

# PANIC

# ATTACK



New Indication  
NEW DOSE FOR  
**PANIC**  
37.5mgXL

**EFEXOR<sup>®</sup> XL**  
VENLAFAXINE XL

Stop **PANIC** in its tracks<sup>1</sup>

• DEPRESSION • PANIC • DEPRESSION WITH ANXIETY • DEPRESSION • PANIC • GENERALISED ANXIETY DISORDER (GAD) • PANIC •

**ABBREVIATED PRESCRIBING INFORMATION (Ireland).** NOTE: refer to the currently Approved Summary of Product Characteristics (SPC) before prescribing. **EFEXOR<sup>®</sup> XL Prolonged Release Capsules/EFEXOR<sup>®</sup> Tablets** venlafaxine. **Presentation:** Efexor XL 37.5mg, 75mg and 150mg Prolonged Release Capsules: capsules containing 37.5mg, 75mg or 150mg venlafaxine (as hydrochloride) in an extended release formulation. **Efexor 37.5mg and 75mg Tablets:** tablets containing 37.5mg or 75mg venlafaxine (as hydrochloride). **Indications:** **Efexor XL Capsules + Efexor Tablets:** Treatment of depressive illness including depression accompanied by anxiety, for the prevention of relapses of the initial episode of depression, for the prevention of the recurrence of new depressive episodes. **Efexor XL Capsules:** Generalised Anxiety Disorder (GAD) primarily characterised by chronic and excessive worry and anxiety for at least 6 months; or for the treatment of panic disorder, with or without agoraphobia. **Dosage and Administration: Adults (including the elderly): Depressive illness including depression accompanied by anxiety: Efexor XL Capsules:** Usually 75mg, given once daily with food, increasing to 150mg once daily if necessary. The dose can be increased further to 225mg once a day. Dose increments should be made at intervals of approximately 2 weeks or more, but not less than 4 days. **Efexor Tablets:** Usually 75mg (37.5mg bd) with food, increasing to 150mg (75mg bd) if necessary. In more severely depressed patients, 150mg/day increasing every 2 to 3 days in up to 75mg/day increments to a maximum of 375mg/day, then reducing to usual dose consistent with patient response. **Prevention of Relapse/Recurrence: Efexor XL Capsules and Efexor Tablets:** Usually, the dosage for prevention of relapse, or for prevention of recurrence of a new episode, is similar to that used during the index episode. Patients should be re-assessed regularly in order to evaluate the benefit of long-term therapy. **Generalised Anxiety Disorder: Efexor XL Capsules:** Usually 75mg, given once daily with food, increasing to 150mg once daily if necessary. The dose can be increased further to 225mg once a day. Dose increments should be made at intervals of approximately 2 weeks or more, but not less than 4 days. Long-term treatment (more than 6 months) is often required. **Panic Disorder: Efexor XL Capsules:** Usually 75mg given once daily with food. Treatment should be started with a dose of 37.5mg per day for the first 4 to 7 days, after which the dose should be increased to 75mg once daily. The dose can be increased further to 225mg once a day. Dose increments should be made at intervals of approximately 2 weeks or more, but not less than 4 days. Long-term treatment (more than 6 months) is often required. **Children:** Efexor should not be used in the treatment of children and adolescents under the age of 18 years. **Renal or Hepatic Impairment:** Moderate renal impairment - doses should be reduced by 50%. Mild to moderate hepatic impairment - doses should be reduced by 50% and reductions of more than 50% may be appropriate for some patients. Not recommended in severe renal or severe hepatic impairment. **Discontinuation:** Discontinue gradually to reduce the possibility of withdrawal reactions. **Contraindications:** Concomitant use with MAOIs, hypersensitivity to venlafaxine or other components. **Precautions/Warnings:** The risk of suicide should be considered in all patients and patients with history of suicide-related events or ideation should be carefully monitored. Venlafaxine has been associated with reports of aggression. Use with caution in patients with myocardial infarction, unstable heart disease, renal or hepatic impairment, narrow angle glaucoma, family history or history of mania, family history or history of bipolar disorder, a history of epilepsy (discontinue in event of seizure), using neuroleptics or diuretics, with conditions which could be compromised by increases in blood rate, or predisposed to bleeding. Patients should not drive or operate