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And isn't it good to know that it's manufactured in Ireland?

PROZAC

fluoxetine

The World's No.1 prescribed antidepressant brand.[1]

'PROZAC' (fluoxetine hydrochloride) REPUBLIC OF IRELAND ABBREVIATED PRESCRIBING INFORMATION

Presentation Capsules containing 20mg fluoxetine, as the hydrochloride. Liquid containing 20mg fluoxetine, as the hydrochloride, per 5ml syrup. **Uses** Treatment of the symptoms of depressive illness and its associated anxiety. Bulimia nervosa. Obsessive-compulsive disorder. **Dosage and Administration** (For full information, see data sheet.) For oral administration to adults only. *Depression - adults and the elderly:* A dose of 20mg/day is recommended. *Bulimia - adults and the elderly:* A dose of 60mg/day is recommended. *Obsessive-compulsive disorder - adults and the elderly:* 20mg/day to 60mg/day. A dose of 20mg/day is recommended as the initial dose. Because of the long elimination half-lives of the parent drug (1-3 days after acute administration; may be prolonged to 4-6 days after chronic administration) and its major metabolite (average 9.3 days), active drug substance will persist in the body for several weeks after dosing is stopped. The maximum daily dose should not exceed 80mg for any indication. The capsule and liquid dosage forms are bioequivalent. *Children:* Not recommended. *Patients with renal and/or hepatic dysfunction:* See 'Contra-indications' and 'Precautions' sections. **Contra-indications** Hypersensitivity to fluoxetine. Prozac should not be administered to patients with severe renal failure (GFR <10ml/min). Unstable epilepsy or convulsant disorders. *Use in conjunction with monoamine oxidase inhibitors:* At least 14 days should elapse between discontinuation of an MAOI and initiation of treatment with Prozac. At least five weeks should elapse between discontinuation of Prozac and initiation of therapy with an MAOI. Serious, sometimes fatal, reactions (including hyperthermia, rigidity, myoclonus, autonomic instability with possible rapid fluctuations of vital signs, and mental status changes that include extreme agitation progressing to delirium and coma) have been reported with concomitant use or when fluoxetine had been recently discontinued and an MAOI started. Some cases presented with features resembling neuroleptic malignant syndrome. Cyproheptadine or dantrolene may benefit patients experiencing such reactions. *Usage in nursing mothers:* Prozac should not be prescribed to nursing mothers. **Warnings** *Rash and possibly allergic events:* Prozac should be discontinued upon appearance of rash or of other possibly allergic phenomena for which an alternative aetiology cannot be identified. Systemic events, possibly related to vasculitis, have developed. Although rare, this may be serious, involving lung, kidney or liver. Death has occurred. Serum sickness, anaphylaxis and pulmonary events, including inflammatory processes and/or fibrosis, have been reported. *Usage in pregnancy:* The safety of Prozac in human pregnancy has not been established. **Precautions** Prozac should be avoided in patients with unstable epilepsy (see 'Contra-indications') and it should be discontinued in any patient who develops seizures. A lower dose of Prozac, eg, alternate day dosing, is recommended in patients with significant hepatic dysfunction or mild to moderate renal failure (GFR 10-50ml/min). Caution is advisable when Prozac is used in patients with acute cardiac disease. Prozac may cause weight loss which may be undesirable in underweight depressed patients. In diabetics, fluoxetine may alter glycaemic control. There is little clinical experience of the concurrent administration of fluoxetine with ECT or lithium therapy (see 'Drug interactions'). There have been case reports of prolonged seizures in patients on fluoxetine receiving ECT treatment. Rare reports of altered platelet function and/or abnormal laboratory values, and several reports of abnormal bleeding. *Drug interactions:* Monoamine oxidase inhibitors - see 'Contra-indications'. Because fluoxetine's metabolism involves the hepatic cytochrome P450IID6 isoenzyme system, concomitant therapy with other drugs also metabolised by this system, and which have a narrow therapeutic index (eg, carbamazepine, tricyclic antidepressants), should be initiated at or adjusted to the low end of their dose range. Greater than 2-fold increases of previously stable plasma levels of other antidepressants have been observed when Prozac has been administered in combination. Agitation, restlessness and gastro-intestinal distress have been reported in five patients receiving fluoxetine in combination with tryptophan. Patients on stable doses of phenytoin have developed elevated phenytoin concentrations and phenytoin toxicity. Increased (with lithium toxicity) or decreased lithium levels have been reported. Lithium levels should be monitored. Pharmacokinetic data suggest that the half-life of diazepam may be prolonged in some patients. *For further information, see data sheet.* **Side-effects** Asthenia, fever, nausea, diarrhoea, dry mouth, appetite loss, dyspepsia, vomiting, headache, nervousness, insomnia, drowsiness, anxiety, tremor, dizziness, fatigue, decreased libido, seizures, hypomania or mania, dysphoria, hallucinations, psychosis, pharyngitis, dyspnoea, rash, urticaria, excessive sweating, sexual dysfunction. Hyponatraemia (including serum sodium below 110mmol/l) has been rarely reported. This appears to be reversible upon discontinuation. Elevated serum transaminase values and/or depressed leucocyte counts without accompanying symptoms occurred infrequently in patients given fluoxetine. The following have been reported in association with fluoxetine but no causal relationship has been established: aplastic anaemia, cerebral vascular accident, confusion, ecchymoses, eosinophilic pneumonia, gastro-intestinal haemorrhage, hyperprolactinaemia, immune-related haemolytic anaemia, pancreatitis, pancytopenia, suicidal ideation, thrombocytopenia, thrombocytopenic purpura, vaginal bleeding after drug withdrawal and violent behaviour. Voluntary reports of adverse events temporally associated with fluoxetine, that have been received since market introduction and which may have no causal relationship with the drug, include: aplastic anaemia, cerebral vascular accident, confusion, dyskinesia, ecchymoses, eosinophilic pneumonia, gastro-intestinal haemorrhage, hyperprolactinaemia, immune-related haemolytic anaemia, movement disorders, neuroleptic malignant syndrome-like events, pancreatitis, pancytopenia, suicidal ideation, thrombocytopenia, thrombocytopenic purpura, vaginal bleeding after drug withdrawal, violent behaviours and visual disturbance. Any adverse reactions or events should be reported to the NDAB. **Overdosage** As of December 1987, there have been 2 deaths in patients who took overdoses of fluoxetine in combination with other drugs (maprotiline, codeine, temazepam). Except for these deaths, all other 36 overdose cases which involved fluoxetine either alone or in combination with other drugs and/or alcohol recovered without complications. One patient who reportedly took 3000mg of fluoxetine experienced 2 grand mal seizures that remitted spontaneously. Since introduction, reports of death attributed to overdosage of fluoxetine alone have been extremely rare. **Legal Category** S.1.A. **Product Authorisation Numbers** Capsules: 447/5/1 Liquid: 47/77/1 **Date of Preparation or Last Review** September 1995

