



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

14 April 2023
EMA/163351/2023
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance(s): fluvastatin

Procedure No.: PSUSA/00001457/202208



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
FLUVASTATINE CEVIDRA L.P. 80 mg, comprimé pelliculé à libération prolongée	not available	34009 394 312 7 7	DOUBLE-E PHARMA LTD	FR
FLUVASTATINE CEVIDRA L.P. 80 mg, comprimé pelliculé à libération prolongée	not available	34009 394 313 3 8	DOUBLE-E PHARMA LTD	FR
FLUVASTATINE CEVIDRA L.P. 80 mg, comprimé pelliculé à libération prolongée	not available	34009 394 315 6 7	DOUBLE-E PHARMA LTD	FR
FLUVASTATINE CEVIDRA L.P. 80 mg, comprimé pelliculé à libération prolongée	not available	34009 394 316 2 8	DOUBLE-E PHARMA LTD	FR
FLUVASTATINE CEVIDRA L.P. 80 mg, comprimé pelliculé à libération prolongée	not available	34009 394 317 9 6	DOUBLE-E PHARMA LTD	FR
FLUVASTATINE CEVIDRA L.P. 80 mg, comprimé pelliculé à libération prolongée	not available	34009 394 318 5 7	DOUBLE-E PHARMA LTD	FR
FLUVASTATINE CEVIDRA L.P. 80 mg, comprimé pelliculé à libération prolongée	not available	34009 394 319 1 8	DOUBLE-E PHARMA LTD	FR
FLUVASTATINE CEVIDRA L.P. 80 mg, comprimé pelliculé à libération prolongée	not available	34009 394 321 6 8	DOUBLE-E PHARMA LTD	FR
FLUVASTATINE CEVIDRA L.P. 80 mg, comprimé pelliculé à libération prolongée	not available	34009 394 322 2 9	DOUBLE-E PHARMA LTD	FR
FLUVASTATINE CEVIDRA L.P. 80 mg, comprimé pelliculé à libération	not available	34009 394 323 9 7	DOUBLE-E PHARMA LTD	FR

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prolongée				
FLUVASTATINE CEVIDRA L.P. 80 mg, comprimé pelliculé à libération prolongée	not available	34009 394 324 5 8	DOUBLE-E PHARMA LTD	FR
FLUVASTATINE CEVIDRA L.P. 80 mg, comprimé pelliculé à libération prolongée	not available	34009 394 325 1 9	DOUBLE-E PHARMA LTD	FR
FLUVASTATINE BIOGARAN LP 80 mg, comprimé pelliculé à libération prolongée	not available	3400939378428	BIOGARAN	FR
FLUVASTATINE BIOGARAN LP 80 mg, comprimé pelliculé à libération prolongée	not available	3400939378138	BIOGARAN	FR
FLUVASTATINE BIOGARAN LP 80 mg, comprimé pelliculé à libération prolongée	not available	3400939378077	BIOGARAN	FR
FLUVASTATINE BIOGARAN LP 80 mg, comprimé pelliculé à libération prolongée	not available	3400939378367	BIOGARAN	FR
FLUVASTATINE BIOGARAN LP 80 mg, comprimé pelliculé à libération prolongée	not available	3400939378947	BIOGARAN	FR
FLUVASTATINE BIOGARAN LP 80 mg, comprimé pelliculé à libération prolongée	not available	3400939379258	BIOGARAN	FR
FLUVASTATINE BIOGARAN LP 80 mg, comprimé pelliculé à libération prolongée	not available	3400939378886	BIOGARAN	FR
FLUVASTATINE BIOGARAN LP 80 mg,	not available	3400939379029	BIOGARAN	FR

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comprimé pelliculé à libération prolongée				
FLUVASTATINE BIOGARAN LP 80 mg, comprimé pelliculé à libération prolongée	not available	3400939379197	BIOGARAN	FR
FLUVASTATINE BIOGARAN LP 80 mg, comprimé pelliculé à libération prolongée	not available	3400939378718	BIOGARAN	FR
FLUVASTATINE BIOGARAN LP 80 mg, comprimé pelliculé à libération prolongée	not available	3400939378657	BIOGARAN	FR
FLUVASTATINE BIOGARAN LP 80 mg, comprimé pelliculé à libération prolongée	not available	34009 393 785 9 6	BIOGARAN	FR
FLUVASTATINE ARROW L.P. 80 mg, comprimé pelliculé à libération prolongée	not available	NL 34 586	ARROW GENERIQUES	FR
Fluvastatin Holsten 80 mg Retardtabletten	DE/H/5739/001	69848.00.00	DOUBLE-E PHARMA LTD	DE
CRANOC® 80 mg Retardtabletten	DE/H/3066/003	48880.00.00	NOVARTIS PHARMA GMBH	DE
Digaril Prolib 80 mg comprimidos de liberación prolongada	DE/H/3066/003	64.692	NOVARTIS FARMACÉUTICA S.A.	ES
Lipaxan 80 mg compresse a rilascio prolungato	DE/H/3066/003	029199041	NOVARTIS FARMA S.P.A.	IT
Lipaxan 80 mg compresse a rilascio prolungato	DE/H/3066/003	029199066	NOVARTIS FARMA S.P.A.	IT
Lipaxan 80 mg compresse a rilascio prolungato	DE/H/3066/003	029199078	NOVARTIS FARMA S.P.A.	IT

