



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

30 November 2017
EMA/806818/2017
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: pravastatin

Procedure no.: PSUSA/00002500/201703



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
PRAVASINE 10 mg, tabletten	FR/H/0252/001	BE156807	BRISTOL-MYERS SQUIBB BELGIUM NV	BE
PRAVASINE 20 mg, tabletten	FR/H/0252/002	BE156861	BRISTOL-MYERS SQUIBB BELGIUM NV	BE
PRAVASINE 40 mg, tabletten	FR/H/0252/003	BE192263	BRISTOL-MYERS SQUIBB BELGIUM NV	BE
PRAVASINE 10 mg, comprimés	FR/H/0252/001	BE156807	BRISTOL-MYERS SQUIBB BELGIUM S.A.	BE
PRAVASINE 20 mg, comprimés	FR/H/0252/002	BE156861	BRISTOL-MYERS SQUIBB BELGIUM S.A.	BE
PRAVASINE 40 mg, comprimés	FR/H/0252/003	BE192263	BRISTOL-MYERS SQUIBB BELGIUM S.A.	BE
Pravastatine Sandoz 30 mg tabletten	DK/H/0603/004	BE466391	SANDOZ N.V.	BE
Pravalam 30 mg tabletten	UK/H/3406/003	BE 261554	SANDOZ N.V.	BE
Pravalam 30 mg tabletten	UK/H/3406/003	BE 261563	SANDOZ N.V.	BE
Pravalam 30 mg tabletten	UK/H/3406/003	BE 261572	SANDOZ N.V.	BE
PRAREDUCT 10mg, tabletten	not available	BE 213997	DAIICHI SANKYO BELGIUM S.A	BE
PRAREDUCT 20mg, tabletten	not available	BE 214006	DAIICHI SANKYO BELGIUM S.A	BE
PRAREDUCT 40mg, tabletten	not available	BE 214015	DAIICHI SANKYO BELGIUM S.A	BE
PRAREDUCT 10mg, comprimés	not available	BE 213997	DAIICHI SANKYO BELGIUM S.A	BE
PRAREDUCT 20mg, comprimés	not available	BE 214006	DAIICHI SANKYO BELGIUM S.A	BE
PRAREDUCT 40mg, comprimés	not available	BE 214015	DAIICHI SANKYO BELGIUM S.A	BE
PravaLich 40 mg Tabletten	DE/H/0547/003	42437.03.00	WINTHROP ARZNEIMITTEL GMBH	DE
PravaLich 40 mg Tabletten	DE/H			

