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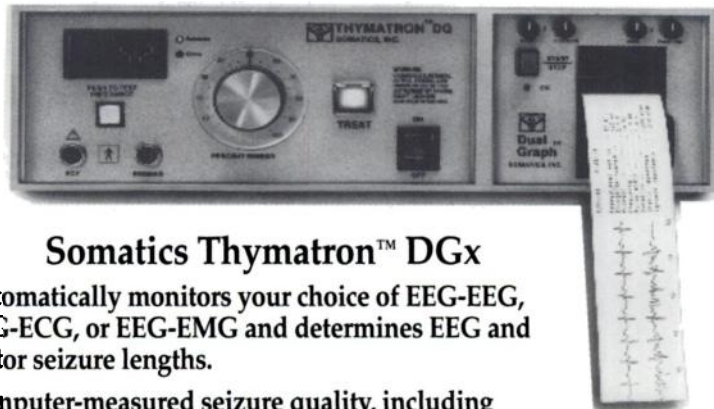
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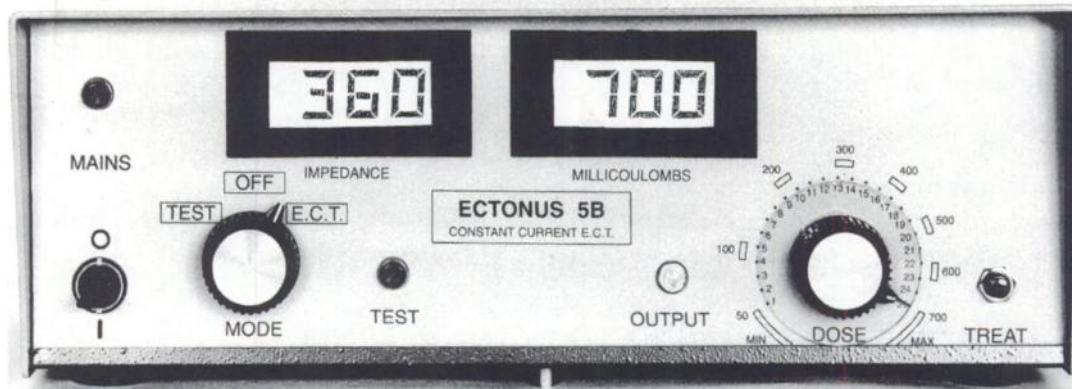
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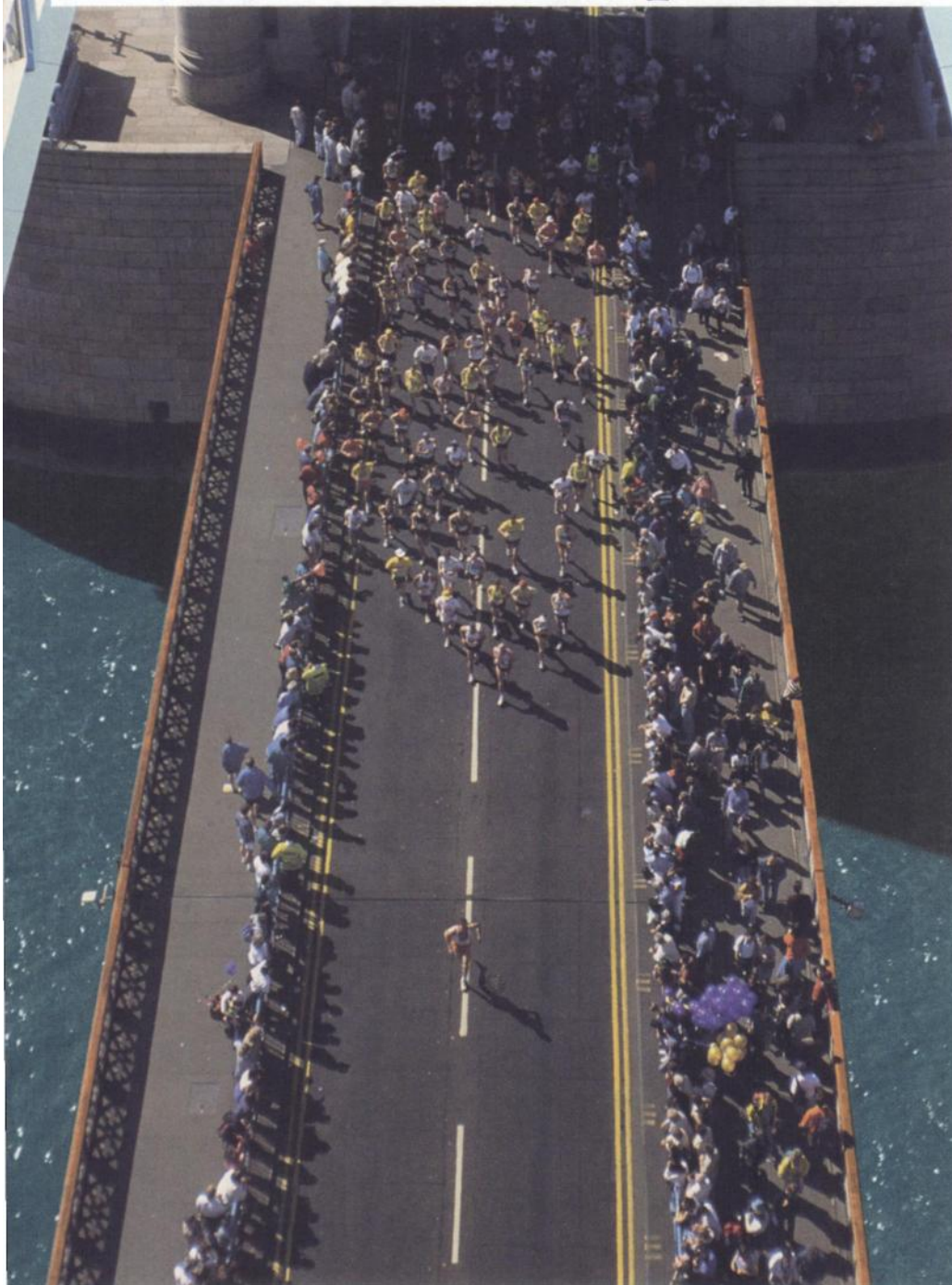
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'PROZAC' ABBREVIATED PRESCRIBING INFORMATION (FLUOXETINE HYDROCHLORIDE)
Presentation Capsules containing 20mg or 60mg fluoxetine, as the hydrochloride. Liquid containing 20mg fluoxetine, as the hydrochloride, per 5ml syrup. **USES Depression: TREATMENT OF THE SYMPTOMS OF DEPRESSIVE ILLNESS, WITH OR WITHOUT ASSOCIATED ANXIETY SYMPTOMS.** *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, with or without associated anxiety symptoms - 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 initiated during breastfeeding. **Drug interactions:** Increased (with lithium toxicity) or decreased lithium levels

