



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

30 May 2018
EMA/443956/2018
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: fluvastatin

Procedure no.: PSUSA-00001457-201708

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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
FLUVASTATINE TEVA L.P. 80 mg, comprimé pelliculé à libération prolongée	not available	NL34588	TEVA SANTÉ	FR
FRACTAL 20 mg, gélule	not available	339 579-5	SAS PIERRE FABRE MEDICAMENT	FR
FRACTAL 40 mg, gélule	not available	339 580-3	SAS PIERRE FABRE MEDICAMENT	FR
FRACTAL L.P. 80 mg, comprimé pelliculé à libération prolongée	not available	356 195-7	SAS PIERRE FABRE MEDICAMENT	FR
FRACTAL 20 mg, gélule	not available	342 145.2	SAS PIERRE FABRE MEDICAMENT	FR
FRACTAL 20 mg, gélule	not available	371 976-6	SAS PIERRE FABRE MEDICAMENT	FR
FRACTAL 20 mg, gélule	not available	372 381-6	SAS PIERRE FABRE MEDICAMENT	FR
FRACTAL 20 mg, gélule	not available	372 382-2	SAS PIERRE FABRE MEDICAMENT	FR
FRACTAL 40 mg, gélule	not available	342 146.9	SAS PIERRE FABRE MEDICAMENT	FR
FRACTAL 40 mg, gélule	not available	371 977-2	SAS PIERRE FABRE MEDICAMENT	FR
FRACTAL 40 mg, gélule	not available	372 383-9	SAS PIERRE FABRE MEDICAMENT	FR
FRACTAL 40 mg, gélule	not available	372 384-5	SAS PIERRE FABRE MEDICAMENT	FR
FRACTAL L.P. 80 mg, comprimé pelliculé à libération prolongée	not available	371 978-9	SAS PIERRE FABRE MEDICAMENT	FR
FRACTAL L.P. 80 mg, comprimé pelliculé à libération prolongée	not available	372 385-1	SAS PIERRE FABRE MEDICAMENT	FR
FRACTAL L.P. 80 mg, comprimé pelliculé à libération prolongée	not available	372 386-8	SAS PIERRE FABRE MEDICAMENT	FR
FRACTAL L.P. 80 mg, comprimé pelliculé à libération prolongée	not available	567 172-7	SAS PIERRE FABRE MEDICAMENT	FR
Fluvastatin AbZ 80 mg Retardtabletten	UK/H/1182/001	69849.00.00	ABZ-PHARMA GMBH	DE
Cardiol 20, 20 mg, cápsulas	not available	2448785	BIALPORT - PRODUTOS FARMACÉUTICOS, S.A.	PT

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
Cardiol 40, 40 mg, cápsulas	not available	5740485	BIALPORT - PRODUTOS FARMACÊUTICOS, S.A.	PT
CARDIOL XL 80 mg comprimidos de libertação prolongada	not available	3674991	BIALPORT - PRODUTOS FARMACÊUTICOS, S.A.	PT
Cardiol 20, 20 mg, cápsulas	not available	2448884	BIALPORT - PRODUTOS FARMACÊUTICOS, S.A.	PT
Cardiol 40, 40 mg, cápsulas	not available	2474484	BIALPORT - PRODUTOS FARMACÊUTICOS, S.A.	PT
Cardiol 40, 40 mg, cápsulas	not available	2448983	BIALPORT - PRODUTOS FARMACÊUTICOS, S.A.	PT
Cardiol 40, 40 mg, cápsulas	not available	5650080	BIALPORT - PRODUTOS FARMACÊUTICOS, S.A.	PT
CARDIOL XL 80 mg comprimidos de libertação prolongada	not available	3322591	BIALPORT - PRODUTOS FARMACÊUTICOS, S.A.	PT
CARDIOL XL 80 mg comprimidos de libertação prolongada	not available	5649991	BIALPORT - PRODUTOS FARMACÊUTICOS, S.A.	PT
FLUVASTATINE ARROW L.P. 80 mg, comprimé pelliculé à libération prolongée	not available	34586	ARROW GENERIQUES	FR
Fluvastatin Sandoz 40 mg harde capsules	DK/H/1004/002	BE303703	SANDOZ N.V.	BE
Fluvastatin Sandoz 40 mg harde capsules	DK/H/1004/002	BE303712	SANDOZ N.V.	BE
Fluvastatin-ratiopharm® 80 mg Retardtabletten	UK/H/1181/001	69848.00.00	RATIOPHARM GMBH	DE
Fluvastatin-CT 80 mg Retardtabletten	UK/H/1183/001	69850.00.00	ABZ-PHARMA GMBH	DE
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	34009 393 780 7 7	BIOGARAN	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 BIOGARAN LP 80 mg, comprimé pelliculé à libération prolongée	not available	34009 393 783 6 7	BIOGARAN	FR
FLUVASTATINE BIOGARAN LP 80 mg, comprimé pelliculé à libération prolongée	not available	34009 393 789 4 7	BIOGARAN	FR
FLUVASTATINE BIOGARAN LP 80 mg, comprimé pelliculé à libération prolongée	not available	34009 393 792 5 8	BIOGARAN	FR
FLUVASTATINE BIOGARAN LP 80 mg, comprimé pelliculé à libération prolongée	not available	34009 393 788 8 6	BIOGARAN	FR
FLUVASTATINE BIOGARAN LP 80 mg, comprimé pelliculé à libération prolongée	not available	34009 393 790 2 9	BIOGARAN	FR
FLUVASTATINE BIOGARAN LP 80 mg, comprimé pelliculé à libération prolongée	not available	34009 393 791 9 7	BIOGARAN	FR
FLUVASTATINE BIOGARAN LP 80 mg, comprimé pelliculé à libération prolongée	not available	34009 393 787 1 8	BIOGARAN	FR
FLUVASTATINE BIOGARAN LP 80 mg, comprimé pelliculé à libération prolongée	not available	34009 393 786 5 7	BIOGARAN	FR
FLUVASTATINE BIOGARAN LP 80 mg, comprimé pelliculé à libération prolongée	not available	34009 393 785 9 6	BIOGARAN	FR
Fluvastatine 40 mg PCH, capsules	UK/H/0977/002	RVG 34893	PHARMACHEMIE B.V	NL
Fluvastatin-ratiopharm [®] 40 mg Hartkapseln	UK/H/0977/002	67848.00.00	RATIOPHARM GMBH	DE
Fluvastatina Teva 40 mg Cápsulas	UK/H/0977/002	5127832	TEVA PHARMA – PRODUTOS FARMACÊUTICOS LDA	PT
Fluvastatina Teva 20 mg Cápsulas	UK/H/0977/001	5127816	TEVA PHARMA – PRODUTOS FARMACÊUTICOS LDA	PT
Fluvastatina Teva 40 mg Cápsulas	UK/H/0977/002	5127824	TEVA PHARMA – PRODUTOS FARMACÊUTICOS LDA	PT