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PravaLich 10 mg Tabletten	DE/H/0547/001	42437.01.00	WINTHROP ARZNEIMITTEL GMBH	DE
PravaLich 20 mg Tabletten	DE/H/0547/002	42437.02.00	WINTHROP ARZNEIMITTEL GMBH	DE
PravaLich 10 mg Tabletten	DE/H/0547/001	42437.01.00	WINTHROP ARZNEIMITTEL GMBH	DE
PravaLich 20 mg Tabletten	DE/H/0547/002	42437.02.00	WINTHROP ARZNEIMITTEL GMBH	DE
PravaLich 20 mg Tabletten	DE/H/0547/002	42437.02.00	WINTHROP ARZNEIMITTEL GMBH	DE
PravaLich 20 mg Tabletten	DE/H/0547/002	42437.02.00	WINTHROP ARZNEIMITTEL GMBH	DE
PravaLich 10 mg Tabletten	DE/H/0547/001	42437.01.00	WINTHROP ARZNEIMITTEL GMBH	DE
PravaLich 10 mg Tabletten	DE/H/0547/001	42437.01.00	WINTHROP ARZNEIMITTEL GMBH	DE
Pravasin protect 10 mg, Tabletten	FR/H/0252/001	41852.01.00	BRISTOL-MYERS SQUIBB GMBH & CO. KGAA	DE
Pravasin protect 20 mg, Tabletten	FR/H/0252/002	41852.02.00	BRISTOL-MYERS SQUIBB GMBH & CO. KGAA	DE
Pravasin protect 40 mg, Tabletten	FR/H/0252/003	41852.03.00	BRISTOL-MYERS SQUIBB GMBH & CO. KGAA	DE
Mevalotin protect 20 mg, Tabletten	not available	41856.02.00	DAIICHI SANKYO EUROPE GMBH	DE
Mevalotin protect 40 mg, Tabletten	not available	41856.03.00	DAIICHI SANKYO EUROPE GMBH	DE
Pravastatin "Sandoz"	DK/H/0603/004	46528	SANDOZ A/S	DK
LIPLAT 10 mg comprimidos	not available	59.029	LABORATORIOS DR. ESTEVE S.A.	ES
LIPLAT 20 mg comprimidos	not available	59.030	LABORATORIOS DR. ESTEVE S.A.	ES
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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
LIPEMOL 20 mg comprimidos	FR/H/0252/002	59.028	BRISTOL-MYERS SQUIBB SA	ES
BRISTACOL® 10 mg comprimidos	not available	61.334	EXELTIS HEALTHCARE S.L	ES
BRISTACOL® 20mg comprimidos	not available	60.162	EXELTIS HEALTHCARE S.L	ES
BRISTACOL® 40mg comprimidos	not available	62.374	EXELTIS HEALTHCARE S.L	ES
BRISTACOL® 20mg comprimidos	not available	60.162	EXELTIS HEALTHCARE S.L	ES
Minuscol 40 mg comprimidos	not available	67.703	TEVA PHARMA S.L.U	ES
Minuscol 10 mg comprimidos	not available	67.704	TEVA PHARMA S.L.U	ES
Minuscol 20 mg comprimidos	not available	67702	TEVA PHARMA S.L.U	ES
PRAREDUCT 20 mg comprimidos	not available	61.112	DAIICHI SANKYO ESPAÑA, S.A.	ES
PRAREDUCT 40 mg comprimidos	not available	62.688	DAIICHI SANKYO ESPAÑA, S.A.	ES
ELISOR 10 mg, comprimé sécable	FR/H/0252/001	3400933221126	BRISTOL-MYERS SQUIBB	FR
ELISOR 10 mg, comprimé sécable	FR/H/0252/001	3400937139823	BRISTOL-MYERS SQUIBB	FR
PRAVASTATINE TEVA 40 mg, comprimé sécable	NL/H/543/003	NL30679	TEVA SANTÉ	FR
PRAVASTATINE ZENTIVA 40 MG, COMPRIME	not available	34009 585 460 0 6	SANOFI-AVENTIS FRANCE	FR
PRAVASTATINE ZENTIVA 40 MG, COMPRIME	not available	34009 585 459 2 4	SANOFI-AVENTIS FRANCE	FR
PRAVASTATINE ZENTIVA 40 MG, COMPRIME	not available	34009 275 181 6 4	SANOFI-AVENTIS FRANCE	FR
PRAVASTATINE ZENTIVA 40 MG, COMPRIME	not available	34009 275 177 9 2	SANOFI-AVENTIS FRANCE	FR
PRAVASTATINE ZENTIVA 40 MG, COMPRIME	not available			