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Lipaxan 80 mg compresse a rilascio prolungato	DE/H/3066/003	029199080	NOVARTIS FARMA S.P.A.	IT
Lipaxan 80 mg compresse a rilascio prolungato	DE/H/3066/003	029199522	NOVARTIS FARMA S.P.A.	IT
Lipaxan 80 mg compresse a rilascio prolungato	DE/H/3066/003	029199534	NOVARTIS FARMA S.P.A.	IT
Lipaxan 80 mg compresse a rilascio prolungato	DE/H/3066/003	029199546	NOVARTIS FARMA S.P.A.	IT
Lipaxan 80 mg compresse a rilascio prolungato	DE/H/3066/003	029199559	NOVARTIS FARMA S.P.A.	IT
Lipaxan 80 mg compresse a rilascio prolungato	DE/H/3066/003	029199561	NOVARTIS FARMA S.P.A.	IT
Lipaxan 80 mg compresse a rilascio prolungato	DE/H/3066/003	029199573	NOVARTIS FARMA S.P.A.	IT
Lipaxan 80 mg compresse a rilascio prolungato	DE/H/3066/003	029199585	NOVARTIS FARMA S.P.A.	IT
Lipaxan 80 mg compresse a rilascio prolungato	DE/H/3066/003	029199597	NOVARTIS FARMA S.P.A.	IT
Lipaxan 80 mg compresse a rilascio prolungato	DE/H/3066/003	029199609	NOVARTIS FARMA S.P.A.	IT
Lipaxan 80 mg compresse a rilascio prolungato	DE/H/3066/003	029199611	NOVARTIS FARMA S.P.A.	IT
Lipaxan 80 mg compresse a rilascio prolungato	DE/H/3066/003	029199623	NOVARTIS FARMA S.P.A.	IT
Lipaxan 80 mg compresse a rilascio prolungato	DE/H/3066/003	029199635	NOVARTIS FARMA S.P.A.	IT
Lipaxan 80 mg compresse a rilascio prolungato	DE/H/3066/003	029199647	NOVARTIS FARMA S.P.A.	IT

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Lipaxan 80 mg compresse a rilascio prolungato	DE/H/3066/003	029199650	NOVARTIS FARMA S.P.A.	IT
Lipaxan 80 mg compresse a rilascio prolungato	DE/H/3066/003	029199662	NOVARTIS FARMA S.P.A.	IT
Lipaxan 80 mg compresse a rilascio prolungato	DE/H/3066/003	029199674	NOVARTIS FARMA S.P.A.	IT
Lipaxan 80 mg compresse a rilascio prolungato	DE/H/3066/003	029199686	NOVARTIS FARMA S.P.A.	IT
Lipaxan 80 mg compresse a rilascio prolungato	DE/H/3066/003	029199698	NOVARTIS FARMA S.P.A.	IT
Lipaxan 80 mg compresse a rilascio prolungato	DE/H/3066/003	029199700	NOVARTIS FARMA S.P.A.	IT
Lipaxan 80 mg compresse a rilascio prolungato	DE/H/3066/003	029199712	NOVARTIS FARMA S.P.A.	IT
FLUVASTATINE SANDOZ RETARD 80 MG, TABLETTEN MET VERLENGDE AFGIFTE	DK/H/1224/001	RVG 35264	SANDOZ B.V.	NL
Fluvastatin Double-E Pharma 40 mg Hartkapseln	not available	88886.00.00	DOUBLE-E PHARMA LTD	DE
Lescol Exel 80 mg, comprimé à libération prolongée	DE/H/0116/003	2004108429	NOVARTIS PHARMA N.V.	LU
Lescol Exel 80 mg Retardtabletten	DE/H/0116/003	BE230395	NOVARTIS PHARMA N.V.	BE
Lescol Exel 80 mg Retardtabletten	DE/H/0116/003	BE230386	NOVARTIS PHARMA N.V.	BE
Lescol Exel 80 mg Retardtabletten	DE/H/0116/003	2004108429	NOVARTIS PHARMA N.V.	LU
Lescol XL 80 mg tablete s produljenim oslobađanjem	DE/H/0116/003	HR-H-337032317-02	NOVARTIS HRVATSKA D.O.O.	HR
Lescol XL 80 mg tablete s produljenim oslobađanjem	DE/H/0116/003	HR-H-337032317-03	NOVARTIS HRVATSKA D.O.O.	HR
Lescol XL 80 mg tablete s produljenim	DE/H/0116/003	HR-H-337032317-04	NOVARTIS HRVATSKA D.O.O.	HR

