

IRISH JOURNAL OF PSYCHOLOGICAL MEDICINE

VOL 27 NO 2 June 2010

ISSN 0790-9667



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So many symptoms...

Treat the CORE of depression with Lexapro[®]



Lexapro[®]
escitalopram

The No.1 prescribed anti-depressant in Ireland¹

ABBREVIATED PRESCRIBING INFORMATION: Please refer to the Summary of Product Characteristics before prescribing.

Presentation: Lexapro[™] tablets 5 mg, 10 mg, 15 mg and 20 mg containing escitalopram as the oxalate. **Indications:** Treatment of major depressive episodes. Panic disorder with or without agoraphobia. Social Anxiety Disorder. Generalised Anxiety Disorder. Obsessive Compulsive Disorder. **Dosage:** Treating depression: Adults: Usual dosage is 10 mg once daily. The dose may be increased to a maximum of 20 mg/day. **Panic Disorder with or without agoraphobia:** An initial dose of 5 mg is recommended for the first week before increasing the dose to 10 mg/day. The dose may be further increased, up to a maximum of 20 mg/day. **Social Anxiety Disorder:** Usual dosage is 10 mg once daily. The dose may subsequently be decreased to 5 mg or increased to a maximum of 20 mg/day. **Generalised Anxiety Disorder:** Initial dosage is 10 mg once daily. The dose may subsequently be increased to a maximum of 20 mg/day. **Obsessive Compulsive Disorder:** Initial dosage is 10 mg once daily. The dose may be increased to a maximum of 20 mg daily. **Elderly (>65 yrs):** Initial treatment with half the usually recommended dose and a lower maximum dose should be considered. The efficacy of Lexapro in social anxiety disorder has not been studied in elderly patients. **Children and adolescents (<18 years):** Not recommended. **Reduced hepatic/renal function:** In mild/moderately impaired hepatic function an initial dose of 5 mg/day for the first two weeks of treatment is recommended, the dose may be increased to 10 mg/day. Caution and careful dose titration advised in patients with severely reduced hepatic function. Dosage adjustment is not necessary in patients with mild or moderate renal impairment. Caution is advised in patients with severely reduced renal function (CL_{cr}<30 ml/min). **Contraindications:** Hypersensitivity to escitalopram or to any of the excipients. Concomitant treatment with a nonselective, irreversible monoamine oxidase inhibitor (MAOI). Concomitant treatment with a reversible MAO-A inhibitor e.g. moclobemide or reversible non-selective MAO-inhibitors e.g. linezolid. Lexapro may be started 14 days after discontinuing treatment with an irreversible MAOI. At least 7 days should elapse after discontinuing Lexapro treatment, before starting a non-selective irreversible MAOI. **Pregnancy and Lactation:** Lexapro should not be used during pregnancy unless clearly necessary. Neonates should be observed if maternal use of Lexapro continues into the later stages of pregnancy, particularly the third trimester. Abrupt discontinuation should be avoided during pregnancy. Refer to the full prescribing information for a list of serotonergic or discontinuation symptoms, which may occur in the neonate after maternal SSRI/SNRI use in later stages of pregnancy. Breast-feeding is not recommended during treatment. **Precautions:** Patients should be cautioned about the risk to their ability to drive a car and operate machinery. No pharmacokinetic or pharmacodynamic interactions are expected with concomitant alcohol intake, however the combination is not advised. Combination with serotonergic compounds is not recommended. Insulin and/or oral hypoglycaemic dosage may need to be readjusted in diabetics. Hyponatraemia has been observed rarely with SSRI use, caution required in patients at risk of hyponatraemia. Caution is advised with coadministration of ECT and in patients with a history of mania/hypomania. Caution advised with concomitant use of oral anticoagulants, products affecting platelet function and in patients with known bleeding tendencies. Avoid in patients with unstable epilepsy and monitor patients with controlled epilepsy. Stop treatment immediately if patient develops serotonin syndrome. Use at a low starting dose for panic disorders. Avoid abrupt discontinuation. Gradual discontinuation by dose tapering is advised. As with all SSRIs it is advisable to closely monitor patients for suicide and self-harm risk in the first few weeks of treatment and until significant remission occurs. Caution is advised in patients with coronary heart disease. The use of SSRIs/SNRIs has been associated with the development of akathisia, increasing the dose in these patients may be detrimental. **Drug Interactions:** MAO inhibitors (see Contraindications/ Precautions), advise caution in use with irreversible selective MAO-B inhibitors (selegiline). Caution in use with lithium, tryptophan, serotonergic medicinal products or with products capable of lowering the seizure threshold. Avoid concomitant use with St. John's Wort. In known poor metabolisers, with respect to CYP2C19, an initial 5 mg/day dose should be used, which can be increased to 10 mg after assessment. Caution is advised with co-administration of drugs metabolised by enzymes CYP2C19 and CYP2D6. Co-administration with CYP2C19 inhibitors, and general enzyme inhibitors e.g. cimetidine may require reduction of the Lexapro dose. Caution recommended with concomitant use of products metabolised by CYP2D6 with a narrow therapeutic index and those metabolised by CYP2C19. **Adverse Events:** Adverse reactions are most frequent during the first or second week of treatment and usually decrease in intensity and frequency with continued treatment. Very Common (≥1/10) & common (≥1/100 to <1/10) adverse drug reactions are listed below. Frequencies are not placebo-corrected. Very Common: Nausea; Common: Decreased & increased appetite, anxiety, restlessness, abnormal dreams, libido decreased, female anorgasmia, insomnia, somnolence, dizziness, paraesthesia, tremor, sinusitis, yawning, diarrhoea, constipation, vomiting, dry mouth, sweating increased, arthralgia, myalgia, ejaculation disorder, impotence, fatigue, pyrexia, weight increased. **Overdosage:** Clinical data on escitalopram overdose is limited and many cases involve concomitant overdoses with other drugs. Doses between 400-800 mg of Lexapro alone have been taken without any severe symptoms. Symptoms seen in reported overdose of Lexapro mainly relate to the central nervous system, the gastrointestinal system, the cardiovascular system and electrolyte/fluid balance conditions. There is no specific antidote. Treatment is symptomatic and supportive with monitoring of cardiac and vital signs. Gastric lavage and the use of activated charcoal should be considered. **Legal Category:** POM. **Product Licence Holder:** H. Lundbeck A/S, Othellovej 9, DK-2500, Copenhagen – Valby, Denmark. **PA Numbers:** 5 mg PA805/2/1; 10 mg PA805/2/2; 15 mg PA805/2/3; 20 mg PA805/2/4. Further information is available upon request from Lundbeck (Ireland) Ltd., 7 Riverwalk, Citywest Business Campus, Citywest, Dublin 24. "Lexapro" is a registered trademark © 2002 Lundbeck Ltd. **Date of preparation:** May 2008. Reference 1. Combined IMS Hospital & Retail Data (Unit Sales) YTD August 2009.

