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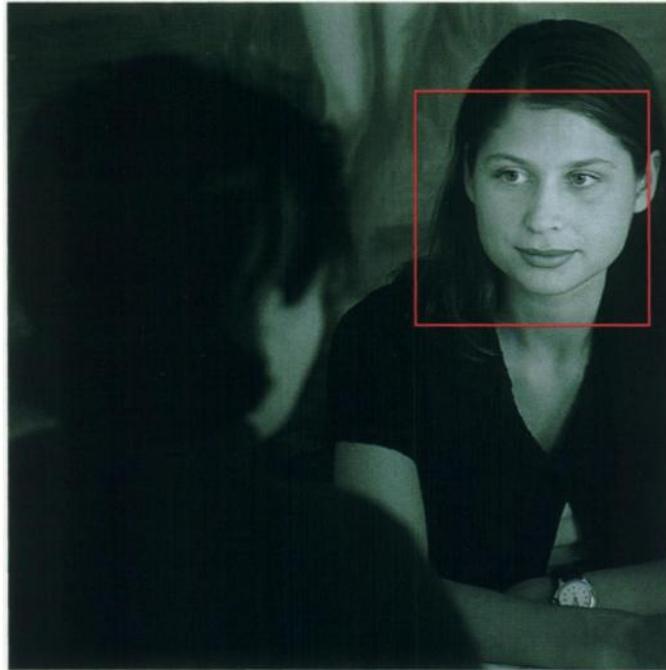
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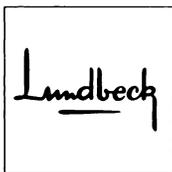
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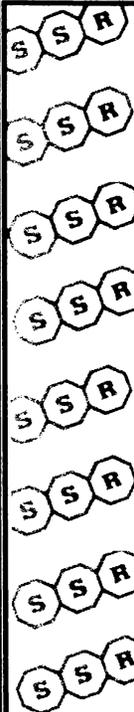
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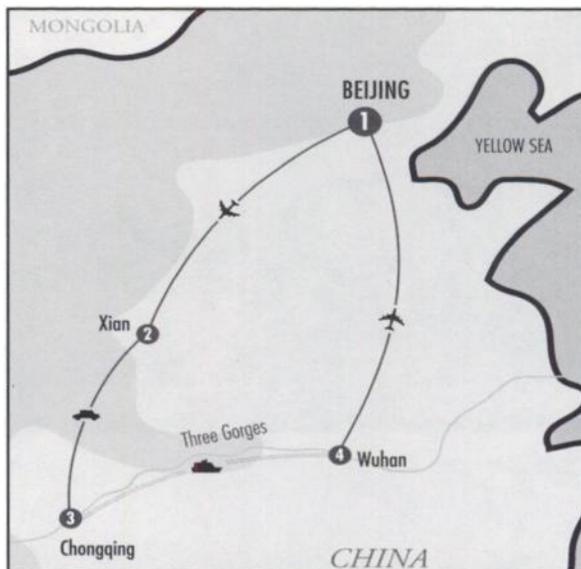
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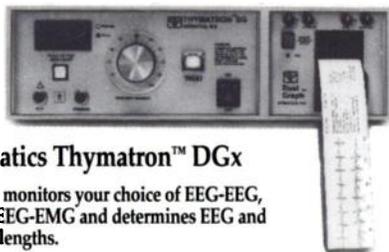
