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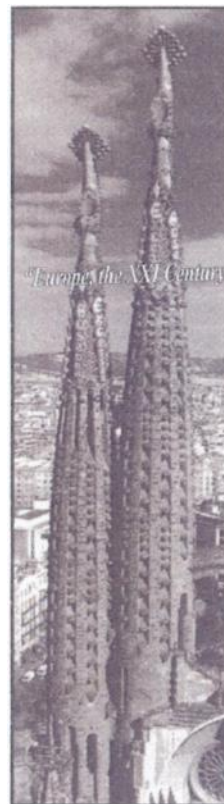
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Please read Summary of Product Characteristics before prescribing.

Presentation: Tablets containing 25 mg, 50 mg, 100 mg, or 200 mg topiramate. **Uses:** Adjunctive therapy of inadequately controlled seizures: partial seizures; seizures associated with Lennox Gastaut Syndrome and primary generalised tonic/clonic seizures. **Dosage and Administration:** Oral administration. **Over 16 years of age:** Usual dose: 200-400 mg/day in two divided doses. Initiate at 50 mg daily then titrate to an effective dose. A lower dose may be used. Patients with significant renal disease may require a dose modification. See SmPC for additional information. **Children age 2 to 16:** Usual dose: Approximately 5 to 9 mgs/kg/day in two divided doses. Initiate at 25 mg nightly, and increase at 1 to 2 week intervals in 1 to 3 mg/kg increments, to an effective dose. **Contraindications:** Hypersensitivity to any component. **Precautions and Warnings:** Withdraw all antiepileptic drugs slowly. Hydrate to reduce the risk of nephrolithiasis (especially if predisposed). Drowsiness likely. Topamax may be sedating; therefore caution if driving or operating machinery. Do not use in pregnancy unless potential benefit outweighs risk. Woman of childbearing potential should use adequate contraception. Do not use if breastfeeding. **Interactions:** *Other Antiepileptic Drugs:* No clinically significant effect except in some patients on phenytoin where phenytoin plasma concentrations may increase. Phenytoin level monitoring is advised. *Effects of other antiepileptic drugs:* Phenytoin and carbamazepine decrease topiramate plasma concentration. Digoxin: A decrease in serum digoxin level by 50% has been reported. **Withdrawal of TOPAMAX®:** Oral Contraceptives: Should contain not less than 50µg of oestrogen. Ask patients to report any

slowing, somnolence, speech disorders/related speech problems, abnormal vision and weight decrease. May cause agitation and emotional lability (mood problems and nervousness) and depression. Less common adverse effects include, gait abnormal, aggressive reaction, apathy, cognitive problems, coordination problems, leucopenia, psychotic symptoms (such as hallucinations), and taste perversion. Venous thromboembolic events reported - causal association not established. **Children:** In 5% or more: somnolence, anorexia, fatigue, insomnia, nervousness, personality disorder (behaviour problems), difficulty with concentration/attention, aggressive reaction, weight decrease, gait abnormal, mood problems, ataxia, saliva increased, nausea, difficulty with memory, hyperkinesia, dizziness, speech disorders/related speech problems and paraesthesia. Less frequently but potentially relevant: emotional lability, agitation, apathy, cognitive problems, psychomotor slowing, confusion, hallucination, depression and leucopenia. Topamax increases the risk of nephrolithiasis. **Overdosage:** If ingestion recent, empty stomach. Activated charcoal not recommended. Supportive treatment as appropriate. Haemodialysis is effective in removing topiramate. **Pharmaceutical Precautions:** Store in a dry place at or below 25°C. **Legal Category:** POM. **Package Quantities and Prices:** Bottles of 60 tablets. 25 mg (PL0242/0301) = £22.02, 50 mg (PL0242/0302) = £36.17; 100 mg (PL0242/0303) = £64.80; 200 mg (PL0242/0304) = £125.83. **Product licence holder:** JANSSEN-CILAG LIMITED, SAUNDERTON, HIGH WYCOMBE, BUCKINGHAMSHIRE HP14 4HJ ENGLAND. APIVER200498. Further information is available on request from the Marketing Authorisation Holder: Janssen-Cilag Limited, Saunderton, High Wycombe, Buckinghamshire HP14 4HJ.