Lundbeck



Editor-in-Chief: Brian A Lawlor,
Professor of Old Age Psychiatry,
St Patrick's Hospital, Dublin 8

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Consultant Psychiatrist, Department of
Adult Psychiatry, The Mater
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Submissions & correspondence to:
The Editor,
Irish Journal of Psychological Medicine,
25 Adelaide Street, Dun Laoghaire,
Co Dublin, Ireland.

Telephone: 00-353-1-2803967

Fax: 00-353-1-2807076

Email: psychological@medmedia.ie

Website: www.ijpm.org

Publisher 
MedMedia Ltd,
25 Adelaide Street,
Dun Laoghaire, Co Dublin, Ireland.
www.medmedia.ie

Printing: W&G Baird Ltd

Subscriptions

Rates per volume of four issues
(Mar, Jun, Sept, Dec): €170
Incl. airmail postage internationally.

Subscription enquiries, orders and cheques made payable to:

MedMedia Ltd,
25 Adelaide St, Dun Laoghaire,
Co Dublin, Ireland
Tel: + 353 1 280 3967
Email: psychological@medmedia.ie
www.medmedia.ie

Circulation

2,200 to 54 countries. The Journal
participates in the World Health
Organisation project to improve
distribution of scientific materials on
mental health. Publication does not
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Indexed and abstracted by BIOLOGICAL ABSTRACTS (BIOSIS Previews); CENTRE NATIONAL DE LA RECHERCHE SCIENTIFIQUE/INIST: PASCAL; EXCERPTA MEDICA/EMBASE; INSTITUTE FOR SCIENTIFIC INFORMATION: CURRENT CONTENTS/ Social & Behavioural Sciences (Social Science CITATION INDEX, Research Alert); PSYCHOLOGICAL ABSTRACTS (PsycINFO/PsycLIT); Cumulative Index to Nursing & Allied Health Literature, Current AIDS Literature (CAB Abstracts), International Pharmaceutical Abstracts, Linguistics & Language Behaviour Abstracts, Nutritional Abstracts and Reviews, (CAB Abstracts), Referativnyi Zhurnal, Social Planning/Policy & Development Abstracts, Social Work Research & Abstracts, Sociological Abstracts.