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oslobađanjem				
Lescol XL 80 mg tablete s produljenim oslobađanjem	DE/H/0116/003	HR-H-337032317-05	NOVARTIS HRVATSKA D.O.O.	HR
Lescol XL 80 mg tablete s produljenim oslobađanjem	DE/H/0116/003	HR-H-337032317-06	NOVARTIS HRVATSKA D.O.O.	HR
Lescol XL 80 mg tablete s produljenim oslobađanjem	DE/H/0116/003	HR-H-337032317-07	NOVARTIS HRVATSKA D.O.O.	HR
Lescol XL 80 mg tablete s produljenim oslobađanjem	DE/H/0116/003	HR-H-337032317-08	NOVARTIS HRVATSKA D.O.O.	HR
Lescol XL 80 mg tablete s produljenim oslobađanjem	DE/H/0116/003	HR-H-337032317-09	NOVARTIS HRVATSKA D.O.O.	HR
Lescol XL 80 mg tablete s produljenim oslobađanjem	DE/H/0116/003	HR-H-337032317-10	NOVARTIS HRVATSKA D.O.O.	HR
Lescol XL 80 mg tablete s produljenim oslobađanjem	DE/H/0116/003	HR-H-337032317-11	NOVARTIS HRVATSKA D.O.O.	HR
Lescol XL 80 mg tablete s produljenim oslobađanjem	DE/H/0116/003	HR-H-337032317-12	NOVARTIS HRVATSKA D.O.O.	HR
Lescol XL 80 mg tablete s produljenim oslobađanjem	DE/H/0116/003	HR-H-337032317-13	NOVARTIS HRVATSKA D.O.O.	HR
Lescol XL 80 mg tablete s produljenim oslobađanjem	DE/H/0116/003	HR-H-337032317-14	NOVARTIS HRVATSKA D.O.O.	HR
Lescol XL 80 mg tablete s produljenim oslobađanjem	DE/H/0116/003	HR-H-337032317-15	NOVARTIS HRVATSKA D.O.O.	HR
Lescol XL 80 mg tablete s produljenim oslobađanjem	DE/H/0116/003	HR-H-337032317-16	NOVARTIS HRVATSKA D.O.O.	HR
Lescol XL 80 mg tablete s produljenim oslobađanjem	DE/H/0116/003	HR-H-337032317-17	NOVARTIS HRVATSKA D.O.O.	HR
Lescol XL 80 mg tablete s produljenim oslobađanjem	DE/H/0116/003	HR-H-337032317-18	NOVARTIS HRVATSKA D.O.O.	HR

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oslobađanjem				
Lescol XL 80 mg tablete s produljenim oslobađanjem	DE/H/0116/003	HR-H-337032317-19	NOVARTIS HRVATSKA D.O.O.	HR
Lescol XL 80 mg tablete s produljenim oslobađanjem	DE/H/0116/003	HR-H-337032317-20	NOVARTIS HRVATSKA D.O.O.	HR
Lescol XL 80 mg tablete s produljenim oslobađanjem	DE/H/0116/003	HR-H-337032317-21	NOVARTIS HRVATSKA D.O.O.	HR
Lescol XL 80 mg tablete s produljenim oslobađanjem	DE/H/0116/003	HR-H-337032317-22	NOVARTIS HRVATSKA D.O.O.	HR
Lescol XL 80 mg tablete s produljenim oslobađanjem	DE/H/0116/003	HR-H-337032317-23	NOVARTIS HRVATSKA D.O.O.	HR
Lescol XL 80 mg tablete s podaljšanim sproščanjem	DE/H/0116/003	H/94/00899/017	NOVARTIS PHARMA GMBH	SI
Lescol XL 80 mg tablete s podaljšanim sproščanjem	DE/H/0116/003	H/94/00899/039	NOVARTIS PHARMA GMBH	SI
Lescol XL 80 mg tablete s podaljšanim sproščanjem	DE/H/0116/003	H/94/00899/040	NOVARTIS PHARMA GMBH	SI
Lescol XL 80 mg tablete s podaljšanim sproščanjem	DE/H/0116/003	H/94/00899/041	NOVARTIS PHARMA GMBH	SI
Lescol XL 80 mg tablete s podaljšanim sproščanjem	DE/H/0116/003	H/94/00899/042	NOVARTIS PHARMA GMBH	SI
Lescol XL 80 mg tablete s podaljšanim sproščanjem	DE/H/0116/003	H/94/00899/029	NOVARTIS PHARMA GMBH	SI
Lescol XL 80 mg tablete s podaljšanim sproščanjem	DE/H/0116/003	H/94/00899/030	NOVARTIS PHARMA GMBH	SI
Lescol XL 80 mg tablete s podaljšanim sproščanjem	DE/H/0116/003	H/94/00899/031	NOVARTIS PHARMA GMBH	SI
Lescol XL 80 mg tablete s podaljšanim sproščanjem	DE/H/0116/003	H/94/00899/032	NOVARTIS PHARMA GMBH	SI

