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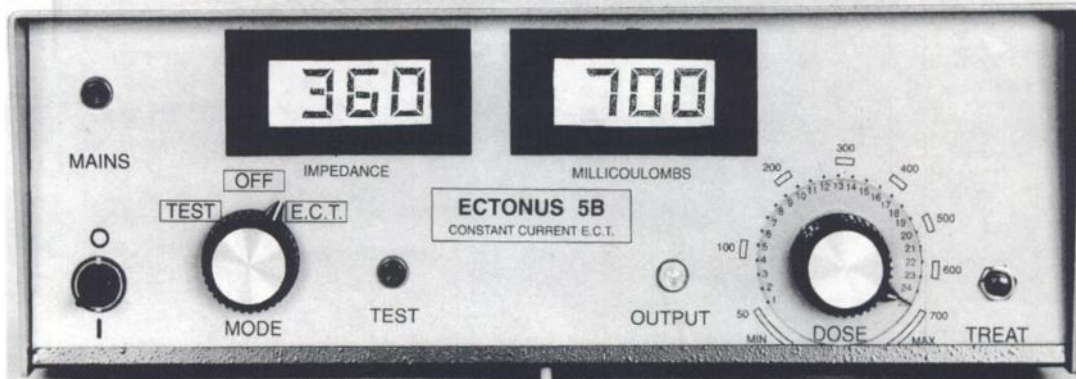
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Doses above 10mg/day may increase the risk of extrapyramidal symptoms and should only be used if the benefit is considered to outweigh the risk. Doses above 16mg/day should not be used. **Elderly, renal and liver disease:** A starting dose of 0.5mg b.d. is recommended. This can be individually adjusted with 0.5mg b.d. increments to 1 to 2mg b.d. Use with caution in these patients. 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. 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concentration. No clinically significant changes in plasma concentrations on sodium valproate addition or withdrawal. Digoxin: A decrease in serum digoxin occurs. Monitor serum digoxin on addition or withdrawal of TOPAMAX. Oral Contraceptives: Should contain not less than 50µg of oestrogen. Ask patients to report any change in bleeding patterns. <https://doi.org/10.1023/0007125090258911> Published online by Cambridge University Press. Confusion, dizziness, fatigue, paraesthesia, somnolence and abnormal thinking. May cause agitation and emotional

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 (PL0242/0301) = £22.02; 50mg (PL0242/0302) = £36.17; 100mg (PL0242/0303) = £64.80; 200mg (PL0242/0304) = £125.83. **Product Licence Holder:** JANSSEN-CILAG LIMITED, SAUNDERTON, HIGH WYCOMBE, BUCKINGHAMSHIRE HP14 4HJ Further information is available on request from the Marketing Authorisation Holder.

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

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

The facts about xerostomia

and how extra saliva can help.

How big a problem is xerostomia? Over 10 million people in the UK suffer from a sensation of dry mouth (xerostomia),¹ the subjective report of oral dryness.

The use of medications is one of the most common causes of xerostomia.² Over 400 commonly used drugs have been implicated in its aetiology.² These include antidepressants, antihistamines, antihypertensives, antipsychotics, antiemetics, anticholinergics, decongestants, diuretics and other blood pressure drugs.²

Dry mouth is also associated with Rheumatoid Arthritis, Systemic Lupus Erythematosus, Diabetes, Sjögren's Syndrome, Parkinson's Disease and HIV/AIDS.²

Oral dryness and quality of life Xerostomias commonly suffer from caries and oral soft tissue irritation, resulting in soreness and painful inflammation within the oral cavity.³ Dry mouth sufferers are more susceptible to bacteria and yeast infections (candidiasis).² Diminished salivary flow results in problems with tasting, chewing and swallowing food.² Mouth malodour (halitosis) is a common symptom. Speaking is also uncomfortable and inhibited.² Individuals who suffer with dry mouth experience both psychological distress and social embarrassment.

What to look out for: clinical signs and symptoms

- Cracked and fissured tongue.
- Frothy saliva and oral mucosa appears pale, thin and has lost its shine.
- A sudden increase in dental caries.
- No pooling of saliva in the floor of the mouth.
- Recurrent oral candida infections.
- A tongue blade or instrument sticking to soft tissues.
- Angular cheilosis.

