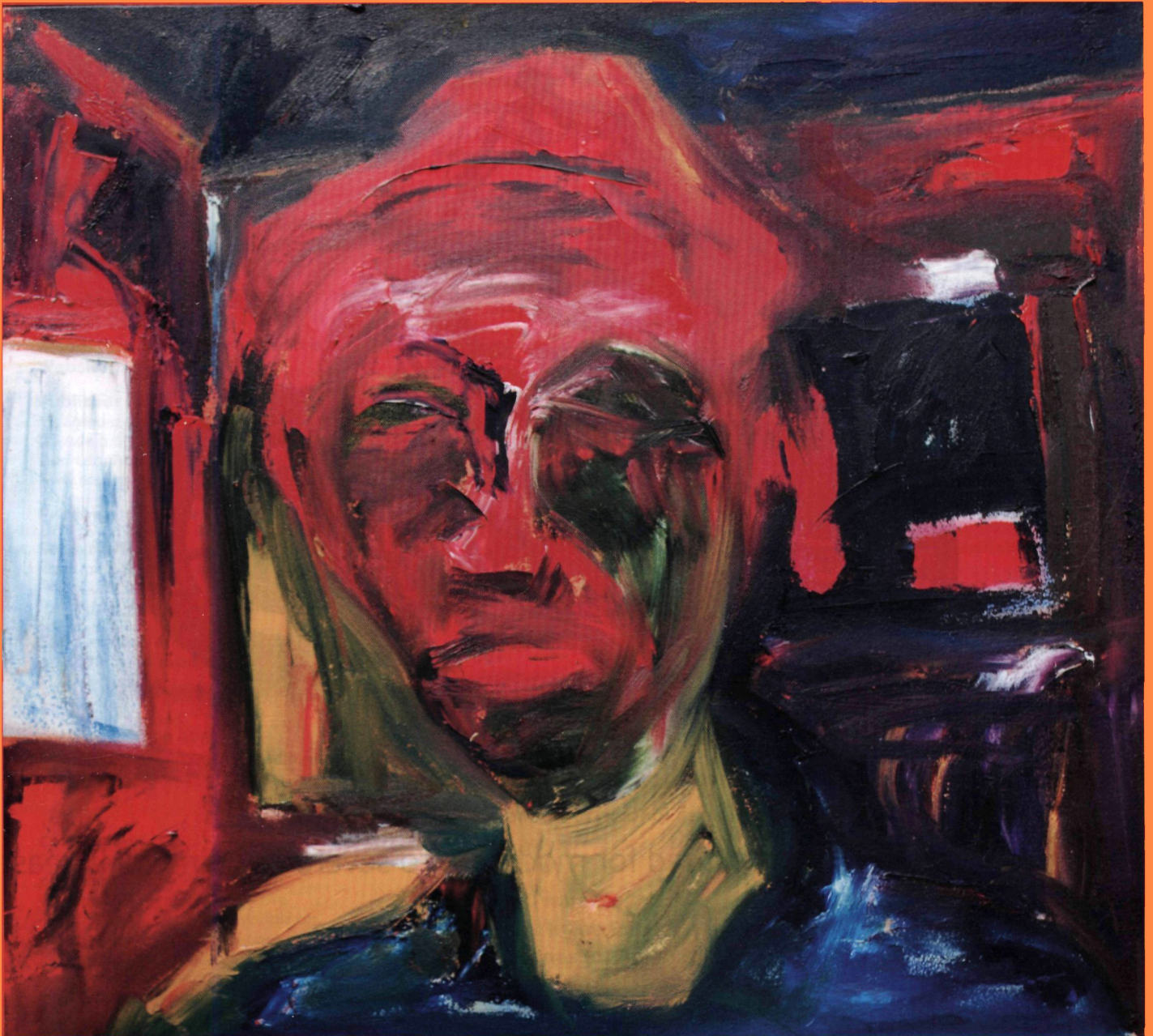


# IRISH JOURNAL OF PSYCHOLOGICAL MEDICINE

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**'Self-portrait' by MD.** Reproduced with kind permission from the Art Therapy Group at the Central Mental Hospital, Dublin, Ireland

# You can make a difference sooner with Ebixa<sup>®</sup> 1,2

*for a life worth living*



**Ebixa<sup>®</sup>**  
memantine

Approved for moderate to severe Alzheimer's Disease

**ABBREVIATED PRESCRIBING INFORMATION:** for full prescribing information refer to the Summary of Product Characteristics.