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 reaction:* 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 Prozac has not been established. **Adverse Effects** (increased with lithium toxicity) or decreased lithium levels

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, rarely abnormal LFTs, 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, excessive sweating, arthralgia, myalgia, serum sickness, anaphylactoid reactions, hair loss, 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

Hyponaatraemia (including serum sodium below 110mmol/l) 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 0006/0198 0006/0272 **Basic NHS Cost** £20.77 per pack of 30 capsules (20mg), £67.85 per pack of 98 capsules (20mg), £62.31 per pack of 30 capsules (60mg), £19.39 per 70ml bottle. **Date of Preparation or Last Review** October 1996. **Full Prescribing Information is Available** From Dista Products Limited, Dextra Court, Chapel Hill, Basingstoke, Hampshire, RG21 5SY. Telephone: Basingstoke (01256) 52011 'PROZAC' is a Dista trademark

References: 1. Data on file, Dista Products Ltd. 2. Tignol J. *J Clin Psychopharm* 1993; 13 (6, suppl. 2): 18S-22S. 3. Bennie EH, Mullin JM, Martindale JJ. *J Clin Psychiatry* 1995; 56: 229-237. 4. Prozac Data Sheet 24M.

Date of preparation: May 1997

PZ 906



An advance in the treatment of depression



DIRECTLY ACTS ON BOTH
SEROTONIN AND NORADRENALINE¹



HIGH RESPONSE RATES^{2,3}



REDUCES AGITATION⁴ AND IMPROVES
SLEEP PATTERNS⁵ AFTER 1 WEEK



LOW POTENTIAL FOR DRUG
INTERACTIONS^{**6-9}

** HEALTHY VOLUNTEER STUDIES

EFEXOR^{*}

VENLAFAXINE 37.5mg b.d.

SEROTONIN NORADRENALINE REUPTAKE INHIBITOR

PRESCRIBING INFORMATION: PRESENTATION: Tablets containing 37.5mg, 50mg or 75mg venlafaxine (as hydrochloride). USE: Treatment of depressive illness. DOSAGE: Usually 75mg/day (37.5mg bd) with food, increasing to 150mg/day (75mg bd) if necessary. In more severely depressed patients, 150mg/day (75mg bd) increasing every 2 or 3 days in up to 75mg/day increments to a maximum of 375mg/day, then reducing to usual dose consistent with patient response. Discontinue gradually. Elderly: use normal adult dose. Children: contraindicated. Doses should be reduced by 50% for moderate renal or moderate hepatic impairment. CONTRA-INDICATIONS: Pregnancy, lactation, concomitant use with MAOIs, hypersensitivity to venlafaxine or other components, patients aged below 18 years. PRECAUTIONS: Use with caution in patients with myocardial infarction, unstable heart disease, renal or hepatic impairment, or a history of epilepsy (discontinue in event of seizure). Possibility of postural hypotension (especially in the

elderly). Prescribe smallest quantity of tablets according to good patient management. Monitor blood pressure with doses > 200mg/day. Advise patients to notify their doctor should an allergy develop or if they become or intend to become pregnant. Use with caution in patients taking other CNS-active drugs or in the elderly or hepatically-impaired patients taking cimetidine. Patients with a history of drug abuse should be monitored carefully. Not recommended in severe renal or severe hepatic impairment. INTERACTIONS: MAOIs: do not use Efexor in combination with MAOIs or within 14 days of stopping MAOI treatment. Allow 7 days after stopping Efexor before starting a MAOI. SIDE-EFFECTS: Nausea, headache, insomnia, somnolence, dry mouth, dizziness, constipation, asthenia, sweating, nervousness, anorexia, dyspepsia, abdominal pain, anxiety, impotence, abnormality of accommodation, vasodilation, vomiting, tremor, paraesthesia, abnormal ejaculation/orgasm, chills, agitation, weight gain, agitation, decreased libido, rise in blood pressure, postural hypotension, reversible increases in liver

BASIC NHS PRICE: 37.5mg tablet (PL 0011/0199) – Calendar pack of 56 tablets: £23.97, 50mg tablet (PL 0011/0200) – Blister pack of 42 tablets: £23.97, 75mg tablet (PL 0011/0201) – Calendar pack of 56 tablets: £39.97. LEGAL CATEGORY: POM. Further information is available upon request. PRODUCT LICENCE HOLDER: Wyeth Laboratories (John Wyeth & Brother Limited), Taplow, Maidenhead, Berkshire, SL6 0PH. Space photography provided courtesy of National Aeronautics and Space Administration (NASA). References: 1. Muth EA *et al.* *Biochem Pharmacol* 1986; 35(24): 4493-4497. (EX00007). 2. Dierick M *et al.* *Prog Neuropsychopharmacol Biol Psychiat* 1996; 20: 57-71. 3. Clerc GE *et al.* *Int Clin Psychopharmacol* 1994; 9(3): 139-143. (EX00101). 4. Entsuah R *et al.* *Human Psychopharmacol* 1995; 10: 195-200. 5. Data on file, 635. 6. Troy SM *et al.* *J Clin Pharmacol* 1995; 35: 410-419. 7. Data on file, 20276. 8. Parker V *et al.* *J Clin Pharmacol* 1991; 3(9): 867 (Abstract 110). (EX00023). 9. Troy S *et al.* *Clin Neuropharm* 1992; 15(Suppl 1 pt B): 324B. (EX00067). Date of preparation: 1/9/99

