



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: simvastatin

Procedure no.: PSUSA/00002709/202004

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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
Simvastatine Sandoz 60 mg, filmomhulde tabletten	FI/H/0141/007	RVG 32196	SANDOZ B.V.	NL
Lipcut 60 mg tabletti, kalvopäällysteinen	FI/H/0141/007	18449	SANDOZ A/S	FI
LIPEX 10 mg filmom obložene tablete	not available	HR-H-509178324	MERCK SHARP & DOHME D.O.O.	HR
LIPEX 40 mg filmom obložene tablete	not available	HR-H-597927430	MERCK SHARP & DOHME D.O.O.	HR
LIPEX 80 mg filmom obložene tablete	not available	HR-H-164284956	MERCK SHARP & DOHME D.O.O.	HR
LIPEX 20 mg filmom obložene tablete	not available	HR-H-604977393	MERCK SHARP & DOHME D.O.O.	HR
COLEMIN FORTE 40 mg comprimidos	not available	62.329	VIFOR PHARMA ESPAÑA, S.L.	ES
COLEMIN 10 mg comprimidos	not available	59.181	VIFOR PHARMA ESPAÑA, S.L.	ES
COLEMIN 20 mg comprimidos	not available	59.180	VIFOR PHARMA ESPAÑA, S.L.	ES
Simvasim 10 mg Comprimido revestido por película	not available	3521697	BLUEMED UNIPESSOAL, LDA	PT
SIVASTIN 20 mg compresse rivestite con film.	not available	027208103	ALFASIGMA S.P.A.	IT
SIVASTIN 40 mg compresse rivestite con film.	not available	027208115	ALFASIGMA S.P.A.	IT
SIVASTIN 40 mg compresse rivestite con film.	not available	027208040	ALFASIGMA S.P.A.	IT
SIVASTIN 20 mg compresse rivestite con film.	not available	027208026	ALFASIGMA S.P.A.	IT
SIVASTIN 10 mg compresse rivestite con film.	not available	027208014	ALFASIGMA 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
Simvastatin 10 mg film-coated tablets	not available	PL 11311/0398	TILLOMED LABORATORIES LTD	UK
Simvastatin 20 mg film-coated tablets	not available	PL 11311/0399	TILLOMED LABORATORIES LTD	UK
Simvastatin 40 mg film-coated tablets	not available	PL11311/0400	TILLOMED LABORATORIES LTD	UK
Simvastatin 80 mg film-coated tablets	not available	PL11311/0401	TILLOMED LABORATORIES LTD	UK
ЗОКОР ФОРТЕ 40 mg филмирани таблетки	not available	9900075	MERCK SHARP & DOHME BULGARIA EOOD	BG
ЗОКОР 20 mg филмирани таблетки	not available	9600024	MERCK SHARP & DOHME BULGARIA EOOD	BG
ЗОКОР 10 mg филмирани таблетки	not available	20010478	MERCK SHARP & DOHME BULGARIA EOOD	BG
ZOCOR 80 mg filmom obalené tablety	not available	31/0043/13-S	MERCK SHARP & DOHME BV	SK
ZOCOR 10 mg filmom obalené tablety	not available	31/0155/92-CS	MERCK SHARP & DOHME BV	SK
ZOCOR 40 mg filmom obalené tablety	not available	31/0042/13-S	MERCK SHARP & DOHME BV	SK
ZOCOR 20 mg filmom obalené tablety	not available	31/0041/13-S	MERCK SHARP & DOHME BV	SK
SINVACOR 10 mg filmsko obložene tablete	not available	H/97/01426/001	MERCK SHARP & DOHME INOVATIVNA ZDRAVILA D.O.O.	SI
