



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

4 October 2018  
EMA/710683/2018  
Human Medicines Evaluation Division

## List of nationally authorised medicinal products

Active substance: lisdexamfetamine

Procedure no.: PSUSA/00010289/201802

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An agency of the European Union



<b>Product Name (in authorisation country)</b>	<b>MRP/DCP Authorisation number</b>	<b>National Authorisation Number</b>	<b>MAH of product in the member state</b>	<b>Member State where product is authorised</b>
Aduvanz, hårde kapsler	UK/H/5567/001	53795	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	DK
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/5567/002	53796	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	DK
Aduvanz, hårde kapsler	UK/H/5567/003	53797	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	DK
Aduvanz, hårde kapsler	UK/H/5567/003	53797	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	DK
Elvanse 20 mg capsules, hard	UK/H/3326/004	PL 08081/0062	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	UK
Elvanse 20 mg capsules, hard	UK/H/3326/004	PL 08081/0062	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	UK
Elvanse 20 mg Hartkapseln	UK/H/3326/004	93471.00.00	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	DE
Elvanse 20 mg Hartkapseln	UK/H/3326/004	93471.00.00	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	DE
Elvanse 20 mg kapselit, kovat	UK/H/3326/004	32537	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	FI
Elvanse 20 mg kapselit, kovat	UK/H/3326/004	32537	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	FI
Elvanse 20 mg kapslar, hårda	UK/H/3326/004	32537	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	FI
Elvanse 20 mg kapslar, hårda	UK/H/3326/004	32537	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	FI
Elvanse 20 mg kapslar, hårda	UK/H/3326/004	51596	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	SE
Elvanse 20 mg kapslar, hårda	UK/H/3326/004	51596	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	SE
Elvanse 20 mg kapsler, harde	UK/H/3326/004	14-10265	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	NO
Elvanse 20 mg kapsler, harde	UK/H/3326/004	14-10265	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	NO

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Elvanse 20 mg kapsler, hårde	UK/H/3326/004	54624	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	DK
Elvanse 20 mg kapsler, hårde	UK/H/3326/004	54624	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	DK
Elvanse 30 mg cápsulas	UK/H/3326/001	5674726	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	PT
Elvanse 30 mg cápsulas	UK/H/3326/001	5674734	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	PT
Elvanse 30 mg cápsulas duras	UK/H/3326/001	77642	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	ES
Elvanse 30 mg cápsulas duras	UK/H/3326/001	77642	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	ES
Elvanse 30 mg capsules, hard	UK/H/3326/001	PL 08081/0050	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	UK
Elvanse 30 mg capsules, hard	UK/H/3326/001	PL 08081/0050	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	UK
Elvanse 30 mg Hartkapseln	UK/H/3326/001	136851	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	AT
Elvanse 30 mg Hartkapseln	UK/H/3326/001	136851	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	AT
Elvanse 30 mg Hartkapseln	UK/H/3326/001	86155.00.00	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	DE
Elvanse 30 mg Hartkapseln	UK/H/3326/001	86155.00.00	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	DE
Elvanse 30 mg kapselit, kovat	UK/H/3326/001	30382	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	FI
Elvanse 30 mg kapselit, kovat	UK/H/3326/001	30382	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	FI
Elvanse 30 mg kapslar, hårda	UK/H/3326/001	30382	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	FI
Elvanse 30 mg kapslar, hårda	UK/H/3326/001	30382	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	FI
Elvanse 30 mg kapslar, hårda	UK/H/3326/001	47382	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	SE

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Elvanse 30 mg kapslar, hårda	UK/H/3326/001	47382	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	SE
Elvanse 30 mg kapsler, harde	UK/H/3326/001	11-8762	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	NO
Elvanse 30 mg kapsler, harde	UK/H/3326/001	11-8762	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	NO
Elvanse 30 mg kapsler, hårde	UK/H/3326/001	49980	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	DK
Elvanse 30 mg kapsler, hårde	UK/H/3326/001	49980	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	DK
Elvanse 30 mg tvrdé tobolky	UK/H/3326/001	06/082/16-C	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	CZ
Elvanse 30 mg tvrdé tobolky	UK/H/3326/001	06/082/16-C	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	CZ
Elvanse 40 mg capsules, hard	UK/H/3326/005	PL 08081/0063	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	UK
Elvanse 40 mg capsules, hard	UK/H/3326/005	PL 08081/0063	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	UK
Elvanse 40 mg Hartkapseln	UK/H/3326/005	93472.00.00	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	DE
Elvanse 40 mg Hartkapseln	UK/H/3326/005	93472.00.00	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	DE
Elvanse 40 mg kapselit kovat	UK/H/3326/005	32538	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	FI
Elvanse 40 mg kapselit kovat	UK/H/3326/005	32538	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	FI
Elvanse 40 mg kapslar, hårda	UK/H/3326/005	32538	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	FI
Elvanse 40 mg kapslar, hårda	UK/H/3326/005	32538	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	FI
Elvanse 40 mg kapslar, hårda	UK/H/3326/005	51597	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	SE
Elvanse 40 mg kapslar, hårda	UK/H/3326/005	51597	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	SE

