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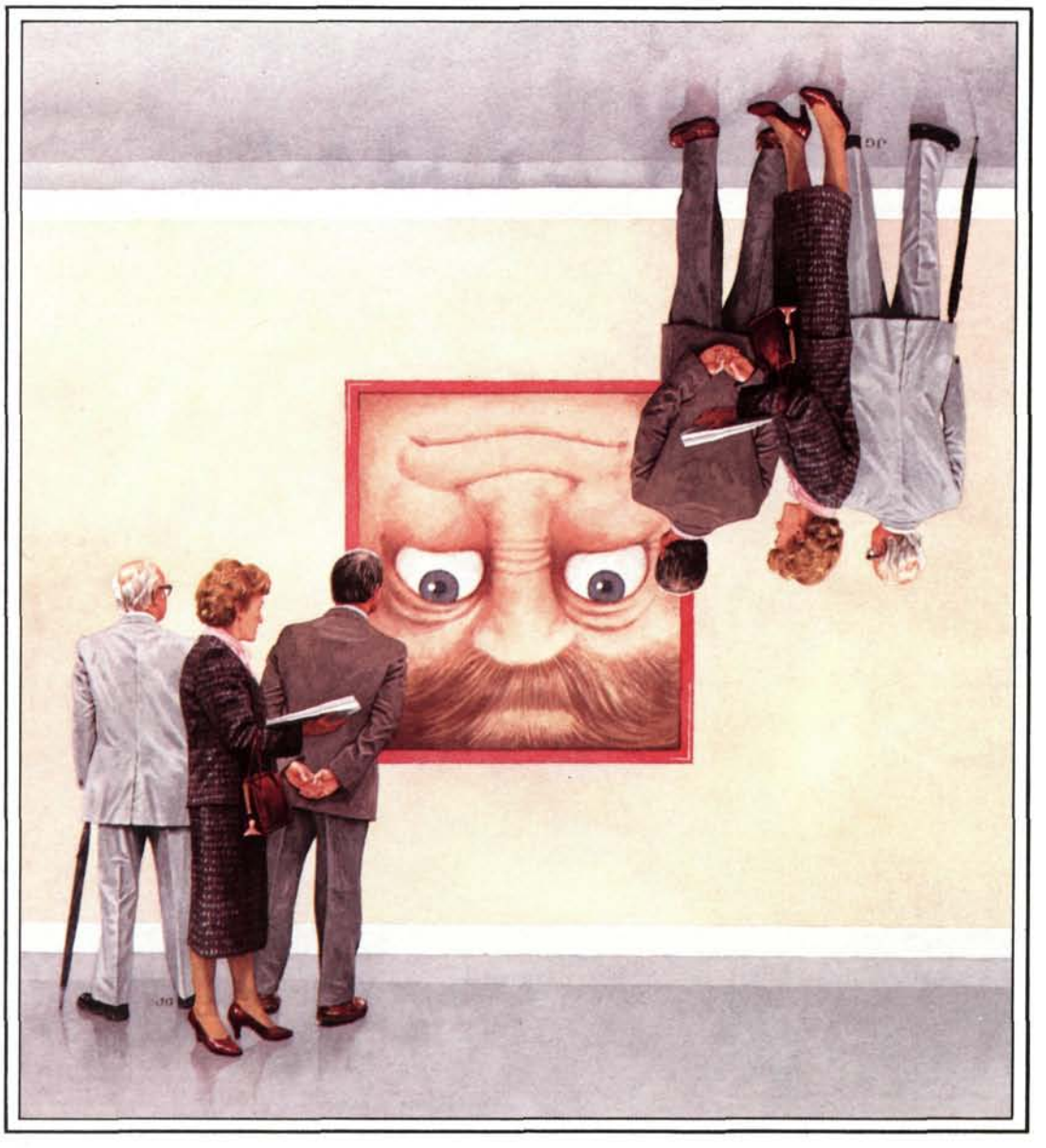

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1) Johnson DAW Br J Psychiat 1975; 126: 457-461.

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CONTENTS

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PROZAC REPUBLIC OF IRELAND ABBREVIATED PRESCRIBING INFORMATION
(FLUOXETINE HYDROCHLORIDE)

Presentation Capsules containing 20mg fluoxetine hydrochloride.
Uses: Treatment of the symptoms of depressive illness.
Dosage and Administration:
(For full information, see data sheet).
For oral administration to adults only.
Depression: A dose of 20mg/day is recommended. Because of the long elimination half-lives of the parent drug and its major metabolite, changes in dose will not be fully reflected in plasma for several weeks.
Bulimia: A dose of 60mg/day is recommended.
The maximum daily dose should not exceed 80mg for any indication.
The elderly: The maximum total daily dose should not exceed 40mg.
Children: Not recommended.
Patients with renal and/or hepatic dysfunction: See 'Contra-indications' and 'Precautions' sections.
Contra-indications, Warning, etc.: *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 has been recently discontinued and an MAOI started. 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, e.g. 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.

SEE THE PROBLEM
IN A NEW LIGHT

Prozac 20 mg
Once daily

IN DEPRESSION

fluoxetine
PROZAC

Drug interactions: Monoamine oxidase inhibitors – see 'Contra-indications'.
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 gastrointestinal distress have been reported in five patients receiving fluoxetine in combination with tryptophan.
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: cerebral vascular accident, confusion, dyskinesia, ecchymoses, gastro-intestinal haemorrhage, hyperprolactinaemia, pancreatitis, 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 3000mg of fluoxetine experienced 2 grand mal seizures that remitted spontaneously.
Since introduction, a single death, attributed to overdose of fluoxetine alone, has been reported.
Legal Category S.L.A. Product Authorisation Number 447/5/1
Date of Preparation or Last Review February 1991
Further information is available from: Eli Lilly & Co Ltd, 3 Kingram Place, Dublin 2. Telephone: Dublin 614377 or 614475
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