


Aim for...

freedom from
the pain of depression

Introducing Cymbalta 60mg once daily.

A new balanced approach to delivering sustained relief from
the psychological and somatic symptoms of depression...


new
Cymbalta[®]
duloxetine
because depression hurts

CYMBALTA* REPUBLIC OF IRELAND (DULOXETINE) ABBREVIATED PRESCRIBING INFORMATION **Presentation:** Hard gastro-resistant capsules, 30mg or 60mg of duloxetine. Also contains sucrose. **Uses:** Treatment of major depressive episodes. **Dosage and Administration:** Starting and maintenance dose is 60mg once daily, with or without food. Dosages up to a maximum dose of 120mg per day, administered in evenly divided doses, have been evaluated from a safety perspective in clinical trials. However, there is no clinical evidence suggesting that patients not responding to the initial recommended dose may benefit from dose up-titrations. Therapeutic response is usually seen after 2-4 weeks. After establishing response, it is recommended to continue treatment for several months, in order to avoid relapse. When discontinuing after more than 1 week of therapy, the dose should be tapered over no less than 2 weeks before discontinuation, generally reducing the treatment to half-dose or alternate day dosing, and accounting for individual patient circumstances, such as duration of treatment and final dose. **Contra-indications:** Hypersensitivity to any of the components. **Combination with MAOIs:** Liver disease resulting in hepatic impairment. Use with potent inhibitors of CYP1A2, eg, fluvoxamine, ciprofloxacin, enoxacin. Severe renal impairment (creatinine clearance <30ml/min). Should be used in pregnancy only if the potential benefit justifies the potential risk to the foetus. Breast-feeding is not recommended. **Precautions:** Use in children or adolescents is not recommended. Until more efficacy data are available, use in the very elderly population (>75 years) is not recommended. Use with caution in patients with a history of mania, bipolar disorder, or seizures. Caution in patients with increased intra-ocular pressure, or those at risk of acute narrow-angle glaucoma. In patients with known hypertension and/or other cardiac disease, blood pressure monitoring is recommended as appropriate. Caution in patients taking anticoagulants or products known to affect platelet function, and those with bleeding tendencies. Hyponatraemia has been reported rarely, predominantly in the elderly. Depression is associated with an increased risk of suicidal thoughts, self-harm, and suicide. As with other drugs with similar pharmacological action, isolated cases of suicidal ideation/behaviour or thoughts of harming themselves and to seek medical advice immediately if these symptoms present. Since treatment may be associated with sedation, patients should be cautioned about their ability to drive a car or operate hazardous machinery. Duloxetine is used under different trademarks in several indications (major depressive episodes as well as stress urinary incontinence). The use of more than one of these products concomitantly should be avoided. **Interactions:** Caution is advised when taken in combination with other centrally acting medicinal products and substances, including alcohol and sedative medicinal products; exercise caution when using in combination with antidepressants. In rare cases, serotonin syndrome has been reported in patients using SSRIs concomitantly with serotonergic products. Caution is advisable if duloxetine is used concomitantly with serotonergic antidepressants like SSRIs, tricyclics, St John's Wort, venlafaxine, or triptans, tramadol, pethidine, and tryptophan. Undesirable effects may be more common during use with herbal preparations containing St John's Wort. Effects on other drugs: Caution is advised if co-administered with products that are predominantly metabolised by CYP2D6 if they have a narrow therapeutic index. **Undesirable Effects:** The majority of common adverse reactions were mild to moderate, usually starting early in therapy, and most tended to subside as therapy continued. Those occurring at a rate of >2% and significantly different to the placebo rate, or where the event is clinically relevant are: Very common (≥10%): Nausea, dry mouth, and constipation. Common (≥1% and <10%): Appetite decreased, weight decreased, insomnia, libido decreased, anorgasmia, dizziness, somnolence, tremor, blurred vision, hot flushes, diarrhoea, vomiting, sweating increased, erectile dysfunction, ejaculation delay or disorder, fatigue. Dizziness, nausea, insomnia, headache, and anxiety were also reported as common adverse events, particularly upon abrupt discontinuation. In trials, treatment was associated with numerically significant, but not clinically related, increases in ALT, AST, and creatinine phosphokinase. These transient, abnormal values were infrequently observed compared with placebo-treated patients. Duloxetine is known to affect urethral resistance. In placebo-controlled trials, urinary hesitation was reported rarely (<1%) in male patients. If symptoms develop during treatment, consideration should be given that they might be drug-related. Cases of suicidal ideation and suicidal behaviours have been reported during duloxetine therapy or early after treatment discontinuation. ECGs evaluated during the clinical trials demonstrated no difference in QTc intervals in duloxetine-treated patients compared with those on placebo. There is limited clinical experience of overdose with duloxetine. No fatal overdose was demonstrated, including doses up to 1400mg either alone or in combination with other medicinal products. No specific antidote is known but routine monitoring and appropriate symptomatic supportive measures should be used, including, if appropriate, early gastric lavage or activated charcoal. For further information see Summary of Product Characteristics, which is available at <http://emc.medicines.org.uk/>. **Legal Category:** POM **Marketing Authorisation Numbers and Holder:** EU/1/04/296/001, EU/1/04/296/002, EU/1/04/296/003, EU/1/04/296/004, Eli Lilly Nederland BV, Grootslag 1-5, NL-3991 RA Houten, The Netherlands. **Date of Preparation or Last Review:** January 2005. **Full Prescribing Information is Available From:** Eli Lilly and Company Limited, Lilly House, Priestley Road, Basingstoke, Hampshire, RG24 9NL Tel: Basingstoke (01256) 315 999 or Eli Lilly and Company (Ireland) Limited, Hyde House, 65 Adelaide Road, Dublin 2, Republic of Ireland Tel: Dublin (01) 661 4377 *CYMBALTA (duloxetine) is a trademark of Eli Lilly and Company

