



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

26 November 2020
EMA/646100/2020
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: pravastatin

Procedure no.: PSUSA/00002500/202003



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
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 - S.R.L.	GR
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	67.702	TEVA PHARMA S.L.U.,	ES
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

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
SELECTIN 10 mg comprimido	FR/H/0252/001	027297023	BRISTOL-MYERS SQUIBB S.R.L.	IT
ELISOR 40 mg, comprimé	FR/H/0252/003	3400937140072	BRISTOL-MYERS SQUIBB	FR
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 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
Pravacol 40 mg comprimidos	FR/H/0252/003	5013578	BRISTOL-MYERS SQUIBB FARMACÊUTICA PORTUGUESA, SA	PT

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ELISOR 10 mg, comprimé sécable	FR/H/0252/001	3400933221126	BRISTOL-MYERS SQUIBB	FR
ELISOR 20 mg, comprimé sécable	FR/H/0252/002	3400956081660	BRISTOL-MYERS SQUIBB	FR
ELISOR 20 mg, comprimé sécable	FR/H/0252/002	3400933221294	BRISTOL-MYERS SQUIBB	FR
ELISOR 20 mg, comprimé sécable	FR/H/0252/002	3400937139991	BRISTOL-MYERS SQUIBB	FR
ELISOR 40 mg, comprimé	FR/H/0252/003	3400956164158	BRISTOL-MYERS SQUIBB	FR
ELISOR 40 mg, comprimé	FR/H/0252/003	3400935114167	BRISTOL-MYERS SQUIBB	FR
ELISOR 10 mg, comprimé sécable	FR/H/0252/001	3400937139823	BRISTOL-MYERS SQUIBB	FR
PRAREDUCT 10mg, comprimés	not available	1851/09030060	DAIICHI SANKYO BELGIUM S.A	LU
PRAREDUCT 20mg, comprimés	not available	1851/09050057	DAIICHI SANKYO BELGIUM S.A	LU

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
PRAREDUCT 40mg, comprimés	not available	1851/09050058	DAIICHI SANKYO BELGIUM S.A	LU
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
PRASTEROL 20 mg compresse	not available	027776069	ISTITUTO LUSO FARMACO D'ITALIA S.P.A.	IT
PRASTEROL 40 mg compresse	not available	027776071	ISTITUTO LUSO FARMACO D'ITALIA S.P.A.	IT
PRAVASTATINE TEVA 40 mg, comprimé sécable	NL/H/0543/003	NL30679	TEVA SANTÉ	FR
Pravastatin Teva 10 mg tabletter	NL/H/0543/001	04-2883	TEVA SWEDEN AB	NO
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

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
Pravalich 40 mg Tabletten	DE/H/0547/003	42437.03.00	WINTHROP ARZNEIMITTEL GMBH	DE
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
VASTEN 40 MG, COMPRIME	not available	34009 369 089-6 3	SANOFI-AVENTIS FRANCE	FR
VASTEN 40 MG, COMPRIME	not available	34009 351 142-2 8	SANOFI-AVENTIS FRANCE	FR
VASTEN 40 MG, COMPRIME	not available	34009 561 642-1 9	SANOFI-AVENTIS FRANCE	FR
PRAVASTATINE ZENTIVA 40 mg, comprimé	not available	34009 585 459 2 4	ZENTIVA FRANCE	FR
PRAVASTATINE ZENTIVA 40 mg, comprimé	not available	34009 275 177 9 2	ZENTIVA FRANCE	FR
PRAVASTATINE ZENTIVA 40 mg, comprimé	not available	34009 275 178 5 3	ZENTIVA FRANCE	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
PRAVASTATINE ZENTIVA 40 mg, comprimé	not available	34009 585 460 0 6	ZENTIVA FRANCE	FR
PRAVASTATINE ZENTIVA 40 mg, comprimé	not available	34009 275 179 1 4	ZENTIVA FRANCE	FR
PRAVASTATINE ZENTIVA 40 mg, comprimé	not available	34009 275 181 6 4	ZENTIVA FRANCE	FR
VASTEN 20 MG, COMPRIME SECABLE	not available	34009 369 087 3 4	SANOFI-AVENTIS FRANCE	FR
VASTEN 20 MG, COMPRIME SECABLE	not available	34009 332 214 1 6	SANOFI-AVENTIS FRANCE	FR
VASTEN 20 MG, COMPRIME SECABLE	not available	34009 560 922 0 8	SANOFI-AVENTIS FRANCE	FR
VASTEN 20 mg, comprimé sécable	not available	34009 274 064 6 1	SANOFI-AVENTIS FRANCE	FR
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