Use of sugarfree gum to stimulate saliva Saliva is a protectant against plaque acid attack,⁴ tooth demineralisation,⁵ periodontal gingival disease and oral infections.⁶

Recently, considerable success has been achieved in the use of sugarfree gum to relieve the symptoms of xerostomia by stimulating salivary flow.^{3,7,8} Research among xerostomia patients has shown chewing gum stimulates saliva by up to 7 times its normal flow rate relative to resting saliva, providing immediate relief.⁹ Several studies have also shown that frequent chewing of sugarfree gum has a residual effect on salivary flow even when gum is no longer chewed.

Sugarfree gum for symptomatic relief Xerostomia is likely to become more widespread and take on increasing significance as our population becomes older and more reliant on medications. Sugarfree gum provides simple and effective relief from this common and often debilitating condition.

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1. Data on file. The Wrigley Company Ltd. 2. FDI Working Group. 10. International Dental Journal 1992; 42(4) Suppl. 2:296. 3. Whelton H *et al.* Data on file, The Wrigley Company Limited. 4. Manning RH *et al.* *Caries Res* 1991; 25(3): Abstract #78. 5. Leach SA *et al.* *J Dent Res* 1988;67: Abstract #647. 6. Council on Dental Therapeutics. *JADA* 1988; 116: 757. 7. Odulosa F. *NYSDJ* April 1991; 28-31. 8. Markovic N *et al.* *Gerontology* 1988; 7(2): 71-75. 9. Abelson DC *et al.* *J Clin Dent* 1990; 2(1): 3-5. 10. Edgar WM *et al.* *J Dent Res* 1981; 60 Sp.iss. 1137

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Going to the Doctor

*By Sheila Hollins, Jane Bernal and Matthew Gregory
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Going to the doctor can be a worrying experience. For people with a learning disability, there is the added fear of not being able to explain what's wrong, as well as not understanding what's happening. Feelings, information and consent are all addressed. A variety of scenarios are covered (examination, blood test, prescription, etc.). Ideally, this book should be used to prepare someone before going to the doctor but it will also be invaluable to General Practitioners and primary health care workers during consultations and before treatments.

£10.00 73pp. 1996 ISBN 1 874439 13 3

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10592/0001-2, each containing either 20 mg or 30 mg paroxetine as the hydrochloride. 30 (OP) 20 mg tablets, £20.77; 30 (OP) 30 mg tablets, £31.16. **Indications:** Treatment of symptoms of depressive illness of all types including depression accompanied by anxiety. Treatment of symptoms of obsessive compulsive disorder (OCD). Treatment of symptoms and prevention of relapse of panic disorder with or without agoraphobia. **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. Give orally once a day in the morning with food. The tablets should not be chewed. Continue treatment for a sufficient period, which may be several months for depression or 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. 1.7.96. † In the UK. **References** 1. Fleming J. *Prog Neuro-Psychopharmacol, Biol Psychiatr* 1989;13:419-29. 2. Hutchinson D et al. *Br J Clin Res* 1991;2:43-57. 3. Hindmarch I. *Int Clin Psychopharmacol* 1992;6(Suppl 4):65-7. 4. Dunbar GC et al. *Acta Psychiatr Scand* 1993;87:302-5. 5. Medicines Resource Centre. *Int Pharm J* 1992;6:6-9. 6. Dunbar GC, Fuell DL. *Int Clin Psychopharmacol* 1992;6(Suppl 4):81-9. 7. Dorman T. *Int Clin Psychopharmacol* 1992;6(Suppl 4):53.

