THE CANADIAN JOURNAL OF
Neurological Sciences

LE JOURNAL CANADIEN DES
Sciences Neurologiques

VOLUME 36 NUMBER 2 MARCH 2009

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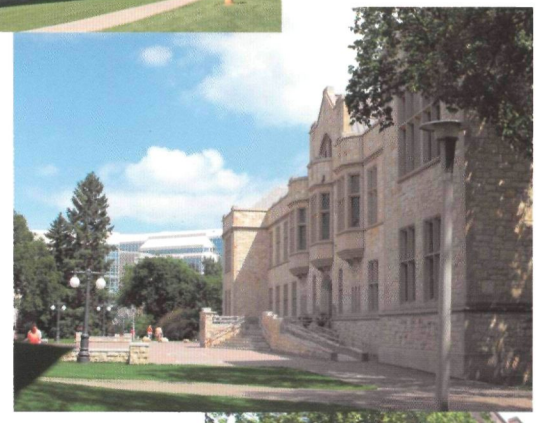

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AN INTERNATIONAL JOURNAL PUBLISHED BY THE CANADIAN NEUROLOGICAL SCIENCES FEDERATION

The official Journal of: The Canadian Neurological Society, The Canadian Neurosurgical Society, The Canadian Society of Clinical Neurophysiologists, The Canadian Association of Child Neurology

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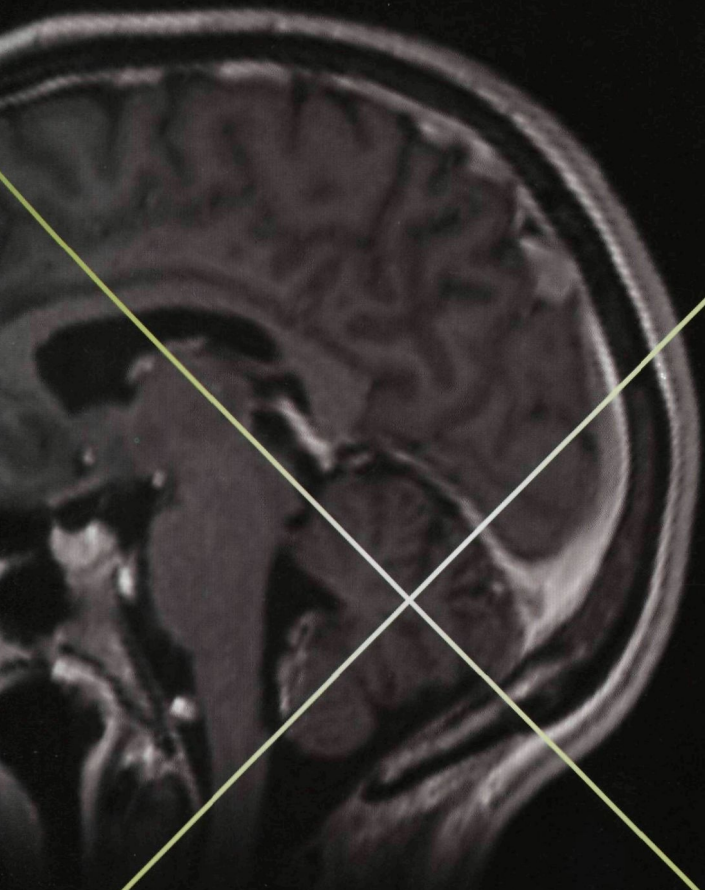

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https://doi.org/10.1017/S0317167100117500 Published online by Cambridge University Press

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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.

If you are interested in submitting pictures, please send them to maggie-mccallion@cnsfederation.org in high resolution format, (i.e. tif or jpeg). Please also indicate your willingness to provide these pictures free of charge. Picture 'acknowledgement' will be provided.