**Name:** Ebixa. **Active Substance:** Memantine Hydrochloride. **Indication:** Treatment of patients with moderate to severe Alzheimer's disease. **Dosage & Administration:** Treatment should be initiated and supervised by a physician experienced in the diagnosis and treatment of Alzheimer's dementia. Therapy should only be started if a caregiver is available who will regularly monitor the intake of the medicinal product by the patient. Treatment is orally either as tablets (10 mg) or solution (10 mg/g) taken with or without food at the same time every day. Maintenance dose is 20mg/day, (two tablets or 40 drops once a day). Treatment starts with 5mg/day (half a tablet or 10 drops once a day) for the first week; the 2nd week 10mg/day (one tablet or 20 drops once a day); the 3rd week 15mg/day (one and a half tablets or 30 drops once a day) and the 4th week 20mg/day (two tablets or 40 drops once a day). Moderate renal impairment 10mg/day (one tablet or 20 drops once a day), if well tolerated after 7 days the dose can be titrated up to 20mg/day (two tablets or 40 drops once a day). Severe renal impairment- dose is 10 mg/day. Mild-moderate hepatic impairment- no dose adjustment. Severe hepatic impairment- no data available. **Children & Adolescents:** Not recommended. **Contraindications:** Hypersensitivity to the active substance or any of the excipients. **Pregnancy and Lactation:** Memantine should not be used in pregnant women unless clearly necessary. **Lactation:** Memantine should not be used in women who are breastfeeding. **Special Warnings and Precautions for use:** Caution is recommended in patients with epilepsy. Caution is advised in patients with raised urine pH as this may elevate plasma levels. Clinical trial data are limited on patients with myocardial infarction, uncompensated congestive heart failure and uncontrolled hypertension and patients with these conditions should be closely supervised. Avoid concomitant use of NMDA antagonists (see also interactions). Patients with sugar intolerance should not take Ebixa. Patients should be warned to take special care if driving and using machines as Ebixa has minor to moderate influence on these tasks. **Interactions:** Effects of L-Dopa, dopaminergic agonists and anticholinergics may be enhanced. Effects of barbiturates and neuroleptics may be reduced. Effect of concomitant treatment with antispasmodic agents e.g. dantrolene and baclofen may be modified. Plasma levels of cimetidine, ranitidine, procainamide, quinidine, quinine and nicotine may be increased. Co-administration with hydrochlorothiazide (HCT) may lead to a reduced serum level of HCT. Concomitant use of NMDA antagonist- amantadine, ketamine, dextromethorphan or phenytoin should be avoided. Close monitoring of prothrombin time or INR is advisable for patients treated concomitantly with oral anticoagulants. **Adverse reactions:** Common ( $\geq 1/100$  and  $< 1/10$ ) headache, somnolence, hypertension, constipation, dizziness and dyspnoea. Uncommon reactions ( $\geq 1/1000$  and  $< 1/100$ ): cardiac failure, fatigue, fungal infections, confusion, hallucinations (mainly in severe Alzheimer's disease), venous thrombosis/thromboembolism, vomiting, gait abnormal. Very rare ( $< 1/10,000$ ): seizures. Not known: Isolated cases of pancreatitis and psychotic reactions have been reported post-marketing. Alzheimer's disease has been associated with depression, suicidal ideation and suicide. In post-marketing experience these events have been reported in patients treated with memantine. **Overdose:** Symptomatic treatment. **Elimination:** Mainly in unchanged form via the kidneys. **Legal Category:** POM. **Marketing Authorisation Holder:** H.Lundbeck A/S, 9 Østlævej, DK-2500, Valby, Denmark. **Marketing Authorisation Numbers:** EU/1/02/219/005 Ebixa 10mg/g Oral drops solution-50g bottle. EU/1/02/219/006 Ebixa 10mg/g Oral drops solution-100g bottle. EU/1/02/219/007 Ebixa Tablets 10mg, 28 pack size. EU/1/02/219/008 Ebixa Tablets 10mg, 56 pack size. Further information may be obtained from: Lundbeck (Ireland) Ltd., 7 Riverwalk, Citywest Business Campus, Citywest, Dublin 24. **Date of Preparation:** July 2009. **References** 1. Wilkinson et al. Dement Geriatr Cogn Disord 2007; 24:138-145 2. Reisberg et al. 2006. Arch Neurol. 63:49-54 3. Claxton et al. Clinical Therapeutics 2001; 23:1296-1310. 4. Summary of Product Characteristics (SmPC).



