



THE CANADIAN JOURNAL OF

# Neurological Sciences

LE JOURNAL CANADIEN DES

# Sciences Neurologiques

AN INTERNATIONAL JOURNAL / UN JOURNAL INTERNATIONAL

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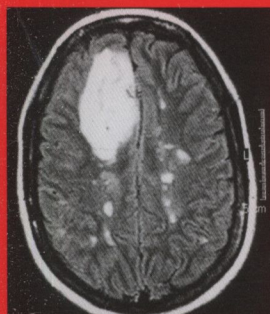
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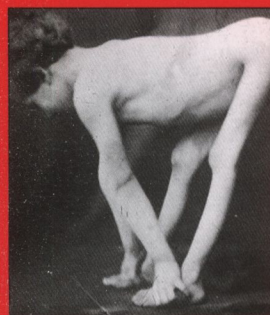
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Neuroimaging Highlight



Duchenne on clinical pathology

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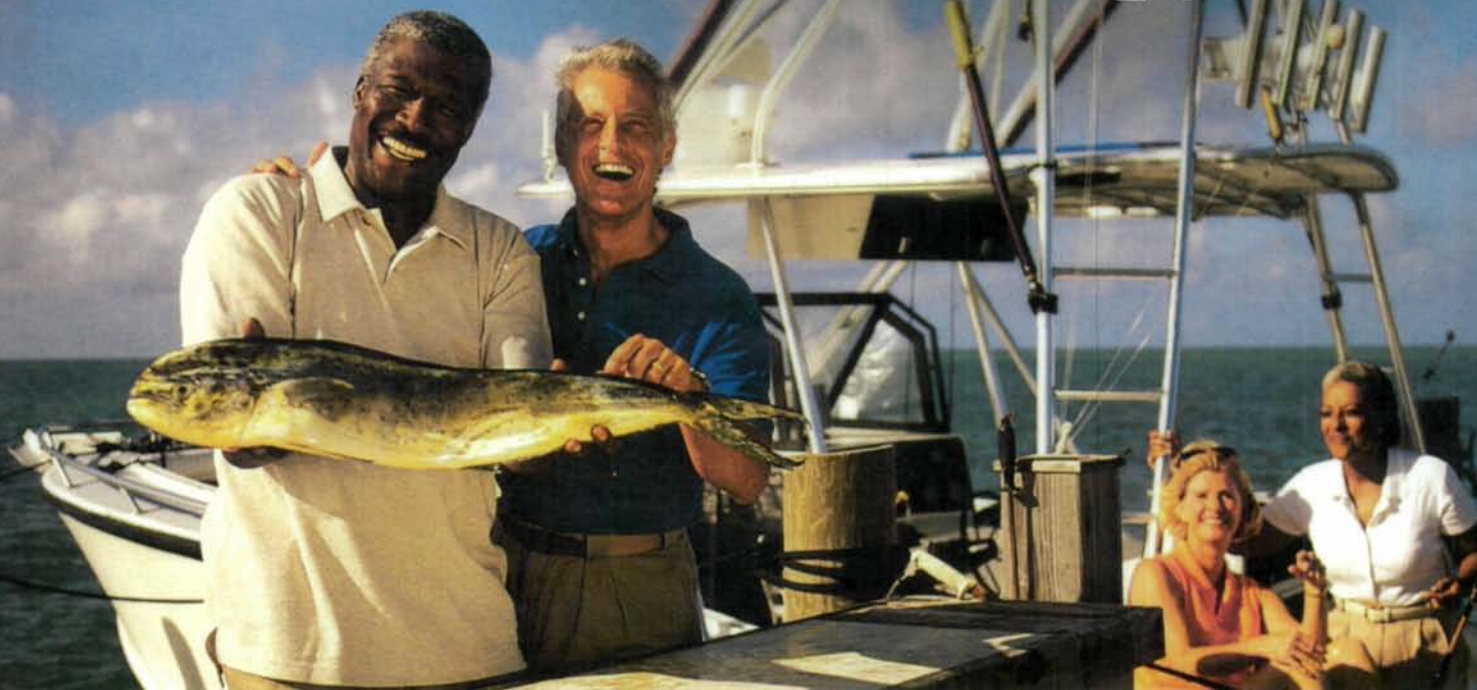
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<sup>2</sup> Prior to supplementation with L-dopa

