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DUTONIN

FOR DEPRESSION

TOWARDS NORMAL NIGHTS AND PRODUCTIVE DAYS

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References 1. Dutonin Data Sheet, B.M.S. Ireland 1994. **Abbreviated Prescribing Information** PRESENTATION: Tablets containing 100mg and 200mg nefazodone hydrochloride. INDICATIONS: Symptomatic treatment of all types of depressive illness, including depressive syndromes accompanied by anxiety or sleep disturbances. Initially, this product should only be used under the surveillance of psychiatrists. All adverse drug reactions should be reported to the N.D.A.B. DOSAGE: Usual therapeutic dose 200mg twice daily. Range -200 mg -600mg daily, see data sheet. ELDERLY: Usual therapeutic dose 100-200mg twice daily. Renal and Hepatic Impairment: Lower end of dose range. Children: Not recommended below the age of 18 years. CONTRA-INDICATIONS: Hypersensitivity to nefazodone hydrochloride, tablet excipients or other phenylpiperazine antidepressants. WARNING/PRECAUTIONS: Hepatic or renal impairment. Patients at high risk of self harm should be kept under close supervision during initial treatment phase. Modest decrease in some psychomotor function tests but no impairment of cognitive function. Not recommended in pregnancy and lactation. Use with caution in epilepsy, history of mania/hypomania. No clinical studies available on concurrent use of ECT and nefazodone. DRUG INTERACTIONS: With other CNS medication, see data sheet. SIDE EFFECTS: Most frequently asthenia, dry mouth, nausea, somnolence and dizziness; see data sheet. OVERDOSAGE: There is no specific antidote for nefazodone. Gastric lavage recommended for suspected overdose. Treatment should be symptomatic and supportive in the case of hypotension or excessive sedation. PRODUCT LICENCE NUMBERS: Dutonin Tablets 100mg P.A. 2/60/2; Dutonin Tablets 200mg P.A 2/60/3. PRODUCT LICENCE HOLDER: Bristol-Myers Squibb Pharmaceuticals Limited. LEGAL CATEGORY: POM
Further information from: Medical Information, Bristol-Myers Squibb Pharmaceuticals Ltd., Swords, Co. Dublin. Telephone: (01) 840 6244. Date of Preparation: March 1995.

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CONTENTS

Cover Illustration: 'ST PATRICK'S CLOSE, DUBLIN', by Walter Osborne

Walter Osborne (1859-1903) was born in Dublin and attended the Schools of the Royal Hibernian Academy. He subsequently studied at the Antwerp Academy and worked in Brittany among a group of English Realist painters. Thereafter, he spent his life between England and Ireland, and died in Dublin of pneumonia at the age of 44. During his life his subject pictures, like this one, often remained unsold, and he was obliged to earn his living by portrait painting. Osborne called this picture *'Near St Patrick's Close, an old Dublin Street'*. The view, which is exact, is looking south along what is now Patrick Street, towards the Cathedral.

Our thanks to Bristol-Myers Squibb for sponsoring this Cover image

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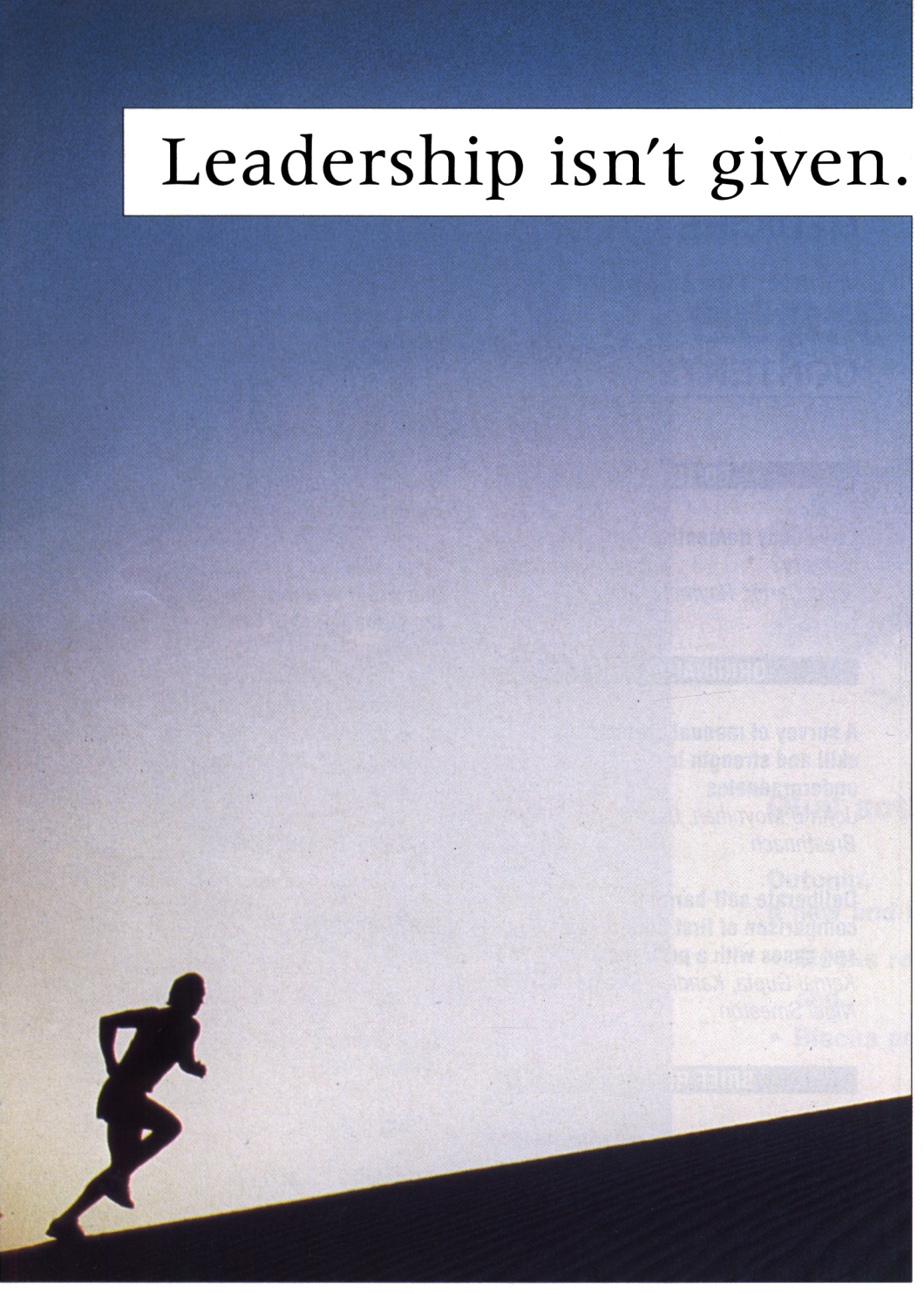

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'PROZAC' (fluoxetine hydrochloride) REPUBLIC OF IRELAND ABBREVIATED PRESCRIBING INFORMATION
Presentation Capsules containing 20mg fluoxetine, as the hydrochloride. Liquid containing 20mg fluoxetine, as the hydrochloride, per 5ml syrup. **Uses** Treatment 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
Reference: 1. Data on file, Eli Lilly Ltd.
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