

**Health Canada Endorsed Important Safety Information on
IMOVANE® (zopiclone)**



SANOFI

November 19, 2014

Dear Healthcare Professional,

Subject: New dosage recommendations for IMOVANE®(zopiclone) to minimize the risk of next-day impairment

Sanofi-aventis Canada Inc., in collaboration with Health Canada, is informing you about important new dosing information which has been added to the Product Monograph for IMOVANE® (zopiclone) related to the risk of next-day impairment.

Like other sedative/hypnotic drugs, IMOVANE® has Central Nervous System (CNS)-depressant effects and can cause next-day impairment of activities requiring alertness, including driving a car. The impairment can be present despite the patient feeling fully awake. Even if IMOVANE is taken as instructed, some patients may still have zopiclone blood levels high enough to produce impairment.

- The recommended starting dose has been reduced to 3.75 mg (one-half of the 7.5 mg tablet). IMOVANE should be taken once per night at bedtime. The lowest effective dose for each patient should be used. The prescribed dose should not exceed 5 mg in elderly patients, in patients with hepatic or renal impairment or those currently treated with potent CYP3A4 inhibitors. Dose adjustment may be required with concomitant use with other CNS-depressant drugs.
- ~~Patients should be instructed to wait for at least 12 hours after dosing before driving or engaging in other activities requiring full mental alertness, especially for elderly patients and for patients who take the 7.5 mg dose.~~

Patients should be advised on the risk of next-day impairment and that this risk is increased if dosing instructions are not carefully followed. Inform patients that impairment can be present despite feeling fully awake.

All patients should be advised not to drive a car or engage in hazardous activities requiring full alertness until

they know how their prescribed dose affects them the next day.

The changes in dosage recommendations are supported by data available for zopiclone 7.5 mg showing increased risk of driving impairment when evaluated up to 11 hours after an evening dose. The risks are higher in the elderly and other special populations with increased residual blood levels (hepatic and renal impairment). For some patients taking lower doses, zopiclone blood levels in the morning may be high enough to produce impairment. Therefore, all patients who use IMOVANE should be cautioned about the risks of next-day impairment.

Treatment with IMOVANE should usually not exceed 7-10 consecutive days. Use for more than 2-3 consecutive weeks requires complete re-evaluation of the patient.

The updated Product Monograph for IMOVANE® is posted on Health Canada's and Sanofi-aventis Canada Inc. websites.

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 next-day impairment or other serious or unexpected adverse reactions in patients receiving IMOVANE® should be reported to sanofi-aventis Canada Inc. or Health Canada.

Sanofi-aventis Canada Inc.
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Phone: 1-800-265-7927

To correct your mailing address or fax number, contact sanofi-aventis Canada Inc.

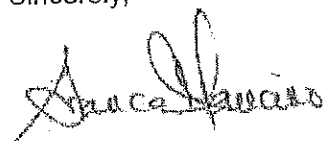
You can report any suspected adverse reactions associated with the use of health products to Health Canada by:

- Calling toll-free at 1-866-234-2345; or
- Visiting MedEffect Canada's Web page on Adverse Reaction Reporting (<http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php>) for information on how to report online, by mail or by fax.

For other health product inquiries related to this communication, contact Health Canada at:
Marketed Health Products Directorate
E-mail: mhpd_dpssc.public@hc-sc.gc.ca
Telephone: (613) 954-6522
Fax: (613) 952-7738

Should you have any questions or require additional information regarding the use of IMOVANE®, please contact the Medical Information Department at Sanofi-aventis Canada Inc. at 1-800-265-7927, Monday to Friday, between 7:30 a.m. and 7:30 p.m. (Eastern Standard Time).

Sincerely,



Franca Mancino, M.Sc.
Vice President, Medical and Regulatory Affairs

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