<sup>3</sup> Data from 3 large phase III double-blind trials of ropinirole monotherapy in early Parkinson's disease were examined: a 5-year L-dopa-controlled trial (n=179), a 3-year bromocriptine-controlled trial (n=168), both with planned interim analysis and a 6-month placebo-controlled trial (n=116).<sup>1</sup>

† Please consult the Warnings section of the Product Monograph.<sup>3</sup>

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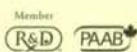
References: 1. Kocczyn AD *et al.* Dosing with ropinirole in a clinical setting. *Acta Neurologica Scandinavica* 2002;106:200-204. 2. Rascol O *et al.* A five-year study of the incidence of dyskinesia in patients with early Parkinson's disease who were treated with ropinirole or levodopa. *N Eng J Med* 2000;342(20):1484-1491. 3. Product Monograph of REQUIP® (ropinirole hydrochloride), GlaxoSmithKline, March 2004.

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† 28-week, randomized, multicentre, double-blind, parallel-group, placebo-controlled U.S. study in patients ( $\geq 50$  years) with moderate to severe Alzheimer's disease. Patients were randomized to treatment with EBIXA<sup>®</sup> 20 mg daily (n=126) or placebo (n=126).

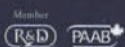
\* Function was measured on the Alzheimer's Disease Cooperative Study - Activities of Daily Living Inventory (ADCS-ADL<sub>...</sub>) scale with LOCF data - Change from baseline at study endpoint for EBIXA<sup>®</sup> vs. placebo: 2.1 units, p=0.02.

\*\* Cognition was measured on the Severe Impairment Battery (SIB) with LOCF data - Change from baseline at study endpoint for EBIXA<sup>®</sup> vs. placebo: 5.9 units, p<0.001.

Ω Less caregiver time was needed per month (45.8 hrs) for patients treated with EBIXA<sup>®</sup> vs. placebo, p=0.01.

1. Cummings JL. Alzheimer's disease (review). *N Engl J Med* 2004;351:56-67. 2. EBIXA<sup>®</sup> Product Monograph. Lundbeck Canada Inc., 2004. 3. Reisberg B, Doody R, Stöffler A, Schmitt F, Ferris S, Möbius HJ for the Memantine Study Group. Memantine in Moderate-to-Severe Alzheimer's Disease. *N Engl J Med* 2003;348(14):1333-1341.

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- Extended daily functioning (ADCS-ADL<sub>sev</sub>)<sup>2,3†\*</sup> and cognition (SIB)<sup>2,3†\*\*</sup> vs. placebo
- Excellent safety and tolerability profile<sup>2</sup>
- 45.8 hrs less caregiver time demonstrated per month vs. placebo<sup>3‡</sup>

A new hope for patients with moderate to severe Alzheimer's disease.

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EBIXA<sup>®</sup>, indicated for the symptomatic treatment of patients with moderate to severe dementia of the Alzheimer's type, 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 the clinical benefit. Patients should be advised of the nature of the authorization assessment.

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Caution should be observed when EBIXA<sup>®</sup> is initiated in patients with cardiovascular conditions or in patients with a history of seizure disorder as these patient groups were not included in the clinical trials.

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<sup>†</sup> Cholinesterase inhibitors refers to only those which are approved in Canada for the symptomatic treatment of Alzheimer's disease.



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AVONEX® (Interferon beta-1a) is indicated for the treatment of relapsing forms of multiple sclerosis to slow the progression of disability, decrease the frequency of clinical exacerbations, and reduce the number and volume of active brain lesions identified on Magnetic Resonance Imaging (MRI) scans. AVONEX® is also indicated for the treatment of people who have experienced a single demyelinating event, accompanied by abnormal Magnetic Resonance Imaging (MRI) scans, with lesions typical of MS, to delay the onset of clinically definite multiple sclerosis (as determined by a second demyelinating event), and to decrease the number and volume of active brain lesions and overall disease burden (as identified by MRI scans). Before initiating treatment with AVONEX®, alternate diagnoses should first be excluded.

AVONEX® is generally well-tolerated. The most common side effects associated with treatment are flu-like symptoms, muscle ache, fever, chills, and asthenia. AVONEX® should be used with caution in patients with depression and in patients with seizure disorders. Patients with cardiac disease should be closely monitored. Routine periodic blood chemistry and hematologic tests are recommended during treatment with AVONEX®.

\* Comparative clinical significance has not been established.

