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April 1999, £25.00, 208pp, Paperback, ISBN 1 901242 26 9

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Edited by Dinesh Bhugra

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Series Editors: Hugh Freeman, Ian Pullen, George Stein and Greg Wilkinson

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1998 216pp ISBN 1 901242 03 X £15.00

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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. **Renal/Hepatic Insufficiency** 2 mg b.i.d.

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. **Other medicaments and other forms of**

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 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

NHS Price: Pack of 60 tablets in blisters £19.80. **Legal Category:** POM **Marketing Authorisation Holder:** Pharmacia & Upjohn Limited, Davy Avenue, Milton Keynes, MK5 8PH, UK. **Marketing Authorisation Number:** PL 0032/0216 **References:** 1. Brunello N et al. *Human Psychopharmacology* 1998;13:S13-S19. 2. Dubini A et al. *J Psychopharmacol* 1997; 11(4):S17-S23. 3. Montgomery SA. *Prescriber* April 1998; 116-119. Further information is available from the Marketing Authorisation Holder: Pharmacia & Upjohn Limited, Davy Avenue, Knowlhill, Milton Keynes, MK5 8PH, UK. Telephone: 01908 661101. © Edronax is a registered trademark. Code No.P4008/12/98. Date of preparation:

<https://doi.org/10.1093/095026880152870> Published online by Cambridge University Press

Campral EC acomprasate
Presentation: Off-white round enteric-coated tablets, containing 333mg acomprasate calcium. Printed on one side with 333. **Properties:** Acomprasate may act by stimulating GABAergic inhibitory neurotransmission and antagonising excitatory amino acids, particularly glutamic acid. **Indication:** Maintenance of abstinence in alcohol dependent patients. It should be combined with counselling. **Dosage and Administration:** *Adults ≥ 60kg:* 6 tablets per day (2 tablets taken three times daily with meals) *Adults < 60kg:* 4 tablets per day (2 tablets in the morning, 1 at noon and 1 at night with meals). Recommended treatment period one year, starting as soon as possible after the withdrawal period. Treatment should be maintained if the patient relapses. **Elderly:** Not recommended. **Children:** Not recommended. **Contraindications:** Known hypersensitivity to the drug, renal insufficiency (serum creatinine > 120 micromol/L), severe hepatic failure (Childs-Pugh classification C), pregnancy, lactation. Precautions and

warnings: Campral EC does not constitute treatment during the withdrawal period. **Interactions:** None observed in studies with diazepam, disulfiram or imipramine. The concomitant intake of alcohol and acomprasate does not affect the pharmacokinetics of either alcohol or acomprasate. **Side Effects:** Diarrhoea, and less frequently nausea, vomiting and abdominal pain; pruritus. These are usually mild and transient. An occasional maculopopular rash and rare cases of bullous skin reactions have been reported. Fluctuations in libido have been reported. Campral EC should not impair the patient's ability to drive or operate machinery. **Overdose:** Gastric lavage; should hypercalcaemia occur, treat patient for acute hypercalcaemia. **Legal Category:** POM. **Pharmaceutical Precautions:** None. **Package Quantities and Basic NHS Price:** 84 blister packed tablets £24.95. **Marketing Authorisation Number/Holder:** 13466/0001, Lipo SA, Lyon, France. **Date of Preparation:** August 1997. Further information is available on request from Merck Pharmaceuticals, Harrier House, High Street, West Drayton, Middlesex, UB7 7QG.



**SPECIAL COMMENDATION
AWARDED 1998
PRIX GALIEN AWARD
FOR INNOVATIVE
PHARMACEUTICAL PRODUCTS**

BRAIN BIOCHEMISTRY ADAPTS TO
LIFE WITH ALCOHOL

CAMPRAL EC HELPS PATIENTS ADAPT TO
LIFE WITHOUT ALCOHOL



Non-aversive **Campral EC** can help reduce the craving in patients who are adapting to a life without alcohol.

EFFECTIVE IN MAINTAINING ABSTINENCE

Campral EC

Every day he's frustrated and alone.
Every day he wants to be different.
Every day goes by the same.

Many schizophrenia patients are crying out for reassessment. Conventional neuroleptics may have controlled some initial symptoms. However, for many patients, everyday life is still impaired by residual symptoms and side effects. Switching to Risperdal could give them a life worth living.



