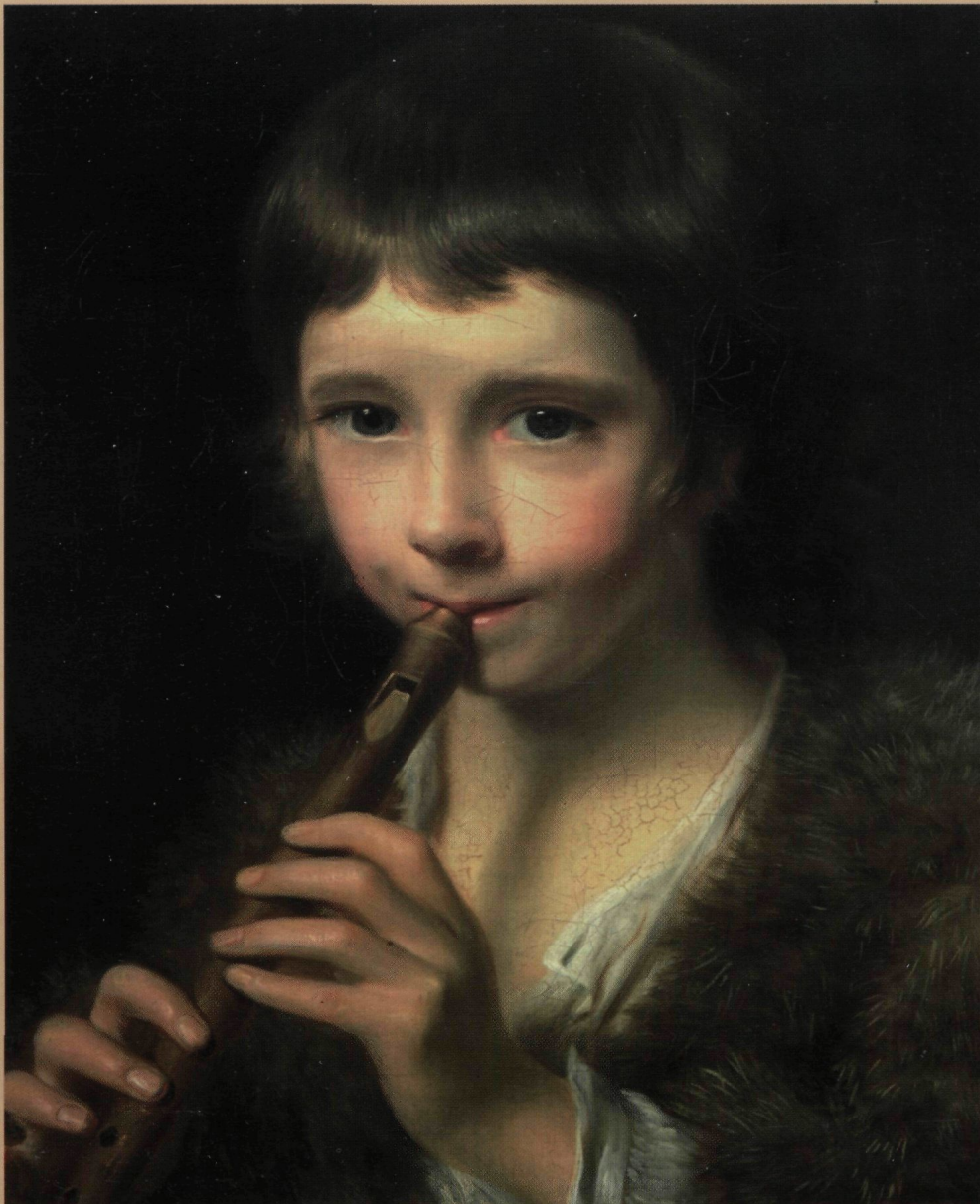


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References 1. Dutonin Data Sheet, B.M.S. Ireland 1994. **Abbreviated Prescribing Information** PRESENTATION: Tablets containing 100mg and 200mg nefazodone hydrochloride. INDICATIONS: Symptomatic treatment of all types of depressive illness, including 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