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CLOZARIL ABBREVIATED PRESCRIBING INFORMATION. Please see Summary of Product Characteristics (SPC) before prescribing Clozaril. The use of Clozaril is restricted to patients, physicians and nominated pharmacists registered with the Clozaril Patient Monitoring Service (CPMS). **White cell count with differential count must be monitored according to the Irish Official Recommendations. Indications:** Treatment-resistant schizophrenia and patients who have severe, untreatable neurological adverse reactions to other antipsychotic agents, including an atypical antipsychotic agent prescribed for adequate duration. Psychotic disorders occurring during the course of Parkinson's disease, where standard treatment has failed. **Presentations:** 25mg and 100mg clozapine tablets. **Dosage and Administration:** *Treatment-resistant schizophrenic patients.* 12.5 mg once or twice on the first day, followed by 25 mg tablets once or twice on the second day. Increase dose slowly, by increments (see Summary of Product Characteristics (SPC)). In most patients, antipsychotic efficacy can be expected with 200 to 450 mg/day given in divided doses. If dose does not exceed 200mg/day, it can be given as a single administration in the evening. Once control is achieved, a lower maintenance dose may be effective. Treatment should be maintained for at least 6 months. Doses up to 900mg/day can be used but the possibility of increased adverse events especially seizures must be considered. See SPC for details on re-starting therapy, ending treatment or switching from another antipsychotic. **Elderly:** Initiate at 12.5 mg once on the first day, with subsequent dose increments restricted to 25 mg/day. **Children and Adolescents:** Children and adolescents under the age of 16 should not use Clozaril due to the lack of data on safety and efficacy. **Psychotic disorders occurring during the course of Parkinson's disease.** The starting dose must not exceed 12.5 mg/day taken in the evening. Increase dose by 12.5 mg increments, with a maximum of two increments a week up to a maximum of 50 mg, preferably given as a single dose in the evening. The mean effective dose is usually between 25 and 37.5 mg/day. The maximum dose of 100 mg/day must never be exceeded. Dose increases should be limited or deferred if orthostatic hypotension, excessive sedation or confusion occurs. Blood pressure should be the first weeks of treatment. When there has been complete remission of psychotic symptoms for at least two weeks, an increase in anti-parkinsonian medication is possible on the basis of motor status. See SPC for information on ending therapy. **Contraindications:** Hypersensitivity to the active substance or to any of the excipients. Patients unable to undergo regular blood tests. History of toxic or idiosyncratic granulocytopenia/agranulocytosis (with the exception of granulocytopenia/agranulocytosis from previous chemotherapy). History of Clozaril induced agranulocytosis. Impaired bone marrow function. Uncontrolled epilepsy. Alcoholic and other toxic psychoses, drug intoxication, comatose conditions. Circulatory collapse and/or CNS depression of any cause. Severe renal or cardiac disorders (e.g. myocarditis). Active liver disease associated with nausea, anorexia or jaundice; progressive liver disease, hepatic failure. Paralytic ileus. Concurrent treatment with substances known to have a substantial potential for causing agranulocytosis. Concomitant use of narcotics is discouraged. **Warnings and Precautions:** Before initiating clozapine therapy, patients should have a blood test and a history and physical examination. Clozaril can cause agranulocytosis, so is restricted to patients who have initially normal leukocyte findings. (White Blood Cell (WBC) count $\geq 3.5 \times 10^9/l$ and Absolute Neutrophil Count (ANC) $\geq 2.0 \times 10^9/l$), and in whom regular WBC counts and ANC can be performed within 10 days prior to starting Clozaril, weekly for first 18 weeks, thereafter at 4 week intervals throughout treatment and for 4 weeks after complete discontinuation. Patients with history of cardiac illness or abnormal cardiac findings on physical examination