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PRAVASTATINE ZENTIVA 40 MG, COMPRIME	not available	34009 275 179 1 4	SANOFI-AVENTIS FRANCE	FR
VASTEN 20 mg, comprimé séable	not available	34009 274 065 2 2	SANOFI-AVENTIS FRANCE	FR
VASTEN 20 mg, comprimé séable	not available	34009 585 030 6 1	SANOFI-AVENTIS FRANCE	FR
VASTEN 20 mg, comprimé séable	not available	34009 369 087 3 4	SANOFI-AVENTIS FRANCE	FR
VASTEN 20 mg, comprimé séable	not available	34009 274 064 6 1	SANOFI-AVENTIS FRANCE	FR
VASTEN 20 mg, comprimé séable	not available	34009 332 214 1 6	SANOFI-AVENTIS FRANCE	FR
VASTEN 20 mg, comprimé séable	not available	34009 560 922 0 8	SANOFI-AVENTIS FRANCE	FR
PRAVASTATINE ZENTIVA 20 MG, COMPRIME SECABLE	not available	34009 585 458 6 3	SANOFI-AVENTIS FRANCE	FR
PRAVASTATINE ZENTIVA 20 MG, COMPRIME SECABLE	not available	34009 585 456 3 4	SANOFI-AVENTIS FRANCE	FR
PRAVASTATINE ZENTIVA 20 MG, COMPRIME SECABLE	not available	34009 275 173 3 4	SANOFI-AVENTIS FRANCE	FR
PRAVASTATINE ZENTIVA 20 MG, COMPRIME SECABLE	not available	34009 275 176 2 4	SANOFI-AVENTIS FRANCE	FR
PRAVASTATINE ZENTIVA 20 MG, COMPRIME SECABLE	not available	34009 275 172 7 3	SANOFI-AVENTIS FRANCE	FR
PRAVASTATINE ZENTIVA 20 MG, COMPRIME SECABLE	not available	34009 275 175 6 3	SANOFI-AVENTIS FRANCE	FR
PRAVASTATINE ZENTIVA 20 MG, COMPRIME SECABLE	not available	374 549-1	SANOFI-AVENTIS FRANCE	FR
PRAVASTATINE ZENTIVA 40 MG, COMPRIME	not available	374 548-5	SANOFI-AVENTIS FRANCE	FR
VASTEN 20 mg, comprimé séable	not available	34009 369 087 3 4	SANOFI-AVENTIS FRANCE	FR
VASTEN 40 mg, comprimé	not available	34009 369 089 6 3	SANOFI-AVENTIS FRANCE	FR
VASTEN 40 mg,				

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PRAVASTATINE ZENTIVA 20 MG, COMPRIME SECABLE	not available	374 551-6	SANOFI-AVENTIS FRANCE	FR
PRAVASTATINE ZENTIVA 40 MG, COMPRIME	not available	374 547-9	SANOFI-AVENTIS FRANCE	FR
PRAVASTATINE ZENTIVA 10 MG, COMPRIME SECABLE	not available	374 553-9	SANOFI-AVENTIS FRANCE	FR
PRAVASTATINE ZENTIVA 10 MG, COMPRIME SECABLE	not available	374 552-2	SANOFI-AVENTIS FRANCE	FR
PRAVASTATINE ZENTIVA 20 MG, COMPRIME SECABLE	not available	568 972-7	SANOFI-AVENTIS FRANCE	FR
VASTEN 20 mg, comprimé sécable	not available	34009 332 214 1 6	SANOFI-AVENTIS FRANCE	FR
PRAVASTATINE ZENTIVA 40 MG, COMPRIME	not available	568 971-0	SANOFI-AVENTIS FRANCE	FR
VASTEN 20 mg, comprimé sécable	not available	560 922-0	SANOFI-AVENTIS FRANCE	FR
VASTEN 40 MG, COMPRIME	not available	34009 561 642-1 9	SANOFI-AVENTIS FRANCE	FR
VASTEN 40 MG, COMPRIME	not available	34009 274 066 9 0	SANOFI-AVENTIS FRANCE	FR
VASTEN 40 MG, COMPRIME	not available	34009 274 067 5 1	SANOFI-AVENTIS FRANCE	FR
VASTEN 40 MG, COMPRIME	not available	34009 585 031 2 2	SANOFI-AVENTIS FRANCE	FR
PRAVACHOL 20 mg δισκία	FR/H/0252/002	77366/7-12-2006	BRISTOL-MYERS SQUIBB A.E.	GR
PRAVACHOL 40 mg δισκία	FR/H/0252/003	77378/7-12-2006	BRISTOL-MYERS SQUIBB A.E.	GR
MAXUDIN 20 mg δισκία	not available	11144	A. MENARINI - INDUSTRIE FARMACEUTICHE RIUNITE - S.R.L.	GR
MAXUDIN 10 mg δισκία	not available	4502	A. MENARINI - INDUSTRIE FARMACEUTICHE RIUNITE - S.R.L.	GR
MAXUDIN 20 mg δισκία	not available	4501	A. MENARINI - INDUSTRIE FARMACEUTICHE RIUNITE - S.R.L.	GR
MAXUDIN 40 mg δισκία	not available	10610	A. MENARINI - INDUSTRIE FARMACEUTICHE RIUNITE	

