Canadian Agency for Drugs and Technologies in Health | Agence canadienne des médicaments et des technologies de la santé

CEDAC FINAL RECOMMENDATION and REASONS for RECOMMENDATION

TRAMADOL HYDROCHLORIDE (Tridural™ – Paladin Labs Inc.)

Description:
Tridural™ is an extended release formulation of tramadol hydrochloride, a synthetic opioid analgesic. It is approved for the management of pain of moderate severity in adults who require treatment for several days or more.

Dosage Forms:
100, 200 and 300 mg tablets. The recommended initial dose is 100 mg daily and the maximum recommended daily dose is 300 mg.

Recommendation:
The Canadian Expert Drug Advisory Committee (CEDAC) recommends that Tridural™ not be listed.

Reasons for the Recommendation:
1. There is insufficient evidence that Tridural™ provides a therapeutic advantage over less expensive analgesics.

Summary of Committee Considerations:
The Committee considered a systematic review of double blind, randomized controlled trials (RCTs) of tramadol hydrochloride extended release tablets with other oral opiates available in Canada in the treatment of pain of at least several days duration in adults. No trials of Tridural™ met the inclusion criteria for the systematic review.

The Committee also reviewed the results of published systematic reviews of tramadol in chronic pain conditions which have reported that tramadol is more effective than placebo. These systematic reviews did not assess extended release formulations of tramadol separately.

Tridural™ costs $1.15 to $3.05 for doses ranging from 100 mg to 300 mg daily. Given the lack of comparative trials, it is difficult to establish the dose equivalency for Tridural™ relative to other analgesics. The Committee noted that there are short-acting analgesic combination products (e.g. codeine 30 mg/acetaminophen 300 mg, oxycodone 5 mg/acetaminophen 325 mg) and long acting formulations of morphine and non-steroidal anti-inflammatory drugs (NSAIDs) that are less costly than Tridural™.

Background:
CEDAC provides formulary listing recommendations to publicly funded drug plans. Recommendations are based on an evidence-based review of the medication's effectiveness and safety and an assessment of

its cost-effectiveness in comparison to other available treatment options. For example, if a new medication is more expensive than other treatments, the Committee considers whether any advantages of the new medication justify the higher price. If the recommendation is not to list a drug, the Committee has concerns regarding the balance between benefit and harm for the medication, and/or concerns about whether the medication provides good value for public drug plans.