Important Information for Healthcare Professionals:
Change of Pack Size

30th October 2020

Stilnoct (zolpidem tartrate) 5 mg film-coated tablets (PA: 540/160/001)
Stilnoct (zolpidem tartrate) 10 mg film-coated tablets (PA: 540/160/002)

Dear Healthcare professional,

Sanofi-aventis Ireland Ltd. T/A SANOFI, the Marketing Authorisation Holder of zolpidem-containing medicines marketed in Ireland under the Stilnoct brand, would like to inform you of an upcoming change of pack size from the currently available 28 pack size to a pack size of 14, which is intended to reduce the risk of abuse and dependence related to the duration of treatment.

Zolpidem is a benzodiazepine derivative used as a hypnotic agent, indicated for the treatment of insomnia. The usual dose is 10 mg, with a lower starting dose of 5 mg recommended for elderly and patients with hepatic impairment. The duration of treatment should be as short as possible and should generally not exceed 4 weeks.

Restriction of the currently available 28 pack size to a pack size of 14 for Stilnoct (zolpidem tartrate) 5 mg film-coated tablets (PA: 540/160/001) and Stilnoct (zolpidem tartrate) 10 mg film-coated tablets (PA: 540/160/002):

Distribution of the new 14 pack size will commence upon depletion of the 28 packs at primary wholesale level.

The first sales of the 14 pack size are therefore expected from:
November 2020 - Stilnoct (zolpidem tartrate) 10 mg film-coated tablets (PA: 540/160/002)
January 2021 - Stilnoct (zolpidem tartrate) 5 mg film-coated tablets (PA: 540/160/001)

This communication has been agreed with the Health Products Regulatory Authority (HPRA).

Call for reporting
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.

Healthcare professionals are asked to report any suspected adverse reactions via: HPRA Pharmacovigilance website: www.hpra.ie

Suspected adverse reactions should also be reported to Sanofi: Tel: 01 403 5600.
Email: IEpharmacovigilance@sanofi.com

Further Information
If you require any further information, please contact Sanofi Medical Information Department: Telephone: 01 403 5600; Email: IEmedinfo@sanofi.com

Yours Sincerely,

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Dr Nabeel Shafaat
EP Therapeutic Area Medical Head
Sanofi UK and Ireland