Wyeth

**WE WON'T
PROMISE
THE WORLD**



**BUT ZYPREXA MAY
FIND A PLACE**

ABBREVIATED PRESCRIBING INFORMATION: **Presentation:** Coated tablets containing 5mg, 7.5mg or 10mg of olanzapine. The tablets also contain lactose. **Uses:** Schizophrenia, both as initial therapy and for maintenance of response. **Further Information:** In studies of patients with schizophrenia and associated depressive symptoms, mood score improved significantly more with olanzapine than with haloperidol. Olanzapine was associated with significantly

greater improvements in both negative and positive schizophrenic symptoms than placebo or comparator in most studies. **Dosage and Administration:** 10mg/day orally, as a single dose without regard to meals. Dosage may subsequently be adjusted within the range of 5-20mg daily. An increase to a dose greater than the routine therapeutic dose of 10mg/day is recommended only after clinical assessment. **Children:** Not recommended under 18 years of age. **The elderly:** A lower starting dose (5mg/day) is not routinely indicated but should be considered when clinical factors warrant. **Hepatic and/or renal impairment:** A lower starting dose (5mg) may be considered. When more than one factor is present which might result in slower metabolism (female gender, elderly age, non-smoking status), consideration should be given to decreasing the starting dose. Dose escalation should be conservative in such patients. Known hypersensitivity to any ingredient of the product. Known risk for narrow-angle glaucoma. **Warnings and Special**

Precautions: Caution in patients with prostatic hypertrophy, or paralytic ileus and related conditions. Caution in patients with elevated ALT and/or AST, signs and symptoms of hepatic impairment pre-existing conditions associated with limited hepatic functional reserve, and in patients who are being treated with potentially hepatotoxic drugs. As with other neuroleptic drugs, caution in patients with low leucocyte and/or neutrophil counts for any reason, a history of drug-induced bone marrow depression/toxicity, bone marrow depression caused by concomitant illness, radiation therapy or chemotherapy and in patients with hypereosinophilic conditions or with myeloproliferative disease. Thirty-two patients with clozapine-related neutropenia or agranulocytosis histories received olanzapine without decreases in baseline neutrophil counts. Although, in clinical trials, there were no reported cases of NMS in patients receiving olanzapine, if such an event occurs, or if there is unexplained high fever, all patients should be treated with caution.

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promise to put patients' lives back the way they were. But the right choice of medication may help them find a place in their community.

Zyprexa demonstrated improvement in the negative as well as the positive symptoms of schizophrenia (in four out of five controlled trials in patients presenting with both positive and negative symptoms).¹⁻³

With a simple once-daily dosage and no requirement for routine blood or ECG monitoring,⁴ Zyprexa may offer a step towards community re-integration.

Antipsychotic Efficacy for First-line Use

ZYPREXA
Olanzapine 
Making Community Re-integration the Goal

**HELP HIM
 IN IT**

Caution in patients who have a history of seizures or have conditions associated with seizures. If signs or symptoms of tardive dyskinesia appear a dose reduction or drug discontinuation should be considered. Caution when taken in combination with other centrally acting drugs and alcohol. Olanzapine may antagonise the effects of direct and indirect dopamine agonists. Postural hypotension was infrequently observed in the elderly. However, blood pressure should be measured periodically in patients over 65 years, as with other antipsychotics. As with other antipsychotics, caution when prescribed with drugs known to increase QTc interval, especially in the elderly. In clinical trials, olanzapine was not associated with a persistent increase in absolute QT intervals. **Interactions:** Metabolism may be induced by concomitant smoking or carbamazepine therapy. **Pregnancy and Lactation:** Olanzapine had no teratogenic effects in animals. Because human experience is limited, olanzapine should be used in pregnancy only if the potential benefit justifies the potential risk to the foetus. Olanzapine was excreted in the milk of treated rats but it is not known if it is excreted in human milk. Patients should be advised not to breast feed an infant if they are taking olanzapine. **Driving, etc:** Because olanzapine may cause somnolence, patients should be cautioned about operating hazardous machinery, including motor vehicles. **Undesirable Effects:** The only frequent (>10%) undesirable effects associated with the use of olanzapine in clinical trials were somnolence and weight gain. Occasional undesirable effects included dizziness, increased appetite, peripheral oedema, orthostatic hypotension, and mild, transient anticholinergic effects, including constipation and dry mouth. Transient, asymptomatic elevations of hepatic transaminases, ALT, AST have been seen occasionally. Olanzapine-treated patients had a lower incidence of Parkinsonism, akathisia and dystonia in trials compared with orally active doses of haloperidol. Photosensitivity reaction or high creatinine phosphokinase were reported rarely. Plasma prolactin levels were sometimes

elevated, but associated clinical manifestations were rare. Asymptomatic haematological variations were occasionally seen in trials. *For further information see summary of product characteristics. Legal Category: POM Marketing Authorisation Numbers: EU/1/96/022/004 EU/1/96/022/004 EU/1/96/022/009 EU/1/96/022/010. Basic NHS Cost: £52.73 per pack of 21 x 5mg tablets. £105.47 per pack of 28 x 10mg tablets. £158.20 per pack of 51 x 7.5mg tablets. £210.93 per pack of 56 x 10mg tablets. Date of Preparation August 1996. Full Prescribing Information is Available From: Lilly Industries Limited, Dextra Court, Chapel Hill, Basingstoke, Hampshire RG2 5SY. Telephone: Basingstoke (01256) 315000. ZYPREXA is a Lilly trademark. References: 1. Data on file, Lilly Industries. 2. Data on file, Lilly Industries. 3. Zyprexa Summary of Product Characteristics, Section 5.1: Pharmacodynamic Properties. 4. Zyprexa Summary of Product Characteristics*

