

PUBLIC COMMUNICATION
Health Canada Endorsed Important Safety Information on
SUBLINOX™ (zolpidem tartrate)



2011-12-05

Subject: Association of Sublinox™ (zolpidem tartrate) with abnormal sleep behaviours

MEDA VALEANT PHARMA CANADA INC., in consultation with Health Canada, would like to bring to your attention important safety information about Sublinox™ (zolpidem) and abnormal sleep behaviours called complex sleep behaviours.

Sublinox™ is a medication to help people sleep that was recently authorised for use in adults in Canada. In other countries, it has been associated with side effects called complex sleep behaviours, where people get out of bed while not fully awake and do activities they do not know they are doing. Activities can include driving a car, leaving the house, eating food, making phone calls. The next morning, people do not remember doing those activities. Complex sleep behaviours can be dangerous because of the risk of accident.

It is the first time that Sublinox™ or zolpidem has been marketed in Canada. Canadians should know that:

- Sublinox™ cannot be taken by patients who have a personal or family history of sleepwalking.
- Sublinox™ must not be taken with alcohol.
- Complex sleep behaviours have occurred in patients who have taken certain drugs in combination with zolpidem.
- Sublinox™ should be immediately stopped in patients who experience abnormal sleep behaviours.

People with a history of sleep-walking, either in the family or personal, people who drink alcohol with Sublinox™ or take certain drugs at the same time as Sublinox™, or people who take Sublinox™ at higher doses than those recommended may be more at risk of complex sleep behaviours. Some people have had complex sleep behaviours even when they took the recommended dose of Sublinox™.

Patients, their families, and their caregivers should know about the benefits and risks of Sublinox™ and how to use it properly. People should speak with their doctors about their difficulty sleeping. If the difficulty sleeping lasts longer than 7 to 10 days despite treatment, it may mean that something else is going on. Patients should also tell their doctor if they are taking other drugs including over the counter medicines and herbal products.

Sublinox™ tablets must be taken right before going to bed and only when people are

able to stay in bed a full night (7-8 hours) before being active again. Sublinox™ tablets should not be taken in the middle of the night or at any time other than bed time.

Patients should not take more than the maximum dose of 10 mg for adults. The 10 mg tablet cannot be split in half. So there is no smaller dose than 10 mg. Sublinox is not recommended for the elderly or for children below the age of 18.

If people have side effects with Sublinox™, they should speak with their doctor as soon as possible. However, in the case of complex sleep behaviours, they should speak with a healthcare professional immediately.

Managing marketed health product-related adverse reactions depends on health care professionals and consumers reporting them. Reporting rates determined on the basis of spontaneously reported post-marketing adverse reactions are generally presumed to underestimate the risks associated with health product treatments. Any case of serious complex sleep behaviours or other serious or unexpected adverse reactions in patients receiving Sublinox™ should be reported to Valeant Canada or Health Canada.

Valeant Canada
4787 rue Levy, Montreal
Quebec, H4R 2P9
Tel. 1-800-361-4261

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to: Canada Vigilance Program
Health Canada
Postal Locator 0701E
Ottawa, Ontario K1A 0K9

The Reporting Forms, postage paid labels, and Guidelines can be found on the MedEffect™ Canada Web site in the [Adverse Reaction Reporting](http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php) section (<http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php>). The Reporting Form is also in the *Canadian Compendium of Pharmaceuticals and Specialties*.

For other health product inquiries related to this communication, please contact Health Canada at:

Lead Directorate: Marketed Health Product Directorate
E-mail: mhpd_dpssc@hc-sc.gc.ca
Telephone: 613-954-6522
Fax: 613-952-7738

We hope that the information provided will help you in making the right decision with your doctor.

If you would like more information you can call the medical information line at 1-800-361-4261.

Sincerely,
original signed by
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Senior Director,
Medical and Regulatory Affairs
Valeant Canada