SINVACOR 20 mg filmsko obložene tablete	not available	H/97/01426/002	MERCK SHARP & DOHME INOVATIVNA ZDRAVILA D.O.O.	SI
SINVACOR 20 mg filmsko obložene tablete	not available	H/97/01426/003	MERCK SHARP & DOHME INOVATIVNA ZDRAVILA D.O.O.	SI

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SINVACOR FORTE 40 mg filmsko obložene tablete	not available	H/97/01426/004	MERCK SHARP & DOHME INOVATIVNA ZDRAVILA D.O.O.	SI
SINVACOR FORTE 40 mg filmsko obložene tablete	not available	H/97/01426/005	MERCK SHARP & DOHME INOVATIVNA ZDRAVILA D.O.O.	SI
Simvastatin - 1 A Pharma 60 mg Filmtabletten	DE/H/2046/007	62540.00.00	1 A PHARMA GMBH	DE
Medipo 20 mg, compresse rivestite con film.	not available	028370029	NEOPHARMED GENTILI SPA	IT
Medipo 10 mg, compresse rivestite con film.	not available	028370017	NEOPHARMED GENTILI SPA	IT
Medipo 20 mg, compresse rivestite con film.	not available	028370106	NEOPHARMED GENTILI SPA	IT
Medipo 40 mg, compresse rivestite con film.	not available	028370118	NEOPHARMED GENTILI SPA	IT
Medipo 40 mg, compresse rivestite con film.	not available	028370043	NEOPHARMED GENTILI SPA	IT
Simvastatin Heumann 30 mg Filmtabletten	not available	85905.00.00	HEUMANN PHARMA GMBH & CO. GENERICA KG	DE
Simvastatin Heumann 60 mg Filmtabletten	not available	85906.00.00	HEUMANN PHARMA GMBH & CO. GENERICA KG	DE
Simvasim 20 Comprimido revestido por película	not available	3521895	BLUEMED UNIPESSOAL, LDA	PT
Simvastatin 10 mg film-coated tablets	not available	PL 45994/0001	IMPERIAL WORLDWIDE LIMITED	UK
Simvastatin 20 mg film-coated tablets	not available	PL 45994/0002	IMPERIAL WORLDWIDE LIMITED	UK
Simvastatin 40 mg film-coated tablets	not available	PL 45994/0003	IMPERIAL WORLDWIDE 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
ZOCOR® 20 mg Filmtabletten	FI/H/0995/ 003	BE147235	MSD BELGIUM BVBA/SPRL	BE
ZOCOR 80 mg filmdragerade tabletter	FI/H/0995/005	13311	MERCK SHARP & DOHME BV	FI
ZOCOR 40 mg, filmdragerade tabletter	FI/H/0995/004	12198	MERCK SHARP & DOHME BV	FI
ZOCOR 20 mg, filmdragerade tabletter	FI/H/0995/003	10661	MERCK SHARP & DOHME BV	FI
ZOCOR 10 mg, filmdragerade tabletter	FI/H/0995/002	10660	MERCK SHARP & DOHME BV	FI
ZOCOR® 40 mg Filmtabletten	FI/H/0995/ 004	BE190206	MSD BELGIUM BVBA/SPRL	BE
Zocor 10 mg tabletti, kalvopäällysteinen	FI/H/0995/002	10660	MERCK SHARP & DOHME BV	FI
ZOCOR 20 mg, comprimé pelliculé sécable	FI/H/0995/ 003	34009 377 623 8 0	MSD FRANCE	FR
Zocor® 10 mg, film-coated tablets	FI/H/0995/ 002	PL 00025/0241	MERCK SHARP & DOHME LTD.	UK
Zocor 10 mg, film-coated tablets	FI/H/0995/ 002	PA1286/022/002	MERCK SHARP & DOHME IRELAND (HUMAN HEALTH) LTD	IE
ZOCOR 10 mg filmdrasjerte tabletter	FI/H/0995/002	0000-07907	MERCK SHARP & DOHME BV	NO