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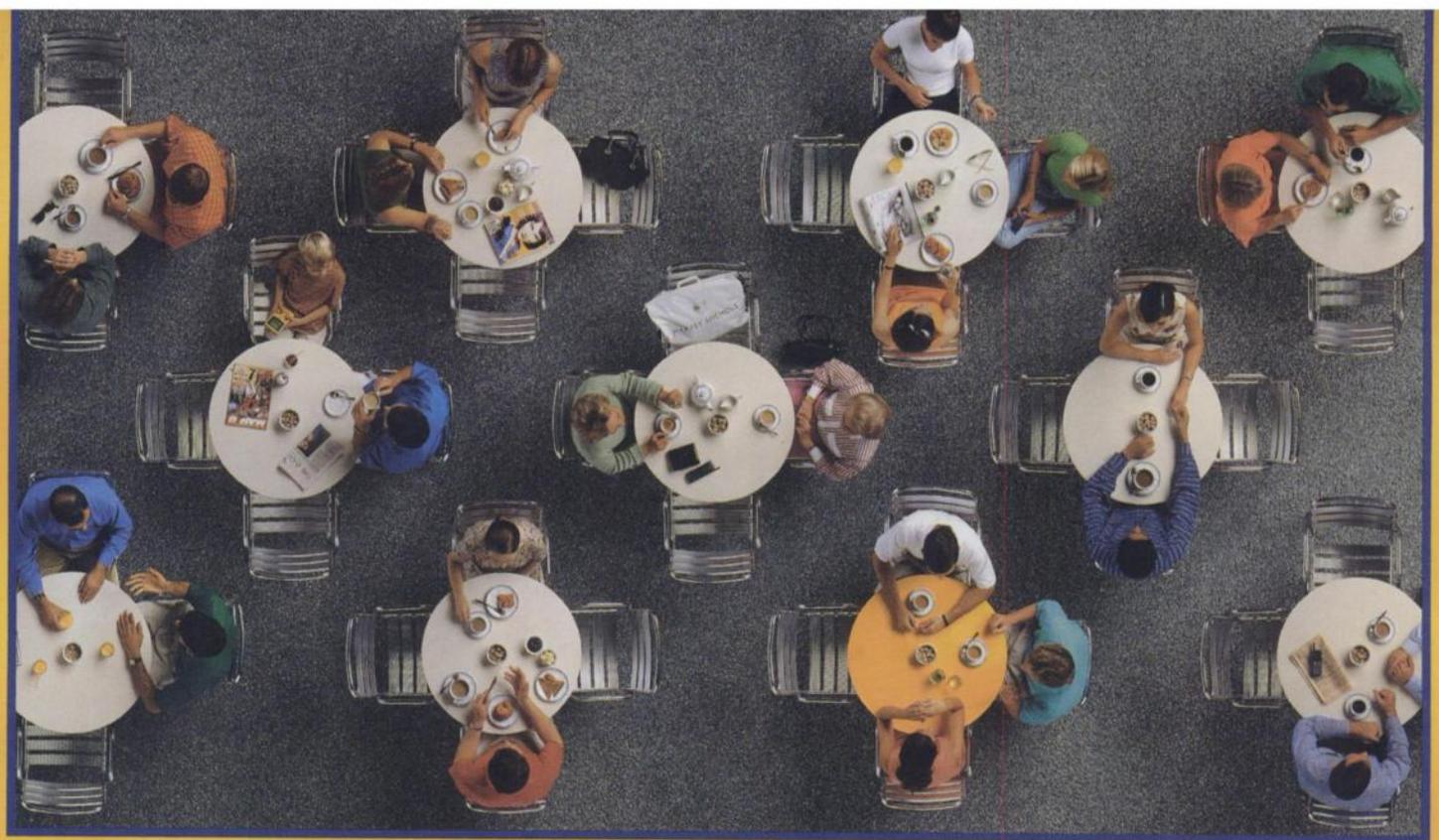
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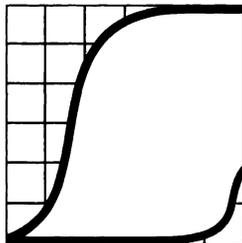
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- Sedation at placebo level⁴
- No clinically significant changes in haematological parameters⁴
- Mean serum prolactin levels maintained within normal limits⁴
- Once daily dosage
- One price for all routine maintenance doses