prior to treatment should be referred to a specialist for other examinations that might include an ECG, and the patient treated only if the expected benefits clearly outweigh the risks. The treating physician should consider performing a pre-treatment ECG. Prior to treatment initiation, physicians must ensure that the patient has not experienced an adverse haematological reaction to clozapine that necessitated discontinuation, immediate discontinuation of Clozaril is mandatory if either the WBC count is less than $3.0 \times 10^9/l$ or the ANC is less than $1.5 \times 10^9/l$ at any time during Clozaril treatment. Patients in whom Clozaril has been discontinued as a result of either WBC or ANC deficiencies must not be re-exposed to Clozaril. Following discontinuation of Clozaril, haematological evaluation is required until haematological recovery has occurred. If Clozaril has been withdrawn and either a further drop in the WBC count below $2.0 \times 10^9/l$ occurs or the ANC falls below $1.0 \times 10^9/l$ the management of this condition must be guided by an experienced haematologist. The patient should be educated to contact the treating physician immediately if any kind of infection, fever, sore throat or other flu-like symptoms develop. WBC and differential blood counts must be performed immediately if any symptoms or signs of an infection occur. If, during Clozaril therapy, either the WBC count falls to between $3.5 \times 10^9/l$ and $3.0 \times 10^9/l$ or the ANC falls to between $2.0 \times 10^9/l$ and $1.5 \times 10^9/l$, haematological evaluations must be performed at least twice weekly until the patient's WBC count and ANC stabilise within the range $3.0-3.5 \times 10^9/l$ and $1.5-2.0 \times 10^9/l$ respectively, or higher. Discontinuation of Clozaril is recommended if the eosinophil count rises above $3.0 \times 10^9/l$; therapy should be restarted only after the eosinophil count has fallen below $1.0 \times 10^9/l$. Discontinuation of Clozaril therapy is recommended if the platelet count falls below $50 \times 10^9/l$. Orthostatic hypotension, with or without syncope, can occur during Clozaril treatment. Rarely, collapse can be profound and may be accompanied by cardiac and/or respiratory arrest which is more likely to occur with concurrent use of certain medications (See SPC for more details) and during initial titration with rapid dose escalation. Patients starting Clozaril treatment require close medical supervision. Clozaril is associated with an increased risk of myocarditis, pericarditis/pericardial effusion and cardiomyopathy, and if suspected, Clozaril treatment should be promptly stopped and the patient immediately referred to a cardiologist. Patients with clozapine-induced myocarditis or cardiomyopathy should not be re-exposed to Clozaril. Myocarditis or cardiomyopathy should be suspected in patients who experience persistent tachycardia at rest, especially in the first two months of treatment, and/or palpitations, arrhythmias, chest pain and other signs and symptoms of heart failure or symptoms mimicking myocardial infarction. Flu-like symptoms may also be present. Patients with a history of epilepsy should be closely observed during Clozaril therapy since dose related convulsions have been reported. Patients with stable pre-existing liver disorders or liver dysfunction need regular liver function tests. If the LFT is elevated, discontinue Clozaril and resume only if LFTs return to normal. Use with care in patients with a history of colonic disease, a history of lower abdominal surgery, glaucoma, narrow angle glaucoma, prostatic enlargement and in patients receiving concomitant medication known to cause constipation. High temperatures should be evaluated carefully to rule out underlying infection, agranulocytosis or Neuroleptic Malignant Syndrome. Patients with rare hereditary problems of galactose intolerance, should not take Clozaril. Impaired glucose tolerance and/or development or exacerbation of diabetes mellitus has been reported rarely during treatment with clozapine. Immobilisation of patients should be avoided due to reports of thromboembolism. Caution when prescribing to pregnant women. Mothers receiving Clozaril should not