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'Poppies' by AL. Acrylic (36" x 24")

Keep us from drifting apart, as time goes by

When **Change** causes **Distress** - EXELON offers

- Particular efficacy for patients displaying noticeable change¹
- +
- The benefit of sustained inhibition of both AChE and BuChE²
- +
- Long-term efficacy proven over 5 years³

Bring **Stability** to her life
- EXELON endures

For Alzheimer's Patients

EXELON[®]

(rivastigmine)

Stability in a time of change

PRESCRIBING INFORMATION EXELON[®] (rivastigmine) CAPSULES. Presentation: 1.5mg, 3mg, 4.5mg & 6mg. **EXELON[®] ORAL SOLUTION (rivastigmine).** Presentation: 2mg/ml oral solution. **Indications:** Symptomatic treatment of mild to moderately severe Alzheimer's Dementia. **Dosage and administration:** Adults/Elderly: Initially 1.5mg twice a day with morning and evening meals. If well tolerated after at least two weeks of treatment, the dose should be increased to 3mg twice a day. Further increases to 4.5mg and then 6mg twice a day, should be based on good tolerability after at least two weeks treatment at each dose level. The effective dose is 3 to 6mg twice a day; patients should be maintained on their highest well tolerated dose for as long as therapeutic benefit exists. The recommended maximum daily dose is 6mg twice a day. 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, diazepam 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 overdose 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/1/98/66/1-18. **Full prescribing information is available on request from:** Novartis Ireland Ltd., Beech House, Beech Hill Office Campus, Clonskeagh, Dublin 4. Telephone: 01 260 12 55. **Date of last revision:** March 2004. **References:** 1. Farlow 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 acetyl- and butyryl-cholinesterase in the cerebrospinal fluid of patients with Alzheimer's disease by rivastigmine: correlation with cognitive benefit. *J Neural Transm* 2002; 109: 1053-1065. 3. Data on file, Novartis Pharmaceuticals. NO0400407

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Get a grip_{on} depression and anxiety.

Now indicated for the treatment of¹:
Major Depressive Episodes
Generalised Anxiety Disorder
Social Anxiety Disorder
& Panic Disorder

Lundbeck



Lexapro[®]
escitalopram

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. **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:** Usual dosage is 10 mg once daily. The dose may subsequently be increased to a maximum of 20 mg/day. **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 reduced 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. Caution is 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. Escitalopram should not be used in combination with a non-selective, irreversible monoamine oxidase inhibitor (MAOI). Escitalopram may be started 14 days after discontinuing treatment with an irreversible MAOI and at least one day after discontinuing treatment with a reversible MAOI (RIMA). At least 7 days should elapse after discontinuing esci-

talopram treatment, before starting a non-selective MAOI. **Pregnancy and Lactation:** Lexapro should not be used during pregnancy unless clearly necessary. Avoid use during lactation. **Precautions:** No direct impairment of psychomotor function. Patients should be cautioned about the risk to their ability to drive a car or operate machinery. No pharmacokinetic or pharmacodynamic interactions are expected with concomitant alcohol intake, however the combination is not advised. Combination with the reversible MAOI-A (RIMA) moclobemide or serotonergic compounds is not recommended. Insulin and/or oral hypoglycaemic dosage may need to be readjusted in diabetics. Hyponatraemia has been observed with SSRI use. Caution in patients with a history of mania/hypomania and co-administration of ECT in patients on SSRI's. Caution is recommended in patients taking medicines that will affect clotting of blood, platelet function or patients with bleeding disorders. Patients with epilepsy, especially unstable epilepsy, should be carefully monitored. Stop treatment if patient develops serotonin syndrome. Use at a low starting dose for panic disorders. Do not stop treatment abruptly. As with all SSRI's it is advisable to closely monitor patients for suicide and self-harm risk in the first few weeks of treatment. Caution is advised in patients with coronary heart disease. **Drug Interactions:** MAO inhibitors (see Contraindications/Precautions), also advise caution in use with selegiline (MAOI-B), lithium and tryptophan, or with medicinal products that are capable of lowering the seizure threshold. Avoid concomitant use with St. John's Wort (*Hypericum perforatum*). 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 the enzymes CYP2C19 (weakly inhibited by escitalopram) and CYP2D6 (not inhibited by escitalopram) with CYP2C19 inhibitors (e.g. omeprazole, esomeprazole, fluvoxamine, lansoprazole and ticlopidine) and high doses of cimetidine may require

reduction of the escitalopram dose. **Adverse Events:** Adverse events are in general mild and transient. Most commonly observed events occurring more frequently with escitalopram than placebo in clinical trials include: nausea, sweating, somnolence, dizziness, insomnia, constipation, diarrhoea, appetite decrease, sexual dysfunction, fatigue, pyrexia, sinusitis and yawning. Withdrawal symptoms (dizziness, headache and nausea) have been observed in some patients after abrupt discontinuation. In order to avoid withdrawal reactions, tapered discontinuation over 1-2 weeks is recommended. Abrupt withdrawal of escitalopram should be avoided. The available pre-clinical and clinical evidence does not suggest that SSRI's cause dependence. **Overdosage:** Doses of 190 mg of escitalopram have been taken without any serious symptoms being reported. Symptoms of overdose with racemic citalopram (>600 mg): Dizziness, tremor, agitation, somnolence, unconsciousness, seizures, tachycardia, changes in the ECG with ST-T changes, broadening of the QRS complex, prolonged QT interval, arrhythmias, respiratory depression, vomiting, rhabdomyolysis, metabolic acidosis, hypokalaemia. It is anticipated that overdoses with escitalopram would result in similar symptoms. There is no specific antidote. Treatment is symptomatic and supportive with monitoring of cardiac and vital signs. Early gastric lavage suggested. **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 PA 805/2/3; 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 trademark [™] 2002 Lundbeck Ltd. **Date of preparation:** May 2006. **References:** 1. Lexapro (escitalopram) Summary of Product Characteristics March 2006.