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sertindole

Separates efficacy from EPS

monitoring on treatment. Serdolect should not be initiated or should be discontinued if the QTc2 interval exceeds 520 msec. Hypokalaemia and hypomagnesaemia should be corrected and maintained within normal limits during treatment. If signs and symptoms of tardive dyskinesia appear, consider dose reduction or discontinuation. **Drug interactions:** (Also see contra-indications). Combined use of agents known to inhibit hepatic isoenzymes may necessitate lower maintenance doses. Combined use of agents known to induce hepatic isoenzymes may necessitate maintenance doses toward the upper dose range. **Adverse events:** Most commonly (>1 % of patients): nasal congestion, decreased ejaculatory volume, dizziness, dry mouth, postural hypotension, weight gain, peripheral oedema, dyspnoea, paraesthesia and prolonged QT interval. Incidence of EPS adverse events similar to placebo. **Overdosage:** Symptoms have included somnolence, slurred speech, tachycardia, hypotension and transient prolongation of QT interval. There is no specific antidote. Discontinuation by gradual dose reduction. Caffeine and

dopamine should not be used (may exacerbate hypotension). Cardiovascular monitoring recommended. Administration of activated charcoal and laxative should be considered. **Package quantities and basic NHS price:** 4mg tablets, £36.63 for 30 tablet pack. 12mg tablets, £102.55 for 28 tablet calendar pack. 16mg tablets, £102.55 for 28 tablet calendar pack. 20mg tablets, £102.55 for 28 tablet calendar pack. **Legal category:** POM. **Product Licence numbers:** 4mg: 13761/0001. 12mg: 13761/0003. 16mg: 13761/0004. 20mg: 13761/0005. **Date of last review:** November 1996. Further information is available on request from Lundbeck Limited, Sunningdale House, Caldecotte Lake Business Park, Caldecotte, Milton Keynes, MK7 8LF. Serdolect® is a registered trademark of H. Lundbeck A/S. **References:** 1. Arnt J *et al.* Poster presented at the 34th ACNP Meeting, December 1995, Puerto Rico. 2. Zborowski J *et al.* Poster presented at 148th APA Meeting, May 1995, Miami, Florida. 3. Daniel DG *et al.* J Psych: In Press. 4. Data on file, H. Lundbeck A/S.



EDRONAX®
ABBREVIATED PRESCRIBING INFORMATION

Presentation: Tablets containing 4mg reboxetine. **Indications:** Use in the acute treatment of depressive illness, and maintenance of clinical benefit in patients responsive to treatment. **Posology and method of administration:** Adults 4 mg b.i.d. (8 mg/day) administered orally. After 3-4 weeks, can increase to 10 mg/day. **Elderly and children:** Elderly patients have been studied in comparative clinical trials at doses of 2 mg b.i.d., although not in placebo controlled conditions. There is no experience in children and therefore reboxetine cannot be recommended in either

of these groups. **Renal/Hepatic Insufficiency** 2 mg b.i.d. which can be increased based on patient tolerance. **Contra-indications:** Hypersensitivity to the compound or its constituents. Use in pregnancy/lactation. **Special warnings and precautions for use:** Close supervision is required for subjects with a history of convulsive disorders and must be discontinued if the patient develops seizures. Avoid concomitant use with MAO inhibitors. Close supervision of bipolar patients is recommended. Close supervision should be applied in patients with current evidence of urinary retention, glaucoma, prostatic hypertrophy and cardiac disease. At doses higher than the maximum recommended, orthostatic hypotension has

been observed with greater frequency. Particular attention should be paid when administering reboxetine with other drugs known to lower blood pressure. **Interactions with other medications and other forms of interaction:** Reboxetine should not be co-administered with macrolide antibiotics, fluvoxamine, azole anti-fungal agents. Caution when co-administered with drugs that have a narrow therapeutic margin and are metabolised by CYP3A4 or CYP2D6 e.g. anti-arrhythmics (flecainide), anti-psychotic drugs and tricyclic anti-depressants. No pharmacokinetic interaction with lorazepam. Reboxetine does not appear to potentiate the effect of alcohol. **Pregnancy and lactation:** Reboxetine is

When you next see your depressed patient, ask about her new sweeper.

Depression. It's not a game, but it can be viewed in two halves. Most antidepressants play a valuable part in the first half – they lift mood and relieve anxiety. But what of the second? Do they reduce fatigue, improve motivation and improve social functioning, so your patient can play a full part again, in the things they once enjoyed? Here's some information about new Edronax, you be the referee:

Edronax is a new selective NorAdrenaline Re-uptake Inhibitor (NARI). It not only lifts depressed mood,¹ but also significantly improves social interaction.²

These improvements in social functioning have been trial-proven by using the innovative SASS questionnaire (Social Adaptation Self-evaluation Scale).³

Edronax improves mood one week earlier than fluoxetine.¹ Additionally, when compared to fluoxetine, Edronax shows a significantly better outcome in terms of social functioning.²

Edronax helps restore patients' appreciation of friends, family, work and hobbies, and improves their self-perception.

