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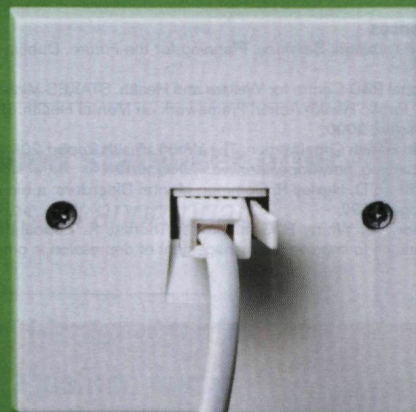
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'Transition in Blue' by Francis Tansey, 2001. Giclee print (76 x 76cm)

Get patients with depression back in touch with life



EFEXOR XL

VENLAFAXINE XL

First-line reconnection

Presentation: Efexor XL: capsules containing 75mg or 150mg venlafaxine (as hydrochloride) in an extended release formulation. **Efexor:** tablets containing 37.5mg or 75mg venlafaxine (as hydrochloride). **Use:** Treatment of depressive illness including depression accompanied by anxiety, Generalised Anxiety Disorder (GAD) primarily characterised by chronic and excessive worry and anxiety for at least 6 months; for the prevention of relapses of the initial episode of depression or for the prevention of the recurrence of new depressive episodes. **Dosage:** Adults (including the elderly): Depressive illness including depression accompanied by anxiety: **Efexor XL:** 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:** 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: 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:** 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. Discontinuation: Discontinue gradually to reduce the possibility of withdrawal reactions. Children: Contraindicated below 18 years of age. Moderate renal or moderate hepatic impairment: Doses should be reduced by 50%. Not recommended in severe renal or severe hepatic

impairment. **Contra-indications:** Concomitant use with MAOIs, hypersensitivity to venlafaxine or other components, patients aged below 18 years. **Precautions:** The risk of suicide should be considered in all patients. Use with caution in patients with myocardial infarction, unstable heart disease, renal or hepatic impairment, narrow angle glaucoma, mania, a history of epilepsy (discontinue in event of seizure), using neuroleptics or diuretics 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. 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. **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; in patients taking warfarin and in patients taking drugs which inhibit both CYP2D6 and CYP3A4 hepatic enzymes. Caution is advised with concurrent use of ECT. **Side-effects:** Most commonly occurring: constipation, nausea, asthenia, headache, dizziness, dry mouth, insomnia, nervousness, somnolence, abnormal ejaculation/orgasm, sweating. Also reported: vasodilatation, hypotension/postural hypotension, hypertension, palpitation, syncope, ecchymosis, mucous membrane bleeding, GI bleeding, anorexia, appetite decreased, diarrhoea, dyspepsia, vomiting, abdominal pain,

bruxism, abnormal dreams, chills, pyrexia, weight gain or loss, increased serum cholesterol hyponatraemia, increased liver enzymes, arthralgia, myalgia, muscle spasm, agitation, anxiety, confusion, hypertonia, paraesthesia, tremor, myoclonus, apathy, hallucinations, urinary frequency and retention, anorgasmia, erectile dysfunction, decreased libido, impotence, menstrual cycle disorders, menorrhagia, dyspnoea; pruritis, rash, angioedema, maculopapular eruptions, urticaria, photosensitivity reactions, alopecia, mydriasis, tinnitus, abnormal vision/accommodation, altered taste sensation. Hostility and suicidal ideation in paediatric patients. Rarely reported: thrombocytopenia, haemorrhage, prolonged bleeding time, arrhythmias, hepatitis, SIADH, ataxia and disorders of balance and coordination, speech disorders including dysarthria, extrapyramidal disorders including dyskinesia, dystonia, mania or hypomania, neuroleptic malignant syndrome-like effects or serotonergic syndrome, galactorrhoea, erythema multiforme, Stevens-Johnson syndrome, very rarely anaphylaxis, blood dyscrasias, ECG changes, pancreatitis, increased prolactin, rhabdomyolysis, delirium, pulmonary eosinophilia. Symptoms reported on discontinuation of venlafaxine were mostly non-serious and self-limiting and included dizziness, insomnia, nausea and nervousness. **PA numbers:** Efexor XL 75mg capsule (PA 22/65/5) Efexor XL 150mg capsule (PA 22/65/6) Efexor 37.5mg tablet (PA 22/65/2) Efexor 75 mg tablet (PA 22/65/4). **Legal category: S1A. Further information is available upon request from:** Wyeth Pharmaceuticals, M50 Business Park, Ballymount Road Upper, Walkinstown, Dublin 12. **Marketing Authorisation Holder:** John Wyeth & Brother Limited, Taplow, Maidenhead, Berkshire, SL6 0PH. Date of preparation: 21 December 2004