\*\* As demonstrated in 3 years of clinical trials.

Δ Rate ratio = 0.56.

+ Kaplan-Meier methodology. AVONEX® n=158, placebo n=143.

◊ AVONEX® n=85, placebo n=87.

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**AVONEX**  
(Interferon beta-1a)  
IM Injection



2004-AVX-038

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As demonstrated in 3 years of clinical trials

# LIPITOR<sup>®</sup>: Hitting targets.



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**NEW**  
Indication

LIPITOR is an HMG-CoA reductase inhibitor (statin). LIPITOR is indicated as an adjunct to lifestyle changes, including diet, for the reduction of elevated total cholesterol, LDL-C, TG and apolipoprotein B in hyperlipidemic and dyslipidemic conditions (including primary hypercholesterolemia, combined [mixed] hyperlipidemia, dysbetalipoproteinemia, hypertriglyceridemia and familial hypercholesterolemia) when response to diet and other non-pharmacological measures alone has been inadequate.

LIPITOR also raises HDL-cholesterol and therefore lowers the LDL-C/HDL-C and Total-C/HDL-C ratios (Fredrickson Type IIa and IIb).

**NEW** LIPITOR is indicated to reduce the risk of myocardial infarction in adult hypertensive patients without clinically evident coronary heart disease, but with at least three additional risk factors for coronary heart disease such as age  $\geq 55$  years, male sex, smoking, type 2 diabetes, left ventricular hypertrophy, other specified abnormalities on ECG, microalbuminuria or proteinuria, ratio of plasma total cholesterol to HDL-cholesterol  $\geq 6$ , or premature family history of coronary heart disease.

Less than 2% of patients discontinued therapy due to adverse experiences. Most common adverse effects were constipation, diarrhea, dyspepsia, flatulence, nausea, headache, pain, myalgia and asthenia.

LIPITOR is contraindicated: During pregnancy and lactation; active liver disease or unexplained persistent elevations of serum transaminases exceeding 3 times the upper limit of normal; hypersensitivity to any component of this medication. Lipid levels should be monitored periodically and, if necessary, the dose of LIPITOR adjusted based on target lipid levels recommended by guidelines.

Caution should be exercised in severely hypercholesterolemic patients who are also renally impaired, elderly, or are concomitantly being administered digoxin or CYP 3A4 inhibitors.

Liver function tests should be performed before the initiation of treatment, and periodically thereafter. Special attention should be paid to patients who develop elevated serum transaminase levels, and in these patients, measurements should be repeated promptly and then performed more frequently.

Clinical  
research  
program

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beyond.

TC/HDL-C  
29-44%  
(type IIa and IIb)<sup>†</sup>

TG  
25-56%  
(type IV)<sup>†</sup>

LDL-C  
39-60%  
(type IIa and IIb)<sup>†</sup>

**EFFICACY** ➤ Power to start with a **FLEXIBLE FIRST DOSE<sup>†</sup>** at 10 mg, 20 mg, 40 mg<sup>†</sup>

<sup>†</sup> When a  $>45\%$  LDL-C reduction is required, patients may be started at 40 mg o.d.

**EXPERIENCE** ➤ More than 76 million patient-years of experience<sup>2,3</sup>

**EVIDENCE** ➤ **ASCOT<sup>††</sup>** demonstrated LIPITOR's efficacy in reducing the risk of myocardial infarction in adult hypertensive patients without clinically evident CHD, but with at least three additional risk factors for CHD<sup>1,4</sup>

LIPITOR has a leading edge clinical research program exploring new areas that may extend beyond lipid control<sup>3</sup>

<sup>†</sup> Based on Pfizer's analysis of IMS Health data.<sup>2</sup>

<sup>††</sup> A patient-year represents the total time of exposure to LIPITOR as defined by the sum of each patient's time on LIPITOR.<sup>4</sup>

<sup>1</sup> ASCOT = Anglo-Scandinavian Cardiac Outcomes Trial.



power you can trust<sup>®</sup>



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<sup>1</sup>U.S. Food and Drug Administration  
Pittsburg, Kansas, USA