Prescribe 4mg b.d. then make your usual assessments, to see the Edronax difference. The SASS questionnaire, which patients can complete in their own time, may also help.

For free copies of the SASS questionnaire, please telephone 01908 603083.

And the next time you see your depressed patient, ask them how they performed, in both halves.

**Edronax**
REBOXETINE

A NEW SELECTIVE NARI. LIFTS DEPRESSION. HELPS RESTORE SOCIAL INTERACTION.

contraindicated in pregnancy and lactation. Effects on ability to drive and use machines: Reboxetine is not sedative per se. However, as with all psychoactive drugs, caution patients about operating machinery and driving. Undesirable effects: Adverse events occurring more frequently than placebo are: dry mouth, constipation, insomnia, paraesthesia, increased sweating, tachycardia, vertigo, urinary hesitancy/retention, impotence. Overdose: Monitor cardiac function and vital signs. General symptomatic supportive and/or metabolic measures might be required. Package and NHS Price: Pack of 60 tablets in blisters £19.80. Legal

Davy Avenue, Milton Keynes, MK5 8PH, UK. Marketing Authorisation Number: PL 0032/0216, Date of Preparation: October 1997. References: 1. Montgomery SA. *Journal of Psychopharmacology* 1997 (in press). 2. Dubini A. et al. *European Neuropsychopharmacol.* 1997; 7 (Suppl 1): S57-S70. 3. Bosc M. et al. *European Neuropsychopharmacol.* 1997; 7 (Suppl 1): S57-S70. Further information is available from Pharmacia & Upjohn Limited, Davy Avenue, Knowlhill, Milton Keynes, MK5 8PH, UK. Telephone: 01908 661101. © Edronax is a registered trademark.



Because
community
re-integration
is not that
simple.

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. **Pharmacodynamics:**

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. **Contra-indications:** 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 antipsychotic drugs, including olanzapine, must be discontinued. 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

Antipsychotic Efficacy for First-line Use

ZYPREXA
Olanzapine



Making Community Re-integration the Goal

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 titrated 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/1/96/022/006 EU/1/96/022/008 EU/1/96/022/009 EU/1/96/022/010. **Basic NHS Cost:** £52.73 per pack of 28 x 5mg tablets. £105.47 per pack of 28 x 10mg tablets. £158.20 per pack of 56 x 7.5mg tablets. £210.93 per pack of 56 x 10mg tablets. **Date of Preparation or Last Review:** April 1997. **Full Prescribing Information is Available From:** Eli Lilly and Company Limited, Dextra Court, Chapel Hill, Basingstoke, Hampshire RG21 5SY. Telephone: Basingstoke (01256) 315000.

'ZYPREXA' is a Lilly trademark.