ONCE DAILY
RisperdalTM
RISPERIDONE

Please refer to Summary of Product Characteristics for 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., Contra-indications:** 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, pruritus, 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, hyperaesthesia, 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 below 30°C, 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. Yellow, circular tablets containing 6 mg risperidone in packs of 28. PL 0242/0317 £109.20. 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 0242/0198 £65.00. **FURTHER INFORMATION IS AVAILABLE FROM THE PRODUCT LICENCE HOLDER, Janssen-Cilag Ltd, Sanderton, High Wycombe, Buckinghamshire HP14 4JU. AP/VER140797**

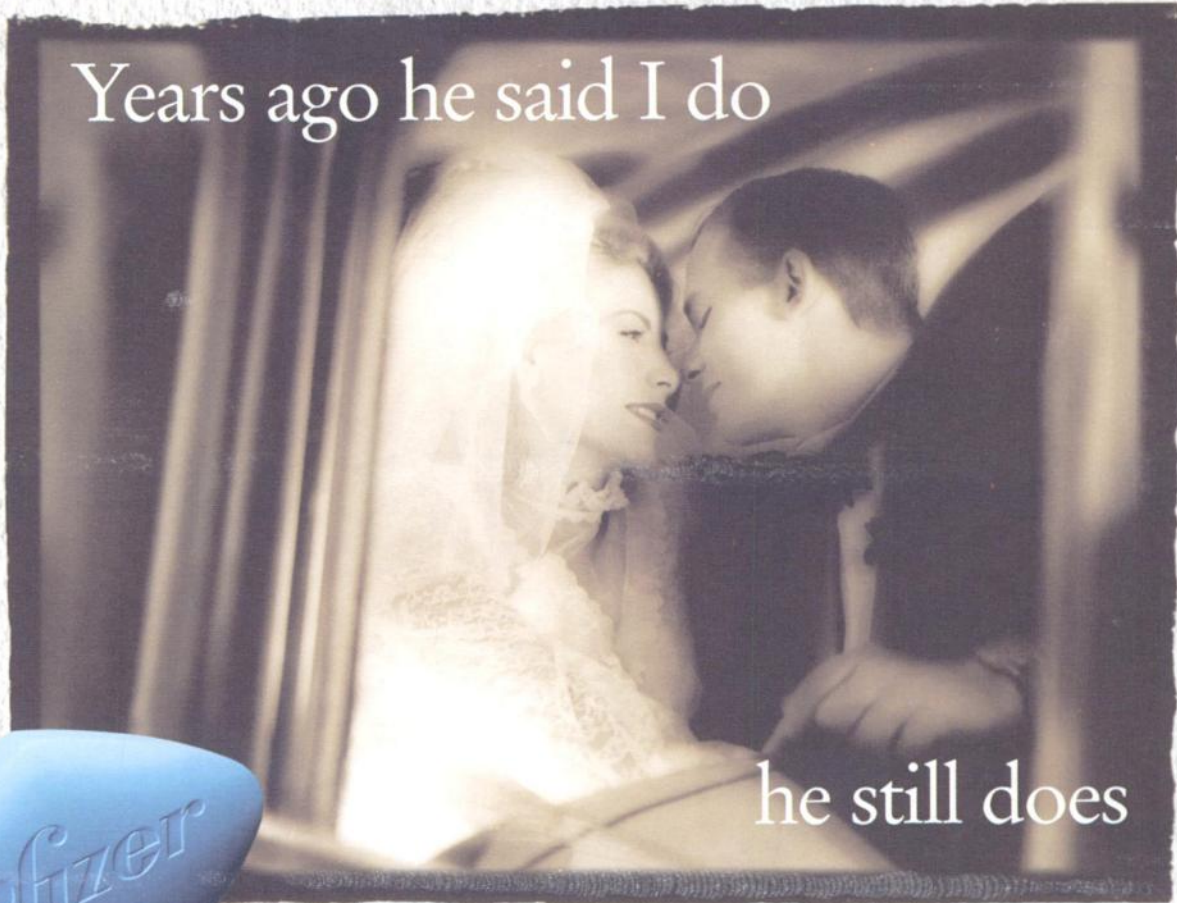
 JANSSEN-CILAG Ltd



Date of preparation: August 1998
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Years ago he said I do



he still does



everyone has something to say about it

now it's our turn

it's not for
men without
erectile dysfunction
it's not an aphrodisiac
or a fertility pill

rather

it works¹ to restore
natural erectile function
it's easy to take
it's well tolerated²
and it's here