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RISPERDAL™ ABBREVIATED PRESCRIBING INFORMATION

Please refer to Summary of Product Characteristics before prescribing Risperdal (risperidone). USES The treatment of acute and chronic schizophrenia, and other psychotic conditions, in which positive and/or negative symptoms are prominent. Risperdal also alleviates affective symptoms associated with schizophrenia. DOSAGE Where medically appropriate, gradual discontinuation of previous antipsychotic treatment while Risperdal therapy is initiated is recommended. Where medically appropriate, when switching patients from depot antipsychotics, consider initiating Risperdal therapy in place of the next scheduled injection. The need for continuing existing antiparkinson medication should be re-evaluated periodically. Adults: Risperdal may be given once or twice daily. All patients, whether acute or chronic, should start with 2 mg/day. This should be increased to 4 mg/day on the second day and 6 mg/day on the third day. However, some patients such as first-episode psychotic patients may benefit from a slower rate of titration. From then on the dosage can be maintained unchanged, or further individualised if needed. The usual effective dosage is 4 to 8 mg/day although in some patients an optimal response may be obtained at lower doses. Doses above 10 mg/day may increase the risk of extrapyramidal symptoms and should only be used if the benefit is considered to outweigh the risk. Doses above 16 mg/day should not be used. Elderly, renal and liver disease: A starting dose of 0.5 mg bd is recommended. This can be individually adjusted with 0.5 mg bd increments to 1 to 2 mg bd. Risperdal is well tolerated by the elderly. Use with caution in patients with renal and liver disease. Not recommended in children aged less than 15 years. CONTRAINDICATIONS, WARNINGS, ETC. Contraindications: Known hypersensitivity to Risperdal. Precautions: Orthostatic hypotension can occur (alpha-blocking effect). Use with caution in patients with known cardiovascular disease. Consider dose reduction if hypotension occurs. For further sedation, give an additional drug (such as a benzodiazepine) rather than increasing the dose of Risperdal. Drugs with dopamine antagonistic properties have been associated with tardive dyskinesia. If signs and symptoms of tardive dyskinesia appear, the discontinuation of all antipsychotic drugs should be considered. Caution should be exercised when treating patients with Parkinson's disease or epilepsy. Patients should be advised of the potential for weight gain. Risperdal may interfere with activities requiring mental alertness. Patients should be advised not to drive or operate machinery until their individual susceptibility is known. Pregnancy and lactation: Use during pregnancy only if the benefits outweigh the risks. Women receiving Risperdal should not breast feed. Interactions: Use with caution in combination with other centrally acting drugs. Risperdal may antagonise the effect of levodopa and other dopamine agonists. On initiation of carbamazepine or other hepatic enzyme-inducing drugs, the dosage of Risperdal should be re-evaluated and increased if necessary. On discontinuation of such drugs, the dosage of Risperdal should be re-evaluated and decreased if necessary. Side effects: Risperdal is generally well tolerated and in many instances it has been difficult to differentiate adverse events from symptoms of the underlying disease. Common adverse events include: insomnia, agitation, anxiety, headache. Less common adverse events include: somnolence, fatigue, dizziness, impaired concentration, constipation, dyspepsia, nausea/vomiting, abdominal pain, blurred vision, priapism, erectile dysfunction, ejaculatory dysfunction, orgasmic dysfunction, urinary incontinence, rhinitis, rash and other allergic reactions. The incidence and severity of extrapyramidal symptoms are significantly less than with haloperidol. However, the following may occur: tremor, rigidity, hypersalivation, bradykinesia, akathisia, acute dystonia. If acute, these symptoms are usually mild and reversible upon dose reduction and/or administration of antiparkinson medication. Rare cases of Neuroleptic Malignant Syndrome have been reported. In such an event, all antipsychotic drugs should be discontinued. Occasionally, orthostatic dizziness, hypotension (including orthostatic), tachycardia (including reflex) and hypertension have been observed. An increase in plasma prolactin concentration can occur which may be associated with galactorrhoea, gynaecomastia and disturbances of the menstrual cycle. Oedema and increased hepatic enzyme levels have been observed. A mild fall in neutrophil and/or thrombocyte count has been reported. Rare cases of water intoxication with hyponatraemia, tardive dyskinesia, body temperature dysregulation and seizures have been reported. Overdosage: Reported signs and symptoms include drowsiness and sedation, tachycardia and hypotension, and extrapyramidal symptoms. A prolonged QT interval was reported in a patient with concomitant hypokalaemia who had ingested 360mg. Establish and maintain a clear airway, and ensure adequate oxygenation and ventilation. Gastric lavage and activated charcoal plus a laxative should be considered. Commence cardiovascular monitoring immediately, including continuous electrocardiographic monitoring to detect possible arrhythmias. There is no specific antidote, so institute appropriate supportive measures. Treat hypotension and circulatory collapse with appropriate measures. In case of severe extrapyramidal symptoms, give anticholinergic medication. Continue close medical supervision and monitoring until the patient recovers. PHARMACEUTICAL PRECAUTIONS Tablets: Store below 30°C. Liquid: Store between 15°C and 30°C and protect from freezing. LEGAL CATEGORY POM. PRESENTATIONS, PACK SIZES, PRODUCT LICENCE NUMBERS & BASIC NHS COSTS White, oblong tablets containing 1 mg risperidone in packs of 20. PL 0242/0186 £13.45. Pale orange, oblong tablets containing 2 mg risperidone in packs of 60. PL 0242/0187 £79.56. Yellow, oblong tablets containing 3 mg risperidone in packs of 60. PL 0242/0188 £117.00. Green, oblong tablets containing 4 mg risperidone in packs of 60. PL 0242/0189 £154.44. Starter packs containing 6 Risperdal 1 mg tablets are also available £4.15. Clear, colourless solution containing 1 mg risperidone per ml in bottles containing 100 ml. PL 0242/0199 £65.00. FURTHER INFORMATION IS AVAILABLE FROM THE PRODUCT LICENCE HOLDER: Janssen-Cilag Ltd, Saunderton, High Wycombe, Buckinghamshire HP14 4HJ.