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Lipostat 40mg tablets	FR/H/0252/003	PA 2/55/6	BRISTOL-MYERS SQUIBB PHARMACEUTICALS LIMITED	IE
Lipostat 10mg tablets	FR/H/0252/001	PA 2/55/4	BRISTOL-MYERS SQUIBB PHARMACEUTICALS LIMITED	IE
Lipostat 20mg tablets	FR/H/0252/002	PA 2/55/5	BRISTOL-MYERS SQUIBB PHARMACEUTICALS LIMITED	IE
SELECTIN 40 mg compresse	FR/H/0252/003	027297035	BRISTOL-MYERS SQUIBB S.R.L.	IT
SELECTIN 20 mg compresse	FR/H/0252/002	027297011	BRISTOL-MYERS SQUIBB S.R.L.	IT
SELECTIN 10 mg compresse	FR/H/0252/001	027297023	BRISTOL-MYERS SQUIBB S.R.L.	IT
APLACTIN 20 mg compresse	not available	027786021	FABBRICA ITALIANA RITROVATI MEDICINALI ED AFFINI F.I.R.M.A. - S.P.A.	IT
PRAVASELECT 20 mg compresse	not available	027309018	A. MENARINI - INDUSTRIE FARMACEUTICHE RIUNITE - S.R.L.	IT
PRAVASELECT 40 mg compresse	not available	027309032	A. MENARINI - INDUSTRIE FARMACEUTICHE RIUNITE - S.R.L.	IT
APLACTIN 40 mg compresse	not available	027786033	FABBRICA ITALIANA RITROVATI MEDICINALI ED AFFINI F.I.R.M.A. - S.P.A.	IT
PRASTEROL 40 mg compresse	not available	027776032	ISTITUTO LUSO FARMACO D'ITALIA S.P.A.	IT
PRASTEROL 20 mg compresse	not available	027776018	ISTITUTO LUSO FARMACO D'ITALIA S.P.A.	IT
SANAPRAV 10 mg compresse	not available	029371010	DAIICHI SANKYO ITALIA S.P.A	IT
SANAPRAV 20 mg compresse	not available	029371022	DAIICHI SANKYO ITALIA S.P.A	IT
SANAPRAV 40 mg compresse	not available	029371034	DAIICHI SANKYO ITALIA S.P.A	IT
PRAREDUCT 10mg, comprimés	not available	1851/09030060	DAIICHI SANKYO BELGIUM S.A	LU

