1 September 2017
EMA/580033/2017
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: sertindole

Procedure no.: PSUSA/00002695/201701

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Product Name (in authorisation country)	MRP/DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Serdolect 12 mg	not available	68/0516/97-S	H. LUNDBECK A/S	SK
Serdolect 12 mg apvalkotas tabletes	not available	97-0298	H. LUNDBECK A/S	LV
Serdolect 12 mg comprimidos recubiertos con película	UK/H/0141/003	61.584	H. LUNDBECK A/S	ES
Serdolect 12 mg film-coated tablets	UK/H/0141/003	PL 13761/0003	H. LUNDBECK A/S	UK
Serdolect 12 mg filmdrasjerte tabletter	UK/H/0141/003	96-0273	H. LUNDBECK A/S	NO
Serdolect 12 mg filmom obložene tablete	not available	UP/I-530-09/12-02/51	LUNDBECK CROATIA D.O.O.	HR
Serdolect 12 mg filmomhulde tabletten	UK/H/0141/003	RVG 20612	H. LUNDBECK A/S	NL
Serdolect 12 mg filmtabletta	not available	OGYI-T-5605/02	H. LUNDBECK A/S	HU
Serdolect 12 mg-Filmtabletten	UK/H/0141/003	1-21727	H. LUNDBECK A/S	AT
Serdolect 12 mg filmuhúðaðar töflur	UK/H/0141/003	IS/1/02/026/03	H. LUNDBECK A/S	IS

Product Name (in authorisation country)	MRP/DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
SERDOLECT 12 mg potahované tablety	not available	68/672/96-B/C	H. LUNDBECK A/S	CZ
Serdolect 12 mg tabletti, kalvopäällysteinen	UK/H/0141/003	12402	H. LUNDBECK A/S	FI
Serdolect 12 mg επικαλυμμένα με λεπτό υμένιο δισκία	UK/H/0141/003	90515/24-11-2016	LUNDBECK HELLAS, GR	GR
Serdolect 16 mg	not available	68/0516/97-S	H. LUNDBECK A/S	SK
Serdolect 16 mg apvalkotas tabletes	not available	97-0299	H. LUNDBECK A/S	LV
Serdolect 16 mg comprimés pelliculés	UK/H/0141/004	BE285591	H. LUNDBECK A/S	BE
Serdolect 16 mg comprimés pelliculés	UK/H/0141/04	BE434393	H. LUNDBECK A/S	BE
Serdolect 16 mg comprimés pelliculés	UK/H/0141/004	BE184265	H. LUNDBECK A/S	BE
Serdolect 16 mg comprimidos recubiertos con película	UK/H/0141/004	61.585	H. LUNDBECK A/S	ES

Product Name (in authorisation country)	MRP/DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Serdolect 16 mg film-coated tablets	UK/H/0141/004	PL 13761/0004	H. LUNDBECK A/S	UK
Serdolect 16 mg filmdrasjerte tabletter	UK/H/0141/004	96-0274	H. LUNDBECK A/S	NO
Serdolect 16 mg filmomhulde tabletten	UK/H/0141/004	BE285591	H. LUNDBECK A/S	BE
Serdolect 16 mg filmomhulde tabletten	UK/H/0141/004	BE434393	H. LUNDBECK A/S	BE
Serdolect 16 mg filmomhulde tabletten	UK/H/0141/004	RVG 20613	H. LUNDBECK A/S	NL
Serdolect 16 mg filmtabletta	not available	OGYI-T-5605/03	H. LUNDBECK A/S	HU
Serdolect 16 mg-Filmtabletten	UK/H/0141/004	1-21728	H. LUNDBECK A/S	AT
Serdolect 16 mg filmuhúðaðar töflur	UK/H/0141/004	IS/1/02/026/04	H. LUNDBECK A/S	IS
SERDOLECT 16 mg potahované tablety	not available	68/672/96-C/C	H. LUNDBECK A/S	CZ

Product Name (in authorisation country)	MRP/DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Serdolect 16 mg tabletti, kalvopäällysteinen	UK/H/0141/004	12403	H. LUNDBECK A/S	FI
Serdolect 16 mg επικαλυμμένα με λεπτό υμένιο δισκία	UK/H/0141/004	90516/24-11-2016	LUNDBECK HELLAS, GR	GR
Serdolect 16 mg, comprimate filmate	not available	7721/2015/01-02	H. LUNDBECK A/S	RO
Serdolect 16 mg, filmomhulde tabletten	UK/H/0141/004	BE184265	H. LUNDBECK A/S	BE
Serdolect 20 mg	not available	68/0516/97-S	H. LUNDBECK A/S	SK
Serdolect 20 mg apvalkotas tabletes	not available	97-0300	H. LUNDBECK A/S	LV
Serdolect 20 mg comprimidos recubiertos con película	UK/H/0141/005	61.586	H. LUNDBECK A/S	ES
Serdolect 20 mg film-coated tablets	UK/H/0141/005	PL 13761/0005	H. LUNDBECK A/S	UK
Serdolect 20 mg filmdrasjerte tabletter	UK/H/0141/005	96-0275	H. LUNDBECK A/S	NO

