



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

17 March 2016
EMA/249896/2016
Procedure Management and Committees Support

List of nationally authorised medicinal products

Active substance: lisdexamfetamine

Procedure no.: PSUSA/00010289/201508



Product full name	MRP/DCP or CP Authorisation number	National Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised
Elvanse Adult 30 mg capsules, hard.	UK/H/5567/001	PL 08081/0059	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	UK
Elvanse Adult 50mg capsules, hard	UK/H/5567/002	PL 08081/0060	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	UK
Elvanse Adult 70mg capsules, hard	UK/H/5567/003	PL 08081/0061	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	UK
Aduvanz, hårde kapsler	UK/H/5567/001	53795	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	DK
Aduvanz, hårde kapsler	UK/H/5567/002	53796	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	DK
Aduvanz, hårde kapsler	UK/H/5567/003	53797	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	DK

Product full name	MRP/DCP or CP Authorisation number	National Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised
Elvanse Vuxen 30 mg kapslar, hårda.	UK/H/5567/001	50796	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	SE
Elvanse Vuxen 50 mg kapslar, hårda.	UK/H/5567/002	50797	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	SE
Elvanse Vuxen 70 mg kapslar, hårda.	UK/H/5567/003	50798	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	SE
Elvanse 20 mg kapsler, harde	UK/H/3326/004	14-10265	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	NO
Elvanse 40 mg kapsler, harde	UK/H/3326/005	14-10266	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	NO
Elvanse 60 mg kapsler, harde	UK/H/3326/006	14-10267	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	NO

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Elvanse 60 mg kapsler, hårde	UK/H/3326/006	54626	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	DK
Elvanse 20 mg kapsler, hårde	UK/H/3326/004	54624	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	DK
Elvanse 40 mg kapsler, hårde	UK/H/3326/005	54625	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	DK
Elvanse 20 mg Hartkapseln	UK/H/3326/004	93471.00.00	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	DE
Elvanse 40 mg Hartkapseln	UK/H/3326/005	93472.00.00	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	DE
Elvanse 60 mg Hartkapseln	UK/H/3326/006	93473.00.00	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	DE

Product full name	MRP/DCP or CP Authorisation number	National Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised
Tyvense 40 mg capsules, hard	UK/H/3326/005	PA 0689/006/005	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	IE
Tyvense 20 mg capsules, hard	UK/H/3326/004	PA 0689/006/004	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	IE
Tyvense 60 mg capsules, hard	UK/H/3326/006	PA 0689/006/006	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	IE
Elvanse 30 mg capsules, hard	UK/H/3326/001	PL 08081/0050	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	UK
Elvanse 50 mg capsules, hard	UK/H/3326/002	PL 08081/0051	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	UK
Tyvense 30 mg capsules, hard	UK/H/3326/001	PA 689/6/1	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	IE

Product full name	MRP/DCP or CP Authorisation number	National Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised
Tyvense 50 mg capsules, hard	UK/H/3326/002	PA 689/6/2	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	IE
Tyvense 70 mg capsules, hard	UK/H/3326/003	PA 689/6/3	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	IE
Elvanse 70 mg capsules, hard	UK/H/3326/003	PL 08081/0052	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	UK
Elvanse, hårde kapsler	UK/H/3326/001	49980	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	DK
Elvanse, hårde kapsler	UK/H/3326/002	49981	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	DK
Elvanse, hårde kapsler	UK/H/3326/003	49982	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	DK

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Elvanse 30 mg kapsler, harde	UK/H/3326/001	11-8762	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	NO
Elvanse 50 mg kapsler, harde	UK/H/3326/002	11-8763	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	NO
Elvanse 70 mg kapsler, harde	UK/H/3326/003	11-8764	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	NO
Elvanse 30 mg kapselit, kovat	UK/H/3326/001	30382	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	FI
Elvanse 50 mg kapselit, kovat	UK/H/3326/002	30383	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	FI
Elvanse 70 mg kapselit, kovat	UK/H/3326/003	30384	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	FI

Product full name	MRP/DCP or CP Authorisation number	National Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised
Elvanse 30 mg cápsulas duras	UK/H/3326/001	77642	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	ES
Elvanse 50 mg cápsulas duras	UK/H/3326/002	77643	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	ES
Elvanse 70 mg cápsulas duras	UK/H/3326/003	77644	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	ES
Elvanse 30 mg kapslar, hårda	UK/H/3326/001	47382	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	SE
Elvanse 50 mg kapslar, hårda	UK/H/3326/002	47383	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	SE
Elvanse 70 mg kapslar, hårda	UK/H/3326/003	47384	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	SE

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Elvanse		14/04/2833	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	FI
Elvanse		15/04/2833	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	FI
Elvanse		16/04/2833	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	FI
Elvanse		86155.00.00	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	DE
Elvanse		86156.00.00	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	DE
Elvanse		86157.00.00	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	DE

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Elvanse 70 mg capsules, hard		PL 08081/0062	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	UK
Elvanse 70 mg capsules, hard		PL 08081/0063	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	UK
Elvanse 70 mg capsules, hard		PL 08081/0064	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	UK
Elvanse 20 mg kapslar, hårda	UK/H/3326/003	51596	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	SE
Elvanse 40 mg kapslar, hårda	UK/H/3326/005	51597	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	SE
Elvanse 60 mg kapslar, hårda	UK/H/3326/006	51598	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	SE

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Elvanse 20 mg capsules, hard	UK/H/3326/004	PL 08081/0062	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	UK
Elvanse 40 mg capsules, hard	UK/H/3326/005	PL 08081/0063	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	UK
Elvanse 60 mg capsules, hard	UK/H/3326/006	PL 08081/0064	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	UK