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Fluvastatina Teva 20 mg Cápsulas	UK/H/0977/001	5127774	TEVA PHARMA – PRODUTOS FARMACÊUTICOS LDA	PT
Fluvastatin-ratiopharm [®] 20 mg Hartkapseln	UK/H/0977/001	67847.00.00	RATIOPHARM GMBH	DE
FLUVASTATINE TEVA 40 mg, gélule	UK/H/0977/002	NL33745	TEVA SANTÉ	FR
FLUVASTATINE TEVA 20 mg, gélule	UK/H/0977/001	NL33744	TEVA SANTÉ	FR
Fluvastatin 20 mg Capsules	UK/H/0977/001	PL 00289/0997	TEVA UK LIMITED	UK
Fluvastatin 40 mg Capsules	UK/H/0977/002	PL 00289/0998	TEVA UK LIMITED	UK
Fluvastatina Teva 40 mg Cápsulas	UK/H/0977/002	5127840	TEVA PHARMA – PRODUTOS FARMACÊUTICOS LDA	PT
Fluvastatina Teva 20 mg Cápsulas	UK/H/0977/001	5127808	TEVA PHARMA – PRODUTOS FARMACÊUTICOS LDA	PT
Fluvastatine 20 mg PCH, capsules	UK/H/0977/001	RVG 34892	PHARMACHEMIE B.V	NL
Fluvastatina Teva 20 mg cápsulas duras EFG	UK/H/0977/001	69981	TEVA PHARMA S.L.U	ES
Fluvastatina Teva 40 mg cápsulas duras EFG	UK/H/0977/002	69982	TEVA PHARMA S.L.U	ES
FLUVASTATINE SANDOZ LP 80 mg, comprimé pelliculé à libération prolongée	DK/H/1097/001	34009 386 715 9 9	SANDOZ	FR
FLUVASTATINE SANDOZ LP 80 mg, comprimé pelliculé à libération prolongée	DK/H/1097/001	34009 386 716 5 0	SANDOZ	FR
FLUVASTATINE SANDOZ LP 80 mg, comprimé pelliculé à libération prolongée	DK/H/1097/001	34009 386 717 1 1	SANDOZ	FR
FLUVASTATINE SANDOZ LP 80 mg, comprimé pelliculé à libération prolongée	DK/H/1097/001	34009 386 718 8 9	SANDOZ	FR
FLUVASTATINE SANDOZ LP 80 mg, comprimé pelliculé à libération prolongée	DK/H/1097/001	34009 386 719 4 0	SANDOZ	FR
FLUVASTATINE SANDOZ LP 80 mg, comprimé pelliculé à libération prolongée	DK/H/1097/001	34009 386 720 2 2	SANDOZ	FR

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FLUVASTATINE SANDOZ LP 80 mg, comprimé pelliculé à libération prolongée	DK/H/1097/001	34009 387 972 5 1	SANDOZ	FR
FLUVASTATINE SANDOZ LP 80 mg, comprimé pelliculé à libération prolongée	DK/H/1097/001	34009 387 973 1 2	SANDOZ	FR
FLUVASTATINE SANDOZ LP 80 mg, comprimé pelliculé à libération prolongée	DK/H/1097/001	34009 387 975 4 1	SANDOZ	FR
FLUVASTATINE SANDOZ LP 80 mg, comprimé pelliculé à libération prolongée	DK/H/1097/001	34009 389 672 9 6	SANDOZ	FR
FLUVASTATINE SANDOZ LP 80 mg, comprimé pelliculé à libération prolongée	DK/H/1097/001	34009 389 673 5 7	SANDOZ	FR
FLUVASTATINE SANDOZ LP 80 mg, comprimé pelliculé à libération prolongée	DK/H/1097/001	34009 573 100 4 2	SANDOZ	FR
FLUVASTATINE SANDOZ LP 80 mg, comprimé pelliculé à libération prolongée	DK/H/1097/001	34009 573 101 0 3	SANDOZ	FR
FLUVASTATINE SANDOZ LP 80 mg, comprimé pelliculé à libération prolongée	DK/H/1097/001	34009 573 102 7 1	SANDOZ	FR
FLUVASTATINE SANDOZ RETARD 80 MG, TABLETTEN MET VERLENGDE AFGIFTE	DK/H/1224/001	RVG 35264	SANDOZ B.V.	NL
Fluvastatin Sandoz 80 mg depottabletti	DK/H/1097/001	22944	SANDOZ A/S	FI
LESCOL 20 MG, GÉLULES	DE/H/0116/001	2004108427	NOVARTIS PHARMA N.V.	LU
LESCOL 40 MG, GÉLULES	DE/H/0116/002	2004108428	NOVARTIS PHARMA N.V.	LU
LESCOL EXEL 80 MG, COMPRIMÉ À LIBÉRATION PROLONGÉE	DE/H/0116/003	2004108429	NOVARTIS PHARMA N.V.	LU
Lescol 20 mg Hartkapseln	DE/H/0116/001	2004108427	NOVARTIS PHARMA N.V.	LU
Lescol 40 mg Hartkapseln	DE/H/0116/002	2004108428	NOVARTIS PHARMA N.V.	LU
Lescol 40 mg Hartkapseln	DE/H/0116/002	BE174605	NOVARTIS PHARMA N.V.	BE