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 years 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 overdose. 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?

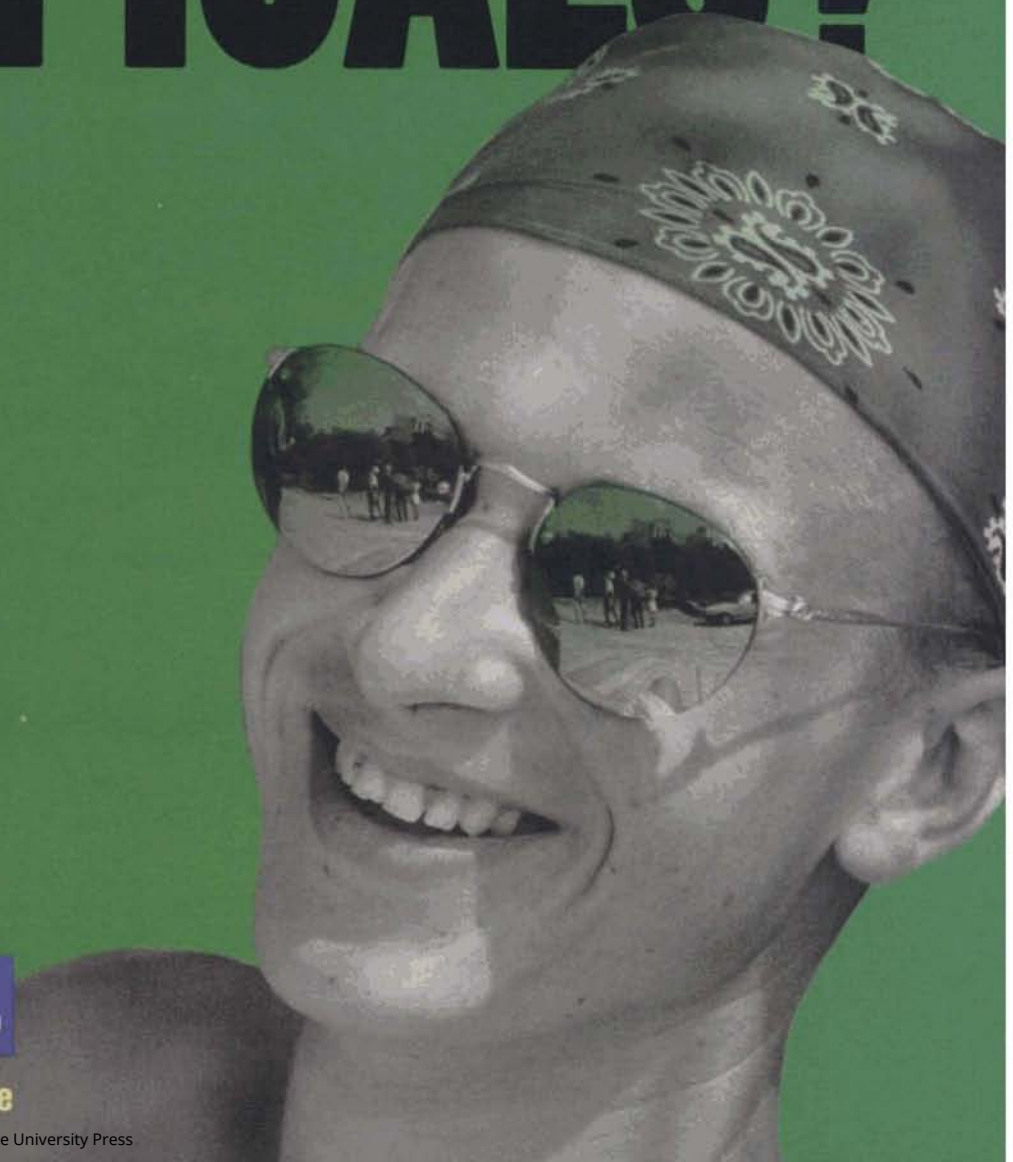
WHY?