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sproščanjem				
Lescol XL 80 mg tablete s podaljšanim sproščanjem	DE/H/0116/003	H/94/00899/033	NOVARTIS PHARMA GMBH	SI
Lescol XL 80 mg tablete s podaljšanim sproščanjem	DE/H/0116/003	H/94/00899/034	NOVARTIS PHARMA GMBH	SI
Lescol XL 80 mg tablete s podaljšanim sproščanjem	DE/H/0116/003	H/94/00899/035	NOVARTIS PHARMA GMBH	SI
Lescol XL 80 mg tablete s podaljšanim sproščanjem	DE/H/0116/003	H/94/00899/036	NOVARTIS PHARMA GMBH	SI
Lescol XL 80 mg tablete s podaljšanim sproščanjem	DE/H/0116/003	H/94/00899/037	NOVARTIS PHARMA GMBH	SI
Lescol XL 80 mg tablete s podaljšanim sproščanjem	DE/H/0116/003	H/94/00899/038	NOVARTIS PHARMA GMBH	SI
Lescol XL 80 mg tablete s podaljšanim sproščanjem	DE/H/0116/003	H/94/00899/019	NOVARTIS PHARMA GMBH	SI
Lescol XL 80 mg tablete s podaljšanim sproščanjem	DE/H/0116/003	H/94/00899/020	NOVARTIS PHARMA GMBH	SI
Lescol XL 80 mg tablete s podaljšanim sproščanjem	DE/H/0116/003	H/94/00899/021	NOVARTIS PHARMA GMBH	SI
Lescol XL 80 mg tablete s podaljšanim sproščanjem	DE/H/0116/003	H/94/00899/022	NOVARTIS PHARMA GMBH	SI
Lescol XL 80 mg tablete s podaljšanim sproščanjem	DE/H/0116/003	H/94/00899/023	NOVARTIS PHARMA GMBH	SI
Lescol XL 80 mg tablete s podaljšanim sproščanjem	DE/H/0116/003	H/94/00899/024	NOVARTIS PHARMA GMBH	SI
Lescol XL 80 mg tablete s podaljšanim sproščanjem	DE/H/0116/003	H/94/00899/025	NOVARTIS PHARMA GMBH	SI
Lescol XL 80 mg tablete s podaljšanim sproščanjem	DE/H/0116/003	H/94/00899/026	NOVARTIS PHARMA GMBH	SI

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sproščanjem				
Lescol XL 80 mg tablete s podaljšanim sproščanjem	DE/H/0116/003	H/94/00899/027	NOVARTIS PHARMA GMBH	SI
Lescol XL 80 mg tablete s podaljšanim sproščanjem	DE/H/0116/003	H/94/00899/028	NOVARTIS PHARMA GMBH	SI
Lescol XL 80 mg tablete s podaljšanim sproščanjem	DE/H/0116/003	H/94/00899/018	NOVARTIS PHARMA GMBH	SI
Lescol XL 80 mg δισκία παρατεταμένης αποδέσμευσης	DE/H/0116/003	19110	NOVARTIS IRELAND LIMITED	CY
Lescol XL 80 mg retard tabletta	DE/H/0116/003	OGYI-T-8273/01	NOVARTIS HUNGÁRIA KFT.	HU
Lescol XL 80 mg retard tabletta	DE/H/0116/003	OGYI-T-8273/02	NOVARTIS HUNGÁRIA KFT.	HU
Lescol Depot 80 mg depottabletter	DE/H/0116/003	16250	NOVARTIS SVERIGE AB	SE
Lescol XL	DE/H/0116/003	31/127/01-C	NOVARTIS S.R.O.,	CZ
Lescol XL 80 mg tablety s predĺženým uvoľňovaním	DE/H/0116/003	31/0154/01-S	NOVARTIS SLOVAKIA S.R.O.	SK
Lescol 80 mg compresse a rilascio prolungato	DE/H/0116/003	029163033	NOVARTIS FARMA S.P.A.	IT
Lescol 80 mg compresse a rilascio prolungato	DE/H/0116/003	029163060	NOVARTIS FARMA S.P.A.	IT
Lescol 80 mg compresse a rilascio prolungato	DE/H/0116/003	029163072	NOVARTIS FARMA S.P.A.	IT
Lescol 80 mg compresse a rilascio prolungato	DE/H/0116/003	029163084	NOVARTIS FARMA S.P.A.	IT
Lescol XL 80 mg comprimidos de libertação prolongada	DE/H/0116/003	3264892	NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A.	PT
Lescol XL 80 mg comprimidos de libertação prolongada	DE/H/0116/003	3420197	NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A.	PT
Lescol XL 80 mg comprimidos de	DE/H/0116/003	5496294	NOVARTIS FARMA - PRODUTOS	PT