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Lescol 20 mg Hartkapseln	DE/H/0116/001	BE174614	NOVARTIS PHARMA N.V.	BE
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 40 mg tvrde kapsule	DE/H/0116/002	HR-H-724933892-02	NOVARTIS HRVATSKA D.O.O.	HR
Lescol 40 mg tvrde kapsule	DE/H/0116/002	HR-H-724933892-03	NOVARTIS HRVATSKA D.O.O.	HR
Lescol 40 mg tvrde kapsule	DE/H/0116/002	HR-H-724933892-04	NOVARTIS HRVATSKA D.O.O.	HR
Lescol 40 mg tvrde kapsule	DE/H/0116/002	HR-H-724933892-05	NOVARTIS HRVATSKA D.O.O.	HR
Lescol 40 mg tvrde kapsule	DE/H/0116/002	HR-H-724933892-06	NOVARTIS HRVATSKA D.O.O.	HR
Lescol 40 mg tvrde kapsule	DE/H/0116/002	HR-H-724933892-07	NOVARTIS HRVATSKA D.O.O.	HR
Lescol 40 mg tvrde kapsule	DE/H/0116/002	HR-H-724933892-08	NOVARTIS HRVATSKA D.O.O.	HR
Lescol 40 mg tvrde kapsule	DE/H/0116/002	HR-H-724933892-09	NOVARTIS HRVATSKA D.O.O.	HR
Lescol 40 mg tvrde kapsule	DE/H/0116/002	HR-H-724933892-10	NOVARTIS HRVATSKA D.O.O.	HR
Lescol 40 mg tvrde kapsule	DE/H/0116/002	HR-H-724933892-11	NOVARTIS HRVATSKA D.O.O.	HR
Lescol 40 mg tvrde kapsule	DE/H/0116/002	HR-H-724933892-12	NOVARTIS HRVATSKA D.O.O.	HR
Lescol 40 mg tvrde kapsule	DE/H/0116/002	HR-H-724933892-13	NOVARTIS HRVATSKA D.O.O.	HR
Lescol 40 mg tvrde kapsule	DE/H/0116/002	HR-H-724933892-14	NOVARTIS HRVATSKA D.O.O.	HR
Lescol 40 mg tvrde kapsule	DE/H/0116/002	HR-H-724933892-15	NOVARTIS HRVATSKA D.O.O.	HR
Lescol 40 mg tvrde kapsule	DE/H/0116/002	HR-H-724933892-16	NOVARTIS HRVATSKA D.O.O.	HR
Lescol 40 mg tvrde kapsule	DE/H/0116/002	HR-H-724933892-17	NOVARTIS HRVATSKA D.O.O.	HR

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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 oslobađanjem	DE/H/0116/003	HR-H-337032317-04	NOVARTIS HRVATSKA D.O.O.	HR
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
Lescol XL 80 mg tablete s produljenim oslobađanjem	DE/H/0116/003	HR-H-337032317-19	NOVARTIS HRVATSKA D.O.O.	HR

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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 produljenim oslobađanjem	DE/H/0116/003	HR-H-337032317-24	NOVARTIS HRVATSKA D.O.O.	HR
Lescol XL 80 mg tablete s podaljsanim sproscanjem	DE/H/0116/003	H/94/00899/017	NOVARTIS PHARMA GMBH	SI
Lescol 40 mg trde kapsule	DE/H/0116/002	H/94/00899/001	NOVARTIS PHARMA GMBH	SI
Lescol XL 80 mg tablete s podaljsanim sproscanjem	DE/H/0116/003	H/94/00899/039	NOVARTIS PHARMA GMBH	SI
Lescol XL 80 mg tablete s podaljsanim sproscanjem	DE/H/0116/003	H/94/00899/040	NOVARTIS PHARMA GMBH	SI
Lescol XL 80 mg tablete s podaljsanim sproscanjem	DE/H/0116/003	H/94/00899/041	NOVARTIS PHARMA GMBH	SI
Lescol XL 80 mg tablete s podaljsanim sproscanjem	DE/H/0116/003	H/94/00899/042	NOVARTIS PHARMA GMBH	SI
Lescol XL 80 mg tablete s podaljsanim sproscanjem	DE/H/0116/003	H/94/00899/029	NOVARTIS PHARMA GMBH	SI
Lescol XL 80 mg tablete s podaljsanim sproscanjem	DE/H/0116/003	H/94/00899/030	NOVARTIS PHARMA GMBH	SI
Lescol XL 80 mg tablete s podaljsanim sproscanjem	DE/H/0116/003	H/94/00899/031	NOVARTIS PHARMA GMBH	SI
Lescol XL 80 mg tablete s podaljsanim sproscanjem	DE/H/0116/003	H/94/00899/032	NOVARTIS PHARMA GMBH	SI
Lescol XL 80 mg tablete s podaljsanim sproscanjem	DE/H/0116/003	H/94/00899/033	NOVARTIS PHARMA GMBH	SI
Lescol XL 80 mg tablete s podaljsanim sproscanjem	DE/H/0116/003	H/94/00899/034	NOVARTIS PHARMA GMBH	SI
Lescol XL 80 mg tablete s podaljsanim sproscanjem	DE/H/0116/003	H/94/00899/035	NOVARTIS PHARMA GMBH	SI
Lescol XL 80 mg tablete s	DE/H/0116/003	H/94/00899/036	NOVARTIS PHARMA GMBH	SI