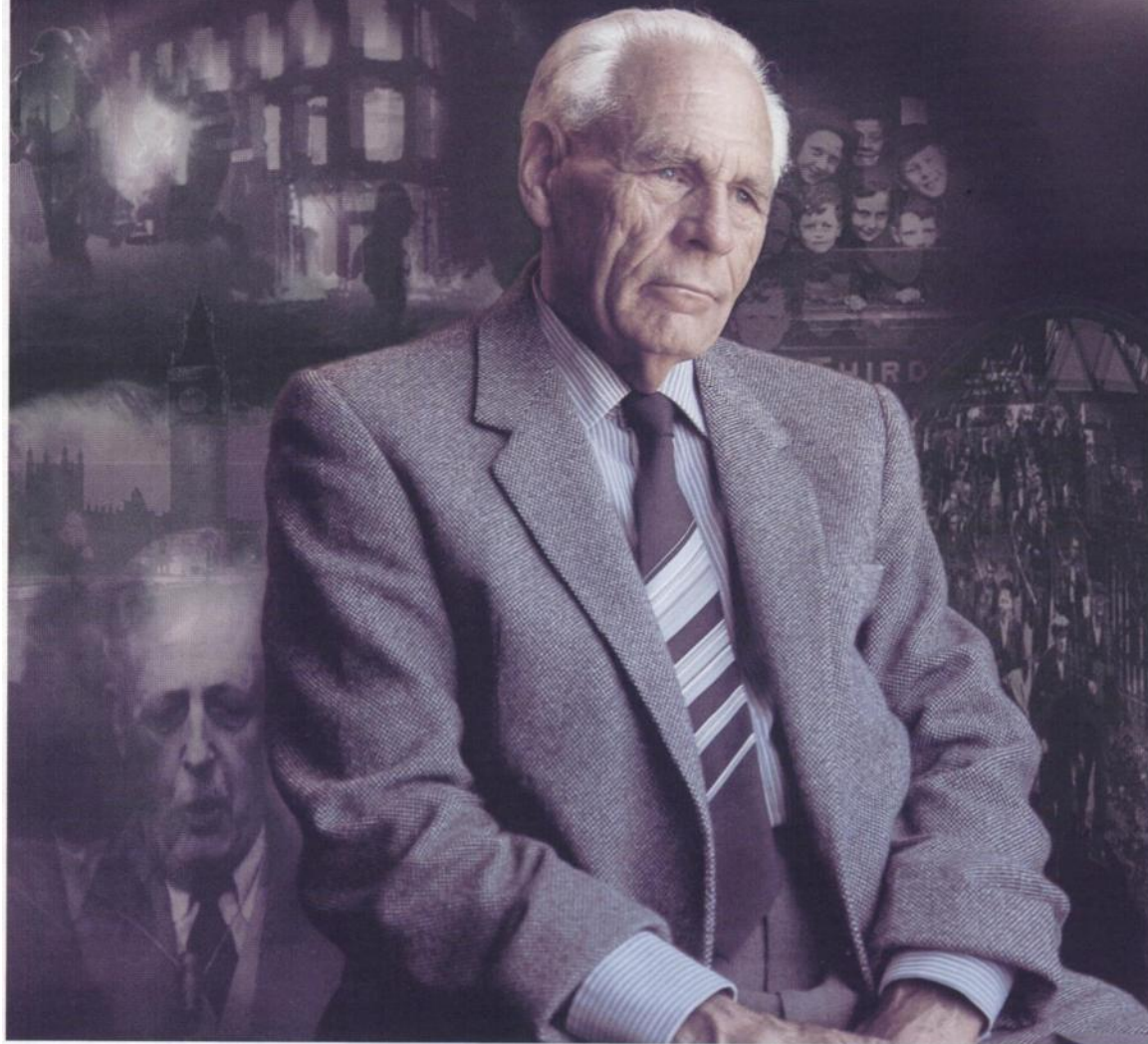
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Molipaxin (trazodone hydrochloride) 50 and 100mg capsules, Molipaxin tablets 150mg, Molipaxin CR tablets 150mg, Molipaxin Liquid (50mg/5ml). **Indications:** Relief of symptoms in all types of depression including depression accompanied by anxiety. Symptoms likely to respond in the first week include depressed mood, insomnia, anxiety, somatic symptoms and hypochondriasis. **Dosage and Administration:** Starting dose of Molipaxin is 150mg daily taken in divided doses after food or as a single dose on retiring. This may be increased to 300mg/day the major portion of which is preferably taken on retiring. In hospitalised patients, dosage may be further increased to 600mg/day in divided doses. **Dosage in the elderly and frail:** Starting dose of 100mg/day in divided doses or as a single night-time dose. This may be increased, under supervision, according to efficacy and tolerance. Doses above 300mg/day are unlikely to be required. Cessation of Molipaxin should be gradual. **Children:** Not recommended. **Contraindications:** Known sensitivity to trazodone. **Precautions:** Avoid during first trimester of pregnancy and in nursing mothers. Warn against risks of handling machinery and driving. May enhance muscle relaxants, some antihypertensive agents, sedatives or antidepressants and alcohol, acute effects of clonidine may be reduced. Avoid concurrent therapy with MAOIs and do not give Molipaxin within 2 weeks of stopping MAOIs or give MAOIs within 1 week of stopping Molipaxin. Use with care in patients with epilepsy, severe hepatic, cardiac or renal disease. Patients receiving long-term therapy with any antidepressant should be kept under regular surveillance. **Side effects:** Molipaxin is a sedative antidepressant. Any dizziness or drowsiness usually disappears on continued dosage. Anticholinergic-like symptoms occur, but the incidence is similar to placebo. Blood dyscrasias, including agranulocytosis, thrombocytopenia and anaemia, have been reported on rare occasions. Adverse effects on hepatic function, including jaundice and hepatocellular damage, sometimes severe, have been rarely reported. Should such effects occur, Molipaxin should be discontinued immediately. As with other drugs with alpha-adrenergic activity, Molipaxin has very rarely been associated with priapism. This may be treated with an intracavernosum injection of alpha-adrenergic agents such as adrenaline or metaraminol. However, there are reports of trazodone-induced priapism which have on occasion required surgical intervention or led to permanent sexual dysfunction. Priapism should be dealt with as a urological emergency and Molipaxin therapy should be discontinued immediately. Other side effects include isolated cases of oedema and postural hypotension. **Overdosage:** No specific antidote is available. Give supportive and symptomatic treatment. **Legal Category:** POM. **Presentations, product licence numbers and basic NHS prices:** Molipaxin 50mg, 84 capsules; 0109/0045; £17.31. Molipaxin 100mg, 56 capsules; 0109/0046; £20.38. Molipaxin 150mg, 28 tablets; 0109/0133; £11.62. Molipaxin CR 150mg, 28 tablets; 0109/0214; £11.62. Molipaxin Liquid 50mg/5ml, 150ml bottle; 0109/0117; £7.74. **Product Licence Holder:** Roussel Laboratories Ltd, Broadwater Park, Denham, Uxbridge, Middlesex UB8 5HP. **Distributor:** Marion Merrell Ltd, Broadwater Park, Denham, Uxbridge, Middlesex UB8 5HP. Further product information is available from Hoechst Marion Roussel Ltd at the above address. Hoechst Marion Roussel is a member of the Hoechst Group. © Molipaxin is a registered trademark.

