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

Meda Valeant Pharma Canada Inc.

2011-11-30

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

Dear Healthcare Professional,

MEDA VALEANT PHARMA CANADA INC., in consultation with Health Canada, would like to bring to your attention important safety information concerning the association of Sublinox™ with complex sleep behaviours.

Sublinox™ is a sublingual formulation of zolpidem that was recently authorised for use in adults in Canada. Sublinox™ (zolpidem tartrate) is indicated for the short-term treatment and symptomatic relief of insomnia characterized by difficulty in falling asleep, frequent nocturnal awakenings and/or early morning awakenings. On the international market, zolpidem has been reported in association with cases of complex sleep behaviours, where people rise from bed while not fully awake and engage unknowingly in activities which they do not remember doing the following morning, such as driving a car, leaving the house, eating food and making phone calls. Complex sleep behaviours are rare but potentially dangerous.

Sublinox™ is the first formulation of zolpidem marketed in Canada. Prescribers should consider the following to ensure appropriate use of this medication:

- Sublinox™ is contraindicated in patients with a personal or family history of somnambulism.
- Sublinox™ is not to be taken with alcohol.
- Complex sleep behaviours have been reported in patients using CNS-active drugs in combination with zolpidem.
- Treatment with Sublinox™ should be immediately discontinued in patients who report complex sleep behaviours.

Complex sleep behaviours may be more likely to occur in patients with a personal or family history of sleep-walking, or when Sublinox™ is taken with alcohol or CNS-active drugs or at doses higher than recommended. Some cases of complex sleep behaviours have occurred when zolpidem was taken as directed.

Patients, their families, and caregivers should be counselled on the benefits, risks and appropriate use of Sublinox™. The failure of insomnia to remit after 7 to 10 days of treatment may indicate the presence of a primary psychiatric and/or medical illness that should be evaluated. Patient selection is therefore important before prescribing this medication.

Sublinox™ tablets must be taken no earlier than bedtime and only if patients are expected to remain in bed for a full night's sleep prior to resuming activity. Sublinox™ tablets should not be taken in the middle of the night or at any other time than bed time.

Patients should be advised not to exceed the maximum dose of 10 mg for adults. The 10 mg tablet of Sublinox™ cannot be split in half and there is no lower strength available for use in the elderly. Zolpidem is not recommended for use in the pediatric population below the age of 18 years.

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 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 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_dpsc@hc-sc.gc.ca
Telephone: 613-954-6522
Fax: 613-952-7738

Should you have any questions regarding the use of Sublinox™, please contact Valeant Canada LP at the address or telephone number listed above. We look forward to answering any questions you may have following this communication.

Sincerely,
original signed by

Dr. Mirela Baranci
Senior Director,
Medical and Regulatory Affairs
Valeant Canada
References: Sublinox™ approved product monograph July 15th, 2011