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



Please refer to summary of product characteristics before prescribing.
Presentation: White to off-white tablets each containing modafinil 100 mg. **Indication:** Narcolepsy. **Dosage:** Adults: 200-400 mg daily either as two divided doses in the morning and at noon or as a single morning dose according to response. **Effect:** Treatment should start at 100 mg daily which may be increased subsequently to the maximum adult daily dose in the absence of renal or hepatic impairment. **Severe renal or hepatic impairment:** Reduce dose by half (100/200 mg daily). **Children:** See contra-indications. **Contra-indications:** Pregnancy, lactation, use in children, moderate to severe hypertension, arrhythmia, hypersensitivity to modafinil or any excipients used in Provigil. **Warnings and precautions:** Patients with major anxiety should only receive Provigil treatment in a specialist unit. Sexually active women of child-bearing potential should be established on a contraceptive programme before starting treatment. Blood pressure and heart rate should be monitored in hypertensive patients. Provigil is not recommended in patients with a history of left ventricular hypertrophy or ischaemic ECG changes, chest pain, arrhythmia or other clinically significant manifestations of mitral valve prolapse in association with CNS stimulant use. Studies of modafinil have demonstrated a low potential for dependence although the possibility of this occurring with long-term use cannot be entirely excluded. **Drug interactions:** Induction of cytochrome P-450 isoenzymes has been observed *in vitro*. Effectiveness of oral

containing at least 50 mg ethinyloestradiol should be taken. Tricyclic antidepressants, no clinically relevant interaction was seen in a single-dose interaction study of Provigil and clomipramine. However, patients receiving such medication should be carefully monitored. Care should be observed with co-administration of anti-convulsant drugs. **Side effects:** Nervousness, excitation, aggressive tendencies, insomnia, personality disorder, anorexia, headache, CNS stimulation, euphoria, abdominal pain, dry mouth, palpitation, tachycardia, hypertension and tremor have been reported. Nausea and gastric discomfort may occur and may improve when tablets are taken with meals. Pruritic skin rashes have been observed occasionally. Buccofacial dyskinesia has been reported very rarely. A dose-related increase in alkaline phosphatase has been observed. **Basic NHS cost:** Packs of 30 blister-packed 100 mg tablets: £60.00. **Marketing authorisation number:** 16260/0001. **Marketing authorisation holder:** Cephalon UK Ltd, 11-13 Frederick Sanger Road, Surrey Research Park, Guildford, GU2 5YD. **Legal category:** POM. **Date of preparation:** January 1998. Provigil and Cephalon are registered trademarks. **References:** 1. Miller MM. Sleep 1994; 17: S103-S106. 2. Data on file, Cephalon [3]. 3. Lin JS *et al* *Prog Natl Acad Sci USA* 1996; 93 (24): 14128-14133. 4. Simon P *et al* *Eur Neuropsychopharmacol* 1995; 5: 509-514.



WAKE UP LITTLE SUZIE, WAKE UP

Excessive sleepiness associated with narcolepsy frequently has a disastrous effect on patients' lives, by impairing their physical, social and emotional well-being. Unfortunately, treatment with amphetamines is often associated with a high incidence of unpleasant side effects, which limit their overall benefit.¹

Now Provigil (modafinil) – a novel wake promoting agent – offers new advantages in narcolepsy. The clinical efficacy of Provigil has been demonstrated in large controlled clinical studies. In one study,² one in five people with severe narcolepsy reached normal levels of daytime wakefulness while receiving Provigil.