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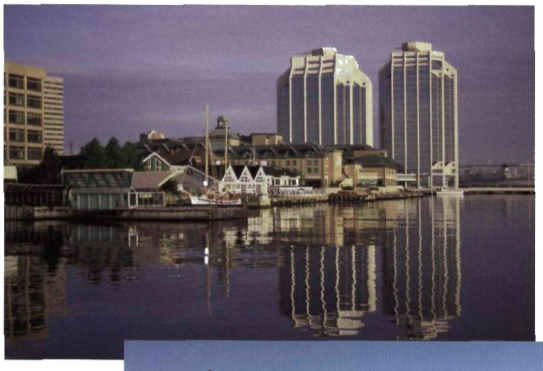

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Calgary, Alberta T2G 4B9

We acknowledge the assistance of the Government of Canada through the Publications Assistance Program towards our mailing costs. Canada

ISSN 0317 - 1671

https://doi.org/10.1017/S0317167100117500 Published online by Cambridge University Press

Patients with neuropathic pain associated with DPN receiving Cymbalta® demonstrated improvement in the following:‡1

- **Stabbing pain**
  - Cymbalta® 60 mg vs. placebo (56.0% vs. 39.0%; p≤0.05)
  - Cymbalta® 120 mg§ vs. placebo (64.8% vs. 39.0%: p≤0.001)
- **Hot-burning pain**
  - Cymbalta® 60 mg vs. placebo (58.3% vs. 45.2%; p=NS)
  - Cymbalta® 120 mg§ vs. placebo (62.9% vs. 45.2%; p≤0.05)
- **Shooting pain**
  - Cymbalta® 60 mg vs. placebo (53.8% vs. 39.4%; p=NS)
  - Cymbalta® 120 mg§ vs. placebo (61.9% vs. 39.4%; p≤0.001)

Cymbalta® (duloxetine hydrochloride) is indicated for the management of neuropathic pain associated with diabetic peripheral neurpathy (DPN).[2]

Cymbalta® is not indicated for use in children under 18 years of age.[2]

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.[2]

Patients currently taking Cymbalta® should NOT be discontinued abruptly due to risk of discontinuation symptoms. A gradual reduction in the dose is recommended.[2]

Cymbalta® is contraindicated in patients with a known hypersensitivity to the drug or the other components of the product.[2]

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

Cymbalta® is contraindicated in patients with any liver disease resulting in hepatic impairment.[2]

Cymbalta® 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 enoxacine); and thioridazine.[2]

Because it is possible that duloxetine and alcohol may interact to cause liver injury or that duloxetine may aggravate pre-existing liver disease, Cymbalta® 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.[2]

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

The most commonly observed adverse events in Cymbalta®-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%).[2]

‡ 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® 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®.[1]

§ 60 mg twice-daily dosing administration[1]

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Cymbalta® DELAYED RELEASE CAPSULES
duloxetine HCl
FOR DIABETIC PERIPHERAL NEUROPATHIC PAIN

Boehringer Ingelheim Lilly

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See prescribing summary on page A-17-20

AZILECT® (rasagiline mesylate) is indicated for the treatment of the signs and symptoms of idiopathic Parkinson's disease as initial monotherapy and as adjunct therapy to levodopa.

AZILECT® is contraindicated with meperidine, tramadol, methadone, propoxyphene, dextromethorphan, St. John's wort, cyclobenzaprine, sympathomimetic amines, antidepressants and other MAO inhibitors. Patients taking AZILECT® should not undergo elective surgery requiring general anesthesia. AZILECT® is contraindicated in patients with pheochromocytoma.[1] AZILECT® may cause hallucinations and as adjunct to levodopa there is the possibility of increased dyskinesia and postural hypotension. AZILECT® should not be used at daily doses exceeding the maximum recommended (1 mg/day) because of the risks associated with nonselective inhibition of MAO. Patients taking ciprofloxacin and other CYP1A2 inhibitors should use 0.5 mg daily of AZILECT®.

No significant differences in safety profile were observed based on age or gender. Overall, in phase II/III clinical trials, the long-term safety profile was similar to that observed with shorter duration exposure.

The most commonly observed adverse events that occurred in ≥ 5% of patients and were at least 1.5 times the incidence in the placebo group were flu syndrome (5%, 1%), arthralgia (7%, 4%), depression (5%, 2%), dyspepsia (7%, 4%) and falls (5%, 3%) in patients receiving AZILECT® 1 mg as monotherapy; and dyskinesia (18%, 10%), accidental injury (12%, 5%), weight loss (9%, 3%), postural hypotension (9%, 3%), vomiting (7%, 1%), anorexia (5%, 1%), arthralgia (8%, 4%), abdominal pain (5%, 1%), nausea (12%, 8%), constipation (9%, 5%), dry mouth (6%, 3%), rash (6%, 3%), ecchymosis (5%, 3%), somnolence (6%, 4%) and paresthesia (5%, 3%) for AZILECT® 1 mg as adjunct therapy.

