04th October 2022

IMPORTANT INFORMATION FOR HEALTHCARE PROFESSIONALS
CAUTION IN USE NOTIFICATION

Provigil® 200 mg Tablets, PA 749/198/2
Batch no. M5047B, Expiry 01 2025

Dear Pharmacist,

In agreement with the Health Products Regulatory Authority, we wish to inform you of the following:

There is a discrepancy in the the EAN (European Article Number) code on the outer carton of Provigil® 200 mg Tablets from batch no. M5047B. The EAN code is erroneously printed as 5035546000035 which is the EAN code for Provigil® 100 mg Tablets. The correct EAN code for Provigil® 200 mg Tablets is 5035546000059.

If your pharmacy uses a robotic dispensing system, please ensure that controls are put in place to prevent a dispensing error as a result of the erroneous EAN code.

All other text on the outer carton is correct, including the Global Trade Item Number (GTIN) code and data embedded in the 2D matrix.

Please ensure all relevant staff are made aware of the content of this letter.

CALL FOR REPORTING
Healthcare professionals are asked to report any suspected adverse events via HPRA Pharmacovigilance, www.hpra.ie.
Adverse events should also be reported to Teva Pharmaceuticals Ireland by telephone to +44 207 540 7117 or via safety.ireland@teva.ie or medinfo@tevauk.com.

If you have any questions, please contact:

Kevin Woods, Senior Manager Commercial Quality
Phone: 087 2392797
E-mail: kevin.woods@teva.ie

Yours faithfully,

DocuSigned by:
Kevin Woods
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Teva Pharmaceuticals Ireland

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