Provigil selectively activates the hypothalamus³ and differs greatly from amphetamines in its pharmacology.⁴ Consequently the incidence of amphetamine

PROVIGIL® ▼
MODAFINIL

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 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 bid is recommended. This can be individually adjusted with 0.5 mg bid increments to 1 to 2 mg bid. 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. **CONTRA-INDICATIONS, 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, 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, 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 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 £19.56. 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 0242/0199 £85.00. **FURTHER INFORMATION IS AVAILABLE FROM THE PRODUCT LICENCE HOLDER**, Janssen-Cilag Ltd, Sandertown, High Wycombe, Buckinghamshire HP14 4JU. APIVER140797



Date of preparation: August 1998

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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; pheochromocytoma; children under 15 years; pregnancy; lactation; women of child-bearing potential unless on effective contraception. **Warnings and Precautions:** As with all neuroleptics, neuroleptic malignant syndrome may occur (discontinue Solian). Caution

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

Indication: Treatment of schizophrenia. **Dosage and Administration:** Zoleptil is given orally in divided doses with or without food. **Adults:** The effective adult dose is 75 to 300mg daily. The recommended starting dose is 25mg taken three times daily. The dose may be adjusted according to clinical response up to a maximum of 100mg three times daily. Dosage adjustments should be made at intervals of four days. Doses above 300mg per day may increase the risk of seizures. **Elderly patients and patients with established hepatic and/or renal impairment:** A starting dose of 25mg twice daily is recommended. Titration should be gradual, based on efficacy and tolerability, up to a maximum of 75mg twice daily. Zoleptil is not recommended for use in children under 18 years of age. **Contraindications:** Known hypersensitivity to Zoleptil or any of its excipients. Patients suffering from acute intoxication with CNS depressants including alcohol. As with other uncouplers, Zoleptil should not be used in patients with acute gout or a history of nephrolithiasis though in practice the risk of increased urate renal stone formation appears to be low. **Precautions:** Zoleptil should not be used to treat patients with a history of epilepsy unless the benefit outweighs the risk. Caution is advised when using Zoleptil in patients at risk of arrhythmias or in combination with drugs known to cause prolongation of the QTc interval. When treating patients from these groups it is recommended that an ECG is performed before starting treatment. Caution is advised in patients with known severe cardiovascular disease including severe hypertension or severely restricted cardiac output. Zoleptil is associated with an increase in heart rate and should therefore be used with caution in patients suffering from angina pectoris. Zoleptil may cause orthostatic hypotension and a dose reduction or more gradual titration should be considered if this occurs. Isolated cases of neuroleptic malignant syndrome have been reported. In this event all antipsychotic drugs including Zoleptil should be discontinued. If a reduction in white cell count is suspected a white cell count should be performed. A lower starting dose, gradual titration and a reduced maximum daily dose should be used in the elderly, and in renally or hepatically impaired patients. Monitoring of liver function tests is recommended in patients with hepatic impairment. Patients should be advised of the possibility for weight gain. Isolated cases of tardive dyskinesia have occurred. In this case the discontinuation or reduction in dose of all antipsychotics should be considered. Zoleptil should be used with caution in patients with prostatic hypertrophy, retention of urine, narrow angle glaucoma and paralytic ileus. Zoleptil has uncoupler properties and should be used with caution in patients with gout or hyperuricaemia. Patients should be advised not to drive or operate machinery until their susceptibility has been established. **Pregnancy and Lactation:** Zoleptil should not be used during pregnancy unless the benefits to the mother outweigh the potential risks to the baby. Nursing mothers taking Zoleptil should not breast-feed. **Interactions:** Zoleptil should be used with caution in combination with other centrally acting drugs, in particular high doses of other antipsychotics which may further lower the seizure threshold, as well as fluoxetine and diazepam which may lead to increased plasma concentrations of zotepine. Caution should be exercised when Zoleptil is co-prescribed with hypotensive agents, including some anaesthetic agents. **Side Effects and Adverse Reactions:** The following adverse events have been reported in association with Zoleptil therapy in clinical trials and spontaneously during clinical usage (approximately 1.98 million patients treated). Most commonly reported adverse events include:

