



Hepatic Concerns with Prexige® (lumiracoxib) August 16, 2007

What has been happening in Canada?

On July 25, 2007 Health Canada approved lumiracoxib for the treatment of signs and symptoms of osteoarthritis in adults.¹ This indication is an expansion of the original indication which was for the treatment of signs and symptoms of osteoarthritis of the knee in adults.

What has been happening in Australia?²

The Therapeutic Goods Administration in Australia has cancelled the registration of lumiracoxib, meaning the drug will be withdrawn from the Australian market. The decision is based on eight reports in Australia of serious hepatic adverse reactions from lumiracoxib.

Isn't this paradoxical?

The most common dose of lumiracoxib that had been prescribed in Australia was 200mg po daily.³ According to one source, the 100mg strength tablet was only approved after the approval and market of the 200mg and 400mg strengths.⁴ In Canada, the indicated dose is 100mg daily and the monograph specifically states doses above this provide no additional benefit and may be associated with greater adverse effects.⁵

Health Canada previously issued a Summary Basis of Decision for lumiracoxib. This document indicates doses of 200mg and 400mg daily have been associated with higher rates of increased liver function enzymes compared with lumiracoxib 100mg and other comparator non-steroidal anti-inflammatory drugs. The rates of elevated ALT at 12 months have been found to be 0.4% (celecoxib 200mg daily), 0.9% (lumiracoxib 100mg daily), 2.6% (lumiracoxib 200mg daily) and 2.2% (lumiracoxib 400mg daily).⁶

What are the recommendations?

Health Canada is currently reviewing lumiracoxib in light of the Australian experience.⁷ As per the Canadian Prexige® product monograph, severe hepatic impairment or active liver disease are contraindications.⁵ Patients are encouraged to use the smallest dose for the shortest duration possible and not to make changes to their treatment without physician consultation.⁷

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