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podaljsanim sproscanjem				
Lescol XL 80 mg tablete s podaljsanim sproscanjem	DE/H/0116/003	H/94/00899/037	NOVARTIS PHARMA GMBH	SI
Lescol XL 80 mg tablete s podaljsanim sproscanjem	DE/H/0116/003	H/94/00899/038	NOVARTIS PHARMA GMBH	SI
Lescol XL 80 mg tablete s podaljsanim sproscanjem	DE/H/0116/003	H/94/00899/019	NOVARTIS PHARMA GMBH	SI
Lescol XL 80 mg tablete s podaljsanim sproscanjem	DE/H/0116/003	H/94/00899/020	NOVARTIS PHARMA GMBH	SI
Lescol XL 80 mg tablete s podaljsanim sproscanjem	DE/H/0116/003	H/94/00899/021	NOVARTIS PHARMA GMBH	SI
Lescol XL 80 mg tablete s podaljsanim sproscanjem	DE/H/0116/003	H/94/00899/022	NOVARTIS PHARMA GMBH	SI
Lescol XL 80 mg tablete s podaljsanim sproscanjem	DE/H/0116/003	H/94/00899/023	NOVARTIS PHARMA GMBH	SI
Lescol XL 80 mg tablete s podaljsanim sproscanjem	DE/H/0116/003	H/94/00899/024	NOVARTIS PHARMA GMBH	SI
Lescol XL 80 mg tablete s podaljsanim sproscanjem	DE/H/0116/003	H/94/00899/025	NOVARTIS PHARMA GMBH	SI
Lescol XL 80 mg tablete s podaljsanim sproscanjem	DE/H/0116/003	H/94/00899/026	NOVARTIS PHARMA GMBH	SI
Lescol XL 80 mg tablete s podaljsanim sproscanjem	DE/H/0116/003	H/94/00899/027	NOVARTIS PHARMA GMBH	SI
Lescol XL 80 mg tablete s podaljsanim sproscanjem	DE/H/0116/003	H/94/00899/028	NOVARTIS PHARMA GMBH	SI
Lescol 40 mg trde kapsule	DE/H/0116/002	H/94/00899/008	NOVARTIS PHARMA GMBH	SI
Lescol 40 mg trde kapsule	DE/H/0116/002	H/94/00899/009	NOVARTIS PHARMA GMBH	SI
Lescol 40 mg trde kapsule	DE/H/0116/002	H/94/00899/010	NOVARTIS PHARMA GMBH	SI
Lescol 40 mg trde kapsule	DE/H/0116/002	H/94/00899/011	NOVARTIS PHARMA GMBH	SI
Lescol 40 mg trde kapsule	DE/H/0116/002	H/94/00899/012	NOVARTIS PHARMA GMBH	SI
Lescol 40 mg trde kapsule	DE/H/0116/002	H/94/00899/013	NOVARTIS PHARMA GMBH	SI
Lescol 40 mg trde kapsule	DE/H/0116/002	H/94/00899/014	NOVARTIS PHARMA GMBH	SI
Lescol 40 mg trde kapsule	DE/H/0116/002	H/94/00899/015	NOVARTIS PHARMA GMBH	SI
Lescol 40 mg trde kapsule	DE/H/0116/002	H/94/00899/016	NOVARTIS PHARMA GMBH	SI
Lescol XL 80 mg tablete s	DE/H/0116/003	H/94/00899/018	NOVARTIS PHARMA GMBH	SI

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podaljsanim sproscanjem				
Lescol 40 mg trde kapsule	DE/H/0116/002	H/94/00899/002	NOVARTIS PHARMA GMBH	SI
Lescol 40 mg trde kapsule	DE/H/0116/002	H/94/00899/003	NOVARTIS PHARMA GMBH	SI
Lescol 40 mg trde kapsule	DE/H/0116/002	H/94/00899/004	NOVARTIS PHARMA GMBH	SI
Lescol 40 mg trde kapsule	DE/H/0116/002	H/94/00899/005	NOVARTIS PHARMA GMBH	SI
Lescol 40 mg trde kapsule	DE/H/0116/002	H/94/00899/006	NOVARTIS PHARMA GMBH	SI
Lescol 40 mg trde kapsule	DE/H/0116/002	H/94/00899/007	NOVARTIS PHARMA GMBH	SI
Lescol 20 mg capsules, hard	DE/H/0116/001	BE459893	NOVARTIS PHARMA N.V.	BE
Lescol 20 mg Hartkapseln	DE/H/0116/001	BE459893	NOVARTIS PHARMA N.V.	BE
Lescol 20 mg, gélules	DE/H/0116/001	BE459893	NOVARTIS PHARMA N.V.	BE
Lescol 40 mg capsules, hard	DE/H/0116/002	BE459902	NOVARTIS PHARMA N.V.	BE
Lescol 40 mg Hartkapseln	DE/H/0116/002	BE459902	NOVARTIS PHARMA N.V.	BE
Lescol 40 mg, gélules	DE/H/0116/002	BE459902	NOVARTIS PHARMA N.V.	BE
LESCOL XL 80 MG ΔΙΣΚΙΑ ΠΑΡΑΤΕΤΑΜ'ΕΝΗΣ ΑΠΟΔ'ΕΣΜΕΥΣΗΣ	DE/H/0116/003	19110	NOVARTIS PHARMACEUTICALS UK LIMITED	CY
LESCOL 20 MG ΚΑΨΟΥΛΕς, ΣΚΛΗΡΕς	DE/H/0116/001	18391	NOVARTIS PHARMACEUTICALS UK LIMITED	CY
LESCOL 40 MG ΚΑΨΟΥΛΕς, ΣΚΛΗΡΕς	DE/H/0116/002	18392	NOVARTIS PHARMACEUTICALS UK LIMITED	CY
LESCOL 20 MG ΚΑΨΑΚΙΑ, ΣΚΛΗΡΑ	DE/H/0116/001	224590101	NOVARTIS (HELLAS) S.A.C.I.	GR
LESCOL 40 MG ΚΑΨΑΚΙΑ, ΣΚΛΗΡΑ	DE/H/0116/002	224590201	NOVARTIS (HELLAS) S.A.C.I.	GR
Lescol 20 mg cápsulas	DE/H/0116/001	2381788	NOVARTIS FARMA - PRODUTOS FARMACÉUTICOS S.A.	PT
Lescol 20 mg cápsulas	DE/H/0116/001	2381887	NOVARTIS FARMA - PRODUTOS FARMACÉUTICOS S.A.	PT
LESCOL 20 mg capsule rigide	DE/H/0116/001	029163019	NOVARTIS EUROPHARM LIMITED	IT
Lescol 40 mg cápsulas	DE/H/0116/002	2381986	NOVARTIS FARMA -	PT