EDITORIAL

- Alcoholism: treating the 'Second
Sex'** 46
Diana G Patterson

ORIGINAL PAPERS

- Outcome of treatment for Irish
alcoholic women** 48
*Eileen M Corrigan, Shane Butler,
Michael J Camasso*

- A descriptive study of juvenile
delinquents** 53
Jim Barnes, Noel O'Gorman

PERSPECTIVE

- Training in psychodynamic
psychotherapy: the psychiatric
trainee's perspective** 57
*Peter J Trigwell, Stephen Curran, John
Milton, Celli Rowe*

- Commentary on: "Training in
psychodynamic psychotherapy: the
psychiatric trainees perspective"** 59
Anthony W Clare

CLINICAL AND BRIEF REPORTS

- Psychiatric presentation of frontal
meningiomas** 61

*Sabina Fahy, Teresa G Carey, John M
Owens, Anthony P Owens*

- Neuroleptic induced blepharospasm
and its treatment with botulinum
toxin type A** 64
Hagen Rampes, Ashok G Patel

- Wernicke-Korsakoff syndrome
following self-induced starvation** 66
Dinesh K Arya

- Secondary mania following cerebral
hypoxia** 68
Gary Sullivan, Peter L Jenkins

- Nicotine patches and paranoid
psychosis** 70
*Geoffrey Michael Marston, Irene Dove
Cormac*

REVIEW

- Non-compliance and related
phenomena** 72
Brian O'Shea

HISTORICAL

- The Tukes of York** 77
Caomhghin S Breathnach

- LETTERS TO THE EDITOR** 81

- BOOK REVIEWS** 79

- John Dunne Medal** 47

- Index to advertisers** 45

- Editorial Board** 46

- Guidelines for authors** 56

Cover Illustration: 'THE PIPING BOY'
by Nathaniel Hone, 1769

Nathaniel Hone (1718-1784) was an Irish artist
who developed a flourishing practice in
London and became a founding member of the
Royal Academy in 1768. The following year
he exhibited the 'Piping Boy' - a portrait of his
son Camillus dressed as a shepherd boy. This
type of subject matter was hugely popular with
the general public at the time. Camillus later
became an artist himself working principally in
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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 and 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. **Use 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 possible allergic phenomena for which and 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. **Use 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 diabetic, 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 P4501D6 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** **Depression:** The following treatment-emergent adverse events were observed during placebo controlled clinical trials at a frequency of one per cent or greater and at a significantly higher incidence than placebo (P value <0.05): Asthenia, fever, nausea, diarrhoea, mouth dryness, appetite loss, dyspepsia, headache, nervousness, insomnia, drowsiness, anxiety, tremor, dizziness, fatigue, decreased libido, pharyngitis, dyspnoea, excessive sweating, rash, see 'Warnings'; sexual dysfunction. **Bulimia:** Using the same criteria: insomnia, nausea, asthenia, tremor, sweating, decreased libido. The more common events listed above that caused discontinuation include nausea, headache, nervousness, insomnia, anxiety, dizziness and asthenia. Other events that have been reported include vomiting, dysphoria, hallucinations, psychosis and convulsions. During pre-marketing testing hypomania or mania occurred in approximately 1 per cent of fluoxetine treated patients. Elevated serum transaminase values and/or depressed leucocyte counts without accompanying symptoms occurred infrequently in patients given fluoxetine. 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 and violent behaviours. Hyponatraemia (including serum sodium below 110mmol/l) has been rarely reported. This appears to be reversible upon discontinuation. 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 300mg 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: 4777/1 **Date of Preparation or Last Review** December 1994 **Full Prescribing Information is Available From** Eli Lilly and Company (Ireland) Limited 3 Kingram Place Dublin 2 Telephone: Dublin 6614377 or 6614475 'PROZAC' is a trade mark **IFD14AUPR94**

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