Date of preparation: April 1997

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BRIEF PRESCRIBING INFORMATION

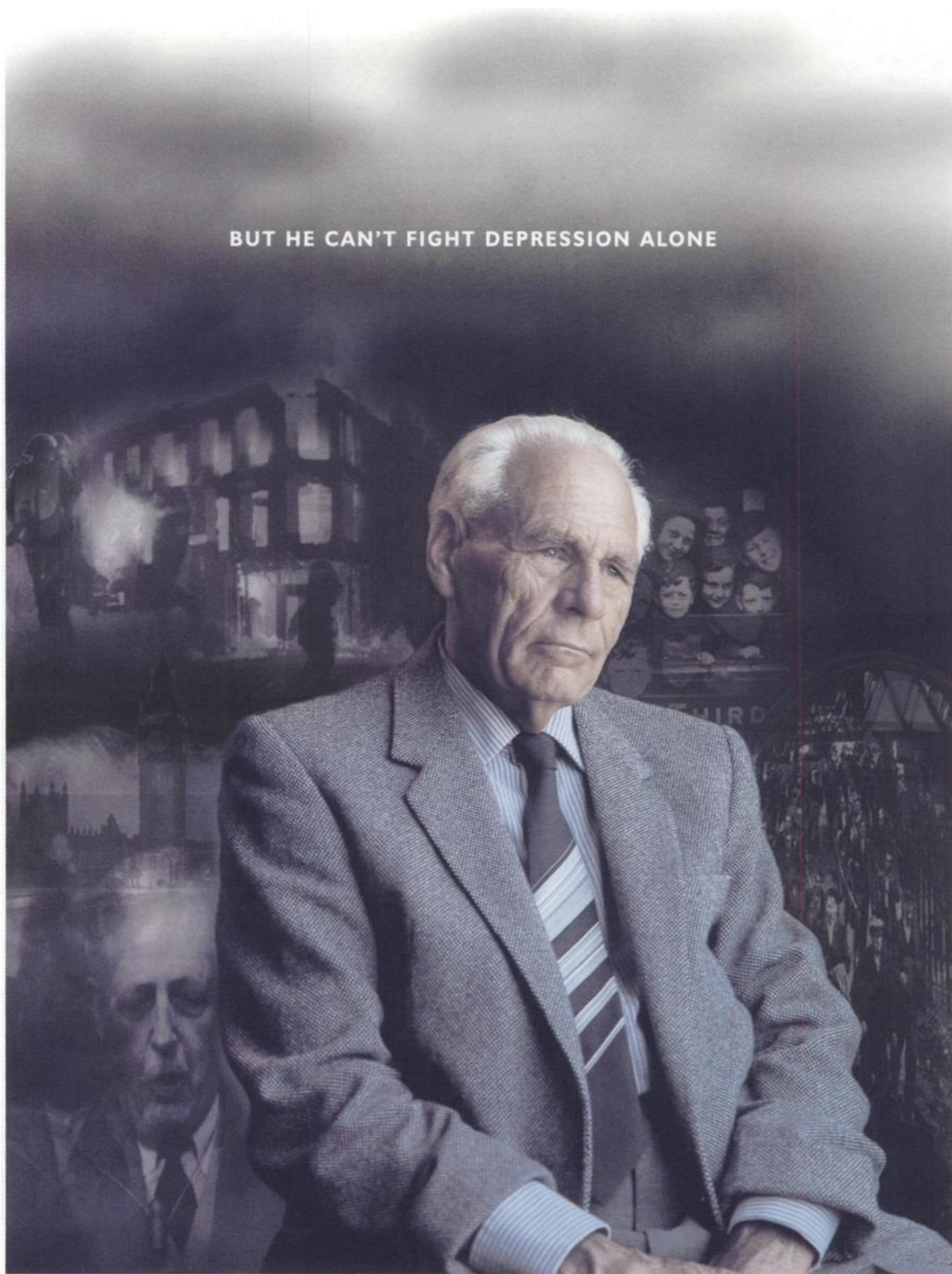
ARICEPT® (donepezil hydrochloride)
 Please refer to the SmPC before prescribing ARICEPT 5mg or ARICEPT 10mg. **Indication:** Symptomatic treatment of mild or moderate dementia in Alzheimer's disease. **Dose and administration:** *Adults/elderly:* 5mg once daily which may be increased to 10mg once daily after at least one month. No dose adjustment necessary for patients with renal or mild-moderate hepatic impairment. **Children;** Not recommended. **Contra-indications:** Hypersensitivity to donepezil, piperidine derivatives or any excipients used in ARICEPT. **Pregnancy and lactation:** Use only if benefit outweighs risk. Excretion into breast milk unknown. **Precautions:** Possible effects upon pre-existing cardiac disease, asthma, or obstructive pulmonary disease, also in patients at increased risk of peptic ulcers. Cholinomimetics may cause urinary retention (not observed in clinical trials), convulsions (may be disease related). **Side effects:** Most commonly diarrhoea, muscle cramps, fatigue, nausea, vomiting, insomnia and dizziness. Minor increases in muscle creatine kinase but no notable laboratory abnormalities reported. **Presentation and basic NHS cost:** Blister packed in strips of 14. ARICEPT 5mg; white, film coated tablets marked 5 and Aricept, packs of 28 £68.32. ARICEPT 10mg; yellow, film coated tablets marked 10 and Aricept, packs of 28 £95.76. **Marketing authorisation numbers:** ARICEPT 5mg; PL 10555/0006 ARICEPT 10mg; PL 10555/0007. **Marketing authorisation holder:** Eisai Europe Ltd. **Further information from/Marketed by:** Eisai Ltd, Hammersmith International Centre, 3 Shortlands, London, W6 8EE and Pfizer Ltd, Sandwich, Kent, CT13 9NJ. **Legal category:** POM. **Date of preparation:** March 1997. **References:** 1. Kelly CA, Harvey RJ, Cayton H. Br Med J 1997; 314: 693-694. 2. Rogers SL et al. In : Becker R, Giacobini E, eds. Cholinergic Basis for Alzheimer Therapy. Boston: Birkhauser; 1991: 314-320. 3. Kawakami Y et al. Bioorganic & Medicinal Chemistry 1996; 4 (6): 1429-1446. 4. Data on file, Integrated Summary of Safety. 5. Data on file (A301). 6. Data on file (A302) and Rogers SL et al. Neurology 1996; 46: A217. 7. Rogers SL et al. Dementia 1996; 7: 293-303.