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
			PRODUTOS FARMACÊUTICOS S.A.	
Lescol 40 mg cápsulas	DE/H/0116/002	2382083	NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A.	PT
Lescol 40 mg cápsulas	DE/H/0116/002	5496385	NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A.	PT
LESCOL 40 mg capsule rigide	DE/H/0116/002	029163021	NOVARTIS EUROPHARM LIMITED	IT
LESCOL 40 mg capsule rigide	DE/H/0116/002	029163045	NOVARTIS EUROPHARM LIMITED	IT
Lescol 20 mg cápsulas duras	DE/H/0116/001	60.821	NOVARTIS FARMACÊUTICA S.A.	ES
Lescol 20 mg kapseli,kova	DE/H/0116/001	12149	NOVARTIS FINLAND OY	FI
Lescol 20 mg kapslar, hårda	DE/H/0116/001	12149	NOVARTIS FINLAND OY	FI
Lescol 40 mg cápsulas duras	DE/H/0116/002	60.822	NOVARTIS FARMACÊUTICA S.A.	ES
Lescol 40 mg kapseli, kova	DE/H/0116/002	12150	NOVARTIS FINLAND OY	FI
Lescol 40 mg kapslar, hårda	DE/H/0116/002	12150	NOVARTIS FINLAND OY	FI
Liposit Prolib 80 mg comprimidos de liberación prolongada	ES/H/0158/003	65.235	NOVARTIS FARMACÊUTICA S.A.	ES
Lescol	DE/H/0116/001	15276	NOVARTIS HEALTHCARE A/S	DK
Lescol	DE/H/0116/002	15277	NOVARTIS HEALTHCARE A/S	DK
CRANOC® 20 mg Hartkapseln	DE/H/3066/001	31713.00.00	NOVARTIS PHARMA GMBH	DE
CRANOC® 40 mg Hartkapseln	DE/H/3066/002	31713.01.00	NOVARTIS PHARMA GMBH	DE
CRANOC® 80 mg Retardtabletten	DE/H/3066/003	48880.00.00	NOVARTIS PHARMA GMBH	DE
Lescol 20 mg capsule	DE/H/0116/001	1264/2008/01	NOVARTIS PHARMA GMBH	RO
Lescol 20 mg capsule	DE/H/0116/001	1264/2008/02	NOVARTIS PHARMA GMBH	RO
Lescol 20 mg capsule	DE/H/0116/001	1264/2008/03	NOVARTIS PHARMA GMBH	RO
Lescol 20 mg capsule	DE/H/0116/001	1264/2008/04	NOVARTIS PHARMA GMBH	RO
Lescol 20 mg capsule	DE/H/0116/001	1264/2008/05	NOVARTIS PHARMA GMBH	RO
Lescol 20 mg capsule	DE/H/0116/001	1264/2008/06	NOVARTIS PHARMA GMBH	RO
Lescol 20 mg capsule	DE/H/0116/001	1264/2008/07	NOVARTIS PHARMA GMBH	RO
Lescol 20 mg capsule	DE/H/0116/001	1264/2008/08	NOVARTIS PHARMA GMBH	RO

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 20 mg capsule	DE/H/0116/001	1264/2008/09	NOVARTIS PHARMA GMBH	RO
Lescol 20 mg capsule	DE/H/0116/001	1264/2008/10	NOVARTIS PHARMA GMBH	RO
Lescol 20 mg capsule	DE/H/0116/001	1264/2008/11	NOVARTIS PHARMA GMBH	RO
Lescol 20 mg capsule	DE/H/0116/001	1264/2008/12	NOVARTIS PHARMA GMBH	RO
Lescol 20 mg capsule	DE/H/0116/001	1264/2008/13	NOVARTIS PHARMA GMBH	RO
Lescol 20 mg capsule	DE/H/0116/001	1264/2008/14	NOVARTIS PHARMA GMBH	RO
Lescol 20 mg capsule	DE/H/0116/001	1264/2008/15	NOVARTIS PHARMA GMBH	RO
Lescol 20 mg capsule	DE/H/0116/001	1264/2008/16	NOVARTIS PHARMA GMBH	RO
Lescol 20 mg capsule	DE/H/0116/001	1264/2008/17	NOVARTIS PHARMA GMBH	RO
Lescol 20, capsules 20 mg	DE/H/0116/001	RVG 18719	NOVARTIS PHARMA B.V.	NL
Лескол 40 мг твърди капсули / Lescol 40 mg capsules, hard	DE/H/0116/002	20000495	NOVARTIS PHARMA GMBH	BG
Lescol 40 mg kemény kapszula	DE/H/0116/002	OGYI-T-8273/03	NOVARTIS HUNGÁRIA KFT. PHARMA	HU
Lescol 40, capsules 40 mg	DE/H/0116/002	RVG 18720	NOVARTIS PHARMA B.V.	NL
Lescol 40 mg capsule	DE/H/0116/002	1265/2008/01	NOVARTIS PHARMA GMBH	RO
Lescol 40 mg capsule	DE/H/0116/002	1265/2008/02	NOVARTIS PHARMA GMBH	RO
Lescol 40 mg capsule	DE/H/0116/002	1265/2008/03	NOVARTIS PHARMA GMBH	RO
Lescol 40 mg capsule	DE/H/0116/002	1265/2008/04	NOVARTIS PHARMA GMBH	RO
Lescol 40 mg capsule	DE/H/0116/002	1265/2008/05	NOVARTIS PHARMA GMBH	RO
Lescol 40 mg capsule	DE/H/0116/002	1265/2008/06	NOVARTIS PHARMA GMBH	RO
Lescol 40 mg capsule	DE/H/0116/002	1265/2008/07	NOVARTIS PHARMA GMBH	RO
Lescol 40 mg capsule	DE/H/0116/002	1265/2008/08	NOVARTIS PHARMA GMBH	RO
Lescol 40 mg capsule	DE/H/0116/002	1265/2008/09	NOVARTIS PHARMA GMBH	RO
Lescol 40 mg capsule	DE/H/0116/002	1265/2008/10	NOVARTIS PHARMA GMBH	RO
Lescol 40 mg capsule	DE/H/0116/002	1265/2008/11	NOVARTIS PHARMA GMBH	RO
Lescol 40 mg capsule	DE/H/0116/002	1265/2008/12	NOVARTIS PHARMA GMBH	RO
Lescol 40 mg capsule	DE/H/0116/002	1265/2008/13	NOVARTIS PHARMA GMBH	RO
Lescol 40 mg capsule	DE/H/0116/002	1265/2008/14	NOVARTIS PHARMA GMBH	RO
Lescol 40 mg capsule	DE/H/0116/002	1265/2008/15	NOVARTIS PHARMA GMBH	RO
Lescol 40 mg capsule	DE/H/0116/002	1265/2008/16	NOVARTIS PHARMA GMBH	RO
Lescol 40 mg capsule	DE/H/0116/002	1265/2008/17	NOVARTIS PHARMA GMBH	RO
Lescol XL 80 mg retard tabletta	DE/H/0116/003	OGYI-T-8273/01	NOVARTIS HUNGÁRIA KFT. PHARMA	HU
Lescol XL 80 mg retard tabletta	DE/H/0116/003	OGYI-T-8273/02	NOVARTIS HUNGÁRIA KFT.	HU