VIAGRATM
sildenafil citrate

ORAL TREATMENT FOR ERECTILE DYSFUNCTION

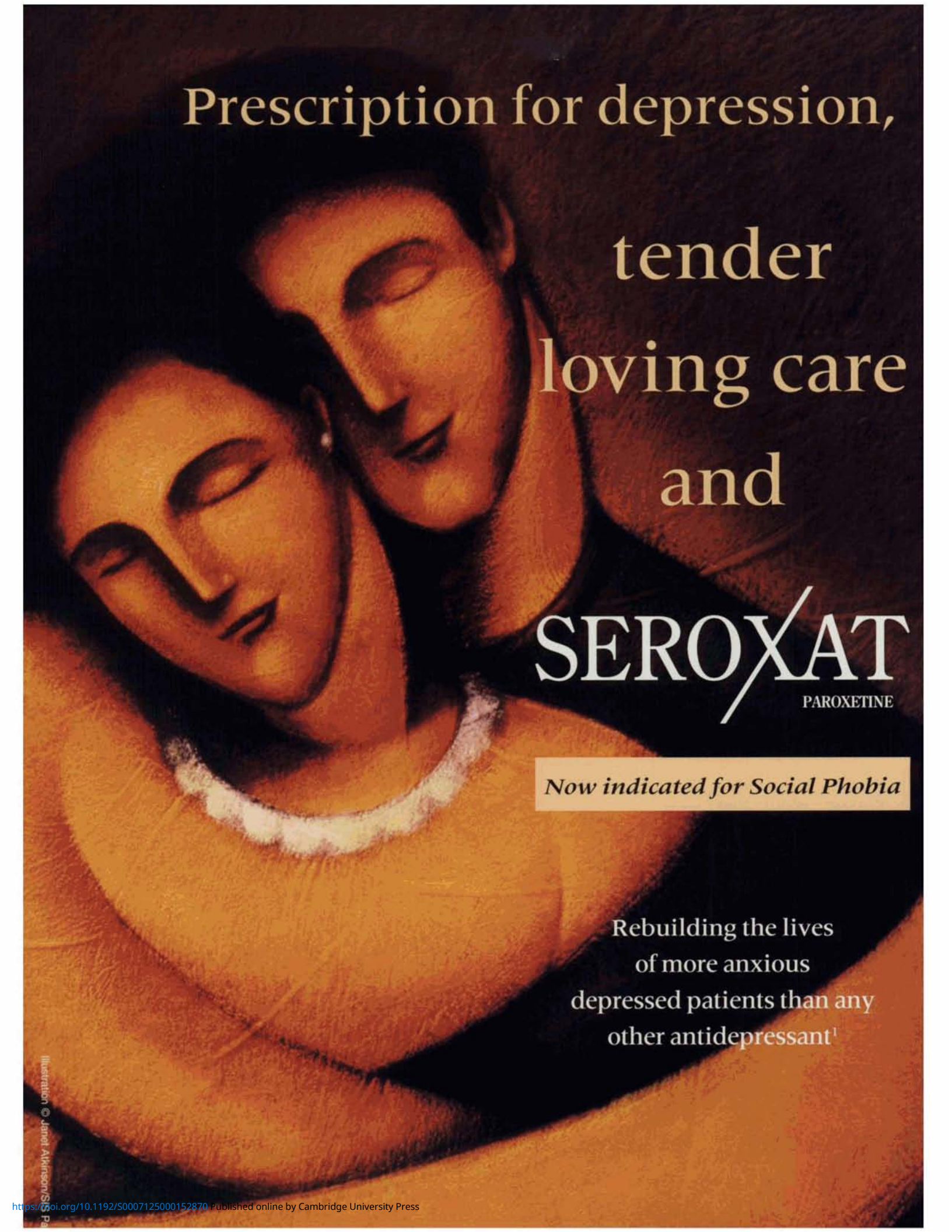
ABBREVIATED PRESCRIBING INFORMATION

Please refer to the SmPC before prescribing VIAGRA 25mg, 50mg or 100mg. **Presentation:** Blue film-coated, rounded diamond-shaped tablets containing sildenafil citrate equivalent to 25mg, 50mg and 100mg sildenafil. **Indications:** Erectile dysfunction. Sexual stimulation is required for efficacy. Not for use by women. **Dosage:** *Adults:* 50mg approximately one hour before sexual activity. Adjust dose based on efficacy and toleration. Maximum dose is 100mg. One single dose per day is recommended. If taken with food, the onset of activity may be delayed. *Elderly:* a first dose of 25mg should be used. **Hepatic impairment, severe renal impairment:** 25mg initial dose should be considered; adjust dose based on efficacy and toleration. *Children under 18 years:* Not indicated. **Contra-indications:** Co-administration with nitric oxide donors (such as amyl nitrite) or nitrates in any form; patients for whom sexual activity is inadvisable (e.g. patients with severe cardiovascular disorders); severe hepatic impairment; hypotension; recent stroke or myocardial infarction; known hereditary degenerative retinal disorders; hypersensitivity to sildenafil or to any of the excipients. **Pregnancy and lactation:** Not indicated for women.

