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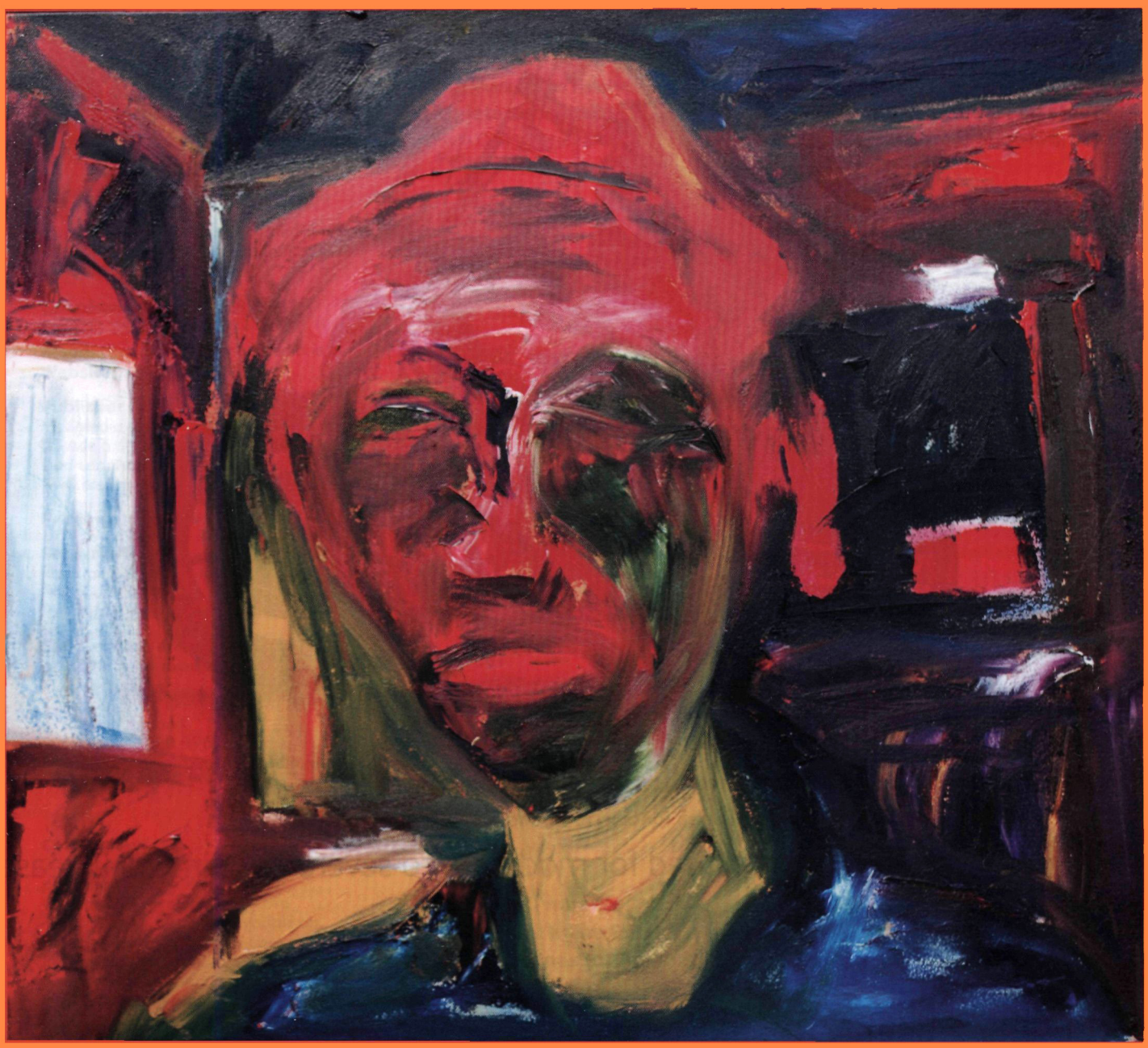

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Treatment should be discontinued gradually over a minimum of one week. *Renal impairment/Haemodialysis:* dosage adjustment necessary; see SmPC. *Hepatic impairment:* No dosage adjustment required. *Elderly:* Dosage adjustment required if impaired renal function. *Children and adolescents:* Not recommended. **Contra-indications:** Hypersensitivity to active substance or excip[illegible]. **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 [illegible] 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 GI, 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.

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