3 September 2020
EMA/270645/2015
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: sertindole

Procedure no.: PSUSA/00002695/202001

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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 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 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 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
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 12 mg filmom obložene tablete	not available	UP/I-530-09/12-02/51	LUNDBECK CROATIA D.O.O.	HR

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 filmom obložene tablete	not available	UP/I-530-09/12-02/50	LUNDBECK CROATIA D.O.O.	HR
Serdolect 4 mg filmtabletta	not available	OGYI-T-5605/01	H. LUNDBECK A/S	HU
Serdolect 12 mg filmtabletta	not available	OGYI-T-5605/02	H. LUNDBECK A/S	HU
Serdolect 16 mg filmtabletta	not available	OGYI-T-5605/03	H. LUNDBECK A/S	HU
Serdolect 20 mg filmtabletta	not available	OGYI-T-5605/04	H. LUNDBECK A/S	HU
Serdolect Tabletki powlekane 4 mg	not available	10892	H. LUNDBECK A/S	PL
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 4 mg	not available	68/0516/97-S	H. LUNDBECK A/S	SK

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 16 mg	not available	68/0516/97-S	H. LUNDBECK A/S	SK
Serdolect 20 mg	not available	68/0516/97-S	H. LUNDBECK A/S	SK
Serdolect 4 mg comprimidos recubiertos con película	UK/H/0141/001	61.582	H. LUNDBECK A/S	ES
Serdolect 12 mg comprimidos recubiertos con película	UK/H/0141/003	61.584	H. LUNDBECK A/S	ES
Serdolect 16 mg comprimidos recubiertos con película	UK/H/0141/004	61.585	H. LUNDBECK A/S	ES
Serdolect 20 mg comprimidos recubiertos con película	UK/H/0141/005	61.586	H. LUNDBECK A/S	ES
SERDOLECT 4 mg potahované tablety	not available	68/672/96-A/C	H. LUNDBECK A/S	CZ
SERDOLECT 12 mg potahované tablety	not available	68/672/96-B/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 potahované tablety	not available	68/672/96-C/C	H. LUNDBECK A/S	CZ
SERDOLECT 20 mg potahované tablety	not available	68/672/96-D/C	H. LUNDBECK A/S	CZ
Serdolect 4 mg-Filmtabletten	UK/H/0141/001	1-21725	H. LUNDBECK A/S	AT
Serdolect 12 mg-Filmtabletten	UK/H/0141/003	1-21727	H. LUNDBECK A/S	AT
Serdolect 16 mg-Filmtabletten	UK/H/0141/004	1-21728	H. LUNDBECK A/S	AT
Serdolect 20 mg-Filmtabletten	UK/H/0141/005	1-21729	H. LUNDBECK A/S	AT
Serdolect 4 mg filmdrasjerte tabletter	UK/H/0141/001	96-0271	H. LUNDBECK A/S	NO
Serdolect 12 mg filmdrasjerte tabletter	UK/H/0141/003	96-0273	H. LUNDBECK A/S	NO
Serdolect 16 mg filmdrasjerte tabletter	UK/H/0141/004	96-0274	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 filmdrasjerte tabletter	UK/H/0141/005	96-0275	H. LUNDBECK A/S	NO
Serdolect 4 mg film-coated tablets	UK/H/0141/001	PL 13761/0001	H. LUNDBECK A/S	UK
Serdolect 12 mg film-coated tablets	UK/H/0141/003	PL 13761/0003	H. LUNDBECK A/S	UK
Serdolect 16 mg film-coated tablets	UK/H/0141/004	PL 13761/0004	H. LUNDBECK A/S	UK
Serdolect 20 mg film-coated tablets	UK/H/0141/005	PL 13761/0005	H. LUNDBECK A/S	UK
Serdolect® 4 mg, Filmtabletten	UK/H/0141/001	38471.00.00	H. LUNDBECK A/S	DE
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