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HE'S SURVIVED 1 WORLD WAR, 2 REDUNDANCIES AND 9 GOVERNMENTS

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Molipaxin
trazodone HCl

150mg capsules, Molipaxin tablets 150mg, Molipaxin CR tablets 150mg, Molipaxin Liquid (50mg/5ml). **Indications:** Relief of symptoms in all types of depression including depression accompanied by anxiety. Symptoms likely to respond in the first week include depressed mood, insomnia, anxiety, somatic symptoms and hypochondriasis. **Dosage and Administration:** Starting dose of Molipaxin is 150mg daily taken in divided doses after food or as a single dose on retiring. This may be increased to 300mg/day the major portion of which is preferably taken on retiring. In hospitalised patients, dosage may be further increased to 600mg/day in divided doses. **Dosage in the elderly and frail:** Starting dose of 100mg/day in divided doses or as a single night-time dose. This may be increased, under supervision, according to efficacy and tolerance. Doses above 300mg/day are unlikely to be required. Cessation of Molipaxin should be gradual. **Children:** Not recommended. **Contraindications:** Known sensitivity to trazodone. **Precautions:** Avoid during first trimester of pregnancy and in nursing mothers. Warn against risks of handling machinery and driving. May enhance muscle relaxants, some antihypertensive agents, sedatives or antidepressants and alcohol, acute effects of clonidine may be reduced. Avoid concurrent therapy with MAOIs and do not give Molipaxin within 2 weeks of stopping MAOIs or give MAOIs within 1 week of stopping Molipaxin. Use with care in patients with epilepsy, severe hepatic, cardiac or renal disease. Patients receiving long-term therapy with any antidepressant should be kept under regular surveillance. **Side effects:** Molipaxin is a sedative antidepressant. Any dizziness or drowsiness usually disappears on continued dosage. Anticholinergic-like symptoms occur, but the incidence is similar to placebo. Blood dyscrasias, including agranulocytosis, thrombocytopenia and anaemia, have been reported on rare occasions. Adverse effects on hepatic function, including jaundice and hepatocellular damage, sometimes severe, have been rarely reported. Should such effects occur, Molipaxin should be discontinued immediately. As with other drugs with alpha-adrenergic activity, Molipaxin has very rarely been associated with priapism. This may be treated with an intracavernosal injection of alpha-adrenergic agents such as adrenalin or metamizolol. However, there are reports of trazodone-induced priapism which have on occasion required surgical intervention or led to permanent sexual dysfunction. Priapism should be dealt with as a urological emergency and Molipaxin therapy should be discontinued immediately. Other side effects include isolated cases of oedema and postural hypotension. **Overdosage:** No specific antidote is available. Give supportive and symptomatic treatment. **Legal Category:** POM. **Presentations, product licence numbers and basic NHS prices:** Molipaxin 50mg, 84 capsules; 0109/0045; £17.31. Molipaxin 100mg, 56 capsules; 0109/0046; £20.38. Molipaxin 150mg, 28 tablets; 0109/0133; £11.62. Molipaxin CR 150mg, 28 tablets; 0109/0214; £11.62. Molipaxin Liquid 50mg/5ml, 150ml bottle; 0109/0117; £7.74. **Product Licence Holder:** Roussel Laboratories Ltd, Broadwater Park, Denham, Uxbridge, Middlesex UB9 5HP. **Distributor:** Marion Merrell Ltd, Broadwater Park, Denham, Uxbridge, Middlesex UB9 5HP. Further product information is available from Hoechst Marion Roussel Ltd at the above address. Hoechst Marion Roussel is a member of the Hoechst Group. © Molipaxin is a registered trademark.