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
			PHARMA	
Lescol, 20 mg, kapsułki twarde	DE/H/0116/001	R/3603	NOVARTIS POLAND SP. Z O. O.	PL
Lescol, 40 mg, kapsułki twarde	DE/H/0116/002	R/3604	NOVARTIS POLAND SP. Z O. O.	PL
LOCOL® 20 mg Hartkapseln	DE/H/0116/001	29689.00.00	NOVARTIS PHARMA GMBH	DE
LOCOL® 40 mg Hartkapseln	DE/H/0116/002	29689.01.00	NOVARTIS PHARMA GMBH	DE
Lescol 20 mg capsules, hard	DE/H/0116/001	088/01601	NOVARTIS PHARMACEUTICALS UK LIMITED	MT
Lescol 40 mg capsules, hard	DE/H/0116/002	088/01602	NOVARTIS PHARMACEUTICALS UK LIMITED	MT
Lescol 20 mg Kapseln	DE/H/0116/001	1-21011	NOVARTIS PHARMA GMBH	AT
Lescol 20 mg kapslar, hårda	DE/H/0116/001	12670	NOVARTIS SVERIGE AB	SE
LESCOL 20 mg, gélule	DE/H/0116/001	3400933957728	NOVARTIS PHARMA S.A.S.	FR
LESCOL 20 mg, gélule	DE/H/0116/001	3400934098185	NOVARTIS PHARMA S.A.S.	FR
LESCOL 20 mg, gélule	DE/H/0116/001	3400937154499	NOVARTIS PHARMA S.A.S.	FR
LESCOL 20 mg, gélule	DE/H/0116/001	3400937208123	NOVARTIS PHARMA S.A.S.	FR
LESCOL 20 mg, gélule	DE/H/0116/001	3400937208291	NOVARTIS PHARMA S.A.S.	FR
Lescol 20mg capsules, hard	DE/H/0116/001	PA0013/053/001	NOVARTIS PHARMACEUTICALS UK LIMITED	IE
Lescol 40 mg Kapseln	DE/H/0116/002	1-21012	NOVARTIS PHARMA GMBH	AT
Lescol 40 mg kapslar, hårda	DE/H/0116/002	12671	NOVARTIS SVERIGE AB	SE
LESCOL 40 mg, gélule	DE/H/0116/002	3400933957896	NOVARTIS PHARMA S.A.S.	FR
LESCOL 40 mg, gélule	DE/H/0116/002	3400934098246	NOVARTIS PHARMA S.A.S.	FR
LESCOL 40 mg, gélule	DE/H/0116/002	3400937176842	NOVARTIS PHARMA S.A.S.	FR
LESCOL 40 mg, gélule	DE/H/0116/002	3400937207751	NOVARTIS PHARMA S.A.S.	FR
LESCOL 40 mg, gélule	DE/H/0116/002	3400937207812	NOVARTIS PHARMA S.A.S.	FR
Lescol 40 mg capsules, hard	DE/H/0116/002	PA0013/053/002	NOVARTIS PHARMACEUTICALS UK LIMITED	IE
Lescol Depot 80 mg depottabletter	DE/H/0116/003	16250	NOVARTIS SVERIGE AB	SE
Lescol XL 80 mg prolonged-release	DE/H/0116/003	088/01603	NOVARTIS	MT

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
tablets			PHARMACEUTICALS UK LIMITED	
Lescol XL 80 mg prolonged-release tablets	DE/H/0116/003	PA0013/053/003	NOVARTIS PHARMACEUTICALS UK LIMITED	IE
Lescol® 40 mg capsules, hard	DE/H/0116/002	PL 00101/0361	NOVARTIS PHARMACEUTICALS UK LIMITED	UK
Lescol 20 mg tvrdé kapsuly	DE/H/0116/001	31/0137/95-S	NOVARTIS, S.R.O.	SK
Lescol 40 mg tvrdé kapsuly	DE/H/0116/002	31/0679/11-S	NOVARTIS, S.R.O.	SK
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, S.R.O.	SK
LESCOL 80 mg compresse a rilascio prolungato	DE/H/0116/003	029163033	NOVARTIS EUROPHARM LIMITED	IT
LESCOL 80 mg compresse a rilascio prolungato	DE/H/0116/003	029163060	NOVARTIS EUROPHARM LIMITED	IT
LESCOL 80 mg compresse a rilascio prolungato	DE/H/0116/003	029163072	NOVARTIS EUROPHARM LIMITED	IT
LESCOL 80 mg compresse a rilascio prolungato	DE/H/0116/003	029163084	NOVARTIS EUROPHARM LIMITED	IT
Lescol XL 80 mg comprimidos de libertação prolongada	DE/H/0116/003	3264892	NOVARTIS FARMA - PRODUTOS FARMACÉUTICOS S.A.	PT
Lescol XL 80 mg comprimidos de libertação prolongada	DE/H/0116/003	3420197	NOVARTIS FARMA - PRODUTOS FARMACÉUTICOS S.A.	PT
Lescol XL 80 mg comprimidos de libertação prolongada	DE/H/0116/003	5496294	NOVARTIS FARMA - PRODUTOS FARMACÉUTICOS S.A.	PT
LESCOL XL 80 MG ΔΙΣΚΊΑ ΠΑΡΑΤΕΤΑΜΈΝΗ΢ ΑΠΟΔΈΣΜΕΥ΢Η΢	DE/H/0116/003	224590301	NOVARTIS (HELLAS) S.A.C.I.	GR
Lescol Depot	DE/H/0116/003	30526	NOVARTIS HEALTHCARE A/S	DK
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	DE/H/0116/003	64.648	NOVARTIS FARMACÉUTICA	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
liberación prolongada			S.A.	
Lescol XL 80 mg ilgstošās darbības tabletes	DE/H/0116/003	00-0939	NOVARTIS FINLAND OY	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 prelungită	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 eliberare prelungită	DE/H/0116/003	1297/2008/11	NOVARTIS PHARMA GMBH	RO
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