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libertação prolongada			FARMACÊUTICOS S.A.	
Lescol Depot 80 mg depottabletit	DE/H/0116/003	16704	NOVARTIS FINLAND OY	FI
Lescol Depot 80 mg depottabletter	DE/H/0116/003	16704	NOVARTIS FINLAND OY	FI
Lescol Prolib 80 mg comprimidos de liberación prolongada	DE/H/0116/003	64.648	NOVARTIS FARMACÉUTICA S.A.	ES
Lescol XL 80 mg ilgstošās darbības tabletes	DE/H/0116/003	00-0939	SIA NOVARTIS BALTICS	LV
Lescol XL 80 mg comprimate cu eliberare prelungită	DE/H/0116/003	1297/2008/01	NOVARTIS PHARMA GMBH	RO
Lescol XL 80 mg comprimate cu eliberare prelungită	DE/H/0116/003	1297/2008/02	NOVARTIS PHARMA GMBH	RO
Lescol XL 80 mg comprimate cu eliberare prelungită	DE/H/0116/003	1297/2008/03	NOVARTIS PHARMA GMBH	RO
Lescol XL 80 mg comprimate cu eliberare prelungita	DE/H/0116/003	1297/2008/04	NOVARTIS PHARMA GMBH	RO
Lescol XL 80 mg comprimate cu eliberare prelungită	DE/H/0116/003	1297/2008/05	NOVARTIS PHARMA GMBH	RO
Lescol XL 80 mg comprimate cu eliberare prelungită	DE/H/0116/003	1297/2008/06	NOVARTIS PHARMA GMBH	RO
Lescol XL 80 mg comprimate cu eliberare prelungită	DE/H/0116/003	1297/2008/07	NOVARTIS PHARMA GMBH	RO
Lescol XL 80 mg comprimate cu eliberare prelungită	DE/H/0116/003	1297/2008/08	NOVARTIS PHARMA GMBH	RO
Lescol XL 80 mg comprimate cu eliberare prelungită	DE/H/0116/003	1297/2008/09	NOVARTIS PHARMA GMBH	RO
Lescol XL 80 mg comprimate cu eliberare prelungită	DE/H/0116/003	1297/2008/10	NOVARTIS PHARMA GMBH	RO
Lescol XL 80 mg comprimate cu	DE/H/0116/003	1297/2008/11	NOVARTIS PHARMA GMBH	RO

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eliberare prelungită				
Lescol XL 80 mg comprimate cu eliberare prelungită	DE/H/0116/003	1297/2008/12	NOVARTIS PHARMA GMBH	RO
Lescol XL 80 mg comprimate cu eliberare prelungită	DE/H/0116/003	1297/2008/13	NOVARTIS PHARMA GMBH	RO
Lescol XL 80 mg comprimate cu eliberare prelungită	DE/H/0116/003	1297/2008/14	NOVARTIS PHARMA GMBH	RO
Lescol XL 80 mg comprimate cu eliberare prelungită	DE/H/0116/003	1297/2008/15	NOVARTIS PHARMA GMBH	RO
Lescol XL 80 mg comprimate cu eliberare prelungită	DE/H/0116/003	1297/2008/16	NOVARTIS PHARMA GMBH	RO
Lescol XL 80 mg comprimate cu eliberare prelungită	DE/H/0116/003	1297/2008/17	NOVARTIS PHARMA GMBH	RO
Lescol XL 80 mg comprimate cu eliberare prelungită	DE/H/0116/003	1297/2008/18	NOVARTIS PHARMA GMBH	RO
Lescol XL 80 mg comprimate cu eliberare prelungită	DE/H/0116/003	1297/2008/19	NOVARTIS PHARMA GMBH	RO
Lescol XL 80 mg comprimate cu eliberare prelungită	DE/H/0116/003	1297/2008/20	NOVARTIS PHARMA GMBH	RO
Lescol XL 80 mg comprimate cu eliberare prelungită	DE/H/0116/003	1297/2008/21	NOVARTIS PHARMA GMBH	RO
Lescol XL 80 mg comprimate cu eliberare prelungită	DE/H/0116/003	1297/2008/22	NOVARTIS PHARMA GMBH	RO
Lescol XL 80 mg comprimate cu eliberare prelungită	DE/H/0116/003	1297/2008/23	NOVARTIS PHARMA GMBH	RO
Lescol XL 80 mg comprimate cu eliberare prelungită	DE/H/0116/003	1297/2008/24	NOVARTIS PHARMA GMBH	RO
Lescol XL 80 mg comprimate cu eliberare prelungită	DE/H/0116/003	1297/2008/25	NOVARTIS PHARMA GMBH	RO