breast-feed. Adequate contraceptive measures must be ensured in women of childbearing potential. Activities such as driving or operating machinery should be avoided, especially during the initial weeks of treatment. **Interactions:** Clozaril must not be used concomitantly with substances having a well known potential to suppress bone marrow function. (See Section 4.3 of the SPC, Contraindications). Long-acting depot antipsychotics (with myelosuppressive potential) must not be used because these cannot be removed from the body in situations where they may be required e.g. neutropenia. Alcohol should not be used with Clozaril due to possible potentiation of sedation. Caution is advised if Clozaril is used concomitantly with other CNS active agents such as, MAOIs, SSRIs especially fluvoxamine, caffeine, CNS depressants including narcotics, antihistamines and benzodiazepines. Caution is advised if Clozaril is used concomitantly with antihypertensive agents, highly protein bound drugs (e.g. warfarin and digoxin), phenytoin, lithium, rifampicin, valproic acid, noradrenaline (norepinephrine), adrenaline (epinephrine) or omeprazole. Cases have been reported of an interaction between citalopram and clozapine, which may increase the risk of adverse events associated with clozapine. The nature of this interaction has not been fully elucidated in cases of sudden cessation of smoking, the plasma clozapine concentration may be increased, thus leading to an increase in adverse effects. See SPC for more details. **Undesirable Effects:** Adverse reactions are ranked under headings of frequency. Very common ($\geq 1/10$), common ($\geq 1/100$, $< 1/10$), uncommon ($\geq 1/1,000$, $< 1/100$), rare ($\geq 1/10,000$, $< 1/1,000$), very rare ($< 1/10,000$), including isolated reports. **Very common:** Drowsiness/sedation, dizziness, tachycardia, constipation, hypersalivation. **Common:** Leukopenia/decreased WBC/neutropenia, eosinophilia, leukocytosis, weight gain, blurred vision, headache, tremor, rigidity, akathisia, extrapyramidal symptoms, seizures, convulsions, myoclonic jerks, ECG changes, hypertension, postural hypotension, syncope, nausea, vomiting, anorexia, dry mouth, elevated liver enzymes, urinary incontinence, urinary retention, fatigue, fever, benign hyperthermia, disturbances in sweating/temperature regulation. **Uncommon:** Agranulocytosis, neuroleptic malignant syndrome. **Rare:** Thromboembolism, anaemia, impaired glucose tolerance, diabetes mellitus, restlessness, agitation, confusion, delirium, circulatory collapse, arrhythmias, myocarditis, pericarditis/pericardial effusion, aspiration of ingested food, dysphagia, hepatitis, cholestatic jaundice, pancreatitis, increased CPK. **Very rare:** Thrombocytopenia, thrombocythaemia, ketoacidosis, hyperosmolar coma, severe hyperglycaemia, hypertriglyceridaemia, hypercholesterolaemia, tardive dyskinesia, cardiomyopathy, cardiac arrest, respiratory depression/arrest, parotid gland enlargement, intestinal obstruction/paralytic ileus/faecal impaction, fulminant hepatic necrosis, skin reactions, interstitial nephritis, priapism, sudden unexplained death. Very rare events of QT prolongation which may be associated with Torsades De Pointes have been observed although there is no conclusive causal relationship to the use of this medicine. **Package Quantities:** 84 x 25 mg tablets. 84 x 100 mg tablets. Supply of CLOZARIL is restricted to hospital pharmacies registered with the CLOZARIL Patient Monitoring Service. **Product Authorisation Numbers:** 25 mg tablets: PA 13/46/L. 100 mg tablets: PA 13/46/Z. **Product Authorisation Holder:** Novartis Pharmaceuticals UK Ltd., Frimley Business Park, Frimley, Camberley, Surrey, GU16 7SR, United Kingdom. **Legal Category:** POM. **Date of last revision:** April 2009. CLOZARIL is a registered Trade Mark. **Full prescribing information, including Summary of Product Characteristics, is available from:** Novartis Ireland Ltd., Beech House, Beech Hill Office Campus, Clonskeagh, Dublin 4. Tel: 01-2601255. Date of Preparation: February 2010. N00210043.

* Clozaril Patient Monitoring Service (CPMS) Customer Satisfaction Survey October 2009.

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