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
eliberare prelungită				
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
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
Lescol XL, 80 mg, tabletki o przedłużonym uwalnianiu	DE/H/0116/003	8872	NOVARTIS POLAND SP. Z O. O.	PL
LOCOL® 80 mg Retardtabletten	DE/H/0116/003	48878.00.00	NOVARTIS PHARMA GMBH	DE
LESCOL LP 80 mg, comprimé pelliculé à libération prolongée	DE/H/0116/003	3400935619341	NOVARTIS PHARMA S.A.S.	FR
LESCOL LP 80 mg, comprimé pelliculé à libération prolongée	DE/H/0116/003	3400937176903	NOVARTIS PHARMA S.A.S.	FR
LESCOL LP 80 mg, comprimé pelliculé à libération prolongée	DE/H/0116/003	3400937207980	NOVARTIS PHARMA S.A.S.	FR
LESCOL LP 80 mg, comprimé pelliculé à libération prolongée	DE/H/0116/003	3400937208062	NOVARTIS PHARMA S.A.S.	FR
LESCOL LP 80 mg, comprimé pelliculé à libération prolongée	DE/H/0116/003	3400956701711	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-	DE/H/0116/003	PL 00101/0587	NOVARTIS	UK

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
release tablets			PHARMACEUTICALS UK LIMITED	
Lescol® 20 mg capsules, hard	DE/H/0116/001	PL 00101/0360	NOVARTIS PHARMACEUTICALS UK LIMITED	UK
LESCOL 20 mg kapsler, harde Novartis	DE/H/0116/001	96-1854	NOVARTIS NORGE AS	NO
LESCOL 40 mg kapsler, harde Novartis	DE/H/0116/002	96-1954	NOVARTIS NORGE AS	NO
LESCOL DEPOT 80 mg depottabletter Novartis	DE/H/0116/003	99-8131	NOVARTIS NORGE AS	NO
Lescol 20 mg capsules, hard	DE/H/0116/001	BE174614	NOVARTIS PHARMA N.V.	BE
Lescol 20 mg, gélules	DE/H/0116/001	BE174614	NOVARTIS PHARMA N.V.	BE
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
Digaril 20 mg cápsulas duras	DE/H/3066/001	62.793	NOVARTIS FARMACÉUTICA S.A.	ES
LESCOL XL 80 MG ΔΙΣΚΪΑ ΠΑΡΑΤΕΤΑΜΈΝΗς ΑΠΟΔΈΣΜΕΥςΗς	DE/H/0116/003	224590302	NOVARTIS (HELLAS) S.A.C.I.	GR
LESCOL XL 80 MG ΔΙΣΚΪΑ ΠΑΡΑΤΕΤΑΜΈΝΗς ΑΠΟΔΈΣΜΕΥςΗς	DE/H/0116/003	224590303	NOVARTIS (HELLAS) S.A.C.I.	GR
LESCOL XL 80 MG ΔΙΣΚΪΑ ΠΑΡΑΤΕΤΑΜΈΝΗς ΑΠΟΔΈΣΜΕΥςΗς	DE/H/0116/003	224590304	NOVARTIS (HELLAS) S.A.C.I.	GR
LESCOL XL 80 MG ΔΙΣΚΪΑ ΠΑΡΑΤΕΤΑΜΈΝΗς ΑΠΟΔΈΣΜΕΥςΗς	DE/H/0116/003	224590305	NOVARTIS (HELLAS) S.A.C.I.	GR
LESCOL XL 80 MG ΔΙΣΚΪΑ ΠΑΡΑΤΕΤΑΜΈΝΗς ΑΠΟΔΈΣΜΕΥςΗς	DE/H/0116/003	224590306	NOVARTIS (HELLAS) S.A.C.I.	GR
LESCOL 20 MG ΚΑΨΑΚΪΑ, ΣΚΛΗΡΑ	DE/H/0116/001	224590102	NOVARTIS (HELLAS) S.A.C.I.	GR
LESCOL 20 MG ΚΑΨΑΚΪΑ, ΣΚΛΗΡΑ	DE/H/0116/001	224590103	NOVARTIS (HELLAS) S.A.C.I.	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
			S.A.C.I.	
LESCOL 20 MG ΚΑΨΑΚΙΑ, ΣΚΛΗΡΑ	DE/H/0116/001	224590104	NOVARTIS (HELLAS) S.A.C.I.	GR
LESCOL 20 MG ΚΑΨΑΚΙΑ, ΣΚΛΗΡΑ	DE/H/0116/001	224590105	NOVARTIS (HELLAS) S.A.C.I.	GR
LESCOL 40 MG ΚΑΨΑΚΙΑ, ΣΚΛΗΡΑ	DE/H/0116/002	224590202	NOVARTIS (HELLAS) S.A.C.I.	GR
LESCOL 40 MG ΚΑΨΑΚΙΑ, ΣΚΛΗΡΑ	DE/H/0116/002	224590203	NOVARTIS (HELLAS) S.A.C.I.	GR
LESCOL 40 MG ΚΑΨΑΚΙΑ, ΣΚΛΗΡΑ	DE/H/0116/002	224590204	NOVARTIS (HELLAS) S.A.C.I.	GR
LESCOL 40 MG ΚΑΨΑΚΙΑ, ΣΚΛΗΡΑ	DE/H/0116/002	224590205	NOVARTIS (HELLAS) S.A.C.I.	GR
Lipaxan 20 mg capsule rigide	DE/H/3066/001	029199015	NOVARTIS EUROPHARM LIMITED	IT
Lescol 40 mg, gélules	DE/H/0116/002	BE174605	NOVARTIS PHARMA N.V.	BE
Lescol 40 mg capsules, hard	DE/H/0116/002	BE174605	NOVARTIS PHARMA N.V.	BE