machinery if their ability to do so is impaired. Possibility of postural hypotension (especially in the elderly). Prescribe smallest quantity of capsules or tablets according to good patient management. Blood pressure monitoring is recommended and pre-existing hypertension should be controlled before treatment with venlafaxine. Advise patients to notify their doctor should an allergy develop or if they become or intend to become pregnant. Patients with a history of drug abuse should be monitored carefully. Cholesterol measurement is recommended with long term use. Venlafaxine should not be used with weight loss agents. Usually not recommended during pregnancy or lactation. Withdrawal reactions may occur especially on abrupt discontinuation of treatment. Undesirable effects may be more common during concomitant use of (serotonin re-uptake inhibitors/ nefazodone/ trazodone/ triptans) and herbal preparations containing St John's Wort (hypericum perforatum). **Interactions:** MAOIs: do not use venlafaxine in combination with MAOIs or within 14 days of stopping MAOI treatment. Allow 7 days after stopping venlafaxine before starting an MAOI. Use with caution in elderly or hepatically-impaired patients taking cimetidine, in patients taking other CNS-active drugs in particular serotonergic drugs, clozapine or haloperidol, metoprolol, in patients taking drugs which inhibit both CYP2D6 and CYP3A4 hepatic enzymes. Caution is advised with concurrent use of ECT. **Adverse Reactions: Very common: >1/10:** constipation, nausea, asthenia, headache, dizziness, dry mouth, insomnia, nervousness, somnolence, abnormal ejaculation/orgasm, sweating. **Common: >1/10 - <1/100:** hypertension, palpitation, vasodilatation, anorexia, appetite decreased, diarrhoea, dyspepsia, vomiting, abdominal pain, chills, pyrexia, weight gain or loss, increased serum cholesterol, arthralgia, myalgia, abnormal dreams, agitation, anxiety, confusion, hyperorthia, paraesthesia, tremor, urinary frequency, anorgasmia, erectile dysfunction, decreased libido, impotence, menstrual cycle disorders, dyspnoea, yawning, abnormal vision/accommodation, mydriasis. **Uncommon: <1/100 - >1/1000:** ecchymosis, mucous membrane bleeding, hypotension/ postural hypotension, syncope, arrhythmias, bruxism, hypoaesthesia including SIA/DH, increased liver enzymes, muscle spasm, epistaxis, myoclonus, hallucinations, urinary retention, menorrhagia, rash, angioedema, maculopapular eruptions, photosensitivity reactions, alopecia, tinnitus, altered taste sensation. **Rare: <1/1000:** prolonged bleeding time, thrombocytopenia, haemorrhage, gastrointestinal bleeding, hepatitis, akathisia, ataxia and disorders of balance and co-ordination, speech disorders including dysarthria, mania or hypomania, neuroleptic malignant syndrome like effects, seizures, serotonergic syndrome, galactorrhoea, erythema multiforme, Stevens-Johnson syndrome, pruritis, urticaria. **Very rare: <1/10000:** blood dyscrasias, torsade de pointes, QT prolongation, ventricular tachycardia, ventricular fibrillation, pancreatitis, anaphylaxis, increased prolactin, rhabdomyolysis, delirium, extrapyramidal disorders including dyskinesia, dystonia, tardive dyskinesia, pulmonary eosinophilia, narrow angle glaucoma. Hostility, suicidal ideation and self harm in paediatric patients. Symptoms reported on discontinuation of venlafaxine were mostly non-serious and self-limiting and included dizziness, insomnia, nausea and nervousness. **Package Quantities:** 37.5mg capsule - blister pack of 7 capsules. 75mg capsule - blister pack of 28 capsules. 150mg capsule - blister pack of 28 capsules. 37.5mg tablet - calendar pack of 56 tablets. 75 mg tablet - calendar pack of 56 tablets. **Legal Category:** S1A. **PA Numbers:** 37.5mg capsule - PA 22/65/7, 75mg capsule - PA 22/65/5, 150mg capsule - PA 22/65/6, 37.5mg tablet - PA 22/65/2, 75 mg tablet - PA 22/65/4. **Product Authorisation Holder:** John Wyeth and Brother Limited, Trading as: Wyeth Laboratories, Huntercombe Lane South, Taplow, Maidenhead, Berkshire SL6 0PH, UK. **Date of Revision of Text:** 6th September 2007. Full prescribing information is available upon request from: Wyeth Pharmaceuticals Limited, M50 Business Park, Ballymount Road Upper, Walkinstown, Dublin 12, <sup>1</sup> trade mark. **Reference 1:** Efexor SmPC July 2007. **Date of Preparation:** February 2008. ZEF1687







