



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

16 September 2021
EMA/619644/2021
Pharmacovigilance Risk Assessment Committee (PRAC)

List of nationally authorised medicinal products

Active substance(s): lisdexamfetamine dimesylate

Procedure no.: EMEA/H/N/PSR/S/0033

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An agency of the European Union



Product Name (in authorisation country)	MRP/DCP Authorisation number	Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised	Legal Basis
UK: Elvanse Adult DK: Aduvanz SE: Elvanse Vuxen AT: Elvanse Erwachsene FI: Elvanse Adult NO: Aduvanz IS: Elvanse Adult ES: Elvanse Adultos DE: Elvanse Adult	SE/H/1825/001-003	30mg, 50mg, 70mg: UK: 08081/0059-0061 DK: 53795 – 7 SE: 50796 – 8 AT: 137800, 137799, 137801 FI: 34923 – 5 NO: 17-11550 - 2 IS: IS/1/17/041/01-03 ES: 82336 – 8 DE: 2203231.00.00 – 2203232.00.00- 2203233.00.00	Shire Pharmaceuticals Ireland Limited	UK, DK, SE, AT, FI, NO, IS, ES, DE	8.3