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**LYRICA®**  
**PREGABALIN**  
*Fast onset. Sustained relief.*

**Lyrica® (pregabalin) Prescribing Information. Refer to Summary of Product Characteristics (SmPC) before prescribing. Presentation:** Lyrica is supplied in hard capsules containing 25mg, 50mg, 75mg, 100mg, 150mg, 200mg or 300mg of pregabalin. **Indications:** Treatment of peripheral and central neuropathic pain in adults. Treatment of epilepsy, as adjunctive therapy in adults with partial seizures with or without secondary generalisation. Treatment of Generalised Anxiety Disorder (GAD) in adults. **Dosage:** *Adults:* 150 to 600mg per day, given in either two or three divided doses taken orally. Treatment may be initiated at a dose of 150mg per day and, based on individual patient response and tolerability, may be increased to 300mg per day after an interval of 3-7 days (for neuropathic pain) or 7 days (for epilepsy or GAD), the dose may be increased to 450mg per day after an additional 7 day interval (for GAD), and to a maximum dose of 600mg per day after a further 7-day interval. Treatment should be discontinued gradually over a minimum of one week. *Renal impairment/Haemodialysis:* dosage adjustment necessary; see SmPC. *Hepatic impairment:* No dosage adjustment required. *Elderly:* Dosage adjustment required if impaired renal function. *Children and adolescents:* Not recommended. **Contra-indications:** Hypersensitivity to active substance or excipients. **Warnings and precautions:** There have been reports of hypersensitivity reactions, including cases of angioedema. Pregabalin should be discontinued immediately if symptoms of angioedema, such as facial, perioral, or upper airway swelling occur. Patients with galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take Lyrica. Some diabetic patients who gain weight may require adjustment to hypoglycaemic medication. Occurrence of dizziness and somnolence could increase accidental injury (fall) in elderly patients. There have also been post marketing reports of loss of consciousness, confusion and mental impairment. Cases of renal failure have been reported and discontinuation of pregabalin did show reversibility of this adverse effect. In controlled studies, a higher proportion of patients treated with pregabalin reported blurred vision than did patients treated with placebo which resolved in a majority of cases with continued dosing. In the clinical studies where ophthalmologic testing was conducted, the incidence of visual acuity reduction and visual field changes was greater in pregabalin-treated patients than in placebo-treated patients; the incidence of fundoscopic changes was greater in placebo-treated patients. In the postmarketing experience, visual adverse reactions have also been reported, most of which refer to transient vision loss, visual blurring or other changes of visual acuity. Discontinuation of pregabalin may result in resolution or improvement of these visual symptoms. Suicidal ideation and behaviour have been reported in patients treated with anti-epileptic agents. A meta-analysis of randomised placebo controlled trials of anti-epileptic drugs has also shown a small increased risk of suicidal ideation and behaviour. The data does not exclude the possibility of an increased risk for pregabalin. Patients should be monitored for signs of suicidal ideation and behaviours and appropriate treatment should be considered. Patients (and caregivers of patients) should be advised to seek medical advice should signs of suicidal ideation or behaviour emerge. Insufficient data for withdrawal of concomitant antiepileptic medication, once seizure control with adjunctive Lyrica has been reached, in order to reach monotherapy with Lyrica. After discontinuation of short and long-term treatment withdrawal symptoms have been observed in some patients; insomnia, headache, nausea, diarrhoea, flu syndrome, nervousness, depression, pain, sweating and