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PRAREDUCT 20mg, comprimés	not available	1851/09050057	DAIICHI SANKYO BELGIUM S.A	LU
PRAREDUCT 40mg, comprimés	not available	1851/09050058	DAIICHI SANKYO BELGIUM S.A	LU
Selektine 10 mg, tabletten	FR/H/0252/001	RVG 13755	BRISTOL-MYERS SQUIBB B.V.	NL
Selektine 20 mg, tabletten	FR/H/0252/002	RVG 13756	BRISTOL-MYERS SQUIBB B.V.	NL
Selektine 40 mg, tabletten	FR/H/0252/003	RVG 20665	BRISTOL-MYERS SQUIBB B.V.	NL
Pravachol 20 mg tabletter	FR/H/0252/002	00-7865	BRISTOL-MYERS SQUIBB AB	NO
Pravachol 40 mg tabletter	FR/H/0252/003	96-1116	BRISTOL-MYERS SQUIBB AB	NO
Pravastatin Teva 10 mg tabletter	NL/H/0543/001	04-2883	TEVA SWEDEN AB	NO
Pravacol 20 mg comprimidos	FR/H/0252/002	8772111	BRISTOL-MYERS SQUIBB FARMACÊUTICA PORTUGUESA, SA	PT
Pravacol 20 mg comprimidos	FR/H/0252/002	5013560	BRISTOL-MYERS SQUIBB FARMACÊUTICA PORTUGUESA, SA	PT
Pravacol 20 mg comprimidos	FR/H/0252/002	8772103	BRISTOL-MYERS SQUIBB FARMACÊUTICA PORTUGUESA, SA	PT
Pravacol 40 mg comprimidos	FR/H/0252/003	2772689	BRISTOL-MYERS SQUIBB FARMACÊUTICA PORTUGUESA, SA	PT
Pravacol 20 mg comprimidos	FR/H/0252/003	5615687	BRISTOL-MYERS SQUIBB FARMACÊUTICA PORTUGUESA, SA	PT
Pravacol 40 mg comprimidos	FR/H/0252/003	2772580	BRISTOL-MYERS SQUIBB FARMACÊUTICA PORTUGUESA, SA	PT
Pravacol 40 mg comprimidos	FR/H/0252/003	5615588	BRISTOL-MYERS SQUIBB FARMACÊUTICA PORTUGUESA, SA	PT

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Pravacol 40 mg comprimidos	FR/H/0252/003	5013578	BRISTOL-MYERS SQUIBB FARMACÊUTICA PORTUGUESA, SA	PT
Pravacol 40 mg comprimidos	FR/H/0252/003	3789989	BRISTOL-MYERS SQUIBB FARMACÊUTICA PORTUGUESA, SA	PT
Sanaprav 10 mg comprimidos	not available	3789880	DAIICHI SANKYO PORTUGAL,LDA	PT
Sanaprav 10 mg comprimidos	not available	3341088	DAIICHI SANKYO PORTUGAL,LDA	PT
Sanaprav 20 mg comprimidos	not available	2504884	DAIICHI SANKYO PORTUGAL,LDA	PT
Sanaprav 40 mg comprimidos	not available	3341187	DAIICHI SANKYO PORTUGAL,LDA	PT
Pravastatin sodium 10mg Tablets	not available	PL 20416/0356	CRESCENT PHARMA LIMITED	UK
Pravastatin sodium 20mg Tablets	not available	PL 20416/0357	CRESCENT PHARMA LIMITED	UK
Pravastatin sodium 40mg Tablets	not available	PL 20416/0358	CRESCENT PHARMA LIMITED	UK
Pravastatin sodium 10mg Tablets	not available	PL 21880/0047	MEDREICH PLC	UK
Pravastatin sodium 20mg Tablets	not available	PL 21880/0048	MEDREICH PLC	UK
Pravastatin sodium 40mg Tablets	not available	PL 21880/0049	MEDREICH PLC	UK
Pravastatin Sodium 30mg Tablets	not available	PL 11311/0497	TILLOMED LABORATORIES LTD	UK
Pravastatin Sodium 40 mg Tablets	DK/H/0603/003	PL 04416/0806	SANDOZ LTD	UK
Pravastatin Sodium 40mg Tablets	not available	PL 04416/0601	SANDOZ LTD	UK
Pravastatin Sodium 10mg Tablets	not available	PL 04416/0599	SANDOZ LTD	UK
Pravastatin Sodium 20mg Tablets	not available	PL 04416/0600	SANDOZ LTD	UK

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Pravastatin Sodium 10mg Tablets	not available	PL 11311/0495	TILLOMED LABORATORIES LTD	UK
Pravastatin sodium 20mg Tablets	not available	PL 11311/0496	TILLOMED LABORATORIES LTD	UK
Pravastatin Sodium 40mg Tablets	not available	PL 11311/0498	TILLOMED LABORATORIES LTD	UK