Life is never 99% work



10 mg

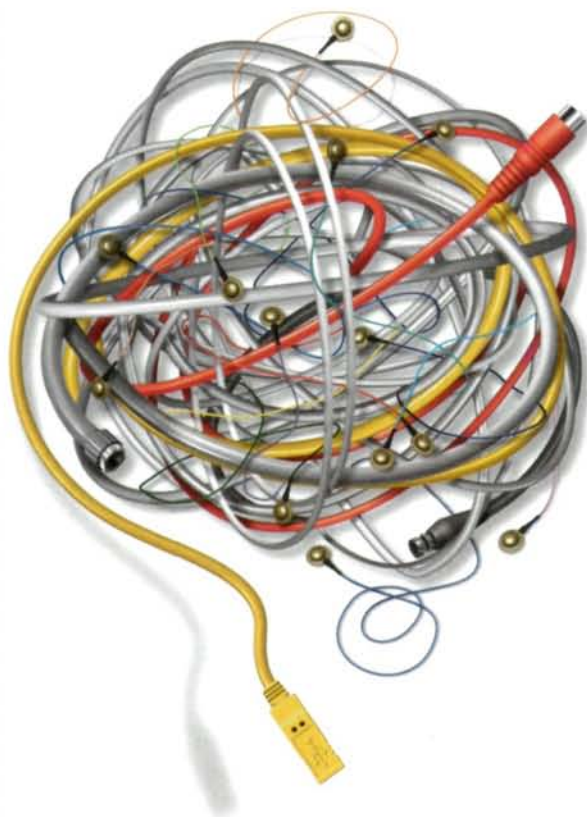
20 mg

40 mg

80 mg

80 mg

## From uncontrolled



Keppra —  
connecting excellent  
profiles in efficacy  
and tolerability

### Effective control of seizures

- Shown to provide up to 4 out of 10 refractory patients with  $\geq 50\%$  reduction in partial onset seizures ( $p < 0.001$ )
- Rapid clinical improvement demonstrated by week 2 during a 14-week evaluation period ( $p < 0.001$ )<sup>11</sup>

Keppra is indicated as adjunctive therapy in the management of patients with epilepsy who are not satisfactorily controlled by conventional therapy.

The most significant CNS adverse events were somnolence (Keppra 15% vs placebo 10%) and asthenia (Keppra 14% vs placebo 10%), behavioural/psychiatric symptoms (nonpsychotic: Keppra 14% vs placebo 6%; psychotic: Keppra 1% vs placebo 0%) and coordination difficulties (Keppra 3% vs placebo 2%). These adverse events were observed in controlled clinical trials with concomitant AEDs.



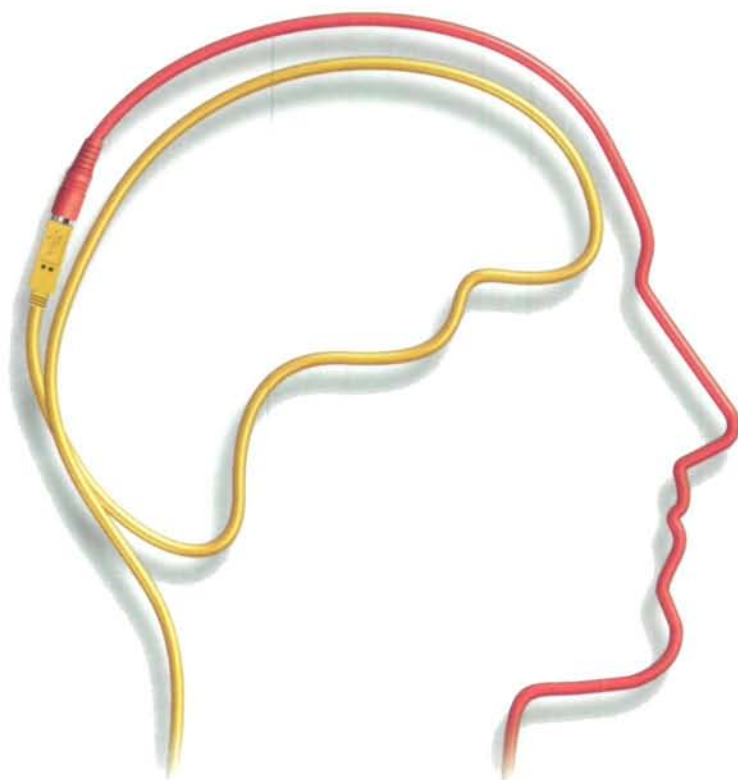
For more information, please refer to the complete Keppra Product Monograph.  
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to control