Date of issue: Dec 1996

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

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

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ABBREVIATED PRESCRIBING INFORMATION: Presentation: Olanzapine 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 nortriptyline. 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. **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.

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 leukocyte 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 hypersplenitic conditions or with myeloproliferative disease. Thirty-two patients with olanzapine-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

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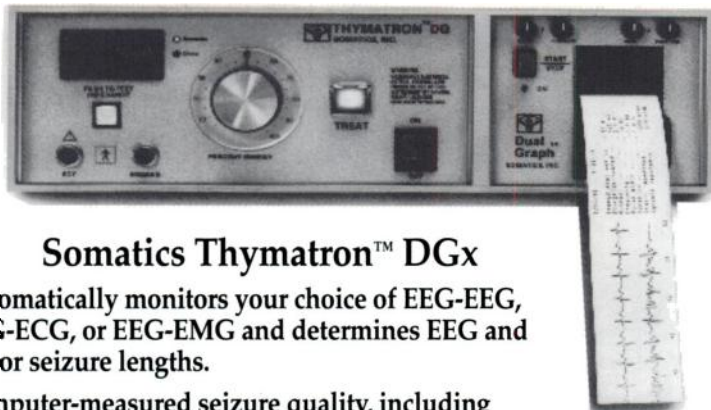
Making Community Re-integration the Goal

Caution in patients who have a history of seizures or have conditions associated with seizures. If signs or symptoms of tardive dyskinesia appear a dose reduction or drug discontinuation should be considered. Caution when taken in combination with other centrally acting drugs and alcohol. Olanzapine may antagonise the effects of direct and indirect dopamine agonists. Postural hypotension was infrequently observed in the elderly. However, blood pressure should be measured periodically in patients over 65 years, as with other antipsychotics. As with other antipsychotics, caution when prescribed with drugs known to increase QTc interval, especially in the elderly. In clinical trials, olanzapine was not associated with a persistent increase in absolute QT intervals. **Interactions:** Metabolism may be induced by cigarette smoking or carbamazepine therapy. **Pregnancy and Lactation:** Olanzapine had no

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

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/1/96/022/005 EU/1/96/022/009 EU/1/96/022/010. **Basic NHS Cost:** £52.73 per pack of 2 x 5mg tablets. £105.47 per pack of 28 x 10mg tablets. £158.20 per pack of 5 x 7.5mg tablets. £210.93 per pack of 56 x 10mg tablets. **Date of Preparation:** August 1996. **Full Prescribing Information is Available From:** Lilly Industries Limited, Dextra Court, Chapel Hill, Basingstoke, Hampshire RG2 5SY. Telephone: Basingstoke (01256) 315000. **ZYPREXA** is a Lilly trademark. **References:** 1. Data on file, Lilly Industries. 2. Data on file, Lilly Industries. 3. Zyprexa Summary of Product Characteristics, Section 4.8.

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World
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We thank all applicants for their interest, only those candidates selected for an interview will be contacted.

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