† Comparative clinical significance unknown.

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Once-Daily AZILECT® (rasagiline tablets)

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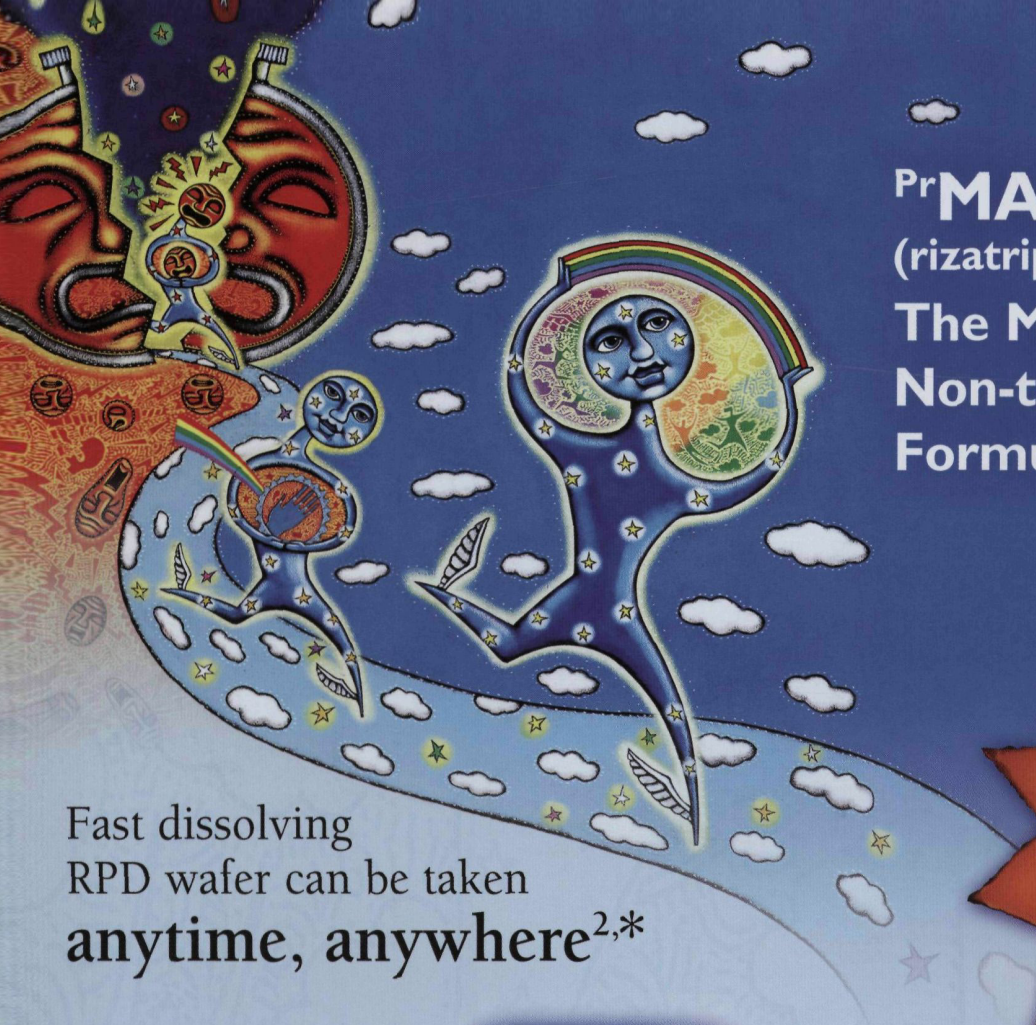
See prescribing summary on page A-23-26



PrMAXALT RPD®
(rizatriptan benzoate):
The Most Dispensed Non-tablet Migraine Formulation in Canada[1]

Fast dissolving
RPD wafer can be taken
anytime, anywhere[2,*]

ALSO AVAILABLE IN TABLET FORMULATION.

MAXALT® (rizatriptan benzoate) is indicated for the acute treatment of migraine attacks with or without aura in adults. MAXALT® is not intended for the prophylactic therapy of migraine or for use in the management of hemiplegic, ophthalmoplegic or basilar migraine. Safety and effectiveness of MAXALT® have not been established for cluster headache, which is present in an older, predominantly male population.