ZOCOR 20 mg, comprimé pelliculé sécable	FI/H/0995/ 003	34009 566 392 3 6	MSD FRANCE	FR
Zocor 20 mg tabletti, kalvopäällysteinen	FI/H/0995/003	10661	MERCK SHARP & DOHME BV	FI
ZOCOR 20 mg, comprimé pelliculé sécable	FI/H/0995/ 003	34009 377 491 4 5	MSD FRANCE	FR
ZOCOR 10 mg comprimidos recubiertos con película	FI/H/0995/ 002	58845	MERCK SHARP & DOHME DE ESPAÑA, S.A	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
ZOCOR 20 mg comprimidos recubiertos con película	FI/H/0995/ 003	58846	MERCK SHARP & DOHME DE ESPAÑA, S.A	ES
ZOCOR® 10 mg Filmtabletten	FI/H/0995/002	35406.01.00	MSD SHARP & DOHME GMBH	DE
Sinvacor 10 mg compresse rivestite con film	FI/H/0995/002	027209016	MSD ITALIA S.R.L.	IT
ZOCOR® 20 mg comprimés pelliculés	FI/H/0995/ 003	2011031037	MSD BELGIUM BVBA/SPRL	LU
ZOCOR 20 mg, comprimé pelliculé sécable	FI/H/0995/ 003	34009 330 954 8 2	MSD FRANCE	FR
ZOCOR 20 mg, comprimé pelliculé sécable	FI/H/0995/ 003	34009 377 624 4 1	MSD FRANCE	FR
ZOCOR 20 mg, comprimé pelliculé sécable	FI/H/0995/ 003	34009 367 668 9 1	MSD FRANCE	FR
ZOCOR 20 mg filmdrasjerte tabletter	FI/H/0995/003	0000-07908	MERCK SHARP & DOHME BV	NO
ZOCOR 20 mg, comprimé pelliculé sécable	FI/H/0995/ 003	34009 556 648 5 7	MSD FRANCE	FR
ZOCOR 20 mg, comprimé pelliculé sécable	FI/H/0995/ 003	34009 342 518 3 2	MSD FRANCE	FR
Zocord 20 mg Filmtabletten	FI/H/0995/003	1-19502	MERCK SHARP & DOHME GES.M.B.H.	AT
Zocord 10 mg filmdragerade tabletter	FI/H/0995/002	10772	MERCK SHARP & DOHME BV	SE
ZOCOR 10 mg, filmomhulde tabletten	FI/H/0995/002	RVG 13193	MERCK SHARP & DOHME BV	NL
ZOCOR FORTE 40 mg comprimidos recubiertos con película	FI/H/0995/ 004	61497	MERCK SHARP & DOHME DE ESPAÑA, S.A	ES
Sinvacor 20 mg compresse	FI/H/0995/003	027209028	MSD ITALIA S.R.L.	IT

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rivestite con film				
ZOCOR® 20 mg Filmtabletten	FI/H/0995/003	35406.02.00	MSD SHARP & DOHME GMBH	DE
ZOCOR 40 mg, comprimé pelliculé	FI/H/0995/ 004	34009 361 104 6 5	MSD FRANCE	FR
Zocord 40 mg filmdragerade tabletter	FI/H/0995/004	12462	MERCK SHARP & DOHME BV	SE
ZOCOR 20 mg comprimidos revestidos por película	FI/H/0995/ 003	8768754	MERCK SHARP & DOHME, LDA.	PT
ZOCOR 40 mg, comprimé pelliculé	FI/H/0995/ 004	34009 361 106 9 4	MSD FRANCE	FR
Zocor 20 mg, film-coated tablets	FI/H/0995/ 003	PA1286/022/003	MERCK SHARP & DOHME IRELAND (HUMAN HEALTH) LTD	IE
ZOCOR 40 mg, comprimé pelliculé	FI/H/0995/ 004	34009 563 036 1 8	MSD FRANCE	FR
ZOCOR 40 mg, filmomhulde tabletten	FI/H/0995/004	RVG 13195	MERCK SHARP & DOHME BV	NL
ZOCOR 20 mg, filmomhulde tabletten	FI/H/0995/003	RVG 13194	MERCK SHARP & DOHME BV	NL
ZOCOR 40 mg, comprimé pelliculé	FI/H/0995/ 004	34009 564 622 1 6	MSD FRANCE	FR
ZOCOR® 40 mg comprimés pelliculés	FI/H/0995/ 004	BE190206	MSD BELGIUM BVBA/SPRL	BE