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Now for bipolar disorder*

**Mania under control.
Stability ahead.**

Proven Efficacy

Trusted Tolerability



Seroquel

quetiapine

Stabilise without Compromise

*Seroquel is indicated for the treatment of moderate to severe manic episodes in Bipolar Disorder and for the treatment of Schizophrenia. Seroquel has not been demonstrated to prevent recurrence of manic or depressive episodes.

References: 1) 600mg is the average effective dose. Please see abridged prescribing information for information on titration

Seroquel® Abridged Prescribing Information (for full details see summary of product characteristics)

Presentations: Film coated tablets containing 25mg, 100mg, 200mg and 300mg of quetiapine (as quetiapine fumarate). **Uses:** Treatment of schizophrenia and moderate to severe manic episode. **Dosage and Administration:** **Schizophrenia: Adults:** Initial titration from 50mg to 300mg over first 4 days. From day 4 onwards the dose should be titrated to the usual effective dose of 300-450 mg/day. Dose range 150 to 750 mg/day. **Bipolar disorder: Adults:** Initial titration from 100mg to 400mg over first 4 days. Dose range: 200-800 mg/day. **Elderly:** Rate of dose titration may need to be slower and daily therapeutic dose lower than in younger patients. **Children & Adolescents:** Not evaluated. **Renal Impairment:** No dose adjustment required. **Hepatic Impairment:** Use with caution. Patients should be started on 25 mg/day and increased by 25 - 50 mg/day until an effective dosage is achieved. **Contra-indications:** Hypersensitivity to quetiapine fumarate or excipients. Concomitant administration of cytochrome P450 3A4 inhibitors, such as HIV-protease inhibitors, azole-antifungal agents, erythromycin, clarithromycin and nefazodone. **Precautions and warnings:** Known cardiovascular disease, cerebrovascular disease, or other conditions predisposing to hypotension. Possible initial orthostatic hypotension during the dose titration period. Caution is recommended in patients with a history of seizures. If signs and symptoms of tardive dyskinesia appear dose reduction or discontinuation should be considered. In the event of neuroleptic malignant syndrome discontinue treatment. Hyperglycaemia or exacerbation of pre-existing diabetes has been reported in very rare cases. **Undesirable effects:** Mild asthenia, dizziness, somnolence, peripheral oedema, syncope, dry mouth, rhinitis, dyspepsia, constipation, leucopenia and tachycardia. Elevations in gamma-GT levels, non-fasting serum triglyceride levels and total cholesterol. Seroquel was associated with dose related decreases in thyroid hormone levels particularly total T₄ and free T₄. **Interactions:** Use with caution with other centrally acting drugs and alcohol. CYP3A4 inhibitors such as ketoconazole are contraindicated. Grapefruit juice, phenytoin, carbamazepine, thioridazine. **Pregnancy & lactation:** Safety with efficacy not established. **Effects on ability to drive:** Patients should be advised not to drive or operate machinery until individual susceptibility is known. **Pharmaceutical precautions:** Do not store above 30°C. **Legal category:** POM. **Product Authorisation Numbers:** Seroquel 25 PA970/18/1; Seroquel 100 PA970/18/2; Seroquel 200 PA970/18/3; Seroquel 300 PA970/18/7) 4 Day starter pack (Schizophrenia) PA 970/18/5. **Product authorisation holder:** AstraZeneca Ltd., Horizon Place, 600 Capability Green, Luton Bedfordshire, LU1 3LU **Further information on request**

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