dizziness. The patient should be informed about this at the start of the treatment. Concerning discontinuation of long-term treatment there are no data of the incidence and severity of withdrawal symptoms in relation to duration of use and dosage of pregabalin. (see side effects). There have been post-marketing reports of congestive heart failure in some patients receiving pregabalin. These were mostly elderly, cardiovascular compromised patients who received treatment for a neuropathic indication. Pregabalin should be used with caution in these patients. Discontinuation of pregabalin may resolve the reaction. **Ability to drive and use machines:** May affect ability to drive or operate machinery. **Interactions:** Pregabalin appears to be additive in the impairment of cognitive and gross motor function caused by oxycodone and may potentiate the effects of ethanol and lorazepam. In the postmarketing experience, there are reports of respiratory failure and coma in patients taking pregabalin and other CNS depressant medications. **Pregnancy and lactation:** Lyrica should not be used during pregnancy unless benefit outweighs risk. Effective contraception must be used in women of childbearing potential. Breast-feeding is not recommended during treatment with Lyrica. **Side effects:** Adverse reactions during clinical trials were usually mild to moderate. Most commonly (>1/10) reported side effects in placebo-controlled, double-blind studies were somnolence and dizziness. Commonly (>1/100, <1/10) reported side effects were appetite increased, euphoric mood, confusion, libido decreased, irritability, ataxia, disturbance in attention, coordination abnormal, memory impairment, tremor, dysarthria, paraesthesia, vision blurred, diplopia, disorientation, balance disorder, insomnia, vertigo, dry mouth, constipation, vomiting, flatulence, erectile dysfunction, fatigue, oedema peripheral, feeling drunk, lethargy, sedation, oedema, gait abnormal and weight increased. See SmPC for less commonly reported side effects. After discontinuation of short and long-term treatment withdrawal symptoms have been observed in some patients; insomnia, headache, nausea, diarrhoea, flu syndrome, nervousness, depression, pain, sweating and dizziness. Concerning discontinuation of long-term treatment there are no data of the incidence and severity of withdrawal symptoms in relation to duration of use and dosage of pregabalin. (see warnings and precautions). In the post-marketing experience, the most commonly reported adverse events observed when pregabalin was taken in overdose included somnolence, confusional state, agitation, and restlessness. **Legal category:** S1A. **Date of revision:** August 2009. **Package quantities, marketing authorisation numbers:** Lyrica 25mg, EU/1/04/279/003, 56 caps; Lyrica 25mg EU/1/04/279/004, 84 caps; Lyrica 50mg, EU/1/04/279/009, 84 caps; Lyrica 75mg, EU/1/04/279/012, 56 caps; Lyrica 100mg, EU/1/04/279/015, 84 caps; Lyrica 150mg, EU/1/04/279/018, 56 caps; Lyrica 200mg, EU/1/04/279/021, 84 caps; Lyrica 300mg, EU/1/04/279/024, 56 caps. **Marketing Authorisation Holder:** Pfizer Limited, Ramsgate Road, Sandwich, Kent, CT13 9NJ, UK. Lyrica is a registered trade mark. **Further information is available on request from:** Pfizer Healthcare Ireland, 9 Riverwalk, National Digital Park, Citywest Business Campus, Dublin 24, Republic of Ireland. **References:** 1. Kavoussi R. Pregabalin: From molecule to medicine. *Eur Neuropsychopharmacol.* 2006;16 Suppl 2:S128-S133. 2. Montgomery SA, Tobias K, Zornberg GJ, et al. Efficacy and safety of pregabalin in the treatment of generalized anxiety disorder: a 6-week, multicenter, randomized, double-blind, placebo-controlled comparison of pregabalin and venlafaxine. *J Clin Psychiatry.* 2006; 67(5):771-82. 3. Smith W, Feltner D, Kavoussi R. Pregabalin in generalized anxiety disorder: Long term efficacy and relapse prevention. *Eur Neuropsychopharmacol.* 2002 Oct;12 (Suppl.3): S350. 4. LYRICA® SmPC 2009.