Zocor® 20 mg, film-coated tablets	FI/H/0995/ 003	PL 00025/0242	MERCK SHARP & DOHME LTD.	UK
Zocord 20 mg filmdragerade tabletter	FI/H/0995/003	10773	MERCK SHARP & DOHME BV	SE
Zocor, filmoverttrukne tabletter	FI/H/0995/ 004	17195	MERCK SHARP & DOHME BV	DK
ZOCOR® FORTE 40 mg Filmtabletten	FI/H/0995/004	35406.03.00	MSD SHARP & DOHME GMBH	DE
ZOCOR 40 mg, comprimé pelliculé	FI/H/0995/ 004	34009 377 625 0 2	MSD FRANCE	FR
ZOCOR 40 mg, comprimé pelliculé	FI/H/0995/ 004	34009 361 105 2 6	MSD 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
Zocord 40 mg Filmtabletten	FI/H/0995/004	1-21714	MERCK SHARP & DOHME GES.M.B.H.	AT
ZOCOR 40 mg filmdrasjerte tabletter	FI/H/0995/004	1994-03357	MERCK SHARP & DOHME BV	NO
ZOCOR 40 mg, comprimé pelliculé	FI/H/0995/ 004	34009 356 188 0 1	MSD FRANCE	FR
ZOCOR® 40 mg filmomhulde tabletten	FI/H/0995/ 004	BE190206	MSD BELGIUM BVBA/SPRL	BE
ZOCOR® 20 mg filmomhulde tabletten	FI/H/0995/ 003	BE147235	MSD BELGIUM BVBA/SPRL	BE
Zocor 40 mg tabletti, kalvopäällysteinen	FI/H/0995/004	12198	MERCK SHARP & DOHME BV	FI
ZOCOR 40 mg, comprimé pelliculé	FI/H/0995/ 004	34009 356 190 5 1	MSD FRANCE	FR
ZOCOR 40 mg, comprimé pelliculé	FI/H/0995/ 004	34009 564 623 8 4	MSD FRANCE	FR
ZOCOR 40 mg, comprimé pelliculé	FI/H/0995/ 004	34009 563 037 8 6	MSD FRANCE	FR
Sinvacor 40 mg compresse rivestite con film	FI/H/0995/004	027209117	MSD ITALIA S.R.L.	IT
ZOCOR 40 mg, comprimé pelliculé	FI/H/0995/ 004	34009 377 492 0 6	MSD FRANCE	FR
Zocor, filmovertukne tabletter	FI/H/0995/ 003	13314	MERCK SHARP & DOHME BV	DK
ZOCOR 20 mg comprimidos revestidos por película	FI/H/0995/ 003	8768739	MERCK SHARP & DOHME, LDA.	PT
Zocor 80 mg tabletti, kalvopäällysteinen	FI/H/0995/005	13311	MERCK SHARP & DOHME BV	FI
Sinvacor 40 mg compresse rivestite con film	FI/H/0995/004	027209042	MSD ITALIA S.R.L.	IT
ZOCOR 40 mg, comprimé pelliculé	FI/H/0995/ 004	34009 356 189 7 9	MSD FRANCE	FR
ZOCOR® 20 mg comprimés pelliculés	FI/H/0995/ 003	BE147235	MSD BELGIUM BVBA/SPRL	BE
Zocor 40 mg, film-coated tablets	FI/H/0995/ 004	PA1286/022/004	MERCK SHARP & DOHME	IE

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			IRELAND (HUMAN HEALTH) LTD	
Zocor ®80 mg, film-coated tablets	FI/H/0995/ 005	PL 00025/0366	MERCK SHARP & DOHME LTD.	UK
ZOCOR 20 mg comprimidos revestidos por película	FI/H/0995/ 003	8768721	MERCK SHARP & DOHME, LDA.	PT
Zocor ®40 mg, film-coated tablets	FI/H/0995/ 004	PL 00025/0243	MERCK SHARP & DOHME LTD.	UK
ZOCOR® 40 mg comprimés pelliculés	FI/H/0995/ 004	2011031036	MSD BELGIUM BVBA/SPRL	LU
Sinvacor 20 mg compresse rivestite con film	FI/H/0995/003	027209105	MSD ITALIA S.R.L.	IT
ZOCOR 40 mg, comprimé pelliculé	FI/H/0995/ 004	34009 377 626 7 0	MSD FRANCE	FR