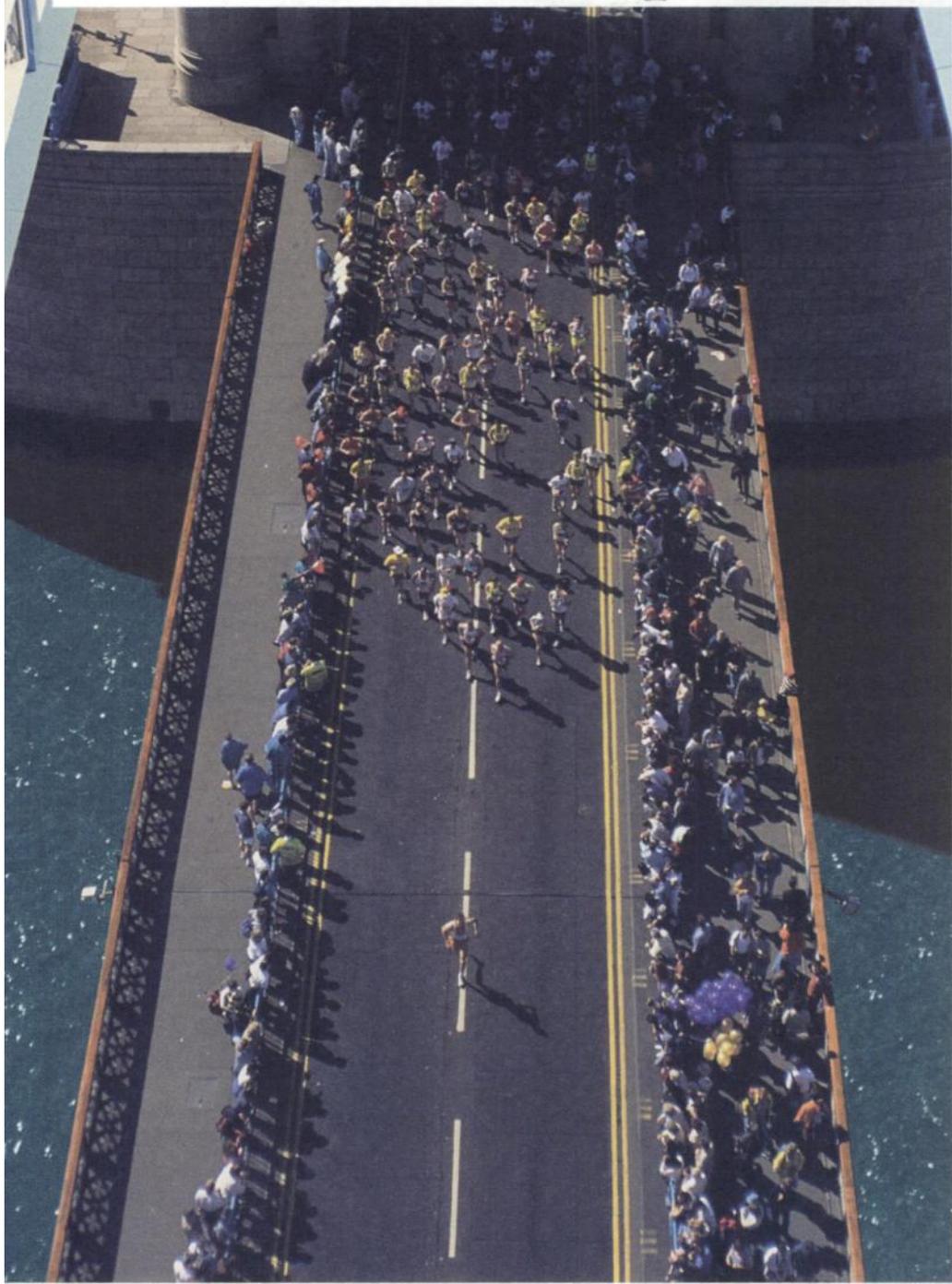


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Prozac has a proven record of efficacy in depression,^{1,2,3} with a confirmed indication in depression with or without associated anxiety symptoms.⁴

A possible reason why Prozac has earned its status around the world.

PROZAC

fluoxetine

The World's No.1 prescribed antidepressant brand.¹

'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 prescribed to nursing mothers. **Monamine 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 (caution). 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, 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 ideation, thrombocytopenia, thrombocytopenic purpura, vaginal bleeding after drug withdrawal and violent behaviour.

Hyponatraemia (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

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This book provides an unusually comprehensive survey of the current state and prospects of psychological methods of treatment for people with schizophrenia and other psychotic illnesses. It will be an invaluable resource for mental health professionals and clinical managers involved in their care, and essential reading for psychiatrists at all levels of experience.

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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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The SDA effect of Risperdal can mean a huge difference to the lives of patients with schizophrenia.

Because SDA is the action of Serotonin and Dopamine Antagonism in a single drug. In positive and negative symptoms. In first episode and acute presentations, and in chronic patients. Risperdal continues to provide this SDA effect to give high efficacy, with low levels of extrapyramidal side-effects, to more and more patients.

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clozapine

CLOZARIL ABBREVIATED PRESCRIBING INFORMATION.