asthenia, chills, headache, infection, pain, hypotension, tachycardia, constipation, dyspepsia, elevated liver function tests, changes in ESR, leucocytosis and leucopenia, weight increase, agitation, anxiety, depression, dizziness, dry mouth, EEG abnormal, extrapyramidal syndrome, insomnia, salivation increased, somnolence, rhinitis, sweating, blurred vision. Occasionally reported were: abdominal pain, chest pain, fever, flu syndrome, malaise, arrhythmia, ECG abnormality, hypertension, postural hypotension, syncope, anorexia, appetite increased, diarrhoea, nausea, vomiting, prolactin increased, abnormal blood cells, anaemia, thrombocythaemia, creatinine increased, hyperglycaemia, hypoglycaemia, hyperlipidaemia, hypouricaemia, oedema, thirst, weight loss, arthralgia, joint disease, myalgia, confusion, convulsions, dysautonomia, hostility, libido decreased, nervousness, speech disorder, vertigo, cough increase, dyspnoea, acne, dry skin, rash, conjunctivitis, impotence, urinary incontinence. **Overdosage:** May result in exaggerated pharmacological effects which include hypotension, tachycardia, arrhythmias, agitation, pronounced extrapyramidal effects, hypo- or hyperthermia, seizures, respiratory depression, stupor or coma. There is no specific antidote, therefore appropriate supportive measures should be instituted. A clear airway should be established and maintained, and adequate oxygenation and ventilation ensured. Gastric lavage and administration of activated charcoal together with a laxative should be considered. Cardiovascular monitoring should commence immediately and should include continuous ECG monitoring to detect possible arrhythmias. Hypotension and circulatory collapse should be treated by plasma volume expansion and other appropriate measures. If sympathomimetic agents are used for vascular support, adrenaline and dopamine should not be used as this may worsen hypotension. In the case of severe extrapyramidal symptoms, anticholinergic medication should be administered. Seizures may be treated with intravenous diazepam. Close medical supervision and monitoring should continue until the patient recovers. **Legal Category:** POM. **Product Licence Numbers:** 25mg tablets: PL00169/0110; 50mg tablets: PL00169/0111; 100mg tablets: PL00169/0112. **Presentations, Nature and Content of Containers, Basic NHS Cost:** Zoleptil 25: white sugar-coated tablets containing 25mg zotepine provided in blister strip packs of 30 £15.00 and 90 £45.00. Zoleptil 50: yellow sugar-coated tablets containing 50mg zotepine provided in blister strip packs of 30 £20.00 and 90 £60.00. Zoleptil 100mg: pink sugar-coated tablets containing 100mg zotepine provided in blister strip packs of 30 £33.00 and 90 £99.00. **Marketing Authorisation Holder:** Knoll Ltd, 9 Castle Quay, Castle Boulevard, Nottingham NG7 1FW, England. Full prescribing information is available on request from Orion Pharma (UK) Ltd, 1st floor, Leat House, Overbridge Square, Hambridge Lane, Newbury, Berkshire, RG14 5UX. Zoleptil is a registered trade mark. **Date of Preparation:** October 1998.

Orion Pharma (UK) Ltd, 1st Floor, Leat House, Overbridge Square, Hambridge Lane, Newbury, BERKS RG14 5UX



ZOL0210

SCHIZOPHRENIA?



TURNING POINT IN



As a modern antipsychotic, it is no surprise that Zoleptil offers effective control of positive symptoms of schizophrenia as well as a significant reduction in SANS total score. But what may come as a surprise is the fact that over 2 million patients have already been treated with Zoleptil.



A SURPRISING ANTIPSYCHOTIC

Campral EC acamprosate

Presentation: Off-white round enteric-coated tablets, containing 333mg acamprosate calcium. Printed on one side with 333. **Properties:** Acamprosate 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* \geq 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

period. **Interactions:** None observed in studies with diazepam, disulfiram or imipramine. The concomitant intake of alcohol and acamprosate does not affect the pharmacokinetics of either alcohol or acamprosate. **Side Effects:** Diarrhoea, and less frequently nausea, vomiting and abdominal pain; pruritus. These are usually mild and transient. An occasional maculopapular 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, Liphia 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