Wyeth

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If adverse effects are observed, these may respond to omitting one or more doses; if they persist, the dose can be temporarily reduced to the previous well tolerated dose. If treatment is interrupted for longer than several days, treatment should be re-initiated at 1.5mg twice daily. Dose titration should then be carried out as described above. For patients with renal or mild-to-moderate hepatic impairment, treatment must be individually titrated based on tolerability. See full prescribing information. The capsules should be swallowed whole. The oral solution may be swallowed directly from the dosing syringe. Exelon oral solution and capsules may be interchanged at equal doses. **Children:** not recommended. **Contra-indications:** Hypersensitivity to rivastigmine, carbamate derivatives or any excipients used in Exelon. **Severe liver impairment. Precautions and warnings:** Initiation and supervision by a physician with experience of Alzheimer's Dementia. A caregiver should be available to monitor compliance. Exelon has not been investigated in patients with severe Alzheimer's Dementia, other types of dementia or other types of memory impairment. **Gastrointestinal disorders** such as nausea and vomiting may occur, especially in women. During therapy patient's weight should be monitored as cholinesterase inhibitors, including Exelon, have been associated with weight loss. As with other cholinomimetics, care must be taken when using Exelon in patients with sick sinus syndrome or other conduction defects, and in patients with active or a predisposition to gastric or duodenal ulcer. Care in patients with asthma and obstructive pulmonary disease. Cholinomimetics may induce or exacerbate urinary obstruction, seizures and extrapyramidal symptoms. **Pregnancy and lactation, ability to drive/operate machinery:** See full prescribing information. **Interactions:** No pharmacokinetic interaction was observed between Exelon and digoxin, warfarin, disopyramide or fluoxetine. Cholinesterase inhibitors may exaggerate the effects of succinylcholine-type muscle relaxants during anaesthesia. Exelon should not be given with other cholinomimetic drugs and may interfere with the activity of anticholinergics. See full prescribing information. **Side-effects:** The most commonly reported adverse drug reactions are gastrointestinal, including nausea (38%) and vomiting (23%), especially during titration. Female patients in clinical studies were found to be more susceptible to gastrointestinal adverse drug reactions and weight loss. The following adverse drug reactions have been accumulated both from clinical studies with Exelon and since the introduction of Exelon into the market. Very common (>1/10): dizziness, nausea, vomiting, diarrhoea and loss of appetite. Common (>1/100, <1/10): agitation, confusion, headache, somnolence, tremor, abdominal pain, dyspepsia, sweating, increased fatigue, asthenia, malaise and weight loss. Uncommon (>1/1,000, <1/100): insomnia, depression, syncope and accidental fall. Rare (>1/10,000, <1/1,000): seizures, angina pectoris, rashes, gastric and duodenal ulcers. Very rare (<1/10,000) including isolated reports: urinary infection, hallucinations, extrapyramidal symptoms, cardiac arrhythmia, hypertension, gastrointestinal haemorrhage, pancreatitis and elevated liver function test. **Overdose:** Most cases of accidental overdosage have not been associated with any clinical signs or symptoms, and almost all of the patients concerned continued Exelon treatment. In overdose accompanied by severe nausea and vomiting, the use of antiemetics should be considered. In massive overdose, atropine sulphate can be used at an initial intravenous dose of 0.03 mg/kg. Use of scopolamine as an antidote is not recommended. **Presentation:** Blister strips with 14 capsules. Marketed pack sizes 28 and 56 for capsules and 120 ml Bottle packed with oral dosing syringe. **Marketing authorisation holder:** Novartis Europharm Limited, Wimblehurst Road, Horsham, West Sussex, RH12 5AB, United Kingdom. **Marketing authorisation number:** EU/1/98/06/1-18. **Full prescribing information is available on request from:** Novartis Ireland Ltd, Beech House, Beech Hill Office Campus, Clonsilla, Dublin 4. Telephone: 01 260 12 55. **Date of last revision:** March 2004. **References:** 1. Fallow MR, et al. Response of patients with Alzheimer Disease to rivastigmine treatment is predicted by the rate of disease progression. *Arch Neurol* 2001; 58: 417-422. 2. Giacobini E. Inhibition of acetylcholinesterase in the cerebrospinal fluid of patients with Alzheimer's disease by rivastigmine: correlation with cognitive benefit. *J Neural Trans* 2002; 109: 1053-1065. 3. Data on file, Novartis Pharmaceuticals. NO3040407

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