



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

14 December 2023
EMA/35243/2024
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: pravastatin

Procedure no.: PSUSA/00002500/202303

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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
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
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
APLACTIN 40 mg compresse	not available	027786072	FABBRICA ITALIANA RITROVATI MEDICINALI ED AFFINI F.I.R.M.A. - S.P.A.	IT
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
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
Minuscol 20 mg comprimidos	not available	67702	TEVA PHARMA S.L.U.,	ES
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
PRAVASTATINE ZENTIVA 40 mg, comprimé	not available	34009 585 460 0 6	ZENTIVA FRANCE	FR

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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
LIPLAT 40 mg comprimidos	not available	62.375	ESTEVE PHARMACEUTICALS, S.A.	ES
Pravastatin Sodium 30mg Tablets	not available	PL 11311/0497	TILLOMED LABORATORIES LTD	XI
LIPLAT 10 mg comprimidos	not available	59.029	ESTEVE PHARMACEUTICALS, S.A.	ES
LIPLAT 20 mg comprimidos	not available	59.030	ESTEVE PHARMACEUTICALS, S.A.	ES
Pravastatin sodium 10mg Tablets	not available	PL 20416/0356	CRESCENT PHARMA LIMITED	XI
Pravastatin sodium 20mg Tablets	not available	PL 20416/0357	CRESCENT PHARMA LIMITED	XI
Pravastatin sodium 40mg Tablets	not available	PL 20416/0358	CRESCENT PHARMA LIMITED	XI
BRISTACOL® 40 mg comprimidos	NA	62.374	EXELTIS HEALTHCARE S.L	ES
BRISTACOL 20 MG COMPRIMIDOS	NA	60.162	EXELTIS HEALTHCARE S.L	ES
VASTEN 40 mg, comprimé	not available	34009 274 067 5 1	SANOFI WINTHROP INDUSTRIE	FR
VASTEN 40 mg, comprimé	not available	34009 274 066 9 0	SANOFI WINTHROP INDUSTRIE	FR
VASTEN 40 mg, comprimé	not available	34009 585 031 2 2	SANOFI WINTHROP INDUSTRIE	FR
VASTEN 20 mg, comprimé sécable	not available	34009 369 087 3 4	SANOFI WINTHROP INDUSTRIE	FR
VASTEN 20 mg, comprimé sécable	not available	34009 332 214 1 6	SANOFI WINTHROP INDUSTRIE	FR
VASTEN 20 mg, comprimé sécable	not available	34009 560 922 0 8	SANOFI WINTHROP INDUSTRIE	FR
VASTEN 40 mg, comprimé	not available	34009 369 089 6 3	SANOFI WINTHROP INDUSTRIE	FR

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VASTEN 40 mg, comprimé	not available	34009 351 142 2 8	SANOFI WINTHROP INDUSTRIE	FR
VASTEN 10 mg, comprimé sécable	not available	34009 332 213 5 5	SANOFI WINTHROP INDUSTRIE	FR
VASTEN 40 mg, comprimé	not available	34009 561 642 1 9	SANOFI WINTHROP INDUSTRIE	FR
VASTEN 20 mg, comprimé sécable	not available	34009 274 064 6 1	SANOFI WINTHROP INDUSTRIE	FR
VASTEN 20 mg, comprimé sécable	not available	34009 274 065 2 2	SANOFI WINTHROP INDUSTRIE	FR
VASTEN 20 mg, comprimé sécable	not available	34009 585 030 6 1	SANOFI WINTHROP INDUSTRIE	FR
MAXUDIN 20 mg δισκία	not available	11144	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
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
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

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PRAREDUCT 40mg, comprimés	not available	1851/09050058	DAIICHI SANKYO BELGIUM S.A	LU
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
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
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