Warnings and precautions: A medical history and physical examination should be undertaken to diagnose erectile dysfunction and determine potential underlying causes. Cardiovascular status, as sexual activity is associated with cardiac risk. Sildenafil has vasodilator properties, resulting in mild and transient decreases in blood pressure and as such potentiates the hypotensive effect of nitrates. Patients with anatomical deformation of the penis (such as angulation, cavernosal fibrosis or Peyronie's disease) or predisposed to priapism (such as sickle cell anaemia, multiple myeloma or leukaemia). Patients with bleeding disorders or active peptic ulceration. Not recommended in combination with other treatments for erectile dysfunction. **Drug Interactions:** In combination with inhibitors of CYP3A4 eg ketoconazole, erythromycin, cimetidine, a 25mg starting dose should be considered. Potentiates the hypotensive effects of nitrates (see contra-indications). No potentiation of the increase in bleeding time caused by acetyl salicylic acid (150mg) or the hypotensive effects of alcohol. No data on non-specific phosphodiesterase inhibitors such as dipyridamole. **Side-effects:** Clinical study experience: headache, flushing, dizziness,

dyspepsia, nasal congestion, altered vision (colour tinge, increased perception of light or blurred vision). Dyspepsia and altered vision more common at 100mg. Muscle aches when sildenafil administered more frequently than recommended. Post marketing experience: priapism. **Driving and operating machinery:** Caution if affected by dizziness or altered vision. **Legal category:** POM. **Basic NHS cost:** Packs of 4, 25mg tablets [EU/1/98/077/002] £16.59; Packs of 8, 25mg tablets [EU/1/98/077/003] £33.19; Packs of 4, 50mg tablets [EU/1/98/077/006] £19.34; Packs of 8, 50mg tablets [EU/1/98/077/007] £38.67; Packs of 4, 100mg tablets [EU/1/98/077/010] £23.50; Packs of 8, 100mg tablets [EU/1/98/077/011] £46.99. **Marketing Authorisation Holder:** Pfizer Limited, Sandwich, Kent, CT13 9NJ, United Kingdom. Last revised: 21 October 1998. Further information on request: Pfizer Limited, Sandwich, Kent, CT13 9NJ. **References:** 1. Goldstein I et al. *New Engl J Med*, 1998, 338(20): 1397-1404. 2. Morales A et al. *Int J Impotence Res*, 1998, 10: 69-74. 10312





Prescription for depression,
tender
loving care
and

SEROXAT
PAROXETINE

Now indicated for Social Phobia

Rebuilding the lives
of more anxious
depressed patients than any
other antidepressant¹

PRESCRIBING INFORMATION

Prescribing information

Presentation: 'Seroxat' Tablets, PL 10592/0001-2, each containing either 20 or 30 mg paroxetine as the hydrochloride. 30 (OP) 20 mg tablets, £20.77; 30 (OP) 30 mg tablets, £31.16.

'Seroxat' Liquid, PL 10592/0092, containing 20 mg paroxetine as the hydrochloride per 10 ml. 150 ml (OP), £20.77.

Indications: Treatment of symptoms of depressive illness of all types including depression accompanied by anxiety. Following satisfactory response, continuation is effective in preventing relapse. Treatment of symptoms and prevention of relapse of obsessive compulsive disorder (OCD). Treatment of symptoms and prevention of relapse of panic disorder with or without agoraphobia. Treatment of symptoms of social anxiety disorder/social phobia.

Dosage: Adults: Depression: 20 mg a day. Review response within two to three weeks and if necessary increase dose in 10 mg increments to a maximum of 50 mg according to response.

Obsessive compulsive disorder: 40 mg a day. Patients should be given 20 mg a day initially and the dose increased weekly in 10 mg increments. Some patients may benefit from a maximum dose of 60 mg a day.

Panic disorder: 40 mg a day. Patients should be given 10 mg a day initially and the dose increased weekly in 10 mg increments. Some patients may benefit from a maximum dose of 50 mg a day. Social anxiety disorder/social phobia: 20 mg a day. Patients should start on 20 mg and if no improvement after at least two weeks they may benefit from weekly 10 mg dose increases up to a maximum of 50 mg/day according to response. 'Seroxat' has been shown to be effective in 12 week placebo-controlled trials. There is only limited evidence of efficacy after 12 weeks' treatment.

Give orally once a day in the morning with food. The tablets should not be chewed. Continue treatment for a sufficient period, which should be at least four to six months after recovery for depression and may be longer for OCD and panic disorder. As with many psychoactive medications abrupt discontinuation should be avoided – see **Adverse reactions**.

Elderly: Dosing should commence at the adult starting dose and may be increased in weekly 10 mg increments up to a maximum of 40 mg a day according to response.

Children: Not recommended.

Severe renal impairment (creatinine clearance <30 ml/min) or severe hepatic impairment: 20 mg a day. Restrict incremental dosage if required to lower end of range.

Contra-indication: Hypersensitivity to paroxetine.

Precautions: History of mania. Cardiac conditions: caution. Caution in patients with epilepsy; stop treatment if seizures develop. Driving and operating machinery.

Drug interactions: Do not use with or within two weeks after MAO inhibitors; leave a two-week gap before starting MAO inhibitor treatment. Possibility of interaction with tryptophan. Great caution with warfarin and other oral anticoagulants. Use lower doses if given with drug metabolising enzyme inhibitors; adjust dosage if necessary with drug metabolising enzyme inducers. Alcohol is not advised. Use lithium with caution and monitor lithium levels. Increased adverse effects with phenytoin; similar possibility with other anticonvulsants.