## But now I can let life in."



This is the story of Sinéad\* and the voices she began to hear who convinced her that her neighbours wanted her dead. So she barricaded herself in her tiny apartment for three years. Today, with the support of her doctor, treatment team and family, Sinéad is managing her schizophrenia with Zyprexa.<sup>1,2</sup> Knowing where you have been is one measure of how far you have come. Together you can find another way to stay on the road to improvement.

**ZYPREXA™ TABLETS REPUBLIC OF IRELAND (OLANZAPINE) ABBREVIATED PRESCRIBING INFORMATION ZYPREXA VELOTABS ZYPREXA INTRAMUSCULAR INJECTION** Presentations: Tablets: 2.5mg, 5mg, 7.5mg, 10mg, 15mg, or 20mg of olanzapine. Also contain lactose. Velotab™ 5mg, 10mg, 15mg, or 20mg erodispersible tablets. Also contain gelatin, aspartame, mannitol, and parahydroxybenzoates. Powder for solution for injection, containing 10mg olanzapine. **Uses** Tablets and Velotabs: Schizophrenia, both as initial therapy and for maintenance. Moderate to severe manic episode; prevention of recurrence in bipolar disorder in patients whose manic episode has responded to olanzapine treatment. **Injection:** Rapid control of agitation and disturbed behaviours in patients with schizophrenia or manic episode, when oral therapy is not appropriate. **Dosage and Administration** Tablets and Velotabs: Schizophrenia: 10mg/day orally. **Manic episode:** 15mg/day in monotherapy; 10mg/day in combination therapy. **Preventing recurrence in bipolar disorder:** 10mg/day, or for patients who have been receiving olanzapine for treatment of manic episode, continue therapy for preventing recurrence at the same dose. May subsequently be adjusted to 5-20mg daily. **Injection:** Intramuscular use only for a maximum of three consecutive days. Initial dose 10mg. A second injection, 5-10mg, may be administered 2 hours after. Maximum daily dose is 20mg, with not more than 3 injections in any 24-hour period. Treatment with Zyprexa Intramuscular Injection should be discontinued, and oral Zyprexa initiated, as soon as clinically appropriate. Do not administer intravenously or subcutaneously. **Children:** Not recommended (under 18 years). **Elderly patients:** Oral therapy - a lower starting dose (5mg/day) is not routinely indicated but should be considered when clinical factors warrant. **Injection - recommended starting dose is 2.5-5mg. Renal and/or hepatic impairment:** 5mg starting dose in moderate hepatic insufficiency. When more than one factor which might cause slower metabolism, consider a decreased starting dose. **Contra-indications** Known hypersensitivity to any ingredient. Known risk of narrow-angle glaucoma. **Warnings and Special Precautions** Olanzapine is not approved for the treatment of dementia-related psychosis and/or behavioural disturbances because of an increase in mortality and the risk of CVAE. **Injection:** Efficacy not established in patients with agitation and disturbed behaviours related to conditions other than schizophrenia or manic episode. Should not be administered to patients with unstable medical conditions (see Summary of Product Characteristics (SPC)). Safety and efficacy have not been evaluated in patients with alcohol or drug intoxication. Patients should be closely observed for hypotension, including postural hypotension, bradycardia, and/or hyperventilation (see SPC). Simultaneous injection with parenteral benzodiazepines is not recommended. Use to treat drug-induced psychosis with Parkinson's disease is not recommended. Caution in patients: • who receive other medicinal products having haemodynamic properties similar to those of Zyprexa Intramuscular Injection. • with prostatic hypertrophy, or paralytic ileus and related conditions. • with elevated ALT and/or AST, hepatic impairment, limited hepatic functional reserve, and in patients treated with hepatotoxic drugs. If