Lescol XL 80 mg pailginto atpalaidavimo tabletės	DE/H/0116/003	LT/1/97/2258/002	NOVARTIS FINLAND OY	LT
Lescol XL 80 mg pailginto atpalaidavimo tabletės	DE/H/0116/003	LT/1/97/2258/003	NOVARTIS FINLAND OY	LT
Lescol XL 80 mg pailginto atpalaidavimo tabletės	DE/H/0116/003	LT/1/97/2258/004	NOVARTIS FINLAND OY	LT
Lescol XL 80 mg pailginto atpalaidavimo tabletės	DE/H/0116/003	LT/1/97/2258/005	NOVARTIS FINLAND OY	LT
Lescol XL 80 mg pailginto atpalaidavimo tabletės	DE/H/0116/003	LT/1/97/2258/006	NOVARTIS FINLAND OY	LT
Lescol XL 80 mg pailginto atpalaidavimo tabletės	DE/H/0116/003	LT/1/97/2258/007	NOVARTIS FINLAND OY	LT
Lescol XL 80 mg pailginto atpalaidavimo tabletės	DE/H/0116/003	LT/1/97/2258/008	NOVARTIS FINLAND OY	LT
Lescol XL 80 mg pailginto atpalaidavimo tabletės	DE/H/0116/003	LT/1/97/2258/009	NOVARTIS FINLAND OY	LT
Lescol XL 80 mg pailginto atpalaidavimo tabletės	DE/H/0116/003	LT/1/97/2258/010	NOVARTIS FINLAND OY	LT
Lescol XL 80 mg pailginto atpalaidavimo tabletės	DE/H/0116/003	LT/1/97/2258/011	NOVARTIS FINLAND OY	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
atpalaidavimo tabletės				
Lescol XL 80 mg pailginto atpalaidavimo tabletės	DE/H/0116/003	LT/1/97/2258/012	NOVARTIS FINLAND OY	LT
Lescol XL 80 mg pailginto atpalaidavimo tabletės	DE/H/0116/003	LT/1/97/2258/013	NOVARTIS FINLAND OY	LT
Lescol XL 80 mg pailginto atpalaidavimo tabletės	DE/H/0116/003	LT/1/97/2258/014	NOVARTIS FINLAND OY	LT
Lescol XL 80 mg pailginto atpalaidavimo tabletės	DE/H/0116/003	LT/1/97/2258/015	NOVARTIS FINLAND OY	LT
Lescol XL 80 mg pailginto atpalaidavimo tabletės	DE/H/0116/003	LT/1/97/2258/016	NOVARTIS FINLAND OY	LT
Lescol XL 80 mg pailginto atpalaidavimo tabletės	DE/H/0116/003	LT/1/97/2258/017	NOVARTIS FINLAND OY	LT
Lescol XL 80 mg pailginto atpalaidavimo tabletės	DE/H/0116/003	LT/1/97/2258/018	NOVARTIS FINLAND OY	LT
Lescol XL 80 mg pailginto atpalaidavimo tabletės	DE/H/0116/003	LT/1/97/2258/019	NOVARTIS FINLAND OY	LT
Digaryl 40 mg cápsulas duras	DE/H/3066/002	62.794	NOVARTIS FARMACÉUTICA S.A.	ES
Digaryl Prolib 80 mg comprimidos de liberación prolongada	DE/H/3066/003	64.692	NOVARTIS FARMACÉUTICA S.A.	ES
Lipaxan 40 mg capsule rigide	DE/H/3066/002	029199027	NOVARTIS EUROPHARM LIMITED	IT
Lipaxan 40 mg capsule rigide	DE/H/3066/002	029199039	NOVARTIS EUROPHARM LIMITED	IT
Lipaxan 80 mg compresse a rilascio prolungato	DE/H/3066/003	029199041	NOVARTIS EUROPHARM LIMITED	IT
Lipaxan 80 mg compresse a rilascio prolungato	DE/H/3066/003	029199066	NOVARTIS EUROPHARM LIMITED	IT
Lipaxan 80 mg compresse a rilascio prolungato	DE/H/3066/003	029199078	NOVARTIS EUROPHARM LIMITED	IT
Lipaxan 80 mg compresse a rilascio prolungato	DE/H/3066/003	029199080	NOVARTIS EUROPHARM LIMITED	IT
Лескол XL 80 мг таблетки с удължено освобождаване	DE/H/0116/003	20010439	NOVARTIS PHARMA GMBH	BG
Lescol XL 80 mg pailginto	DE/H/0116/003	LT/1/97/2258/001	NOVARTIS FINLAND OY	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
atpalaidavimo tabletės				
Lescol XL, 80 mg toimeainet prolongeeritult vabastavad tabletid	DE/H/0116/003	334100	NOVARTIS FINLAND OY	EE
Lescol 40 mg tvrde kapsule	DE/H/0116/002	HR-H-724933892-01	NOVARTIS HRVATSKA D.O.O.	HR
Lescol XL 80 mg tablete s produljenim oslobađanjem	DE/H/0116/003	HR-H-337032317-01	NOVARTIS HRVATSKA D.O.O.	HR