ZOCOR 10 mg, επικαλυμμένα με λεπτό υμένιο δισκία	UK/H/0687/002	28198/5-5-2011	VIANEX S.A.	GR
ZOCOR 20 mg, επικαλυμμένα με λεπτό υμένιο δισκία	UK/H/0687/003	28197/5-5-2011	VIANEX S.A.	GR
ZOCOR 40 mg, επικαλυμμένα με λεπτό υμένιο δισκία	UK/H/0687/004	28196/05-05-2011	VIANEX S.A.	GR
Simvastatin 10mg Tablets	not available	PL 36722/0060	SPECIAL CONCEPT DEVELOPMENT (UK) LTD	UK
Simvastatin 20mg Tablets	not available	PL 36722/0061	SPECIAL CONCEPT DEVELOPMENT (UK) LTD	UK
Simvastatin 40mg Tablets	not available	PL 36722/0062	SPECIAL CONCEPT DEVELOPMENT (UK) LTD	UK
SIMVA BASICS 30 mg Filmtabletten	DE/H/3518/001	86718.00.00	BASICS GMBH	DE
SIMVA BASICS 60 mg Filmtabletten	DE/H/3518/002	86719.00.00	BASICS GMBH	DE
Simva-Aristo® 30 mg Filmtabletten	not available	89391.00.00	ARISTO PHARMA GMBH (ART 57)	DE
Zocor 10 mg filmtablettá	not available	OGYI-T-4005/01	MSD PHARMA HUNGARY 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
Zocor 20 mg filmtabletta	not available	OGYI-T-4005/02	MSD PHARMA HUNGARY KFT.	HU
ZOCOR 80, 80 mg, tabletki powlekane	not available	R/8466	MSD POLSKA SP. Z O.O.	PL
ZOCOR 10, 10 mg, tabletki powlekane	not available	R/3659	MSD POLSKA SP. Z O.O.	PL
ZOCOR 40, 40 mg, tabletki powlekane	not available	7691	MSD POLSKA SP. Z O.O.	PL
ZOCOR 20, 20 mg, tabletki powlekane	not available	R/3660	MSD POLSKA SP. Z O.O.	PL
PANTOK 10 mg comprimidos recubiertos con pelicula	not available	59.182	LACER S.A.	ES
PANTOK 20 mg comprimidos recubiertos con pelicula	not available	59.183	LACER S.A.	ES
PANTOK FORTE 40 mg comprimidos recubiertos con pelicula	not available	62.330	LACER S.A.	ES
Zocor 10 mg, film-coated tablets	not available	12353	MERCK SHARP & DOHME BV	CY
Zocor 20 mg, film-coated tablets	not available	16156	MERCK SHARP & DOHME BV	CY
Simvastatin 10mg Tablets	not available	PL 17496/0027	DALKEITH LABORATORIES LIMITED	UK
Simvastatin 80 mg film-coated tablets	not available	PL 20416/0362	CRESCENT PHARMA LIMITED	UK
Simvastatin-ratiopharm® 30 mg Filmtabletten	not available	85907.00.00	RATIOPHARM GMBH	DE
Simvastatin-ratiopharm® 60 mg Filmtabletten	not available	85908.00.00	RATIOPHARM GMBH	DE
COLEMIN FORTE 40 mg comprimidos	not available	62.329	VIFOR PHARMA ESPAÑA, S.L.	ES

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COLEMIN 10 mg comprimidos	not available	59.181	VIFOR PHARMA ESPAÑA, S.L.	ES
COLEMIN 20 mg comprimidos	not available	59.180	VIFOR PHARMA ESPAÑA, S.L.	ES
Simvastatin 80 mg film-coated tablets	not available	PL 21880/0067	MEDREICH PLC	UK
Simvastatin 10 mg film-coated tablets	not available	PL 21880/0064	MEDREICH PLC	UK
Simvastatin Hexal 30 mg - Filmdabletten	FI/H/0141/004	1-24282	HEXAL PHARMA GMBH	AT
Lipcut 30 mg tabletti, kalvopäällysteinen	FI/H/0141/004	16015	SANDOZ A/S	FI