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
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
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
PRAVASELECT 20 mg compresse	not available	027309069	A. MENARINI - INDUSTRIE FARMACEUTICHE RIUNITE - S.R.L.	IT
PRAVASELECT 40 mg compresse	not available	027309071	A. MENARINI - INDUSTRIE FARMACEUTICHE RIUNITE - S.R.L.	IT
PRAVASTATINE ZENTIVA 20 mg, comprimé sécable	not available	34009 585 456 3 4	ZENTIVA FRANCE	FR
PRAVASTATINE ZENTIVA 20 mg, comprimé sécable	not available	34009 275 173 3 4	ZENTIVA FRANCE	FR
PRAVASTATINE ZENTIVA 20 mg, comprimé sécable	not available	34009 275 172 7 3	ZENTIVA FRANCE	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
PRAVASTATINE ZENTIVA 20 mg, comprimé sécable	not available	34009 275 175 6 3	ZENTIVA FRANCE	FR
PRAVASTATINE ZENTIVA 20 mg, comprimé sécable	not available	34009 585 458 6 3	ZENTIVA FRANCE	FR
PRAVASTATINE ZENTIVA 20 mg, comprimé sécable	not available	34009 275 176 2 4	ZENTIVA FRANCE	FR
LIPLAT 10 mg comprimidos	not available	59.029	ESTEVE PHARMACEUTICALS, S.A.	ES
LIPLAT 40 mg comprimidos	not available	62.375	ESTEVE PHARMACEUTICALS, S.A.	ES
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

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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
Sanapprav 10 mg comprimidos	not available	3789880	DAIICHI SANKYO PORTUGAL, UNIP. LDA	PT
Sanapprav 10 mg comprimidos	not available	3341088	DAIICHI SANKYO PORTUGAL, UNIP. LDA	PT
Sanapprav 20 mg comprimidos	not available	2504884	DAIICHI SANKYO PORTUGAL, UNIP. LDA	PT
Sanapprav 40 mg comprimidos	not available	3341187	DAIICHI SANKYO PORTUGAL, UNIP. LDA	PT
Pravastatin Hexal 30 mg - Tabletten	DE/H/3715/003	1-25459	HEXAL PHARMA GMBH	AT
PRAVASTATINE ZENTIVA 10 mg, comprimé sécable	not available	34009 374 552 2 0	ZENTIVA FRANCE	FR
PRAVASTATINE ZENTIVA 10 mg, comprimé sécable	not available	34009 374 553 9 8	ZENTIVA FRANCE	FR

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Pravastatin sodium 20mg Tablets	not available	PL 21880/0048	MEDREICH PLC	UK
Pravastatin sodium 40mg Tablets	not available	PL 21880/0049	MEDREICH PLC	UK
BRISTACOL 10 mg comprimidos	NA	60.162	EXELTIS HEALTHCARE S.L	ES
BRISTACOL® 40 mg comprimidos	not available	62.374	EXELTIS HEALTHCARE S.L	ES
BRISTACOL 20 MG COMPRIMIDOS	NA	61.334	EXELTIS HEALTHCARE S.L	ES
LIPLAT 20 mg comprimidos	not available	59.030	ESTEVE PHARMACEUTICALS, S.A.	ES
APLACTIN 20 mg compresse	not available	027786021	FABBRICA ITALIANA RITROVATI MEDICINALI ED AFFINI F.I.R.M.A. - S.P.A.	IT
APLACTIN 40 mg compresse	not available	027786033	FABBRICA ITALIANA RITROVATI MEDICINALI ED AFFINI F.I.R.M.A. - S.P.A.	IT
APLACTIN 20 mg compresse	not available	027786060	FABBRICA ITALIANA RITROVATI MEDICINALI ED AFFINI F.I.R.M.A. - 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
APLACTIN 40 mg comprese	not available	027786072	FABBRICA ITALIANA RITROVATI MEDICINALI ED AFFINI F.I.R.M.A. - S.P.A.	IT
SANAPRAV 10 mg comprese	not available	029371010	DAIICHI SANKYO ITALIA S.P.A	IT
SANAPRAV 20 mg comprese	not available	029371022	DAIICHI SANKYO ITALIA S.P.A	IT
SANAPRAV 40 mg comprese	not available	029371034	DAIICHI SANKYO ITALIA S.P.A	IT
Pravastatin Sodium 30mg Tablets	not available	PL 11311/0497	TILLOMED LABORATORIES LTD	UK
VASTEN 10 MG, COMPRIME SECABLE	not available	332 213-5	SANOFI-AVENTIS FRANCE	FR
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