

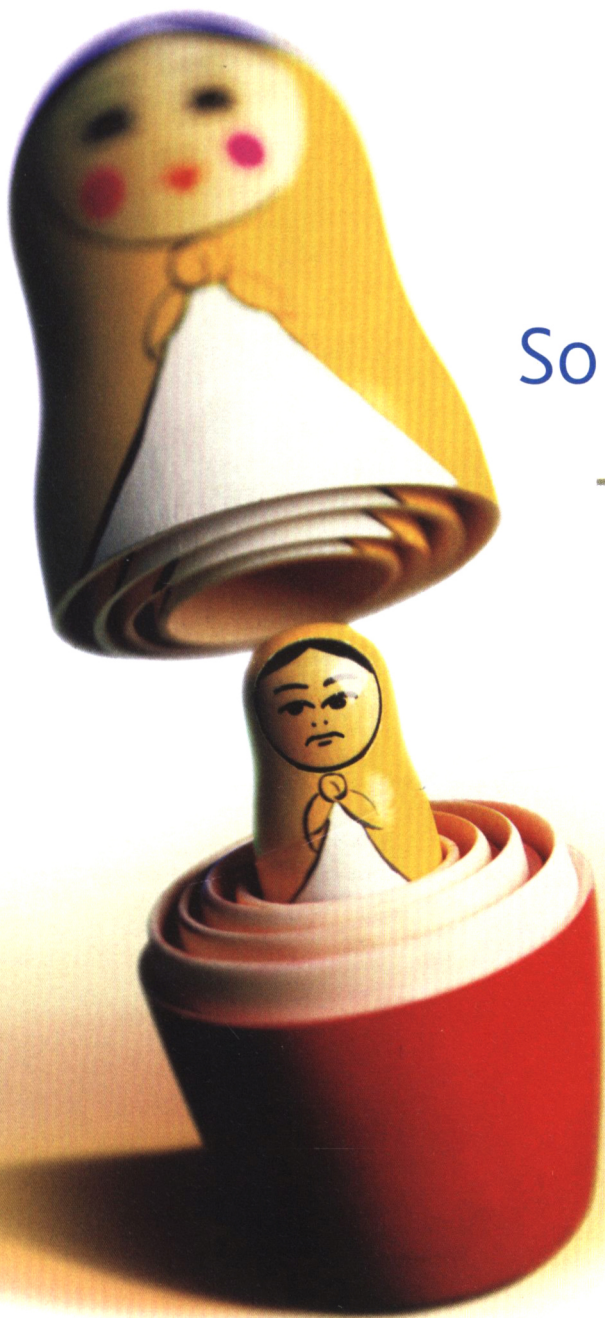
# IRISH JOURNAL OF PSYCHOLOGICAL MEDICINE

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So many symptoms...

Treat the **CORE**  
of depression  
with Lexapro®

**Lexapro**®  
escitalopram

The No.1 prescribed anti-depressant in Ireland

**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<sub>cr</sub><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, Ottiliavej 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 June 2010.



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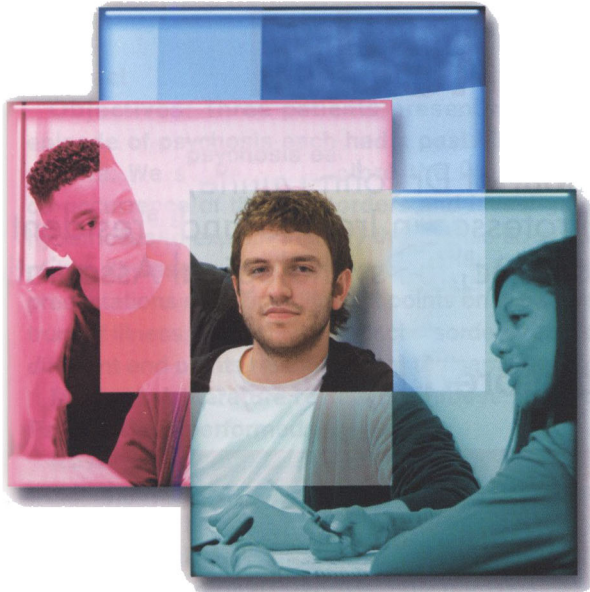
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Indication

Once Daily  
**Seroquel XR™**  
quetiapine



The only agent indicated across all phases of Bipolar Disorder:

- ✓ Acute Mania
- ✓ Major Depressive Episodes
- ✓ Prevention of recurrence\* **NEW**

\* In patients whose manic or depressive episode has responded to quetiapine treatment.