### Generally well tolerated

- Favourable adverse event profile
- Adverse events not dose dependent<sup>‡</sup>
- Low discontinuation or dosage reduction (Keppra 14.3% vs placebo 11.7%) due to adverse events<sup>‡</sup>

### Efficacy and manageability right from the start

- Starting dose of 1000 mg/day (500 mg bid) shown to be effective and may be adjusted to a maximum of 3000 mg/day if required
- No blood level monitoring required
- No drug/drug interactions<sup>§</sup> with other AEDs, warfarin, digoxin or between Keppra 500 mg bid and a combination oral contraceptive (0.03 mg ethinyl estradiol and 0.15 mg levonorgestrel)<sup>§</sup>

¶ Note: Pharmacokinetic interaction studies with contraceptives have not been conducted covering the full recommended dosage range of Keppra. Physicians should advise their female patients to be alert to any irregular vaginal bleeding or spotting and report any occurrences.

\* Restrictions may exist by province. Please refer to your formulary for details.

† Data from a 38-week multicentre, randomised, add-on, double-blind, placebo-controlled, parallel-group trial. Study consisted of a 4-week titration period followed by a 14-week evaluation period. Patients received either levetiracetam 1000 mg/day (n = 98), 3000 mg/day (n = 101) or placebo (n = 95). Patient weekly seizure frequency was reduced over placebo, at week 2 of the evaluation period, by 24.9% (1.120/1.406) for Keppra 1000 mg/day and 38.6% (0.918/1.406) for Keppra 3000 mg/day. The percentage of patients achieving ≥ 50% seizure reduction from baseline after the 18-week titration and evaluation period was 7.4% for placebo, 37.1% for Keppra 1000 mg/day and 39.6% for Keppra 3000 mg/day.

‡ Based on observations in clinical studies.

§ C<sub>max</sub> of levetiracetam's metabolite (ucb L057) was approximately doubled in presence of probenecid. Renal clearance of ucb L057 decreased by 60% in presence of probenecid.

Pr **Keppra**<sup>®</sup>  
levetiracetam

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## COMING SOON

LYRICA is indicated for the management of neuropathic pain associated with:

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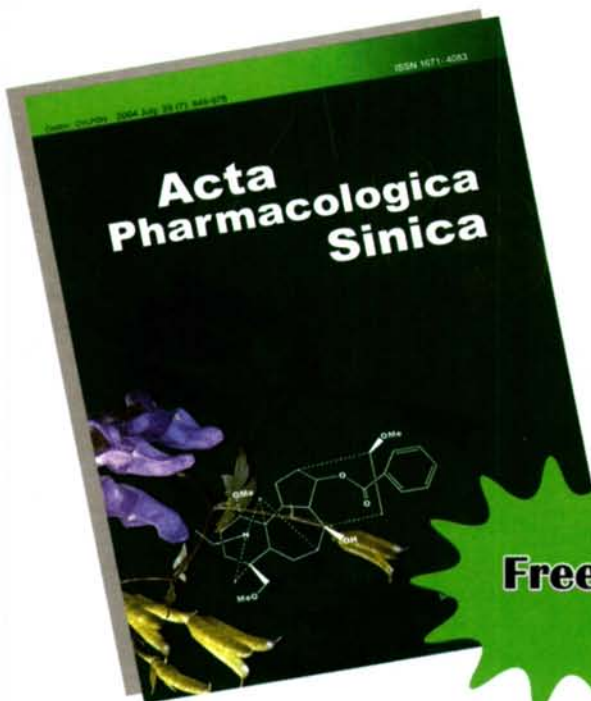