Full Prescribing Information is Available From
Dista Products Limited/Eli Lilly and Company Limited, Dextra Court, Chapel Hill, Basingstoke, Hampshire, RG21 5SY.
Telephone: Basingstoke (01256) 52011 *or* 44 Fitzwilliam Place, Dublin 2.
Telephone: Dublin 6614377 'PROZAC' is a trade mark
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Cover Illustration

'THE DOUBLE JOCKEY ACT', by Jack B. Yeats, 1916

The circus and circus life were among Yeats's richest sources of subject matter. To Yeats, as to other artists, such as Rouault, and writers like his brother, WB, the clown was a ready image of man's tragic situation, at once comical, courageous and pathetic. In his last paintings the clown is sublimated but here, in common with many early paintings, Yeats makes full use of the narrative, combining obvious brush work with heavy use of oils.

The painting was first exhibited at the Royal Hibernian Academy in Dublin in 1917.

Our thanks to Bristol-Myers Squibb for sponsoring the Cover image.

Abbreviated Prescribing Information: LUSTRAL* (sertraline)

Presentation: Tablets containing 50mg or 100mg sertraline. **Indications:** Treatment of symptoms of depressive illness. Prevention of relapse or recurrence of depressive episodes. **Dosage:** LUSTRAL should be given as a single daily dose with food. The initial dose is 50mg and the usual therapeutic dose is 50mg or 100mg daily. Dosage can be further increased, if appropriate, to 150mg or a maximum of 200mg daily. Patients should be maintained on the lowest effective dose. **Use in children:** Not recommended. **Use in the elderly:** Usual adult dose. **Contra-indications:** Hypersensitivity to LUSTRAL. 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 7 days should elapse before starting any MAOI following discontinuation of LUSTRAL. **Precautions, Warnings:** Renal insufficiency, ECT, epilepsy, driving. LUSTRAL should not be administered with benzodiazepines or other tranquillizers in patients who drive or operate machinery. The patient should be monitored for signs of suicide or mania. LUSTRAL has not been observed to produce dependence. **Drug Interactions:** Administer with caution in combination with other centrally active medication (e.g. lithium, tryptophan). 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. The potential of LUSTRAL to interact with e.g. propranolol and phenytoin has not been fully assessed. **Side-Effects:** Dry mouth, nausea, diarrhoea/loose stools, ejaculatory delay, tremor, increased sweating and dyspepsia. **Legal Category:** S1A. **Package Quantities:** 50mg tablet (PA 19/46/4) Calendar pack of 28; 100mg tablet (PA 19/46/5) Calendar pack of 28. Further information on request. Invicta* Pharmaceuticals. A Division of Pfizer Limited, Sandwich, Kent. **Invicta* Pharmaceuticals office in Dublin:** Pharmapark, Chapelizod, Dublin 20. Tel: Dublin 6268340.
*Trade Mark

