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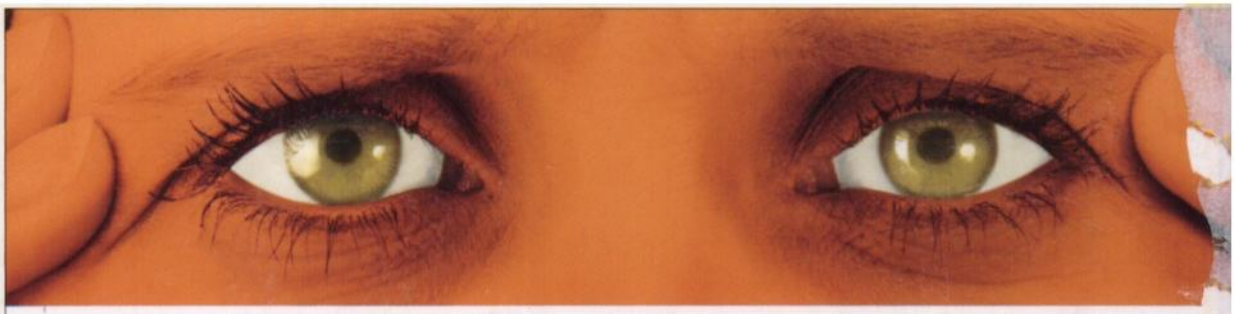
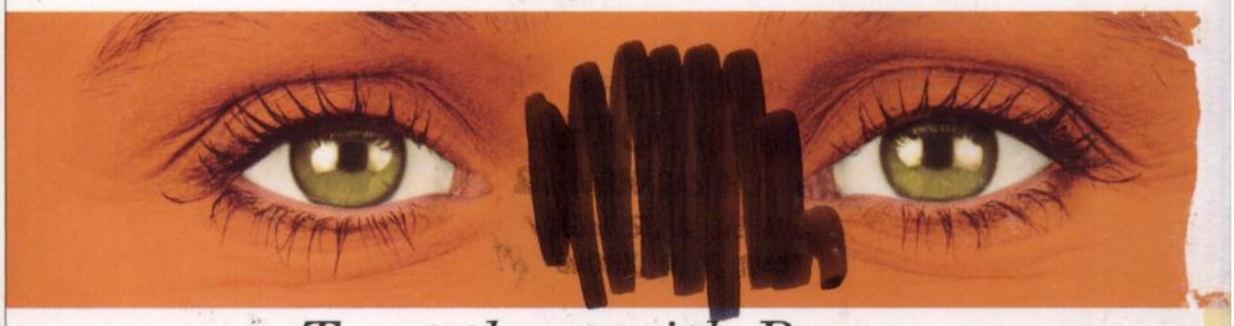


Depressed and anxious, but there's no need for daytime sedation.



Treat them with Prozac.

50-70% of patients with depression also have associated anxiety,[1] but today you can treat them just as effectively without daytime sedation.

Prozac lifts depression and associated anxiety as effectively as tricyclics[2-4] while offering patients a natural nights sleep followed by a sedation-free day.[4,6]

For today's response to depression, rely on Prozac, the World's No. 1 prescribed brand antidepressant.[5]

Once a day

PROZAC

fluoxetine

The World's No.1 prescribed brand name in depression

'PROZAC' (FLUOXETINE HYDROCHLORIDE) **ABBREVIATED PRESCRIBING INFORMATION** **Presentation** Capsules containing 20mg fluoxetine, as the hydrochloride. Liquid containing 20mg fluoxetine, as the hydrochloride, per 5ml syrup. **Uses** *Depression:* Treatment of the symptoms of depressive illness. *Obsessive-compulsive disorder. Bulimia nervosa:* For the reduction of binge-eating and purging activity. **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. *Obsessive-compulsive disorder:* 20mg/day to 60mg/day. A dose of 20mg/day is recommended as the initial dose. *Bulimia - adults and the elderly:* A dose of 60mg/day is recommended. 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 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). *Usage in nursing mothers:* Prozac should not be prescribed to nursing mothers. *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 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. **Warnings** *Rash and allergic reactions:* Angioneurotic oedema, urticaria and other allergic reactions have been reported. Upon appearance of rash, or of other allergic phenomena for which an alternative aetiology cannot be identified, Prozac should be discontinued. *Pregnancy:* Use of Prozac should be avoided unless there is no safer alternative. **Precautions** Prozac should be discontinued in any patient who develops seizures. Prozac should be avoided in patients with unstable epilepsy; patients with controlled epilepsy should be carefully monitored. There have been rare reports of prolonged seizures in patients on fluoxetine receiving ECT treatment. 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 have been reports of abnormal bleeding in several patients, but causal relationship to fluoxetine and clinical importance are unclear. *Drug interactions:* Increased (with lithium toxicity) or decreased lithium levels have been reported. Lithium levels should be monitored. 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 cyclic antidepressants have been observed when Prozac has been administered in combination. Agitation, restlessness and gastro-intestinal symptoms have been reported in a small number of patients receiving fluoxetine in combination with tryptophan. Patients on stable phenytoin doses have developed elevated plasma concentrations and clinical phenytoin toxicity after starting fluoxetine. *For further information, see data sheet.* **Adverse 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, dyskinesia, movement disorders, neuroleptic malignant syndrome-like events, pharyngitis, dyspnoea, pulmonary events (including inflammatory processes and/or fibrosis), rash, urticaria, vasculitis, serum sickness, anaphylactoid reactions, hair loss, excessive sweating, sexual dysfunction. 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. Hyponatremia (including serum sodium below 110mmol/1) has been rarely reported. This appears to be reversible upon discontinuation. **Overdosage** On the evidence available, fluoxetine has a wide margin of safety in overdose. Since introduction, reports of death, attributed to overdosage of fluoxetine alone, have been extremely rare. One patient who reportedly took 3000mg of fluoxetine experienced 2 grand mal seizures that remitted spontaneously. **Legal Category** POM **Product Licence Numbers** 0006/0195, 0006/0272. **Basic NHS Cost** £20.77 per pack of 30 capsules. £67.85 per pack of 98 capsules. £19.39 per 70ml bottle. **Date of Preparation or Last Review:** Oct. 1994. **Full Prescribing Information is Available From** Dista Products Limited, Dextra Court, Chapel Hill, Basingstoke, Hampshire RG21 2SY Telephone: Basingstoke (0256) 52011. 'PROZAC' is a Dista trade mark.

References: 1. Kaplan H.I., Sadock B.J. Pocket Handbook of Clinical Psychiatry, 1990 **2.** Harris, et al, Data on file, Dista Products Ltd. **3.** Judd F, J.A.M.A., S.E.A., 1991; *(Dec. Suppl.)*: 31-33 **4.** Stokes P.E., *Clin Therap.*, 1993; **15(2)**: 216-243 **5.** Data on file, Dista Products Ltd. **6.** Fairweather D.B., *et al, Human Psychopharmacol*, 1993; **8:** 41-47.

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