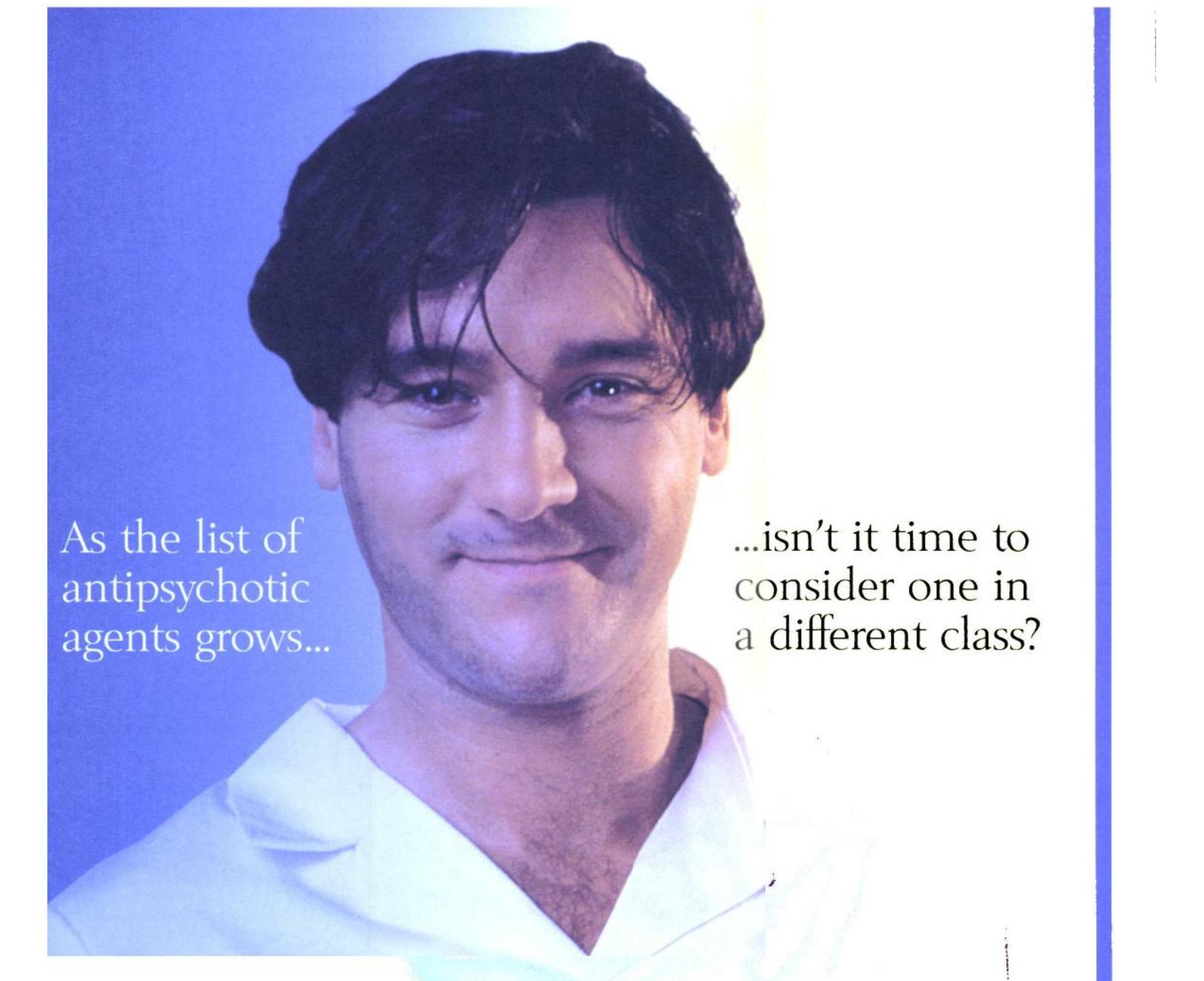
The use of CLOZARIL is restricted to patients registered with the CLOZARIL Patient Monitoring Service. Indication Treatment-resistant schizophrenia (patients non-responsive to, or intolerant of, conventional neuroleptics). Presentations 25mg and 100 mg clozapine tablets. Dosage and Administration Initiation must be in hospital in-patients and is restricted to patients with normal white blood cell and differential counts. Initially, 12.5 mg once or twice on the first day, followed by one or two 25 mg tablets on the second day. Increase dose slowly, by increments to reach a therapeutic dose within the range of 200 - 450mg daily (see data sheet). 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. 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** Allergy to any constituents of the formulation. 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, severe renal or cardiac failure, active liver disease, progressive liver disease or hepatic 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. Therefore, because of this risk its use is limited to treatment-resistant schizophrenic patients:- 1. who have normal leucocyte findings 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 year's treatment, monitoring may be changed to four weekly intervals in patients with stable neutrophil counts. Monitoring must continue throughout treatment and for four weeks after complete discontinuation of CLOZARIL. Patients must be under specialist supervision and CLOZARIL supply is restricted to 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, especially any flu-like symptoms. **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 year's treatment, monitoring may change to four weekly intervals in patients with stable neutrophil counts. Monitoring must continue throughout treatment and for four weeks after complete discontinuation. If signs or symptoms of infection develop an immediate differential count is necessary. 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 when a routine white blood count is 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 and broad spectrum antibiotics 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. Patients affected by the sedative action of CLOZARIL should not drive or

