



6th May 2026
Takeda Pharmaceuticals International AG Ireland Branch
Block 2 Miesian Plaza
50 – 58 Baggot Street Lower
Dublin 2
D02 HW68
Ireland

Important Information for Healthcare Professionals
Tyvense - Introduction of a New Contraindication - Pheochromocytoma

Lisdexamfetamine dimesylate

PA 23211/005/001 - Tyvense 20mg Capsules, hard
PA 23211/005/002 - Tyvense 30mg Capsules, hard
PA 23211/005/003 - Tyvense 40mg Capsules, hard
PA 23211/005/004 - Tyvense 50mg Capsules, hard
PA 23211/005/005 - Tyvense 60mg Capsules, hard
PA 23211/005/006 - Tyvense 70mg Capsules, hard

Dear Healthcare Professional,

Takeda Pharmaceuticals International AG Ireland Branch would like to inform you of the following:

An update was made to add pheochromocytoma as a contraindication within section 4.3 of the Summary of Product Characteristics (SmPC) and section 2 of the Patient Information Leaflet. This change was approved by the Health Products Regulatory Authority (HPRA), on 17th December 2025. There is no further impact on the Irish market resulting from this action.

Please ensure that all relevant staff are made aware of the content of this letter and if relevant, make sure that all staff members are informed.

The communication of this information has been agreed with the HPRA.

Reporting of suspected adverse reactions

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 to HPRA Pharmacovigilance using the report form on the HPRA website, www.hpra.ie.

Adverse events should also be reported to Takeda at 1800 937 970 (freephone from Ireland) or +44 (0) 3333 000 181 or via email on AE.GBR-IRL@takeda.com.

If you have any questions, please contact the Takeda Medical Information Department at medinfoEMEA@takeda.com.

Yours faithfully,

Dr Kenneth Hugh
Ireland Medical Head