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THE CANADIAN JOURNAL OF

# Neurological Sciences

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LE JOURNAL CANADIEN DES

# Sciences Neurologiques

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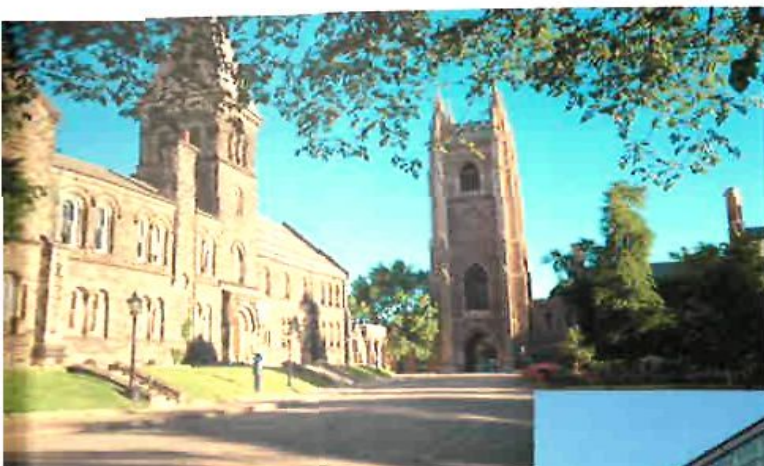


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*The University of Toronto*

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## JOURNAL COVER

**We are investigating different options for the cover of the Journal and thought it might be appropriate to include pictures of major Canadian Cities and/or Universities as taken by our readers.**

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for the long run.



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29% mean reduction at 24 months (**COPAXONE**<sup>®</sup> 1.19, placebo 1.68; n=251, p=0.007)<sup>1†</sup>

**In CIS, delayed time to CDMS<sup>‡§</sup>**

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<sup>1</sup> Clinically Isolated Syndrome. <sup>†</sup> Multicenter, double-blind, randomized, placebo-controlled trial in 251 patients with RRMS who were randomized to receive 20 mg/day glatiramer acetate (n=125) or placebo (n=126) subcutaneously. Patients were diagnosed with RRMS by standard criteria, had at least 2 exacerbations during the 2 years immediately preceding enrollment. Primary outcome measure was the mean number of relapses during treatment. <sup>‡</sup> CDMS: Clinically Definite Multiple Sclerosis. <sup>§</sup> Delay to CDMS is based on the 25<sup>th</sup> percentile; Kaplan-Meier estimates. <sup>¶</sup> 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 features suggestive of MS (at least two cerebral lesions on T2-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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Reference: 1. **COPAXONE**<sup>®</sup> (glatiramer acetate) injection Product Monograph, TEVA Neuroscience, April 2009



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Treat from the start. Treat for the long run.



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**NEW** INDICATION

# Fibromyalgia pain is real. And so is treatment with LYRICA.

The efficacy of LYRICA in the management of pain associated with fibromyalgia for up to 6 months was demonstrated in a placebo-controlled trial in patients who had initially responded to LYRICA during a 6-week open-label phase.

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 ( $\geq 5\%$  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 dose-dependent increase in rate of discontinuation due to adverse events.

LYRICA is contraindicated in patients who are hypersensitive to pregabalin or to any ingredient in the formulation or component of the container.

**Dosage reduction is required in patients with renal impairment (creatinine clearance  $<60$  mL/min) and in some elderly patients as LYRICA is primarily eliminated by renal excretion.**

See Prescribing Information for complete Warnings and Precautions, Adverse Reactions, Dosage and Administration and patient selection criteria.

**References:** 1. LYRICA Product Monograph. Pfizer Canada Inc., Mar 2009. 2. Mease PJ *et al.* A randomized, double-blind, placebo-controlled phase II 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  $\geq 4$  on an 11-point numeric rating scale (NRS) during 1 baseline assessment were randomized to LYRICA 300 mg/day (n=18), 450 mg/day (n=183), 600 mg/day (n=150), 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=120). The primary endpoint was the reduction in endpoint mean pain scores (mean of last 7 daily pain scores while on study medication). Pain-related side effects 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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## **LYRICA is the first treatment indicated in Canada for the management of pain associated with fibromyalgia in adults**

LYRICA is proven to manage the pain associated with fibromyalgia<sup>1</sup>

LYRICA has been demonstrated to significantly improve pain-related sleep difficulties<sup>2</sup>

- LYRICA reduced overall MOS-Sleep Scale scores significantly more from baseline versus placebo

[LYRICA 300 mg/day -19.1 ( $p=0.0174$ ), LYRICA 450 mg/day -20.41 ( $p=0.0026$ ), and LYRICA 600 mg/day -19.49 ( $p=0.0101$ ) vs -14.29 for placebo]<sup>2\*</sup>

**LYRICA**<sup>®</sup>  
PREGABALIN



See prescribing summary on pages A17-18



# Cymbalta®

Now reimbursed by provincial drug plans in Ontario, Québec, Nova Scotia and New Brunswick for Diabetic Peripheral Neuropathic Pain.\*  
\*Reimbursed with criteria.