operate machinery, administer with caution to patients who participate in activities requiring complete mental alertness. Monitor hepatic function regularly in liver disease. Investigate any signs of liver disease immediately with a view to drug discontinuation. Resume only if LFTs return to normal, then closely monitor patient. Use with care in prostatic enlargement, narrow-angle glaucoma and paralytic ileus. Patients with fever should be carefully evaluated to rule out the possibility of an underlying infection or the development of agranulocytosis. Avoid immobilisation of patients due to increased risk of thromboembolism. 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 isoenzymes cytochrome P450 1A2 and P450 2D6. Caution is advised with drugs which possess affinity for these isoenzymes. Concomitant cimetidine and high dose CLOZARIL was associated with increased plasma clozapine levels and the occurrence of adverse effects. Concomitant fluoxetine and fluvoxamine have been associated with elevated clozapine levels. Discontinuation of concomitant carbamazepine resulted in increased clozapine levels. Phenytoin decreases clozapine levels resulting in reduced effectiveness of CLOZARIL. No clinically relevant interactions have been noted with antidepressants, phenothiazines and type 1c antiarrhythmics, to date. 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 by CLOZARIL. 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. Extrapyramidal symptoms are limited mainly to tremor, akathisia and rigidity. Tardive dyskinesia reported very rarely. 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. Rare reports of thromboembolism. Isolated cases of respiratory depression or arrest, with or without circulatory collapse. Rarely aspiration may occur in patients presenting with dysphagia or as a consequence of acute overdose. Nausea, vomiting and usually mild constipation have been reported. Occasionally obstipation and paralytic ileus have occurred. Asymptomatic elevations in liver enzymes occur commonly and usually resolve. Rarely hepatitis and cholestatic jaundice may occur. Very rarely fulminant hepatic necrosis reported. Discontinue CLOZARIL if jaundice develops. Rare cases of acute pancreatitis have been reported. Both urinary incontinence and retention and priapism have been reported. Isolated cases of interstitial nephritis have occurred. 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 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, August 1997. Full prescribing information, including Product Data Sheet is available from Novartis Pharmaceuticals UK Ltd. Trading as: SANDOZ PHARMACEUTICALS, Frimley Business Park, Frimley, Camberley, Surrey, GU16 5SG.



