

**VOLUME 36 NUMBER 6 NOVEMBER 2009** 









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#### THE CANADIAN JOURNAL OF

# Neurological Sciences

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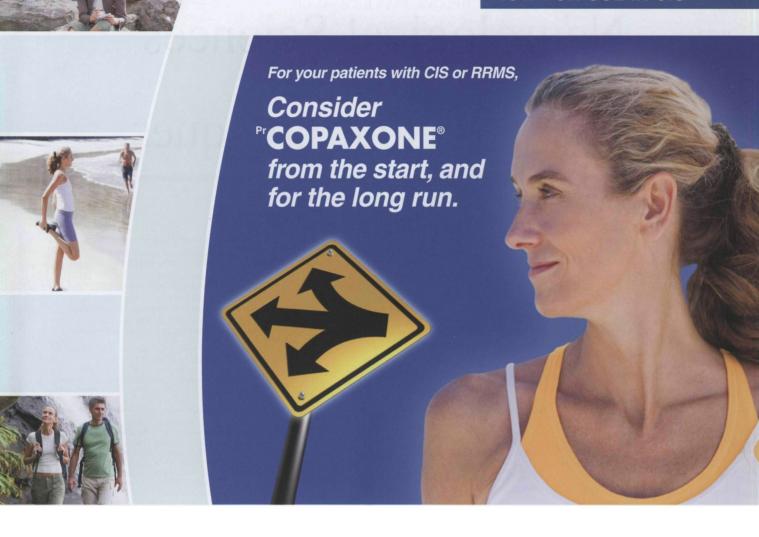
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\* CIS: Clinically isolated Syndrome. † Multicenter, double-blind, randomized, placebo-controlled trial in 251 patients with RRMS who were randomized to receive 20 mg/day glaturamer acetate (m= 125) or placebo (n=126) subcutaneously. Patients were diagnosed with RRMS by standard criteria, and had at least 2 exacerbations during the 2 years immediately preceding enrollment. Primary outcome measure was the mean number of relapses during treatment, 4 CDMS: Clinically Definite Multiple Scienciss. § Delay to CDMS is based on the 25th percentile, Kaplan-Meier estimates. ¶ Multicenter, randomized, double-blind, placebo-controlled, parallel group study in 481 patients for up to three years (glatiramer acetate 20 mg/day. n=243) placebo n=238) was performed in patients with a well-defined, single, unifocal neurological presentation and MRI I features suggestive of MS (at least two cerebral lesions on 12-weighted MRI). A total of 25% of glatiramer acetate patients, and 43% of placebo patients converted to CDMS in an average duration of treatment of 2.4 years.



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#### Advertising representative/Représentant de nublicité:

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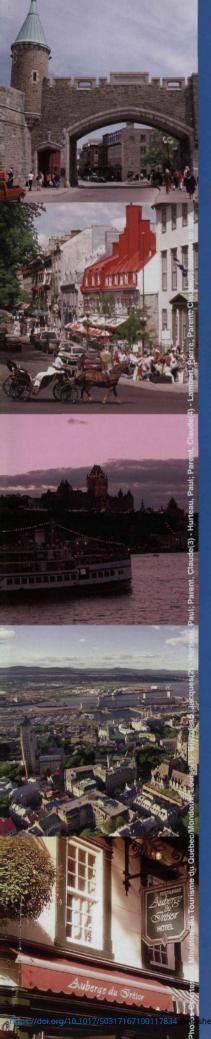
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Thank you for joining us at this years Congress and we look forward to seeing you at our next Congress in Zuebec City!

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There have been post-marketing reports of angioedema in patients, some without reported previous history/episodes, including life-threatening angioedema with respiratory compromise. Caution should be exercised in patients with previous history/episodes of angioedema and in patients who are taking other drugs associated with angioedema.

In clinical trials and in post-marketing experience, there have been reports of patients, with or without previous history, experiencing renal failure alone or in combination with other medications. Caution is advised when prescribing to the elderly or those with any degree of renal impairment.

The most commonly observed dose-related adverse events in LYRICA-treated patients were: dizziness (22.7-46.5%), somnolence (12.9-20.7%), weight gain (7.6-13.7%), peripheral edema (5.3-10.8%). The most commonly reported (≥5% and twice the rate of that seen in placebo) treatment-related adverse events were: dizziness (37.5%), somnolence (18.6%), weight gain (10.6%), dry mouth (7.9%), blurred vision (6.7%), and peripheral edema (6.1%). Adverse events were usually mild to moderate in intensity. Discontinuation rates due to adverse events for LYRICA and placebo, respectively, were 20% and 11%. There was a

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References: 1. LYRICA Product Monograph. Pfizer Canada Inc., March 2009. 2. Mease PJ et al. A randomized, doubleblind, placebo-controlled, phase III trial of pregabalin in the treatment of patients with fibromyalgia. J Rheumatol 2008;35:502:14.

\* A multicenter, double-blind, 13-week, randomized trial. 748 patients who met the ACR criteria for fibromyalgia and who had an average mean pain score of ≥4 on an 11-point numeric rating scale (NRS) during the baseline assessment were randomized to LYRICA 300 mg/day (n=185), 450 mg/day (n=183), 600 mg/day (n=190), or placebo (n=190). Patients were allowed to take acetaminophen up to 4 g/day as needed for pain relief. The number of completers was: LYRICA 300 mg/day (n=123), 450 mg/day (n=121), 600 mg/day (n=111), or placebo (n=130). The primary endpoint was the reduction in endpoint mean pain scores (mean of the last 7 daily pain scores while on study medication). Pain-related sleep difficulties were assessed using the Medical Outcomes Study-Sleep Scale (MOS-SS), a scale that runs from 0-100. Mean baseline MOS-SS score for overall sleep problem index was 65.0.



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