MAXALT® is contraindicated in patients with history, symptoms, or signs of ischemic cardiac, cerebrovascular or peripheral vascular syndromes, valvular heart disease or cardiac arrhythmias (especially tachycardias). In addition, patients with other significant underlying cardiovascular diseases should not receive MAXALT®.

MAXALT® is also contraindicated in patients with uncontrolled or severe hypertension.

MAXALT® is contraindicated in co-administration with monoamine oxidase (MAO) inhibitors within 2 weeks after discontinuation of treatment, and within 24 hours of administration of 5-HT_1 agonists or ergot-type medications. For a complete list of contraindications, please consult the Product Monograph.

The recommended single adult dose is 5 mg. The maximum recommended single dose is 10 mg.

The most common adverse events during treatment with MAXALT® (rizatriptan benzoate) tablets 10 mg were dizziness (8.9%), somnolence (8.4%), asthenia/fatigue (6.9%), nausea (5.7%) and pain/pressure sensation (chest, 3.1%; neck/throat/jaw, 2.5%; upper limb, 1.8%).

The most common adverse events during treatment with PrMAXALT RPD® (rizatriptan benzoate) wafers 10 mg were dizziness (8.6%), nausea (7.0%), dry mouth (6.0%), somnolence (5.3%), asthenia/fatigue (3.6%), and pain/pressure sensation (chest, 1.7%; neck/throat/jaw, 2.0%; upper limb, 2.0%).

MAXALT RPD® wafers contain phenylalanine (a component of aspartame).

*The wafer will dissolve rapidly and be swallowed with saliva. No liquid is needed to take the wafer.[2]
RPD = Rapidly dissolving

References:
1. Brogan Inc. Geographic Prescription Monitor (GPM®) October 2007 to September 2008.
2. Data on file, Merck Frosst Canada Ltd.: Product Monograph, MAXALT®, 2008.

BEFORE PRESCRIBING **MAXALT®**, PLEASE CONSULT THE ENCLOSED PRESCRIBING INFORMATION.

PRODUCT MONOGRAPH AVAILABLE FOR DOWNLOAD AT www.merckfrosst.com

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Pr Maxalt® (rizatriptan benzoate)

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Discovering today for a better tomorrow.
Merck Frosst Canada Ltd., Kirkland, Quebec

PAAB

MXT-08-CDN-34381016-JA

See prescribing summary on pages A-13-16

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LYRICA may be useful in the management of central neuropathic pain (NeP) in adult patients for which it has been issued marketing authorization with conditions to reflect the promising nature of the clinical evidence and the need for a confirmatory study to verify its clinical benefit. Patients should be advised of the nature of the authorization.

NEW

Pregabalin: First and only first-line analgesic with a conditional indication in central neuropathic pain

Pr LYRICA®

Powerful Pain Relief

Powerful. Fast onset. Sustained relief.

- Pain relief shown in postherpetic neuralgia (PHN) and central NeP as early as week 1 and demonstrated over 3 months[1-3*†]
- Improvement shown in pain-related sleep interference in PHN and central NeP as early as week 1 and demonstrated over 3 months[1-4*†]

Significant improvement in overall status.

- Significant improvement demonstrated in patient-reported overall status (Patient Global Impression of Change [PGIC]) in patients with peripheral NeP [diabetic peripheral neuropathy (DPN) or PHN] and central NeP[1-3,5*†‡]

LYRICA (pregabalin) is an analgesic indicated for the management of neuropathic pain (NeP) associated with DPN and PHN.

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

The most commonly observed adverse events (≥5% and twice the rate as that seen with placebo) were dose related for PHN and DPN patients in the recommended dose range of 150 mg/day to 600 mg/day: dizziness (9.0-37.0%), somnolence (6.1-24.7%), peripheral edema (6.1-16.2%), and dry mouth (1.9-14.9%). The most commonly observed adverse events seen in central NeP patients (≥5% and twice the rate as that seen with placebo) in the recommended dose range of 150 mg/day to 600 mg/day were: somnolence (41.4%), dizziness (24.3%), asthenia (15.7%), dry mouth (15.7%), edema (12.9%), constipation (12.9%), amnesia (10.0%), myasthenia (8.6%), amblyopia (8.6%), and thinking abnormal (8.6%). The most commonly observed adverse events in the PHN, DPN, and central NeP patients were usually mild to moderate in intensity. Discontinuation rates due to adverse events for LYRICA and placebo, respectively, were 9% and 4% in DPN, 14% and 7% in PHN and 21% and 13% in central NeP.