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eliberare prelungită				
Lescol XL 80 mg comprimate cu eliberare prelungită	DE/H/0116/003	1297/2008/26	NOVARTIS PHARMA GMBH	RO
Lescol XL 80, tabletten met verlengde afgifte 80 mg	DE/H/0116/003	RVG 25187	NOVARTIS PHARMA B.V.	NL
LOCOL® 80 mg Retardtabletten	DE/H/0116/003	48878.00.00	NOVARTIS PHARMA GMBH	DE
LESCOL L.P. 80 mg, comprimé pelliculé à libération prolongée	DE/H/0116/003	34009 356 193 4 1	NOVARTIS PHARMA S.A.S.	FR
LESCOL L.P. 80 mg, comprimé pelliculé à libération prolongée	DE/H/0116/003	34009 371 769 0 3	NOVARTIS PHARMA S.A.S.	FR
LESCOL L.P. 80 mg, comprimé pelliculé à libération prolongée	DE/H/0116/003	34009 372 079 8 0	NOVARTIS PHARMA S.A.S.	FR
LESCOL L.P. 80 mg, comprimé pelliculé à libération prolongée	DE/H/0116/003	34009 372 080 6 2	NOVARTIS PHARMA S.A.S.	FR
LESCOL L.P. 80 mg, comprimé pelliculé à libération prolongée	DE/H/0116/003	34009 567 017 1 1	NOVARTIS PHARMA S.A.S.	FR
Lescol® MR 80 mg Filmtabletten	DE/H/0116/003	1-23741	NOVARTIS PHARMA GMBH	AT
Lescol® XL 80 mg prolonged-release tablets	DE/H/0116/003	PL 23860/0015	NOVARTIS IRELAND LIMITED	XI
Lescol 80 mg compresse a rilascio prolungato	DE/H/0116/003	029163526	NOVARTIS FARMA S.P.A.	IT
Lescol 80 mg compresse a rilascio prolungato	DE/H/0116/003	029163538	NOVARTIS FARMA S.P.A.	IT
Lescol 80 mg compresse a rilascio prolungato	DE/H/0116/003	029163540	NOVARTIS FARMA S.P.A.	IT
Lescol 80 mg compresse a rilascio prolungato	DE/H/0116/003	029163553	NOVARTIS FARMA S.P.A.	IT
Lescol 80 mg compresse a rilascio	DE/H/0116/003	029163565	NOVARTIS FARMA S.P.A.	IT

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
prolungato				
Lescol 80 mg compresse a rilascio prolungato	DE/H/0116/003	029163577	NOVARTIS FARMA S.P.A.	IT
Lescol 80 mg compresse a rilascio prolungato	DE/H/0116/003	029163589	NOVARTIS FARMA S.P.A.	IT
Lescol 80 mg compresse a rilascio prolungato	DE/H/0116/003	029163591	NOVARTIS FARMA S.P.A.	IT
Lescol 80 mg compresse a rilascio prolungato	DE/H/0116/003	029163603	NOVARTIS FARMA S.P.A.	IT
Lescol 80 mg compresse a rilascio prolungato	DE/H/0116/003	029163615	NOVARTIS FARMA S.P.A.	IT
Lescol 80 mg compresse a rilascio prolungato	DE/H/0116/003	029163627	NOVARTIS FARMA S.P.A.	IT
Lescol 80 mg compresse a rilascio prolungato	DE/H/0116/003	029163639	NOVARTIS FARMA S.P.A.	IT
Lescol 80 mg compresse a rilascio prolungato	DE/H/0116/003	029163641	NOVARTIS FARMA S.P.A.	IT
Lescol 80 mg compresse a rilascio prolungato	DE/H/0116/003	029163666	NOVARTIS FARMA S.P.A.	IT
Lescol 80 mg compresse a rilascio prolungato	DE/H/0116/003	029163678	NOVARTIS FARMA S.P.A.	IT
Lescol 80 mg compresse a rilascio prolungato	DE/H/0116/003	029163680	NOVARTIS FARMA S.P.A.	IT
Lescol 80 mg compresse a rilascio prolungato	DE/H/0116/003	029163692	NOVARTIS FARMA S.P.A.	IT
Lescol 80 mg compresse a rilascio prolungato	DE/H/0116/003	029163704	NOVARTIS FARMA S.P.A.	IT
Lescol 80 mg compresse a rilascio	DE/H/0116/003	029163716	NOVARTIS FARMA S.P.A.	IT

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
prolungato				
Lescol 80 mg compresse a rilascio prolungato	DE/H/0116/003	029163728	NOVARTIS FARMA S.P.A.	IT
Lescol DEPOT 80 mg depottabletter	DE/H/0116/003	99-8131	NOVARTIS NORGE AS	NO
Lescol Exel 80 mg, comprimé à libération prolongée	DE/H/0116/003	BE230386	NOVARTIS PHARMA N.V.	BE
Lescol Exel 80 mg, comprimé à libération prolongée	DE/H/0116/003	BE230395	NOVARTIS PHARMA N.V.	BE
Lescol Exel 80 mg tabletten met verlengde afgifte	DE/H/0116/003	BE230386	NOVARTIS PHARMA N.V.	BE
Lescol Exel 80 mg tabletten met verlengde afgifte	DE/H/0116/003	BE230395	NOVARTIS PHARMA N.V.	BE
Lescol XL 80 mg prolonged-release tablets	DE/H/0116/003	MA1249/02403	NOVARTIS IRELAND LIMITED	MT
Lescol XL 80 mg prolonged-release tablets	DE/H/0116/003	PA0896/016/003	NOVARTIS IRELAND LIMITED	IE
Lescol XL 80 mg pailginto atpalaidavimo tabletės	DE/H/0116/003	LT/1/97/2258/002	SIA NOVARTIS BALTICS	LT
Lescol XL 80 mg pailginto atpalaidavimo tabletės	DE/H/0116/003	LT/1/97/2258/003	SIA NOVARTIS BALTICS	LT
Lescol XL 80 mg pailginto atpalaidavimo tabletės	DE/H/0116/003	LT/1/97/2258/004	SIA NOVARTIS BALTICS	LT
Lescol XL 80 mg pailginto atpalaidavimo tabletės	DE/H/0116/003	LT/1/97/2258/005	SIA NOVARTIS BALTICS	LT
Lescol XL 80 mg pailginto atpalaidavimo tabletės	DE/H/0116/003	LT/1/97/2258/006	SIA NOVARTIS BALTICS	LT
Lescol XL 80 mg pailginto atpalaidavimo tabletės	DE/H/0116/003	LT/1/97/2258/007	SIA NOVARTIS BALTICS	LT

