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

Your attention is drawn to that the Health Canada informs the 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.

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. 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. For details, please refer to the following link:


In Hong Kong, there are 14 registered pharmaceutical products containing zolpidem and none of them is in the sublingual formulation. In view of the Health Canada's recommendation, the issue will be discussed in the meeting of the Registration Committee of the Pharmacy and Poisons Board.

Please remind your members to report any adverse events caused by the drugs to the Adverse Drug Reaction Monitoring Unit of Department of Health (tel. no.: 2319 2920, fax: 2147 0457 or email: adr@dh.gov.hk). For details, please refer to the website: http://www.drugoffice.gov.hk at Drug Office under "Reporting an Adverse Drug Reaction".

Yours sincerely,

(Ms Pamela Li)
for AD(D)

We are committed to providing quality client-oriented service

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