Pregnancy and lactation: Use only if potential benefit outweighs possible risk.

Adverse reactions: In controlled trials most commonly nausea, somnolence, sweating, tremor, asthenia, dry mouth, insomnia, sexual dysfunction (including impotence and ejaculation disorders), dizziness, constipation and decreased appetite.

Also spontaneous reports of dizziness, vomiting, diarrhoea, restlessness, hallucinations, hypomania, rash including urticaria with pruritus or angioedema, and symptoms suggestive of postural hypotension. Extrapyrimal reactions reported infrequently; usually reversible abnormalities of liver function tests and hyponatraemia described rarely. Symptoms including dizziness, sensory disturbance, anxiety, sleep disturbances, agitation, tremor, nausea, sweating and confusion have been reported following abrupt discontinuation of 'Seroxat'. It is recommended that when antidepressant treatment is no longer required, gradual discontinuation by dose-tapering or alternate day dosing be considered.

Overdosage: Margin of safety from available data is wide. Symptoms include nausea, vomiting, tremor, dilated pupils, dry mouth, irritability, sweating and somnolence. No specific antidote. General treatment as for overdosage with any antidepressant. Early use of activated charcoal suggested.

Legal category: POM. 10.9.98

SB **SmithKline Beecham**
Pharmaceuticals

**PARTNERS IN
PSYCHIATRIC CARE**

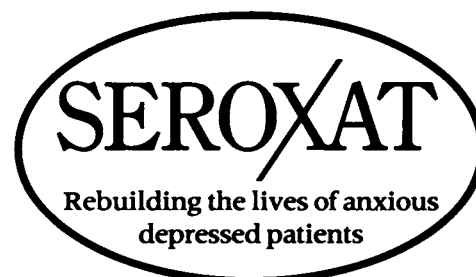
Welwyn Garden City, Hertfordshire AL7 1EY.

'Seroxat' is a trade mark.

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Reference: 1. Data on file.

0098/ST/AD/8/039BJ



short cut from depression



MIRTAZAPINE

ZISPIN[®] 30[▼] mg

There's no time like the present to beat depression

Prescribing Information

Presentation: Blister strips of 28 tablets each containing 30 mg of mirtazapine. **Uses:** Treatment of depressive illness. **Dosage and administration:** The tablets should be taken orally, if necessary with fluid, and swallowed without chewing. **Adults and elderly:** The effective daily dose is usually between 15 and 45 mg. **Children:** Not recommended. The clearance of mirtazapine may be decreased in patients with renal or hepatic insufficiency. Zispin is suitable for once-a-day administration, preferably as a single night-time dose. Treatment should be continued until the patient has been completely symptom-free for 4-6 months. **Contraindications:** Hypersensitivity to mirtazapine or any ingredients of Zispin. **Precautions and warnings:** Reversible white blood cell disorders including agranulocytosis, leukopenia and granulocytopenia have been reported with Zispin. The physician should be alert to symptoms such as fever, sore throat, stomatitis or other signs of infection; if these occur, treatment should be stopped and blood counts taken. Patients should also be advised of the importance of these symptoms. Careful dosing as well as regular and close monitoring is essential. **Interactions:** Zispin should not be administered concomitantly with MAO inhibitors or within two weeks of cessation of therapy with these agents; Mirtazapine may potentiate the sedative effects of benzodiazepines. In vitro data suggest that clinically significant interactions are unlikely with mirtazapine. **Pregnancy and lactation:** The safety of Zispin in human pregnancy has not been established. Use during pregnancy is not recommended. Women of child bearing potential should employ an adequate method of contraception. Use in nursing mothers is not recommended. **Adverse effects:** Common (>1/100): Increase in appetite and weight gain. Drowsiness/sedation,

melitus. Treatment should be discontinued if jaundice occurs. Moreover, as with other antidepressants, the following should be taken into account: worsening of psychotic symptoms can occur when antidepressants are administered to patients with schizophrenia or other psychotic disturbances; when the depressive phase of manic-depressive psychosis is being treated, it can transform into the manic phase. Zispin has sedative properties and may impair concentration and alertness. **Interactions:** Mirtazapine may potentiate the central nervous dampening action of alcohol; patients should therefore be advised to avoid alcohol during treatment with Zispin. Zispin should not be administered concomitantly with MAO inhibitors or within two weeks of cessation of therapy with these agents; Mirtazapine may potentiate the sedative effects of benzodiazepines. In vitro data suggest that clinically significant interactions are unlikely with mirtazapine. **Pregnancy and lactation:** The safety of Zispin in human pregnancy has not been established. Use during pregnancy is not recommended. Women of child bearing potential should employ an adequate method of contraception. Use in nursing mothers is not recommended. **Adverse effects:** Common (>1/100): Increase in appetite and weight gain. Drowsiness/sedation,

levels. **Rare (<1/1000):** Oedema and accompanying weight gain. Reversible agranulocytosis has been reported as a rare occurrence. (Orthostatic) hypotension. Exanthema. Mania, convulsions, tremor, myoclonus. **Overdosage:** Toxicity studies in animals suggest that clinically relevant cardiotoxic effects will not occur after overdosing with Zispin. Experience in clinical trials and from the market has shown that no serious adverse effects have been associated with Zispin in overdose. Symptoms of acute overdosage are confined to prolonged sedation. Cases of overdose should be treated by gastric lavage with appropriate symptomatic and supportive therapy for vital functions. **Marketing authorization number:** PL 0065/0145 **Legal category:** POM **Basic NHS cost:** £24 for 28 tablets of 30 mg.