hepatitis is diagnosed, discontinue Zyprexa. • with low leucocyte and/or neutrophil counts, bone marrow depression, in patients receiving medicines known to cause neutropenia, and in patients with hypersensitivity conditions or with myeloproliferative disease. • who have a history of seizures or are subject to factors which may lower the seizure threshold. • using other centrally acting drugs and alcohol. As with other antipsychotics, caution should be exercised when olanzapine is prescribed with medicines known to increase QTc interval. Discontinue if signs and symptoms indicative of NMS, or unexplained high fever. If tardive dyskinesia appears, consider dose reduction or discontinuation. Clinical monitoring advisable in diabetic patients and those with risk factors for diabetes. Blood pressure should be measured periodically in patients over 65 years. Undesirable alterations in lipids have been observed in olanzapine-treated patients in placebo-controlled clinical trials. Lipid alterations should be managed as clinically appropriate. May antagonise effects of dopamine agonists. Gradual dose reduction should be considered when discontinuing olanzapine. **Phenylalanine:** Velotabs contain aspartame - a source of phenylalanine. **Sodium methyl parahydroxybenzoate and sodium propyl parahydroxybenzoate:** Contained in Velotabs; known to cause urticaria, contact dermatitis, and, rarely, immediate reactions with bronchospasm. **Interactions** Metabolism may be affected by substances that can specifically induce (eg, concomitant smoking or carbamazepine) or inhibit (eg, fluvoxamine) the isoenzyme P450-CYP1A2 which metabolises olanzapine. Activated charcoal reduces the bioavailability of oral olanzapine. Olanzapine may antagonise the effects of direct and indirect dopamine agonists. Olanzapine showed no interaction when co-administered with lithium or biperiden. Zyprexa Intramuscular Injection 5mg, administered 1 hour before lorazepam 2mg, added to the somnolence observed with either drug alone. **Pregnancy and Lactation** Should be used in pregnancy only if the potential benefit justifies the potential risk to the foetus. Patients should be advised not to breast-feed an infant if they are taking Zyprexa. **Driving, etc** May cause somnolence or dizziness. Patients should be cautioned about operating hazardous machinery, including motor vehicles. **Undesirable Effects** Those observed from spontaneous reporting and in placebo-controlled clinical trials at a rate of ≥1%, or where the event is clinically relevant, are: **Clinical Trial Adverse Event Reporting and Investigations With Oral Zyprexa:** Very common (>10%): Weight gain, somnolence, elevated plasma prolactin levels. **Common (1-10%):** Eosinophilia, increased appetite, elevated glucose levels, elevated triglyceride levels, elevated cholesterol levels, glycosuria, dizziness, akathisia, parkinsonism, dyskinesia. Orthostatic hypotension, mild, transient anticholinergic effects, including constipation and dry mouth, transient, asymptomatic elevations of ALT, AST, asthenia, fatigue, oedema. **Uncommon (0.1-1%):** Bradycardia, with or without hypotension or syncope. In clinical trials of elderly patients with dementia, olanzapine was associated with a higher incidence of death and cerebrovascular adverse events compared to placebo. Very common (>10%) undesirable effects in this patient group were abnormal gait and falls. Pneumonia, increased body

temperature, lethargy, erythema, visual hallucinations, and urinary incontinence were observed commonly (1-10%). **Post-Marketing Spontaneous Reports:** Oral Zyprexa: Rare (0.01-0.1%): Leucopenia, seizures, hepatitis, hyperglycaemia, and/or development or exacerbation of diabetes (occasionally associated with ketoacidosis or coma, including some fatal cases). Very rare (<0.01%): Thrombocytopenia, neutropenia, allergic reaction, neuroleptic malignant syndrome, parkinsonism, dystonia (including oculogyration), and tardive dyskinesia. Hypertiglyceridaemia, hypercholesterolaemia, QTc prolongation, ventricular tachycardia/fibrillation and sudden death, thromboembolism, pancreatitis, rhabdomyolysis, and priapism. **Additional Clinical Trial Adverse Event Reporting and Investigations With Zyprexa Intramuscular Injection:** Common (1-10%): Bradycardia, with or without hypotension or syncope, tachycardia, injection site discomfort, somnolence, postural hypotension, hypotension. **Uncommon (0.1-1%):** Sinus pause. **Post-Marketing Spontaneous Events With Zyprexa Intramuscular Injection:** Temporal association in cases of respiratory depression, hypotension, or bradycardia, and death reported very rarely, mostly with concomitant use of benzodiazepines and/or other antipsychotic drugs, or use of olanzapine in excess of recommended dose. For full details of these and other side-effects, please see the Summary of Product Characteristics, which is available at <http://www.medicines.ie/>. **Legal Category** POM. **Marketing Authorisation Numbers and Holder** EU/1/96/022/002 EU/1/96/022/004 EU/1/96/022/006 EU/1/96/022/009 EU/1/96/022/010 EU/1/96/022/012 EU/1/96/022/014 EU/1/96/022/016 EU/1/99/125/001 EU/1/99/125/002 EU/1/99/125/003 EU/1/99/125/004. Eli Lilly Nederland BV, Grootslag 1-5, 3991 RA Houten, The Netherlands. **Date of Preparation or Last Review** January 2008. **Full Prescribing Information is Available From** Eli Lilly and Company Limited, Lilly House, Priestley Road, Basingstoke, Hampshire, RG24 9NL. Telephone: Basingstoke (01256) 315 999 or Eli Lilly and Company (Ireland) Limited, Hyde House, 65 Adelaide Road, Dublin 2, Republic of Ireland. Telephone: Dublin (01) 661 4377. **\*\*ZYPREXA (olanzapine) and VELOTAB are trademarks of Eli Lilly and Company. References:** 1. Tran PV et al. Double-blind comparison of olanzapine versus risperidone in the treatment of schizophrenia and other psychotic disorders. *J Clin Psychopharmacol* 1997;17:407-418. 2. Kinon BJ, Hill AL, Lin L, Perahia DGS. Olanzapine erodispersible tablet in the treatment of acutely ill, non-compliant schizophrenia patients. Poster presented at American Psychiatric Association annual meeting, May 1-6 2004, New York, USA.

\*Case study based on fictional characters

🇮🇪 Zyprexa is manufactured in Cork.

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