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
Lescol XL 80 mg pailginto atpalaidavimo tabletės	DE/H/0116/003	LT/1/97/2258/008	SIA NOVARTIS BALTICS	LT
Lescol XL 80 mg pailginto atpalaidavimo tabletės	DE/H/0116/003	LT/1/97/2258/009	SIA NOVARTIS BALTICS	LT
Lescol XL 80 mg pailginto atpalaidavimo tabletės	DE/H/0116/003	LT/1/97/2258/010	SIA NOVARTIS BALTICS	LT
Lescol XL 80 mg pailginto atpalaidavimo tabletės	DE/H/0116/003	LT/1/97/2258/011	SIA NOVARTIS BALTICS	LT
Lescol XL 80 mg pailginto atpalaidavimo tabletės	DE/H/0116/003	LT/1/97/2258/012	SIA NOVARTIS BALTICS	LT
Lescol XL 80 mg pailginto atpalaidavimo tabletės	DE/H/0116/003	LT/1/97/2258/013	SIA NOVARTIS BALTICS	LT
Lescol XL 80 mg pailginto atpalaidavimo tabletės	DE/H/0116/003	LT/1/97/2258/014	SIA NOVARTIS BALTICS	LT
Lescol XL 80 mg pailginto atpalaidavimo tabletės	DE/H/0116/003	LT/1/97/2258/015	SIA NOVARTIS BALTICS	LT
Lescol XL 80 mg pailginto atpalaidavimo tabletės	DE/H/0116/003	LT/1/97/2258/016	SIA NOVARTIS BALTICS	LT
Lescol XL 80 mg pailginto atpalaidavimo tabletės	DE/H/0116/003	LT/1/97/2258/017	SIA NOVARTIS BALTICS	LT
Lescol XL 80 mg pailginto atpalaidavimo tabletės	DE/H/0116/003	LT/1/97/2258/018	SIA NOVARTIS BALTICS	LT
Lescol XL 80 mg pailginto atpalaidavimo tabletės	DE/H/0116/003	LT/1/97/2258/019	SIA NOVARTIS BALTICS	LT
Nandovar XL 80mg prolonged release tablets.	DE/H/0116/003	PL 23860/0015	NOVARTIS IRELAND LIMITED	XI
Лескол XL 80 mg таблетки с удължено освобождаване	DE/H/0116/003	20010439	NOVARTIS PHARMA GMBH	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
Lescol XL 80 mg pailginto atpalaidavimo tabletės	DE/H/0116/003	LT/1/97/2258/001	SIA NOVARTIS BALTICS	LT
Lescol XL, 80 mg toimeainet prolongeeritult vabastavad tabletid	DE/H/0116/003	334100	SIA NOVARTIS BALTICS	EE
Lescol XL 80 mg tablete s produljenim oslobađanjem	DE/H/0116/003	HR-H-337032317-01	NOVARTIS HRVATSKA D.O.O.	HR
Liposit Prolib 80 mg comprimidos de liberación prolongada	ES/H/0158/003	65.235	NOVARTIS FARMACÉUTICA S.A.	ES
FLUVASTATINE SANDOZ LP 80 mg, comprimé pelliculé à libération prolongée	HU/H/0825/001	34009 386 715 9 9	SANDOZ	FR
FLUVASTATINE SANDOZ LP 80 mg, comprimé pelliculé à libération prolongée	HU/H/0825/001	34009 386 716 5 0	SANDOZ	FR
FLUVASTATINE SANDOZ LP 80 mg, comprimé pelliculé à libération prolongée	HU/H/0825/001	34009 386 717 1 1	SANDOZ	FR
FLUVASTATINE SANDOZ LP 80 mg, comprimé pelliculé à libération prolongée	HU/H/0825/001	34009 386 718 8 9	SANDOZ	FR
FLUVASTATINE SANDOZ LP 80 mg, comprimé pelliculé à libération prolongée	HU/H/0825/001	34009 386 719 4 0	SANDOZ	FR
FLUVASTATINE SANDOZ LP 80 mg, comprimé pelliculé à libération prolongée	HU/H/0825/001	34009 386 720 2 2	SANDOZ	FR
FLUVASTATINE SANDOZ LP 80 mg, comprimé pelliculé à libération prolongée	HU/H/0825/001	34009 387 972 5 1	SANDOZ	FR