For further information, please contact:



Nourypharma

Organon Laboratories Limited, Cambridge Science Park,
Cherry Redden Road, Welwyn Garden City, Herts SG13 7NB

CLOZARIL

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: 25 mg 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 first day, followed by one or two 25 mg tablets on second day. Increase dose slowly, by increments (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. Doses up to 900mg daily may be used. Dose-related convulsions have been reported especially during dose titration. Patients with a history of seizures, those suffering from cardiovascular, renal or hepatic disorders, and 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 and Precautions: 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 then strict haematological monitoring of patients has been demonstrated to be effective in markedly reducing the risk of fatality. Because of this risk, CLOZARIL 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 two-weekly 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 discontinuation of CLOZARIL. Patients must be under specialist supervision. 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 and a drug supply audit so that CLOZARIL is promptly withdrawn from any patient who develops abnormal leucocyte findings. Each time CLOZARIL is prescribed, patients should be reminded to contact their physician immediately if any kind of infection begins to develop, especially if flu-like. Immediate differential count is necessary if signs or symptoms of infection develop. Re-evaluate any patient developing an infection, or when a routine white blood count of 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. 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. 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. Discontinue colony stimulating factor 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, if 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 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, rarely, can be profound and may lead to cardiac and/or respiratory arrest. Caution is advised with concomitant highly protein bound drugs. 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 has been 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 CLOZARIL effectiveness. No clinically relevant interactions have been noted with tricyclic antidepressants, phenothiazines and type Ic antiarrhythmics, to date. Concomitant 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 e.g. dry mouth, disturbances of accommodation and sweating/temperature regulation. Hypersalivation may occur. Tachycardia and postural hypotension, with or without syncope, and less commonly hypertension may occur. Rarely, 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 overdosage. Nausea and vomiting have been reported. Mild constipation may occur, however, it may be more severe and fatal complications including gastrointestinal obstruction and paralytic ileus have occurred. Monitor patients and prescribe laxatives, as required. Care is required in patients receiving other medicines known to cause constipation or with a history of colonic disease or lower abdominal surgery. Asymptomatic elevations in liver enzymes occur commonly and usually resolve without drug discontinuation. 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. 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: January 1999. Full prescribing information, including Summary of Product Characteristics is available from Novartis Pharmaceuticals UK Ltd. Trading as: SANDOZ PHARMACEUTICALS, Frimley Business Park, Frimley, Camberley, Surrey, GU16 5SG.

THE ENVY

A GOLD STANDARD THERAPY FOR

OF OTHER

TREATMENT-RESISTANT SCHIZOPHRENIA

ATYPICALS?