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

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

* A 13-week, multicentre, double-blind, placebo-controlled trial in 368 patients with PHN. A significant difference in pain reduction was shown over placebo for all doses: 150 mg/day, 300 mg/day, and 600 mg/day ($p \leq 0.01$, weeks 1-13). Sleep interference was improved at all time points (weeks 1 to 13 and endpoint) for the three doses evaluated ($p \leq 0.01$ vs. placebo). PGIC was reported as (at least minimally) improved by 51.2%, 47.9% and 67.1% of patients treated with LYRICA doses of 150, 300, and 600 mg/day vs. 35.5% of patients in the placebo group. At study termination, patients in the 150 mg/day ($p=0.02$) and 600 mg/day group ($p=0.003$) were more likely to report global improvement than those in the placebo group.

† Data based on a 12-week, parallel-group, double-blind, flexible-dose, placebo-controlled study. 137 patients with spinal cord injury for ≥1 year and who had a pain score ≥40 mm on the 100-mm visual analog scale (VAS) of the Short-Form-McGill Pain Questionnaire (SF-MPQ) were randomized to LYRICA 150 to 600 mg/day (n=70) or placebo (n=67) BID. Pain scores rated on 11-point numerical scale from 0 (no pain) to 10 (worst possible pain) during the past 24 hours averaged over the last seven days. Pain-related sleep interference scores rated on 11-point numerical scale from 0 (did not interfere) to 10 (completely interferes) during the past 24 hours averaged over the last seven days. A significant difference in pain reduction was demonstrated for the LYRICA group vs. placebo at all time points evaluated ($p \leq 0.001$, weeks 1-7 and endpoint and $p \leq 0.01$, weeks 8-12). Sleep interference was significantly improved at all time points (weeks 1 to 12 and endpoint) vs. placebo ($p \leq 0.01$, weeks 4, 10 and 12 and $p \leq 0.001$ for all other time points evaluated and endpoint). PGIC was reported as (at least minimally) improved by 56.5% and 21.5% of patients in the LYRICA and placebo treatment groups, respectively ($p<0.001$ for overall LYRICA comparison vs. placebo across "improved", "unchanged" and "worse" subgroups).

‡ A 12-week, multicentre, randomized, double-blind, placebo-controlled study in 338 patients with neuropathic pain (DPN [n=249] or PHN [n=89]), resulting in a significant difference from placebo in the flexible dose range 150-600 mg/day ($p \leq 0.05$, week 2-3 and $p \leq 0.01$, weeks 4-12), and the fixed dose of 600 mg/day ($p \leq 0.05$, week 1 and $p \leq 0.01$, weeks 2-12). PGIC was reported as very much improved or much improved by 52.0% of the flexible-dose group, 53.6% of the fixed-dose group and 30.5% of the placebo group ($p<0.01$ for overall comparison of both LYRICA treatment groups vs. placebo across "improved", "unchanged" and "worse" subgroups).

References: 1. Data on file, Pfizer Canada Inc., Study 1008-196. **2.** van Seventer R, Feister HA, Young JP *et al.* Efficacy and tolerability of twice-daily pregabalin for treating pain and related sleep interference in postherpetic neuralgia: a 13-week, randomized trial. *Curr Med Res Opin* 2006; 22(2):375-84. **3.** Siddall PJ *et al.* Pregabalin in central neuropathic pain associated with spinal cord injury: a placebo-controlled trial. *Neurology* 2006; 67:1792-800. **4.** LYRICA Product Monograph, Pfizer Canada Inc., November 8, 2007. **5.** Freynhagen R, Strojek K, Griesing T *et al.* Efficacy of pregabalin in neuropathic pain evaluated in a 12-week, randomised, double-blind, multicentre, placebo-controlled trial of flexible- and fixed-dose regimens. *Pain* 2005; 115:254-63.

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Pr LYRICA® PREGABALIN

Fast onset. Sustained relief.

See prescribing summary A-29, A-30