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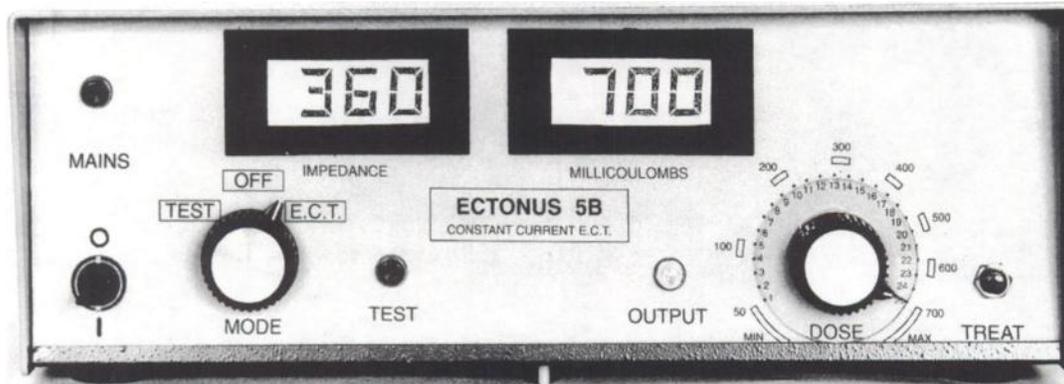
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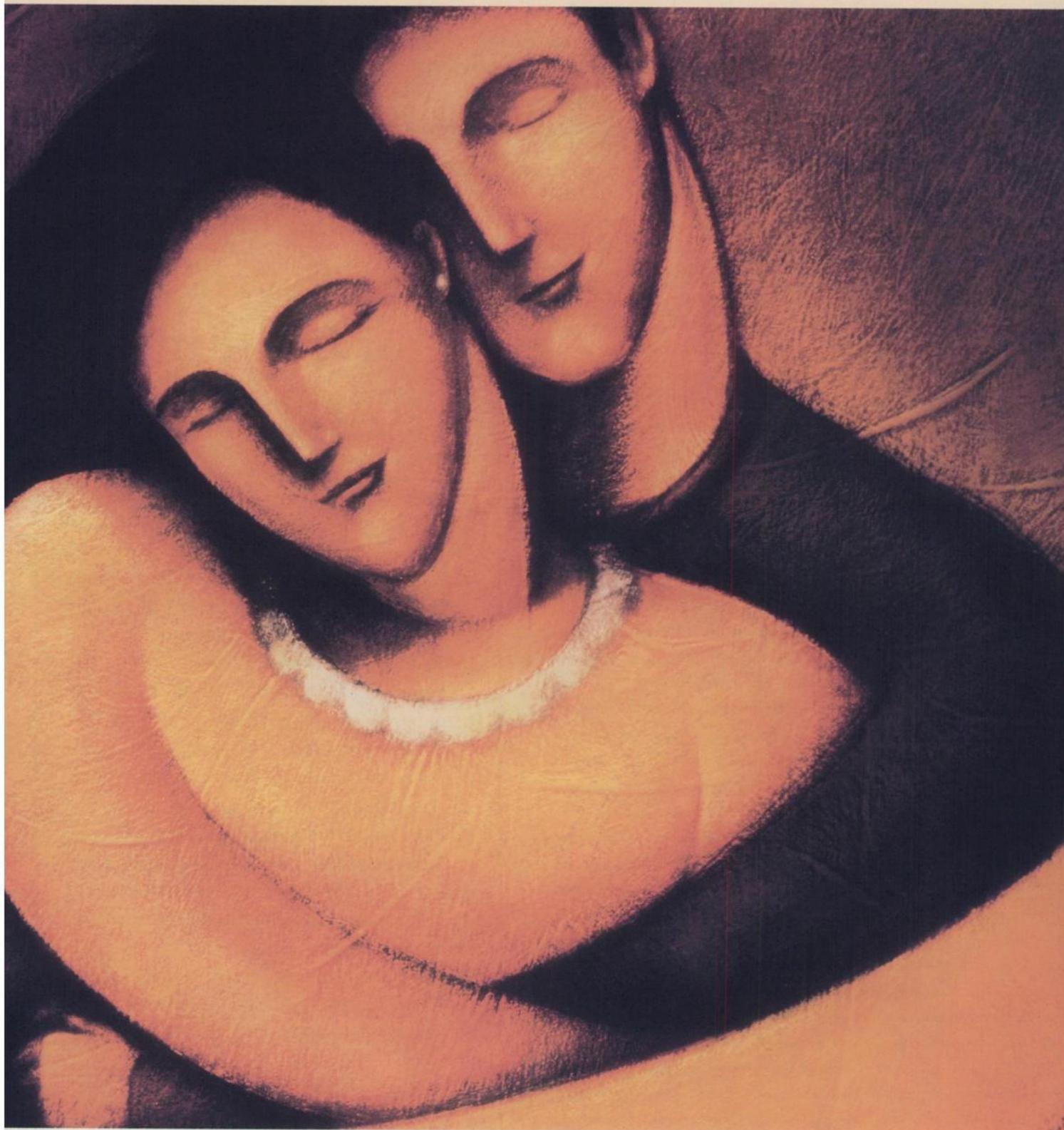


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Contra-indications: Hypersensitivity to any component of the product.

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Elderly patients: Use with caution, starting with 25 mg/day and increasing daily by 25 to 50 mg to an effective dose.

Children and adolescents: Safety and efficacy not evaluated.

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Use with caution in patients with hepatic impairment.

Contra-indications: Hypersensitivity to any component of the product.

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