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	BE184231	H. LUNDBECK A/S	BE
Serdolect 16 mg, filmomhulde tabletten	UK/H/0141/004	BE184265	H. LUNDBECK A/S	BE
Serdolect 4 mg comprimés pelliculés	UK/H/0141/001	BE184231	H. LUNDBECK A/S	BE
Serdolect 16 mg comprimés pelliculés	UK/H/0141/004	BE184265	H. LUNDBECK A/S	BE
Serdolect, filmovertrukne tabletter 4 mg	UK/H/0141/001	18311	H. LUNDBECK A/S	DK
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, 4 mg õhukese polümeerikattega tabletid	not available	168397	H. LUNDBECK A/S	EE

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 õhukese polümeerikattega tabletid	not available	168497	H. LUNDBECK A/S	EE
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 apvalkotas tabletes	not available	97-0296	H. LUNDBECK A/S	LV
Serdolect 12 mg apvalkotas tabletes	not available	97-0298	H. LUNDBECK A/S	LV
Serdolect 16 mg apvalkotas tabletes	not available	97-0299	H. LUNDBECK A/S	LV
Serdolect 20 mg apvalkotas tabletes	not available	97-0300	H. LUNDBECK A/S	LV
Serdolect 4 mg filmuhúðaðar töflur	UK/H/0141/001	IS/1/02/026/01	H. LUNDBECK A/S	IS
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 16 mg filmuhúðaðar töflur	UK/H/0141/004	IS/1/02/026/04	H. LUNDBECK A/S	IS
Serdolect 20 mg filmuhúðaðar töflur	UK/H/0141/005	IS/1/02/026/05	H. LUNDBECK A/S	IS
Serdolect, 4 mg, filmdragerade tabletter	UK/H/0141/01	20576	H. LUNDBECK A/S	SE
Serdolect, 12 mg, filmdragerade tabletter	UK/H/0141/03	20577	H. LUNDBECK A/S	SE
Serdolect 4 mg, tabletti, kalvopäällysteinen	UK/H/0141/001	12400	H. LUNDBECK A/S	FI
Serdolect 12 mg tabletti, kalvopäällysteinen	UK/H/0141/003	12402	H. LUNDBECK A/S	FI
Serdolect 16 mg tabletti, kalvopäällysteinen	UK/H/0141/004	12403	H. LUNDBECK A/S	FI
Serdolect 20 mg tabletti, kalvopäällysteinen	UK/H/0141/005	12404	H. LUNDBECK A/S	FI
Serdolect 4 mg filmomhulde tabletten	UK/H/0141/001	RVG 20610	H. LUNDBECK A/S	NL

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 filmomhulde tabletten	UK/H/0141/003	RVG 20612	H. LUNDBECK A/S	NL
Serdolect 16 mg filmomhulde tabletten	UK/H/0141/004	RVG 20613	H. LUNDBECK A/S	NL
Serdolect 20 mg filmomhulde tabletten	UK/H/0141/005	RVG 20614	H. LUNDBECK A/S	NL
Serdolect 4 mg, comprimate filmate	not available	7720/2015/01-02	H. LUNDBECK A/S	RO
Serdolect 12 mg, comprimate filmate	not available	8289/2006/01-02-03	H. LUNDBECK A/S	RO
Serdolect 16 mg, comprimate filmate	not available	7721/2015/01-02	H. LUNDBECK A/S	RO
Serdolect 20 mg, comprimate filmate	not available	8291/2006/01-02-03	H. LUNDBECK A/S	RO
Serdolect 4 mg επικαλυμμένα με λεπτό υμένιο δισκία	UK/H/0141/001	90337/24-11-2016	LUNDBECK HELLAS, GR	GR
Serdolect 12 mg επικαλυμμένα με λεπτό υμένιο δισκία	UK/H/0141/003	90515/24-11-2016	LUNDBECK HELLAS, GR	GR

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 επικαλυμμένα με λεπτό υμένιο δισκία	UK/H/0141/004	90516/24-11-2016	LUNDBECK HELLAS, GR	GR
Serdolect 20 mg επικαλυμμένα με λεπτό υμένιο δισκία	UK/H/0141/005	90517/24-11-2016	LUNDBECK HELLAS, GR	GR
Сердолект 4 mg филмирани таблетки	not available	980 02 86	H. LUNDBECK A/S	BG
Сердолект 12 mg филмирани таблетки	not available	980 02 85	H. LUNDBECK A/S	BG
Сердолект 16 mg филмирани таблетки	not available	980 02 84	H. LUNDBECK A/S	BG