Date of issue: Dec 1996

Hoechst Marion Roussel

CLOZARIL ABBREVIATED PRESCRIBING INFORMATION. The use of CLOZARIL is restricted to patients registered with the CLOZARIL Patient Monitoring Service. **Indication:** Treatment-resistant schizophrenia (patients non-responsive to, or intolerant of, conventional neuroleptics). **Presentations** 25 mg and 100 mg clozapine tablets. **Dosage and Administration** Initiation of CLOZARIL treatment must be in hospital in-patients and is restricted to those patients with a normal white blood cell count and differential count. Initially, 12.5 mg once or twice on first day, followed by one or two 25 mg tablets on second day. Increase slowly, initially by daily increments of 25 to 50 mg, followed by increments of 50 to 100 mg to reach a therapeutic dose within the range of 200 to 450 mg daily. The total daily dose should be divided and a larger portion of the dose may be given at night. Once control is achieved a maintenance dose of 150 to 300 mg daily may suffice. At daily doses not exceeding 200mg, a single administration in the evening may be appropriate. Exceptionally, doses up to 900 mg daily may be used. Patients with a history of epilepsy should be closely monitored during CLOZARIL therapy since dose-related convulsions have been reported. Therefore, patients with a history of seizures, as well as those suffering from cardiovascular, renal or hepatic disorders, together with the elderly need lower doses (12.5 mg given once on the first day) and more gradual titration. **Contra-Indications** Hypersensitivity to clozapine. History of drug-induced neutropenia/agranulocytosis, myeloproliferative disorders, uncontrolled epilepsy, alcoholic and toxic psychoses, drug intoxication, comatose conditions, circulatory collapse and/or CNS depression of any cause and severe hepatic, renal or cardiac failure. **Warning** CLOZARIL can cause agranulocytosis. A fatality rate of up to 1 in 300 has been estimated when CLOZARIL was used prior to recognition of this risk. Since that time strict haematological monitoring of patients has been demonstrated to be effective in markedly reducing the risk of fatality. Because of the risk associated with CLOZARIL therapy its use is therefore limited to treatment-resistant schizophrenic patients:- 1. who have normal leucocyte findings (white blood cell count and differential blood count), and 2. in whom regular leucocyte counts can be performed weekly during the first 18 weeks and at least every two weeks thereafter for the first year of therapy. After one years treatment monitoring may be changed to four weekly intervals in patients with stable neutrophil counts. Monitoring must continue as long as treatment continues. Patients must be under specialist supervision and CLOZARIL supply is restricted to hospital and community pharmacies registered with the CLOZARIL Patient Monitoring Service. Prescribing physicians must register themselves, their patients and a nominated pharmacist with the CLOZARIL Patient Monitoring Service. This service provides for the required leucocyte counts as well as a drug supply audit so that CLOZARIL treatment is promptly withdrawn from any patient who develops abnormal leucocyte findings. Each time CLOZARIL is prescribed, patients should be reminded to contact the treating physician immediately if any kind of infection begins to develop. Particular attention should be paid to flu-like complaints or other symptoms which might suggest infection, such as fever or sore throat. **Precautions** CLOZARIL can cause agranulocytosis. Perform pre-treatment white blood cell count and differential count to ensure only patients with normal findings receive CLOZARIL. Monitor white blood cell count weekly for the first 18 weeks and at least two-weekly for the first year of therapy. After one years treatment, monitoring may be changed to four weekly intervals in patients with stable neutrophil counts. Monitoring must continue as long as treatment continues. If the white blood count falls below $3.0 \times 10^9/l$ and/or the absolute neutrophil count drops below $1.5 \times 10^9/l$, withdraw CLOZARIL immediately and monitor the patient closely, paying particular attention to symptoms suggestive of infection. Re-evaluate any patient developing an infection, or with a routine white blood count between 3.0 and $3.5 \times 10^9/l$ and/or a neutrophil count between 1.5 and $2.0 \times 10^9/l$, with a view to discontinuing CLOZARIL. Any further fall in white blood/neutrophil count below $1.0 \times 10^9/l$ and/or $0.5 \times 10^9/l$ respectively, after drug withdrawal requires immediate specialised care. Where protective isolation and administration of GM-CSF or G-CSF may be indicated. Colony stimulating factor therapy should be discontinued when the neutrophil count returns above $1.0 \times 10^9/l$. CLOZARIL lowers the seizure threshold. Orthostatic hypotension can occur therefore close medical supervision is required during initial dose titration.

Monitor hepatic function in liver disease. Use with care in prostatic enlargement, narrow-angle glaucoma and paralytic ileus. Patients affected by the sedative action of CLOZARIL should not drive or operate machinery. CLOZARIL should be administered with caution to patients who participate in activities requiring complete mental alertness. Patients with fever should be carefully evaluated to rule out the possibility of an underlying infection or the development of agranulocytosis. Do not give CLOZARIL with other drugs with a substantial potential to depress bone marrow function. CLOZARIL may enhance the effects of alcohol, MAO inhibitors, CNS depressants and drugs with anticholinergic, hypotensive or respiratory depressant effects. Caution is advised when CLOZARIL therapy is initiated in patients who are receiving (or have recently received) a benzodiazepine or any other psychotropic drug as these patients may have an increased risk of circulatory collapse, which, on rare occasions, can be profound and may lead to cardiac and/or respiratory arrest. Caution is advised with concomitant administration of therapeutic agents which are highly bound to plasma proteins. Clozapine binds to and is partially metabolised by the isoenzyme cytochrome P450 2D6. Caution is advised with drugs which possess affinity for the same isoenzyme. Concomitant cimetidine and high dose CLOZARIL was associated with increased plasma clozapine levels and the occurrence of adverse effects. Discontinuation of concomitant carbamazepine resulted in increased clozapine levels. Phenytoin decreases clozapine levels resulting in reduced effectiveness of CLOZARIL. No clinically relevant interactions noted with antidepressants, phenothiazines and type Ic antiarrhythmics observed, to date. Isolated reports of fluvoxamine increasing clozapine plasma levels by 5-10 fold. Concomitant use of lithium or other CNS-active agents may increase the risk of neuroleptic malignant syndrome. The hypertensive effect of adrenaline and its derivatives may be reversed. Do not use in pregnant or nursing women. Use adequate contraceptive measures in women of child bearing potential. **Side-Effects** Neutropenia leading to agranulocytosis (See Warning and Precautions). Rare reports of leucocytosis including eosinophilia. Isolated cases of leukaemia and thrombocytopenia have been reported but there is no evidence to suggest a causal relationship with the drug. Most commonly fatigue, drowsiness, sedation. Dizziness or headache may also occur. CLOZARIL lowers the seizure threshold and may cause EEG changes and delirium. Myoclonic jerks or convulsions may be precipitated in individuals who have epileptogenic potential but no previous history of epilepsy. Rarely it may cause confusion, restlessness, agitation and delirium. Extrapyrmidal symptoms are limited mainly to tremor, akathisia and rigidity. Neuroleptic malignant syndrome has been reported. Transient autonomic effects eg dry mouth, disturbances of accommodation and disturbances in sweating and temperature regulation. Hypersalivation. Tachycardia and postural hypotension, with or without syncope, and less commonly hypertension may occur. In rare cases profound circulatory collapse has occurred. ECG changes, arrhythmias, pericarditis and myocarditis (with or without eosinophilia) have been reported, some of which have been fatal. Isolated cases of respiratory depression or arrest, with or without circulatory collapse. GI disturbances, increases in hepatic enzymes. In rare cases, cholestasis has been reported and very rarely ileus may occur. Rarely aspiration may occur in patients presenting with dysphagia or as a consequence of acute overdose. Both urinary incontinence and retention and priapism have been reported. Benign hyperthermia may occur and isolated reports of skin reactions have been received. Rarely, hyperglycaemia has been reported. Rarely increases in CPK values have occurred. With prolonged treatment considerable weight gain has been observed. Sudden unexplained deaths have been reported in patients receiving CLOZARIL. **Package Quantities and Price** Community pharmacies only. 28 x 25mg tablets: £12.52 (Basic NHS) 28 x 100mg tablets: £50.05 (Basic NHS). Hospital pharmacies only. 84 x 25 mg tablets: £37.54 (Basic NHS). 84 x 100 mg tablets: £150.15 (Basic NHS). Supply of CLOZARIL is restricted to hospital and community pharmacies registered with the CLOZARIL Patient Monitoring Service. **Product Licence Numbers** 25 mg tablets: PL 0101/0228. 100 mg tablets: PL 0101/0229. **Legal Category** POM. CLOZARIL is a registered Trade Mark. **Date of preparation** January 1996. Full prescribing information, including Product Data Sheet is available from SANDOZ PHARMACEUTICALS. Frimley Business Park, Frimley, Camberley, Surrey, GU16 5SG.