#### Seroquel XR™ Abridged prescribing information

(For full details see summary of product characteristics) **Presentations:** Prolonged-release tablets containing 50mg, 200mg, 300mg and 400mg of quetiapine (as quetiapine fumarate). **Uses:** Treatment of schizophrenia including preventing relapse in stable schizophrenic patients who have been maintained on Seroquel XR. Treatment of bipolar disorder: treatment of moderate to severe manic episodes in bipolar disorder; treatment of major depressive episodes in bipolar disorder; prevention of recurrence in bipolar disorder, whose manic or depressive episode has responded to quetiapine treatment. **Dosage and Administration:** Administer once daily, without food. To be swallowed whole, not split, chewed or crushed. **Adults: Treatment of Schizophrenia and moderate to severe manic episodes in bipolar disorder:** To be administered at least one hour before a meal. The daily dose at the start of therapy is 300 mg on Day 1 and 600 mg on Day 2. Recommended daily dose is 600 mg, however if clinically justified the dose may be increased to 800 mg daily. Adjust dose within the effective dose range of 400 mg to 800 mg per day, depending on clinical response and tolerability. For maintenance therapy in schizophrenia no dosage adjustment necessary. **Treatment of depressive episodes in bipolar disorder:** Administer at bedtime. Daily dose for the first four days is: 50 mg (Day 1), 100 mg (Day 2), 200 mg (Day 3) and 300 mg (Day 4). Recommended daily dose is 300 mg. In clinical trials, no additional benefit was seen in the 600 mg group compared to 300 mg group. Individual patients may benefit from a 600 mg dose. Doses greater than 300 mg should be initiated by physicians experienced in treating bipolar disorder. In the event of tolerance concerns, clinical trials have indicated that dose reduction to a minimum of 200mg should be considered. **For preventing recurrence in bipolar disorder:** Patients who have responded to Seroquel XR for acute treatment of bipolar disorder should continue on Seroquel XR at the same dose administered at bedtime. Dose can be adjusted depending on clinical response and tolerability within the dose range of 300 mg to 800 mg/day. Use lowest effective dose for maintenance therapy. **Elderly:** Use with caution. Rate of dose titration may need to be slower and daily therapeutic dose lower than in younger patients. Patients should be started on 50mg/day and can be increased by 50mg/day to an effective dose. Efficacy & safety not evaluated in patients > 65 years with depressive episodes in framework of bipolar disorder. **Children & Adolescents:** Not recommended. **Renal Impairment:** No dose adjustment required. **Hepatic Impairment:** Use with caution. Patients should be started on 50mg/day and can be increased by 50mg/day to an effective dose, depending on clinical response and tolerability. **Contra-indications:** Hypersensitivity to quetiapine fumarate or excipients. Concomitant administration of cytochrome P450 3A4 inhibitors, e.g. HIV-protease inhibitors, azole-antifungal agents, erythromycin, clarithromycin and nefazodone. **Precautions and warnings:** Children and adolescents (10-17yrs): not recommended if <18yrs old. Refer to SPC for specific precautions and warnings relating to this patient group. Suicide/suicidal thoughts or clinical worsening: Depression in bipolar disorder is associated with increased risk of suicidal thoughts, self-harm and suicide (suicide-related events). Risk persists until significant remission occurs. As improvement may not occur during the first few weeks or more of treatment, monitor patients closely until such improvement occurs. Risk of suicide may increase in the early stages of recovery. In clinical studies of patients with major depressive episodes in bipolar disorder an increased risk of suicide-related events was observed in young adult patients < 25 years of age who were treated with quetiapine vs. placebo (3.0% vs. 0%, respectively). Also consider potential risk of suicide-related events after abrupt cessation of quetiapine due to the known risk factors for the disease being treated. Somnolence: quetiapine has been associated with somnolence and related symptoms, e.g. sedation. In clinical trials for bipolar depression onset was usually within the first 3 days of treatment and predominantly of mild to moderate intensity. If somnolence intensity is severe, patients may need more frequent contact for a minimum of 2 weeks after onset or until symptoms improve. Treatment discontinuation may need to be considered. Cardiovascular: Use with caution in known cardiovascular disease (consider slower titration), cerebrovascular disease, or other conditions predisposing to hypotension. Possible initial orthostatic hypotension during the dose titration period (if it occurs consider lower dose or slower titration). Seizures: Caution where history of seizures. Extrapyramidal Symptoms (EPS): In clinical trials, quetiapine associated with increased incidence of EPS vs. placebo in patients treated for major depressive episodes in bipolar disorder. Tardive dyskinesia (TD): If signs and symptoms of TD appear consider dose reduction or discontinuation. Symptoms of TD can worsen or even arise after discontinuation of treatment. Neuroleptic malignant syndrome (NMS): NMS has been associated with antipsychotic treatment, including quetiapine. In the event of NMS discontinue treatment and give appropriate medical treatment. Severe neutropenia: has been uncommonly reported in clinical trials. Possible risk factors include pre-existing low white cell count and history of drug-induced neutropenia. Discontinue quetiapine if neutrophil count < 1.0 x 10<sup>9</sup>/L. Observe patients for signs/symptoms of infection and follow neutrophil counts until they exceed 1.5 x 10<sup>9</sup>/L. Interactions: Hepatic enzyme inducers – see SPC. Hyperglycaemia: Hyperglycaemia or exacerbation of pre-existing diabetes has been reported – monitoring advised in patients with diabetes or risk factors for developing diabetes. Lipids: Increases in triglycerides, LDL- and total cholesterol and decreases in HDL cholesterol observed in clinical trials – manage lipid changes as clinically appropriate. Metabolic risk: Possible worsening of the metabolic risk profile in individual patients, which should be managed as clinically appropriate. QT Prolongation: reported at therapeutic doses and in overdose. As with other antipsychotics, exercise caution in patients with cardiovascular disease or family history of QT prolongation, and when quetiapine is prescribed with medicines known to increase QT interval or with concomitant neuroleptics, especially in the elderly, in patients with congenital long QT syndrome, congestive heart failure, heart hypertrophy, hypokalaemia or hypomagnesaemia. Withdrawal: Acute withdrawal symptoms such as insomnia, nausea, headache, diarrhoea, vomiting, dizziness and irritability have been described after abrupt cessation of quetiapine. Gradual withdrawal (over at least 1–2 weeks) is advisable. Elderly patients with dementia-related psychosis: Not approved for treatment of dementia – related psychosis. Use with caution in patients with risk factors for stroke. Dysphagia: has been reported with quetiapine. Use with caution in patients at risk for aspiration pneumonia. Lactose: Contains lactose, patients with rare hereditary problems of galactose intolerance, the lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine. Venous Thromboembolism: cases have been reported, all possible VTE risk factors should be identified before & during treatment and preventive measures taken. **Interactions:** Use with caution with other centrally acting drugs and alcohol. CYP3A4 inhibitors such as ketoconazole are contraindicated. Grapefruit juice (concomitant use not recommended). Hepatic enzyme inducers such as phenytoin & carbamazepine can significantly increase quetiapine clearance – refer to SPC. Thioridazine. Observe caution when used concomitantly with drugs known to cause electrolyte imbalance or to increase QT interval. **Pregnancy & lactation:** Safety and efficacy not established – refer to SPC. **Effects on ability to drive:** Advise patients not to drive or operate machinery until individual susceptibility known. **Undesirable effects:** Very Common: Dizziness, somnolence, headache, dry mouth, withdrawal (discontinuation) symptoms, elevations in serum triglyceride levels, elevations in total cholesterol (predominantly LDL cholesterol), decreases in HDL cholesterol, weight gain. Common: Leucopenia, hyperprolactinaemia, increased appetite, syncope, extrapyramidal symptoms, tachycardia, vision blurred, orthostatic hypotension, rhinitis, constipation, dyspepsia, mild asthenia, peripheral oedema, irritability, elevations in serum transaminases (ALT, AST), decreased neutrophil count, blood glucose increased to hyperglycaemic levels, abnormal dreams and nightmares, dysarthria. **For a full list of undesirable effects (that also includes data for children/adolescents) refer to SPC. Pharmaceutical precautions:** No special requirements. **Legal category:** POM. **S1A Marketing Authorisation Numbers:** Seroquel XR 50mg, 200mg, 300mg and 400mg PA 970/18/8-11 **Marketing Authorisation Holder(s):** AstraZeneca Ltd., Horizon Place, 600 Capability Green, Luton, Bedfordshire, LU1 3LU. **Further information on request from:** AstraZeneca Pharmaceuticals (Ireland) Limited, College Park House, 20 Nassau Street, Dublin 2, Tel. 01 609 7100; Fax. 01 679 6650. Abridged Prescribing Information prepared: 03/10. Seroquel XR is a trademark of the AstraZeneca group of companies. **Date of Preparation:** March 2010. **URN:** 10/0134.

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