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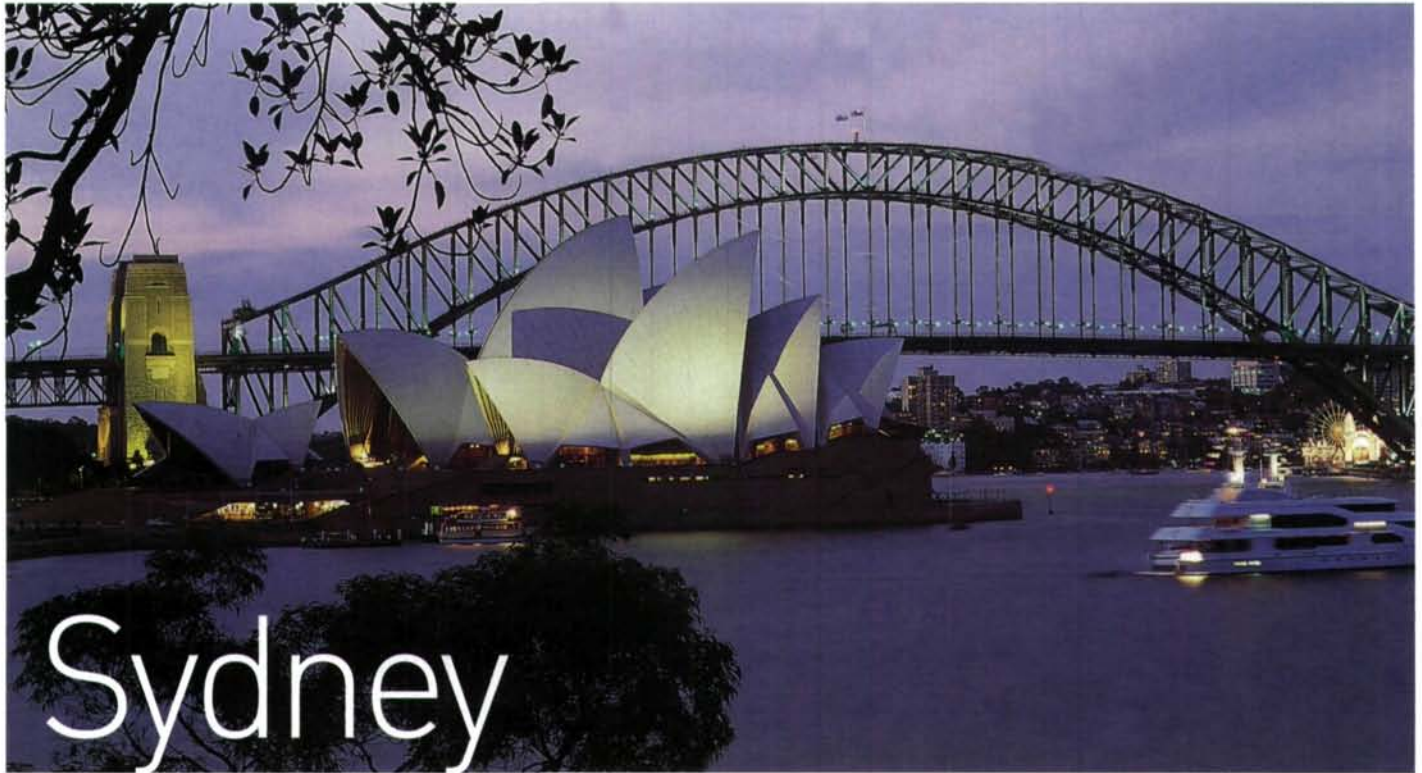
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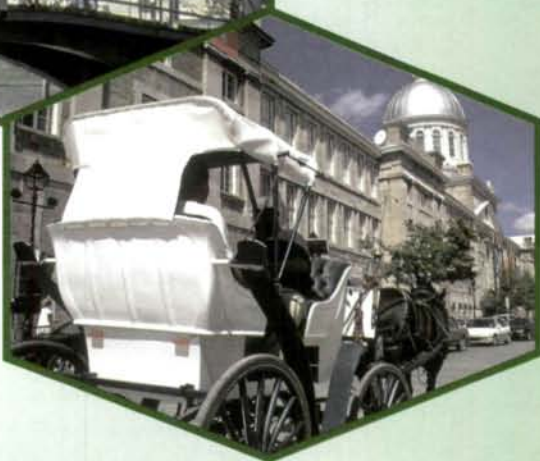
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Les symptômes de  
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**...prennent naissance  
en profondeur**

**Nouveau**  
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PRÉGABALINE



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de brûlure  
Douleur en coup  
de poignard

Douleur fulgurante  
Douleur pulsative  
Sensation de  
chocs électriques

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LYRICA est indiqué pour le traitement de la douleur neuropathique associée à :

- la neuropathie diabétique périphérique
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Veuillez consulter les renseignements thérapeutiques pour obtenir de l'information importante sur les mises en garde, les précautions, les effets indésirables et les critères de sélection des patients.

1. Dworkin RH. An Overview of Neuropathic Pain: Symptoms, Signs, and Several Mechanisms. *The Clinical Journal of Pain* 2002; 18:343-348.



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\*Deux études indépendantes

## Profil d'innocuité établi

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