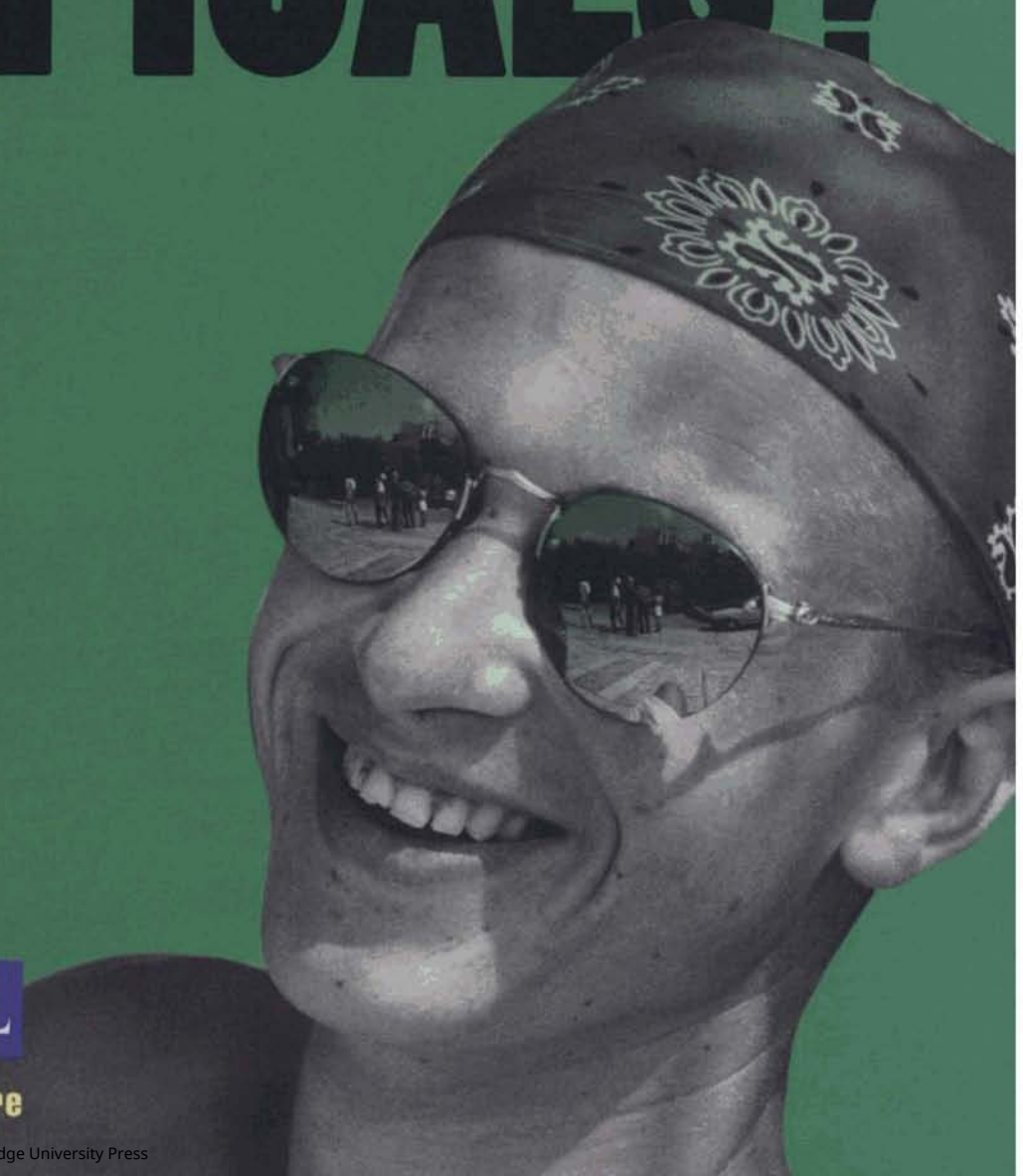
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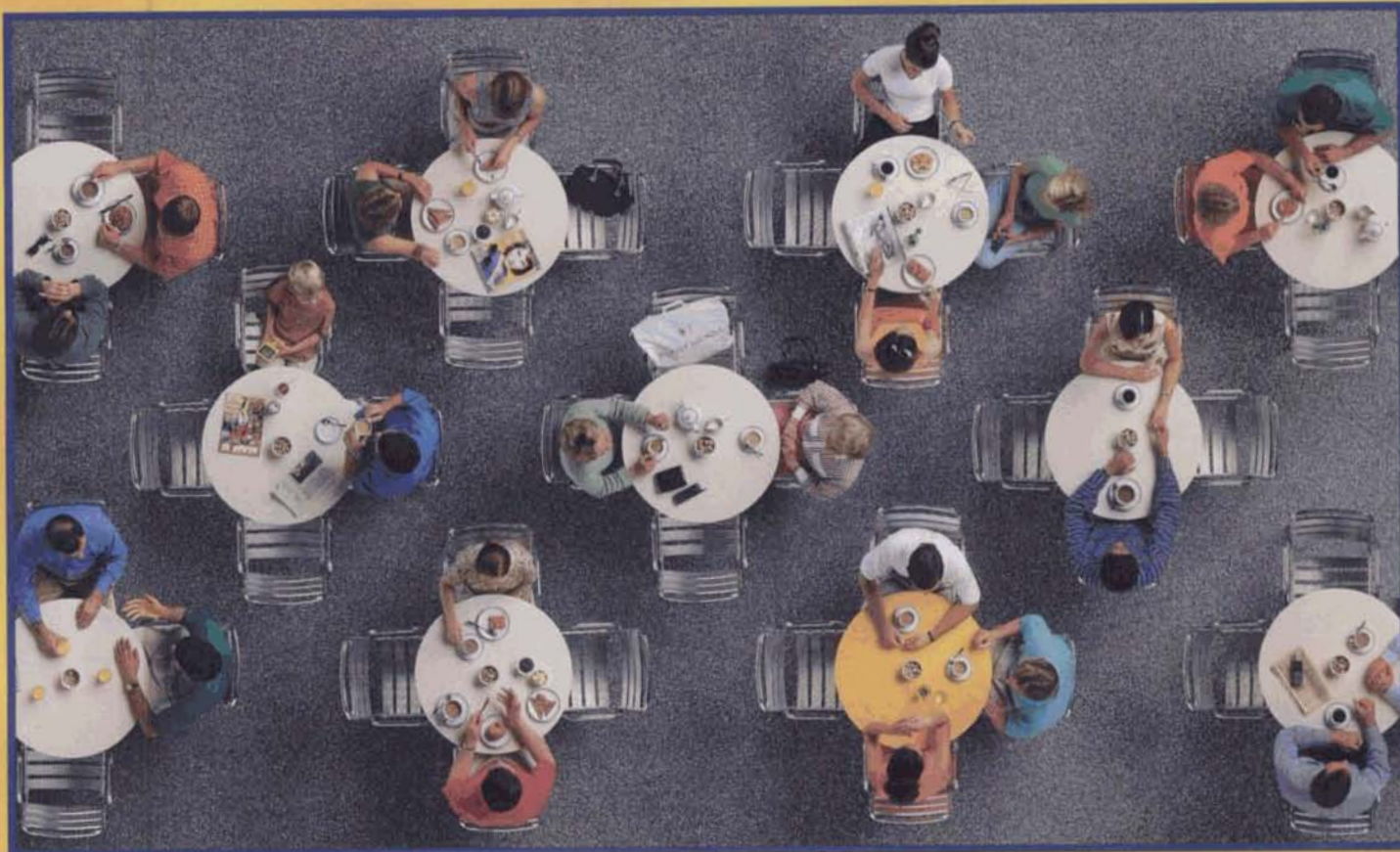
When
others fail,
its
unsurpassed
efficacy
changes
people's
lives.
Why don't
you use
it more?