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Elvanse 40 mg kapsler, harde	UK/H/3326/005	14-10266	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	NO
Elvanse 40 mg kapsler, harde	UK/H/3326/005	14-10266	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	NO
Elvanse 40 mg kapsler, hårde	UK/H/3326/005	54625	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	DK
Elvanse 40 mg kapsler, hårde	UK/H/3326/005	54625	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	DK
Elvanse 50 mg cápsulas	UK/H/3326/002	5674700	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	PT
Elvanse 50 mg cápsulas	UK/H/3326/002	5674718	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	PT
Elvanse 50 mg cápsulas duras	UK/H/3326/002	77643	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	ES
Elvanse 50 mg cápsulas duras	UK/H/3326/002	77643	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	ES
Elvanse 50 mg capsules, hard	UK/H/3326/002	PL 08081/0051	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	UK
Elvanse 50 mg capsules, hard	UK/H/3326/002	PL 08081/0051	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	UK
Elvanse 50 mg Hartkapseln	UK/H/3326/002	136852	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	AT
Elvanse 50 mg Hartkapseln	UK/H/3326/002	136852	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	AT
Elvanse 50 mg Hartkapseln	UK/H/3326/002	86156.00.00	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	DE
Elvanse 50 mg Hartkapseln	UK/H/3326/002	86156.00.00	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	DE
Elvanse 50 mg kapselit, kovát	UK/H/3326/002	30383	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	FI
Elvanse 50 mg kapselit, kovát	UK/H/3326/002	30383	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	FI
Elvanse 50 mg kapslar, hårda	UK/H/3326/002	30383	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	FI

<b>Product Name (in authorisation country)</b>	<b>MRP/DCP Authorisation number</b>	<b>National Authorisation Number</b>	<b>MAH of product in the member state</b>	<b>Member State where product is authorised</b>
Elvanse 50 mg kapslar, hårda	UK/H/3326/002	30383	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	FI
Elvanse 50 mg kapslar, hårda	UK/H/3326/002	47383	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	SE
Elvanse 50 mg kapslar, hårda	UK/H/3326/002	47383	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	SE
Elvanse 50 mg kapsler, harde	UK/H/3326/002	11-8763	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	NO
Elvanse 50 mg kapsler, harde	UK/H/3326/002	11-8763	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	NO
Elvanse 50 mg kapsler, hårde	UK/H/3326/002	49981	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	DK
Elvanse 50 mg kapsler, hårde	UK/H/3326/002	49981	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	DK
Elvanse 50 mg tvrdé tobolky	UK/H/3326/002	06/083/16-C	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	CZ
Elvanse 50 mg tvrdé tobolky	UK/H/3326/002	06/083/16-C	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	CZ
Elvanse 60 mg capsules, hard	UK/H/3326/006	PL 08081/0064	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	UK
Elvanse 60 mg capsules, hard	UK/H/3326/006	PL 08081/0064	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	UK
Elvanse 60 mg Hartkapseln	UK/H/3326/006	93473.00.00	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	DE
Elvanse 60 mg Hartkapseln	UK/H/3326/006	93473.00.00	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	DE
Elvanse 60 mg kapselit kovát	UK/H/3326/006	32539	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	FI
Elvanse 60 mg kapselit kovát	UK/H/3326/006	32539	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	FI
Elvanse 60 mg kapslar, hårda	UK/H/3326/006	32539	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	FI
Elvanse 60 mg kapslar, hårda	UK/H/3326/006	32539	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	FI