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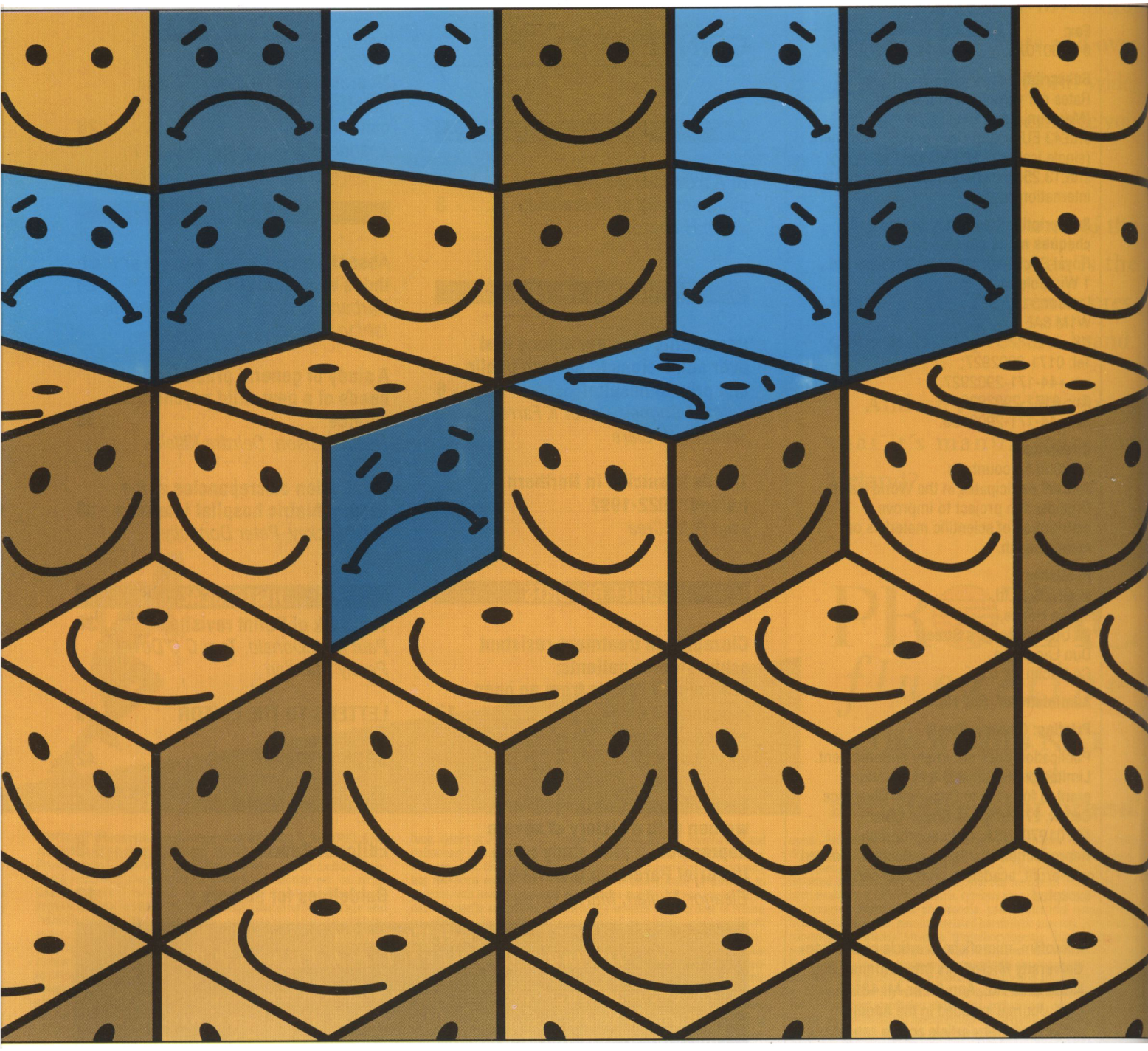

LUSTRAL* 50mg

sertraline

Builds success right from the start

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