Simvastatin 80 mg film-coated tablets	not available	PL 49565/0017	RUDIPHARM LIMITED	UK
Simvastatin 40 mg film-coated tablets	not available	PL 49565/0016	RUDIPHARM LIMITED	UK
Simvastatin 20 mg film-coated tablets	not available	PL 49565/0015	RUDIPHARM LIMITED	UK
Simvastatin 10 mg film-coated tablets	not available	PL 49565/0014	RUDIPHARM LIMITED	UK
Simva-Aristo® 60 mg Filmdabletten	not available	89392.00.00	ARISTO PHARMA GMBH (ART 57)	DE
ZOCOR 20 mg comprimate filmate	not available	6795/2014/01	MERCK SHARP & DOHME ROMANIA SRL	RO
ZOCOR 20 mg comprimate filmate	not available	6795/2014/02	MERCK SHARP & DOHME ROMANIA SRL	RO
Liponorm 40 mg, compresse rivestite con film.	not available	027228081	NEOPHARMED GENTILI SPA	IT
Liponorm 40 mg, compresse rivestite con film.	not available	027228030	NEOPHARMED GENTILI SPA	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
Liponorm 20 mg, compresse rivestite con film.	not available	027228079	NEOPHARMED GENTILI SPA	IT
Liponorm 20 mg, compresse rivestite con film.	not available	027228028	NEOPHARMED GENTILI SPA	IT
Liponorm 10 mg, compresse rivestite con film.	not available	027228016	NEOPHARMED GENTILI SPA	IT
Simvastatin 20 mg film-coated tablets	not available	PL 21880/0065	MEDREICH PLC	UK
Simvastatin 40 mg film-coated tablets	not available	PL 21880/0066	MEDREICH PLC	UK
Sinvastatina Mylan 10 mg comprimidos revestidos por película	not available	3884780	MYLAN, LDA	PT
Sinvastatina Mylan 10 mg comprimidos revestidos por película	not available	3884889	MYLAN, LDA	PT
Sinvastatina Mylan 20 mg comprimidos revestidos por película	not available	3884988	MYLAN, LDA	PT
Sinvastatina Mylan 20 mg comprimidos revestidos por película	not available	3885084	MYLAN, LDA	PT
Sinvastatina Mylan 20 mg comprimidos revestidos por película	not available	4026589	MYLAN, LDA	PT
Sinvastatina Mylan 40 mg comprimidos revestidos por película	not available	3885183	MYLAN, LDA	PT

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Sinvastatina Mylan 40 mg comprimidos revestidos por película	not available	3885282	MYLAN, LDA	PT
Zocor Forte 40 mg filmtabletta	not available	OGYI-T-4005/03	MSD PHARMA HUNGARY KFT.	HU
SIMVASTATINE EG 40 mg, comprimé pelliculé	not available	NL30978	EG LABO LABORATOIRES EUROGENERICIS	FR
Zocor 40 mg, compresse rivestite con film.	not available	027216100	NEOPHARMED GENTILI SPA	IT
Zocor 20 mg, compresse rivestite con film.	not available	027216023	NEOPHARMED GENTILI SPA	IT
Zocor 10 mg, compresse rivestite con film.	not available	027216011	NEOPHARMED GENTILI SPA	IT
Zocor 40 mg, compresse rivestite con film.	not available	027216035	NEOPHARMED GENTILI SPA	IT
Zocor 20 mg, compresse rivestite con film.	not available	027216098	NEOPHARMED GENTILI SPA	IT