<b>Product Name (in authorisation country)</b>	<b>MRP/DCP Authorisation number</b>	<b>National Authorisation Number</b>	<b>MAH of product in the member state</b>	<b>Member State where product is authorised</b>
Elvanse 60 mg kapslar, hårda	UK/H/3326/006	51598	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	SE
Elvanse 60 mg kapslar, hårda	UK/H/3326/006	51598	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	SE
Elvanse 60 mg kapsler, harde	UK/H/3326/006	14-10267	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	NO
Elvanse 60 mg kapsler, harde	UK/H/3326/006	14-10267	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	NO
Elvanse 60 mg kapsler, hårde	UK/H/3326/006	54626	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	DK
Elvanse 60 mg kapsler, hårde	UK/H/3326/006	54626	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	DK
Elvanse 70 mg cápsulas	UK/H/3326/003	5674668	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	PT
Elvanse 70 mg cápsulas	UK/H/3326/003	5674676	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	PT
Elvanse 70 mg cápsulas duras	UK/H/3326/003	77644	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	ES
Elvanse 70 mg cápsulas duras	UK/H/3326/003	77644	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	ES
Elvanse 70 mg capsules, hard	UK/H/3326/003	PL 08081/0052	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	UK
Elvanse 70 mg capsules, hard	UK/H/3326/003	PL 08081/0052	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	UK
Elvanse 70 mg Hartkapseln	UK/H/3326/003	136853	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	AT
Elvanse 70 mg Hartkapseln	UK/H/3326/003	136853	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	AT
Elvanse 70 mg Hartkapseln	UK/H/3326/003	86157.00.00	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	DE
Elvanse 70 mg Hartkapseln	UK/H/3326/003	86157.00.00	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	DE
Elvanse 70 mg kapselit, kovat	UK/H/3326/003	30384	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	FI

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Elvanse 70 mg kapselit, kovat	UK/H/3326/003	30384	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	FI
Elvanse 70 mg kapselit, kovat	UK/H/3326/003	30384	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	FI
Elvanse 70 mg kapselit, kovat	UK/H/3326/003	30384	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	FI
Elvanse 70 mg kapslar, hårda	UK/H/3326/003	47384	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	SE
Elvanse 70 mg kapslar, hårda	UK/H/3326/003	47384	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	SE
Elvanse 70 mg kapsler, harde	UK/H/3326/003	11-8764	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	NO
Elvanse 70 mg kapsler, harde	UK/H/3326/003	11-8764	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	NO
Elvanse 70 mg kapsler, hårde	UK/H/3326/003	49982	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	DK
Elvanse 70 mg kapsler, hårde	UK/H/3326/003	49982	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	DK
Elvanse 70 mg tvrdé tobolky	UK/H/3326/003	06/084/16-C	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	CZ
Elvanse 70 mg tvrdé tobolky	UK/H/3326/003	06/084/16-C	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	CZ
Elvanse Adult 30 mg capsules, hard	UK/H/5567/001	PL 08081/0059	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	UK
Elvanse Adult 30 mg capsules, hard.	UK/H/5567/001	PL 08081/0059	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	UK
Elvanse Adult 50 mg capsules, hard	UK/H/5567/002	PL 08081/0060	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	UK
Elvanse Adult 50mg capsules, hard	UK/H/5567/002	PL 08081/0060	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	UK
Elvanse Adult 70 mg capsules, hard	UK/H/5567/003	PL 08081/0061	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	UK
Elvanse Adult 70mg capsules, hard	UK/H/5567/003	PL 08081/0061	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	UK

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Elvanse Vuxen 30 mg kapslar, hårda	UK/H/5567/001	50796	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	SE
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 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 Vuxen 70 mg kapslar, hårda	UK/H/5567/003	50798	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	SE
Tyvense 20 mg capsules, hard	UK/H/3326/004	PA 0689/006/004	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	IE
Tyvense 20 mg capsules, hard	UK/H/3326/004	PA 0689/006/004	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	IE
Tyvense 30 mg capsules, hard	UK/H/3326/001	PA 689/6/1	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	IE
Tyvense 30 mg capsules, hard	UK/H/3326/001	PA 689/6/1	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	IE
Tyvense 40 mg capsules, hard	UK/H/3326/005	PA 0689/006/005	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	IE
Tyvense 40 mg capsules, hard	UK/H/3326/005	PA 0689/006/005	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	IE
Tyvense 50 mg capsules, hard	UK/H/3326/002	PA 689/6/2	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	IE
Tyvense 50 mg capsules, hard	UK/H/3326/002	PA 689/6/2	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	IE
Tyvense 60 mg capsules, hard	UK/H/3326/006	PA 0689/006/006	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	IE
Tyvense 60 mg capsules, hard	UK/H/3326/006	PA 0689/006/006	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	IE
Tyvense 70 mg capsules, hard	UK/H/3326/003	PA 689/6/3	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	IE

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Tyvense 70 mg capsules, hard	UK/H/3326/003	PA 689/6/3	SHIRE PHARMACEUTICAL CONTRACTS LIMITED	IE