

# Committee to Evaluate Drugs (CED)

## Recommendations and Reasons

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### Zolpidem sublingual tablet

**Product:** zolpidem (Sublinox®)

**Class of Drugs:** sedative/hypnotic

**Reason for Use:** insomnia

**Manufacturer:** Meda Valeant Pharma Canada Inc.

**Date of Review:** October 2013 and March 2014

### CED Recommendation

The CED recommended that sublingual zolpidem (Sublinox®) not be funded. There is insufficient evidence to determine whether sublingual zolpidem provides a clinical advantage compared with less costly alternative drug treatments. Also, sublingual zolpidem has not been shown to fill any clinical care gap.

### Executive Officer Decision\*

Based on the CED's recommendation, the Executive Officer decided not to fund sublingual zolpidem (Sublinox®).

### Funding Status\*

Not funded through the Ontario Public Drug Programs.

\* This information is current as of the posting date of the document. For the most up-to-date information on Executive Officer decision and funding status, see: [www.health.gov.on.ca/en/pro/programs/drugs/status\\_single\\_source\\_subm.aspx](http://www.health.gov.on.ca/en/pro/programs/drugs/status_single_source_subm.aspx).

## Highlights of Recommendation:

- Zolpidem is a sedative/hypnotic used for the short-term treatment of insomnia. There are various formulations of zolpidem, including a regular oral tablet, a long-acting oral tablet, and a sublingual tablet. In Canada, zolpidem is available only in the sublingual form.
- The CED reviewed the funding of sublingual zolpidem in October 2013 and March 2014. During these reviews, the Committee considered:
  - Findings from the Common Drug Review (CDR) and the recommendation of the Canadian Drug Expert Committee (CDEC);
  - Information in the manufacturer's submissions;
  - Submissions from two patient groups.
- The effectiveness and safety of sublingual zolpidem compared with alternative drug treatments are unknown. There are no randomized controlled trials comparing sublingual zolpidem to placebo or to other drug treatments such as benzodiazepines or zopiclone.
- The Committee reviewed a study comparing sublingual zolpidem to oral zolpidem and another study comparing oral zolpidem to oral zopiclone. The findings from these two studies could not be extrapolated to make conclusions about the comparative effectiveness and safety between sublingual zolpidem and alternatives drug treatments because sublingual zolpidem and oral zolpidem have not been proven to be equivalent and the two studies did not use similar efficacy and safety outcomes to enable comparison.
- The Committee acknowledged that benzodiazepines are associated with side effects such as the risk of falls, patient confusion and dependence but there is no clinical trial evidence to show that sublingual zolpidem is better tolerated and is associated with fewer side effects.
- At the submitted price, sublingual zolpidem costs \$1.32 per day. This is more expensive than all the other insomnia treatments currently funded through the Ontario Public Drug Programs.
- The CED considered two patient group submissions. The submissions outlined the impact of insomnia on patients' quality of life. Treatment wishes include effective therapies with little or no side effects.
- Overall, the CED noted that there is a lack of direct comparison trials to determine whether sublingual zolpidem provides a clinical advantage or disadvantage in comparison with other hypnotics available in Canada for the treatment of acute, short-term insomnia. Furthermore, sublingual zolpidem has not been demonstrated to fill any clinical care gap.

## Background:

Insomnia is trouble falling asleep, staying asleep, waking up too early, or feeling unrested after sleep. Episodes of insomnia may come and go (acute, short-term insomnia) or be long-lasting (chronic).

Current guidelines recommend that for treatment to be considered, the sleep problem must be of sufficient severity to produce noticeable impairment in daytime functioning or mood affecting

home, work or social activities. Cognitive behavioural therapy aimed to improve sleep habits and behaviors is the recommended first-line treatment for chronic insomnia but of unlikely benefit for acute, short-term insomnia due to the relatively long time for benefit (6-8 weeks).

Benzodiazepine receptor agonists are recommended first-line drug treatments for acute, short-term insomnia. Zopiclone and sublingual zolpidem are non-benzodiazepine hypnotics.

### **Detailed Discussions:**

No additional relevant details.

#### **Committee to Evaluate Drugs (CED)**

The Committee to Evaluate Drugs (CED) is comprised of practicing physicians, pharmacists, health economists, and patient representatives. In conducting its review, the CED considers data contained in the drug manufacturer's submission, input provided by patient groups, findings from the national Common Drug Review and the pan-Canadian Oncology Drug Review, and other scientific information as necessary.

For more information, please contact:

Ministry of Health and Long-Term Care

Ontario Public Drug Programs

Hepburn Block, 9th Floor

80 Grosvenor Street, Queen's Park

Toronto, Ontario M7A 1R3

[www.health.gov.on.ca/en/pro/programs/drugs/](http://www.health.gov.on.ca/en/pro/programs/drugs/)