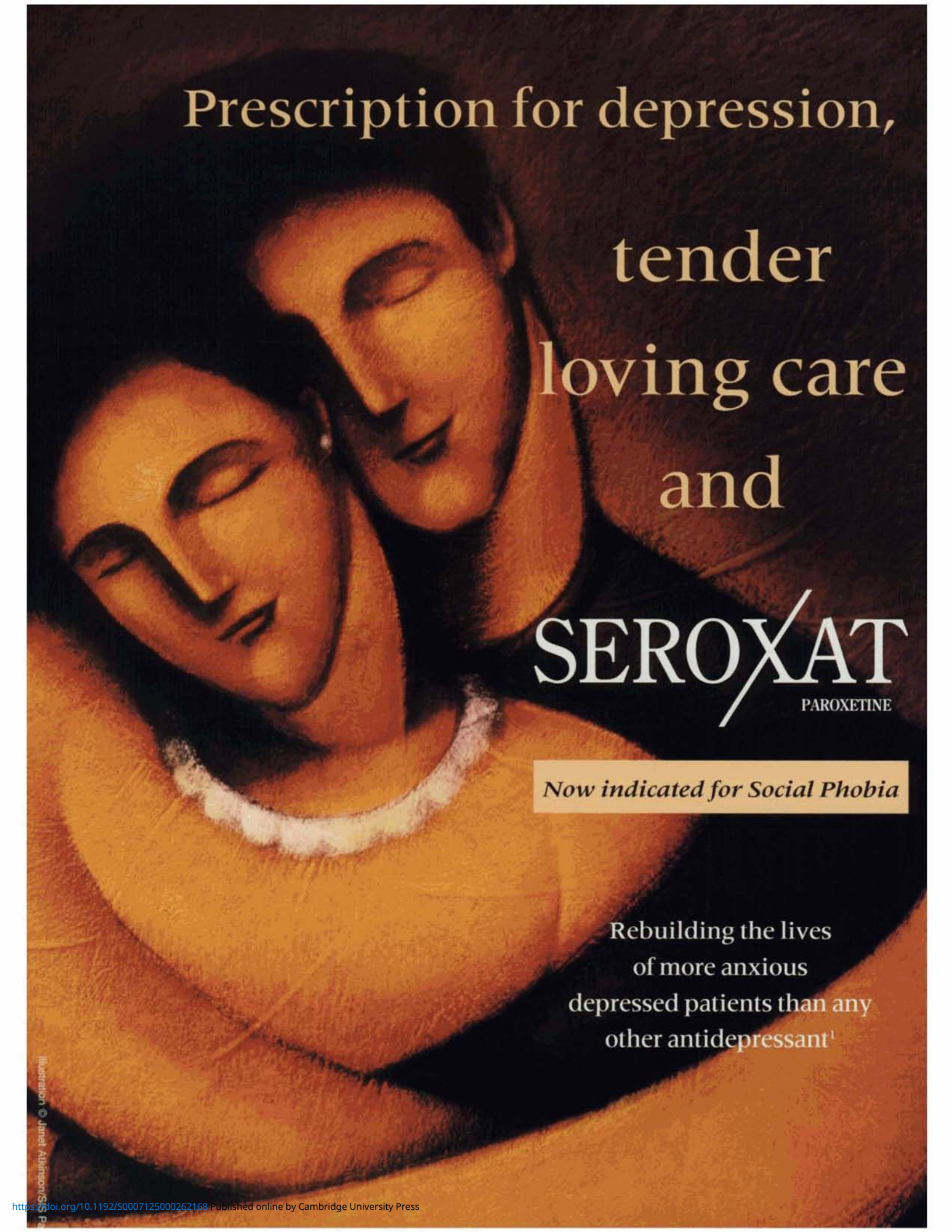
CAMPRAL EC HELPS PATIENTS ADAPT TO
LIFE WITHOUT ALCOHOL



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



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. Extrapyramidal 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



Welwyn Garden City, Hertfordshire AL7 1EY.

'Seroxat' is a trade mark.

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Reference: 1. Data on file.

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