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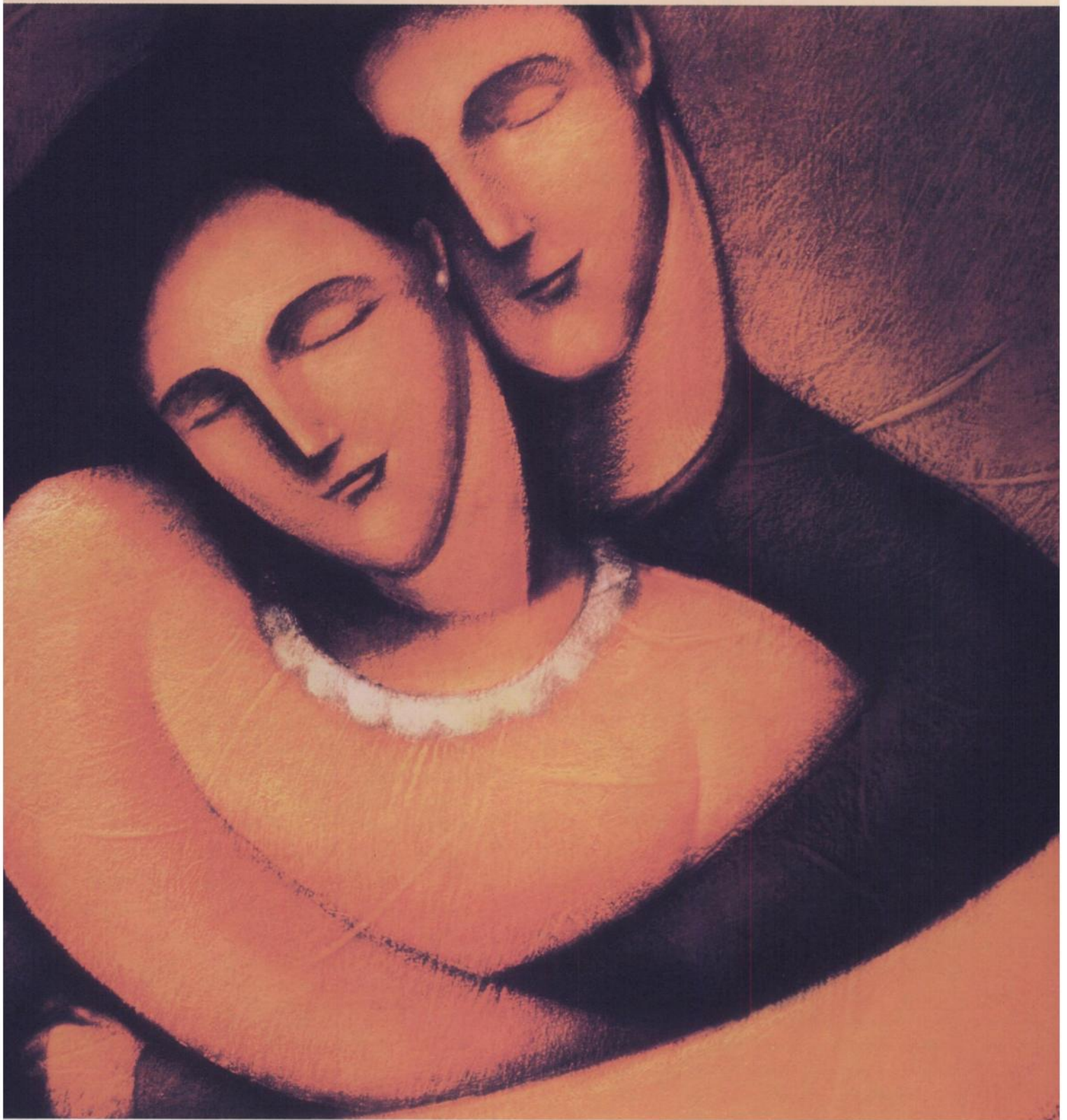


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