## Demonstrated Effective Pain<sup>1</sup> Relief in Diabetic Peripheral Neuropathic Pain (DPNP)<sup>††</sup>

<sup>†</sup> Neuropathic pain associated with diabetic peripheral neuropathy (DPN)

shooting<sup>1</sup>

burning<sup>1</sup>

stabbing<sup>1</sup>

Fictitious patient. May not be representative of the general population.

**Patients with neuropathic pain associated with DPN receiving Cymbalta<sup>®</sup> demonstrated improvement in the following:<sup>††</sup>**

• **Stabbing pain**

- Cymbalta<sup>®</sup> 60 mg vs. placebo (56.0% vs. 39.0%; p<0.05)
- Cymbalta<sup>®</sup> 120 mg<sup>‡</sup> vs. placebo (64.8% vs. 39.0%; p<0.001)

• **Hot-burning pain**

- Cymbalta<sup>®</sup> 60 mg vs. placebo (58.3% vs. 45.2%; p=NS)
- Cymbalta<sup>®</sup> 120 mg<sup>‡</sup> vs. placebo (62.9% vs. 45.2%; p<0.05)

• **Shooting pain**

- Cymbalta<sup>®</sup> 60 mg vs. placebo (53.8% vs. 39.4%; p=NS)
- Cymbalta<sup>®</sup> 120 mg<sup>‡</sup> vs. placebo (61.9% vs. 39.4%; p<0.001)



Cymbalta<sup>®</sup> (duloxetine hydrochloride) is indicated for the management of neuropathic pain associated with diabetic peripheral neuropathy (DPN).<sup>2</sup>

**Cymbalta<sup>®</sup> is not indicated for use in children under 18 years of age.<sup>2</sup>**

**Rigorous clinical monitoring for suicidal ideation or other indicators of potential for suicidal behaviour is advised in patients of all ages. This includes monitoring for agitation-type emotional and behavioural changes. Please see Prescribing Information for complete warnings.<sup>2</sup>**

**Patients currently taking Cymbalta<sup>®</sup> should NOT be discontinued abruptly due to risk of discontinuation symptoms. A gradual reduction in the dose is recommended.<sup>2</sup>**

Cymbalta<sup>®</sup> is contraindicated in patients with a known hypersensitivity to the drug or the other components of the product.<sup>2</sup>

Cymbalta<sup>®</sup> is contraindicated in patients with end-stage renal disease (requiring dialysis) or with severe renal impairment (estimated creatinine clearance <30 mL/min).<sup>2</sup>

Cymbalta<sup>®</sup> is contraindicated in patients with any liver disease resulting in hepatic impairment.<sup>2</sup>

Cymbalta<sup>®</sup> is contraindicated in patients concomitantly taking any of the following medications: monoamine oxidase inhibitors; linezolid or within at least 14 days of discontinuing treatment with an MAOI; potent CYP1A2 inhibitors (e.g. fluvoxamine) and some quinolone antibiotics (e.g. ciprofloxacin or enoxacin); and thioridazine.<sup>2</sup>

Because it is possible that duloxetine and alcohol may interact to cause liver injury or that duloxetine may aggravate pre-existing liver disease, Cymbalta<sup>®</sup> should not ordinarily be prescribed to patients with substantial alcohol use. Physicians should be aware of the signs and symptoms of liver damage and should investigate such symptoms promptly.<sup>2</sup>

In clinical trials, Cymbalta<sup>®</sup> was associated with an increased risk of mydriasis; therefore, it is contraindicated in patients with uncontrolled narrow-angle glaucoma.<sup>2</sup>

The most commonly observed adverse events in Cymbalta<sup>®</sup>-treated patients in placebo-controlled DPN trials (incidence of 5% or greater and at least twice the incidence in placebo patients) were: nausea (24%), constipation (9%), dry mouth (8%), vomiting (6%), fatigue (12%), decreased appetite (10%), somnolence (17%), and hyperhidrosis (9%).<sup>2</sup>

<sup>†</sup> 12-week, multicenter, double-blind study involving 457 patients experiencing pain due to polyneuropathy caused by Type 1 or Type 2 diabetes mellitus. Patients were randomly assigned to treatment with Cymbalta<sup>®</sup> 20 mg/d (20 mg QD), 60 mg/d (60 mg QD), 120 mg/d (60 mg BID), or placebo. The primary efficacy measure was the weekly mean score of the 24-h Average Pain Score, which was rated on an 11-point (0-10) Likert scale (no pain to worst possible pain) and computed from diary scores between two site visits. Patients were permitted up to 4 g of acetaminophen per day as needed for pain, in addition to Cymbalta<sup>®</sup>.<sup>1</sup>

<sup>‡</sup> 60 mg twice-daily dosing administration<sup>1</sup>



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**Cymbalta<sup>®</sup>** DELAYED RELEASE CAPSULES  
duloxetine HCl

FOR DIABETIC PERIPHERAL NEUROPATHIC PAIN



See prescribing summary on page A-13-1

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