Product Name (in authorisation country)	MRP/DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Serdolect 20 mg filmomhulde tabletten	UK/H/0141/005	RVG 20614	H. LUNDBECK A/S	NL
Serdolect 20 mg filmtabletta	not available	OGYI-T-5605/04	H. LUNDBECK A/S	HU
Serdolect 20 mg-Filmtabletten	UK/H/0141/005	1-21729	H. LUNDBECK A/S	AT
Serdolect 20 mg filmuhúðaðar töflur	UK/H/0141/005	IS/1/02/026/05	H. LUNDBECK A/S	IS
SERDOLECT 20 mg potahované tablety	not available	68/672/96-D/C	H. LUNDBECK A/S	CZ
Serdolect 20 mg tabletti, kalvopäällysteinen	UK/H/0141/005	12404	H. LUNDBECK A/S	FI
Serdolect 20 mg επικαλυμμένα με λεπτό υμένιο δισκία	UK/H/0141/005	90517/24-11-2016	LUNDBECK HELLAS, GR	GR
Serdolect 4 mg	not available	68/0516/97-S	H. LUNDBECK A/S	SK
Serdolect 4 mg apvalkotas tabletes	not available	97-0296	H. LUNDBECK A/S	LV

Product Name (in authorisation country)	MRP/DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Serdolect 4 mg comprimés pelliculés	UK/H/0141/001	BE285573	H. LUNDBECK A/S	BE
Serdolect 4 mg comprimés pelliculés	UK/H/0141/001	BE434375	H. LUNDBECK A/S	BE
Serdolect 4 mg comprimés pelliculés	UK/H/0141/001	BE184231	H. LUNDBECK A/S	BE
Serdolect 4 mg comprimidos recubiertos con película	UK/H/0141/001	61.582	H. LUNDBECK A/S	ES
Serdolect 4 mg film-coated tablets	UK/H/0141/001	PL 13761/0001	H. LUNDBECK A/S	UK
Serdolect 4 mg filmdrasjerte tabletter	UK/H/0141/001	96-0271	H. LUNDBECK A/S	NO
Serdolect 4 mg filmom obložene tablete	not available	UP/I-530-09/12-02/50	LUNDBECK CROATIA D.O.O.	HR
Serdolect 4 mg filmomhulde tabletten	UK/H/0141/001	BE285573	H. LUNDBECK A/S	BE
Serdolect 4 mg filmomhulde tabletten	UK/H/0141/001	BE434375	H. LUNDBECK A/S	BE

Product Name (in authorisation country)	MRP/DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Serdolect 4 mg filmomhulde tabletten	UK/H/0141/001	RVG 20610	H. LUNDBECK A/S	NL
Serdolect 4 mg filmtabletta	not available	OGYI-T-5605/01	H. LUNDBECK A/S	HU
Serdolect 4 mg-Filmtabletten	UK/H/0141/001	1-21725	H. LUNDBECK A/S	AT
Serdolect 4 mg filmuhúðaðar töflur	UK/H/0141/001	IS/1/02/026/01	H. LUNDBECK A/S	IS
SERDOLECT 4 mg potahované tablety	not available	68/672/96-A/C	H. LUNDBECK A/S	CZ
Serdolect 4 mg επικαλυμμένα με λεπτό υμένιο δισκία	UK/H/0141/001	90337/24-11-2016	LUNDBECK HELLAS, GR	GR
Serdolect 4 mg, comprimate filmate	not available	7720/2015/01-02	H. LUNDBECK A/S	RO
Serdolect 4 mg, filmomhulde tabletten	UK/H/0141/001	BE184231	H. LUNDBECK A/S	BE
Serdolect 4 mg, tabletti, kalvopäällysteinen	UK/H/0141/001	12400	H. LUNDBECK A/S	FI

Product Name (in authorisation country)	MRP/DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Serdolect Tabletki powlekane 12 mg	not available	10893	H. LUNDBECK A/S	PL
Serdolect Tabletki powlekane 16 mg	not available	10894	H. LUNDBECK A/S	PL
Serdolect Tabletki powlekane 4 mg	not available	10892	H. LUNDBECK A/S	PL
SERDOLECT, 12 mg õhukese polümeerikattega tabletid	not available	168497	H. LUNDBECK A/S	EE
Serdolect, 12 mg, filmdragerade tabletter	UK/H/0141/03	20577	H. LUNDBECK A/S	SE
SERDOLECT, 16 mg õhukese polümeerikattega tabletid	not available	168597	H. LUNDBECK A/S	EE
SERDOLECT, 20 mg õhukese polümeerikattega tabletid	not available	168697	H. LUNDBECK A/S	EE
SERDOLECT, 4 mg õhukese polümeerikattega tabletid	not available	168397	H. LUNDBECK A/S	EE
Serdolect, 4 mg, filmdragerade tabletter	UK/H/0141/01	20576	H. LUNDBECK A/S	SE

Product Name (in authorisation country)	MRP/DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Serdolect, filmovertrukne tabletter 12 mg	UK/H/0141/003	18313	H. LUNDBECK A/S	DK
Serdolect, filmovertrukne tabletter 16 mg	UK/H/0141/004	18314	H. LUNDBECK A/S	DK
Serdolect, filmovertrukne tabletter 20 mg	UK/H/0141/005	18315	H. LUNDBECK A/S	DK
Serdolect, filmovertrukne tabletter 4 mg	UK/H/0141/001	18311	H. LUNDBECK A/S	DK
Serdolect® 12 mg, Filmtabletten	UK/H/0141/003	38471.02.00	H. LUNDBECK A/S	DE
Serdolect® 16 mg, Filmtabletten	UK/H/0141/004	38471.03.00	H. LUNDBECK A/S	DE
Serdolect® 20 mg, Filmtabletten	UK/H/0141/005	38471.04.00	H. LUNDBECK A/S	DE
Serdolect® 4 mg, Filmtabletten	UK/H/0141/001	38471.00.00	H. LUNDBECK A/S	DE
Сердолект 12 mg филмирани таблетки	not available	980 02 85	H. LUNDBECK A/S	BG

Product Name (in authorisation country)	MRP/DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Сердолект 16 mg филмирани таблетки	not available	980 02 84	H. LUNDBECK A/S	BG
Сердолект 4 mg филмирани таблетки	not available	980 02 86	H. LUNDBECK A/S	BG