CLOZARIL
clozapine

A pathway to lasting care
in the community





Add life to living with schizophrenia

Solian is a new benzamide antipsychotic, with the ability to treat both the positive¹ and negative² symptoms of schizophrenia.

Solian offers a lower incidence of EPS than standard neuroleptics such as haloperidol,³ as well as avoiding some of the drawbacks of certain atypicals: it does not require routine cardiovascular^{4,5} or haematological^{4,6}

monitoring and patients gain significantly less weight than those treated with risperidone.²

So when patients need the ability to cope with their condition, Solian has the power to treat their positive¹ and their negative² symptoms whilst still allowing them to do the everyday things that the rest of us take for granted.

Solian[®]
AMISULPRIDE



Efficacy that patients can live with

Prescribing Information - Solian 200 and Solian 50 ▼ **Presentation:** Solian 200mg tablets contain 200mg amisulpride and Solian 50mg tablets contain 50mg amisulpride. **Indication:** Acute and chronic schizophrenia in which positive and/or negative symptoms are prominent. **Dosage:** Acute psychotic episodes: 400-800mg/day, increasing up to 1200mg/day according to individual response (dose titration not required), in divided doses. Predominantly negative symptoms: 50-300mg once daily adjusted according to individual response. Elderly: administer with caution due to the risk of hypotension or sedation. Renal insufficiency: reduce dose and consider intermittent therapy. Hepatic insufficiency: no dosage adjustment necessary. Children: contraindicated in children under 15 years (safety not established). **Contraindications:** Hypersensitivity; concomitant prolactin-dependent tumours e.g. pituitary gland prolactinaemias and breast cancer; phaeochromocytoma; children under 15 years; pregnancy; lactation; women of child-bearing potential unless using adequate contraception. **Warnings and Precautions:** As with all neuroleptics, neuroleptic malignant syndrome may occur (discontinue Solian). Caution in patients with a history of epilepsy and Parkinson's disease. **Interactions:** Caution in

hypotensive medications, and dopamine agonists. **Side Effects:** Insomnia, anxiety, agitation. Less commonly somnolence and GI disorders. In common with other neuroleptics: Solian causes a reversible increase in plasma prolactin levels; Solian may also cause weight gain, acute dystonia, extrapyramidal symptoms, tardive dyskinesia, hypotension and bradycardia; rarely, allergic reactions, seizures and neuroleptic malignant syndrome have been reported. **Basic NHS Cost:** Blister packs of: 200mg x 60 tablets - £60.00; 200mg x 90 tablets - £90.00; 50mg x 60 tablets - £16.45; 50mg x 90 tablets - £24.69. **Legal Category:** POM. **Product Licence Numbers:** Solian 200 - PL 15819/0002, Solian 50 - PL 15819/0001. **Product Licence Holder:** Lorex Synthelabo UK and Ireland Ltd, Foundation Park, Roxborough Way, Maidenhead, Berks, SL6 3UD. **References:** 1. Freeman HL. Int Clin Psychopharmacol 1997;12(Suppl 2):S11-S17. 2. Möller HJ. 6th World Congress of Biological Psychiatry, Nice, France, June 22-27 1997. 3. Coukell AJ, Spencer CM, Benfield P. CNS Drugs (Adis) 1996 Sep 6 (3):237-256. 4. Solian SPC. Lorex Synthelabo. 5. Sertindole SPC. Lundbeck Ltd. 6. Clozapine SPC.

SYNTHELABO
CNS DIVISION