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
FLUVASTATINE SANDOZ LP 80 mg, comprimé pelliculé à libération prolongée	HU/H/0825/001	34009 387 973 1 2	SANDOZ	FR
FLUVASTATINE SANDOZ LP 80 mg, comprimé pelliculé à libération prolongée	HU/H/0825/001	34009 387 975 4 1	SANDOZ	FR
FLUVASTATINE SANDOZ LP 80 mg, comprimé pelliculé à libération prolongée	HU/H/0825/001	34009 389 672 9 6	SANDOZ	FR
FLUVASTATINE SANDOZ LP 80 mg, comprimé pelliculé à libération prolongée	HU/H/0825/001	34009 389 673 5 7	SANDOZ	FR
FLUVASTATINE SANDOZ LP 80 mg, comprimé pelliculé à libération prolongée	HU/H/0825/001	34009 573 100 4 2	SANDOZ	FR
FLUVASTATINE SANDOZ LP 80 mg, comprimé pelliculé à libération prolongée	HU/H/0825/001	34009 573 101 0 3	SANDOZ	FR
FLUVASTATINE SANDOZ LP 80 mg, comprimé pelliculé à libération prolongée	HU/H/0825/001	34009 573 102 7 1	SANDOZ	FR
Fluvastatin-ratiopharm® 40 mg Hartkapseln	DE/H/5738/002	67848.00.00	RATIOPHARM GMBH	DE
Fluvastatin-ratiopharm® 20 mg Hartkapseln	DE/H/5738/001	67847.00.00	RATIOPHARM GMBH	DE
Fluvastatin PUREN 80 mg Retardtabletten	PT/H/2038/001	69296.00.00	PUREN PHARMA GMBH & CO. KG	DE
Fluvastatin Double-E Pharma 80 mg Retardtabletten	DE/H/5540/001	69849.00.00	HOLSTEN PHARMA GMBH	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
Fluvastatina EG 80 mg compresse a rilascio prolungato	IT/H/0681/001	038582019	EG S.P.A.	IT
Fluvastatina EG 80 mg compresse a rilascio prolungato	IT/H/0681/001	038582033	EG S.P.A.	IT
Fluvastatina EG 80 mg compresse a rilascio prolungato	IT/H/0681/001	038582021	EG S.P.A.	IT
Fluvastatina EG 80 mg compresse a rilascio prolungato	IT/H/0681/001	038582058	EG S.P.A.	IT
Fluvastatina EG 80 mg compresse a rilascio prolungato	IT/H/0681/001	038582045	EG S.P.A.	IT
Fluvastatina EG 80 mg compresse a rilascio prolungato	IT/H/0681/001	038582060	EG S.P.A.	IT
Fluvastatina EG 80 mg compresse a rilascio prolungato	IT/H/0681/001	038582072	EG S.P.A.	IT
Fluvastatina Anova 20 mg cápsulas	PT/H/1664/001	5280417	LABORATÓRIOS ANOVA - PRODUTOS FARMACÊUTICOS, LDA	PT
Fluvastatina Anova 20 mg cápsulas	PT/H/1664/001	5280425	LABORATÓRIOS ANOVA - PRODUTOS FARMACÊUTICOS, LDA	PT
Fluvastatina Anova 20 mg cápsulas	PT/H/1664/001	5280433	LABORATÓRIOS ANOVA - PRODUTOS FARMACÊUTICOS, LDA	PT
Fluvastatina Anova 40 mg cápsulas	PT/H/1664/002	5280441	LABORATÓRIOS ANOVA - PRODUTOS FARMACÊUTICOS, LDA	PT
Fluvastatina Anova 40 mg cápsulas	PT/H/1664/002	5280458	LABORATÓRIOS ANOVA - PRODUTOS FARMACÊUTICOS, LDA	PT
Fluvastatina Anova 40 mg cápsulas	PT/H/1664/002	5280466	LABORATÓRIOS ANOVA - PRODUTOS FARMACÊUTICOS, LDA	PT
Vaditon prolib 80 mg comprimidos de liberación prolongada	ES/H/0159/003	64.782	LABORATORIOS VISFARM, S.L.	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
Fluvastatine 40 mg PCH, capsules	NL/H/4738/002	RVG 34893	PHARMACHEMIE B.V	NL
Fluvastatin 20 mg Capsules	NL/H/4738/001	PL 00289/0997	TEVA UK LIMITED	XI
Fluvastatin 40 mg Capsules	NL/H/4738/002	PL 00289/0998	TEVA UK LIMITED	XI
Fluvastatine 20 mg PCH, capsules	NL/H/4738/001	RVG 34892	PHARMACHEMIE B.V	NL
Fluvastatina Teva 20 mg cápsulas duras EFG	NL/H/4738/001	69981	TEVA PHARMA S.L.U.,	ES
Fluvastatina Teva 40 mg cápsulas duras EFG	NL/H/4738/002	69982	TEVA PHARMA S.L.U.,	ES
Fluvastatin Holsten 20 mg Hartkapseln	not available	88887.00.00	HOLSTEN PHARMA GMBH	DE
Fluvastatin Holsten 40 mg Hartkapseln	not available	88888.00.00	HOLSTEN PHARMA GMBH	DE