



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

28 May 2020  
EMA/259032/2020  
Human Medicines Evaluation Division

## List of nationally authorised medicinal products

Active substance: carbidopa / levodopa

Procedure no.: PSUSA/00000548/201910

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**Address for visits and deliveries** Refer to [www.ema.europa.eu/how-to-find-us](http://www.ema.europa.eu/how-to-find-us)

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<b>Product Name (in authorisation country)</b>	<b>MRP/DCP Authorisation number</b>	<b>National Authorisation Number</b>	<b>MAH of product in the member state</b>	<b>Member State where product is authorised</b>
SIRIO 12.5 mg + 125 mg compresse effervescenti	not available	035625045	CHIESI FARMACEUTICI S.P.A.	IT
SIRIO 25 mg + 100 mg compresse effervescenti	not available	035625058	CHIESI FARMACEUTICI S.P.A.	IT
SIRIO 12.5 mg + 125 mg compresse effervescenti	not available	035625060	CHIESI FARMACEUTICI S.P.A.	IT
SIRIO 25 mg + 100 mg compresse effervescenti	not available	035625072	CHIESI FARMACEUTICI S.P.A.	IT
Sinemet Depot Mite 25 mg/100 mg depottabletter	not available	8106	MERCK SHARP & DOHME BV	NO
Sinemet 12,5 mg/50 mg tablett	not available	7284	MERCK SHARP & DOHME BV	NO
Sinemet 25 mg/100 mg tablett	not available	6575	MERCK SHARP & DOHME BV	NO
NACOM® 100 mg/25 mg Retardtabletten Wirkstoffe: Levodopa und Carbidopa	not available	27846.00.00	MSD SHARP & DOHME GMBH	DE
Sinemet 12,5 mg/50 mg tablett	not available	10859	MERCK SHARP & DOHME BV	SE
Sinemet 25 mg/100 mg tablett	not available	10860	MERCK SHARP & DOHME BV	SE
Sinemet Depot, depottabletter	not available	13324	MERCK SHARP & DOHME BV	DK
Sinemet Depot Mite, depottabletter	not available	14211	MERCK SHARP & DOHME BV	DK
SINEMET® CR 50 mg/200 mg Prolonged-Release Tablets	not available	PL 00025/0269	MERCK SHARP & DOHME LTD.	UK
HALF SINEMET® CR 25 mg/100 mg Prolonged-	not available	PL 00025/0287	MERCK SHARP & DOHME LTD.	UK

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Release Tablets				
NACOM® 100 mg/25 mg Tabletten Wirkstoffe: Levodopa und Carbidopa	not available	3026.00.00	MSD SHARP & DOHME GMBH	DE
Duodopa 20 mg/ml + 5 mg/ml Gel zur intestinalen Anwendung	SE/H/0415/001	1-25624	ABBVIE GMBH	AT
Duodopa 20 mg/ml + 5 mg/ml, gel intestinal	SE/H/0415/001	BE276814	ABBVIE S.A.	BE
Duodopa 20 mg/ml + 5 mg/ml, intestinale gel	SE/H/0415/001	BE276814	ABBVIE S.A.	BE
Дуодопа 20 mg/ml + 5 mg/ml гел за прилагане в червата	SE/H/0415/001	20060683	ABBVIE DEUTSCHLAND GMBH&CO KG	BG
Duodopa 20 mg/ml + 5 mg/ml intestinální gel	SE/H/0415/001	27/391/05-C	ABBVIE S.R.O. (CZECH REPUBLIC)	CZ
Duodopa, Enteral gel	SE/H/0415/001	36377	ABBVIE A/S	DK
Duodopa 20 mg/ml + 5 mg/ml, geeli suoleen	SE/H/0415/001	19170	ABBVIE OY	FI
DUODOPA 20 mg/ml + 5 mg/ml, gel intestinal	SE/H/0415/001	34009 365 110 0 2	ABBVIE	FR
Duodopa 20 mg/ml + 5 mg/ml Gel zur intestinalen Anwendung	SE/H/0415/001	59725.00.00	ABBVIE DEUTSCHLAND GMBH & CO. KG	DE
Duodopa 20 mg/ml + 5 mg/ml εντερική γέλη	SE/H/0415/001	44420	ABBVIE PHARMACEUTICALS S.A.	GR
Duodopa 20 mg/ml + 5 mg/ml intesztinális gél	SE/H/0415/001	OGYI-T-10543/01	ABBVIE KFT	HU
Duodopa 20 mg/ml + 5 mg/ml þarmahlaup	SE/H/0415/001	IS/1/05/044/01	ABBVIE A/S	IS
Duodopa 20 mg/ml + 5 mg/ml intestinal gel	SE/H/0415/001	PA 1824/2/1	ABBVIE LIMITED	IE
Duodopa 20 mg/ml + 5 mg/ml gel intestinale	SE/H/0415/001	036885010	ABBVIE S.R.L.	IT

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Duodopa 20 mg/ml + 5 mg/ml intestinals gels	SE/H/0415/001	05-0485	ABBVIE SIA	LV
Duodopa 20/5mg/ml žarnyno gelis	SE/H/0415/001	LT/1/05/0331/001	ABBVIE SIA	LT
Duodopa 20 mg/ml + 5 mg/ml intestinale gel	SE/H/0415/001	RVG 30589	ABBVIE B.V.	NL
Duodopa, 20 mg/ml + 5 mg/ml, intestinalgel	SE/H/0415/001	04-2473	ABBVIE AS	NO
Duodopa 20 mg/ml + 5 mg/ml żel dojelitowy	SE/H/0415/001	11929	ABBVIE POLSKA SP. Z O.O.	PL
Duodopa, 20 mg/ml + 5 mg/ml, gel intestinal	SE/H/0415/001	5135587	ABBVIE, LDA.	PT
Duodopa intestinálny gél 20 mg/ml + 5 mg/ml	SE/H/0415/001	27/0389/05-S	ABBVIE S.R.O. (SLOVAKIA)	SK
Duodopa 20 mg/ml + 5 mg/ml intestinal gel	SE/H/0415/001	19210	ABBVIE AB	SE
Duodopa, 20 mg/ml + 5 mg/ml, intestinal gel	SE/H/0415/001	PL 41042/0001	ABBVIE LTD (UK)	UK
Duodopa, 20 mg/ml + 5 mg/ml, intestinaalgeel	SE/H/0415/001	502105	ABBVIE SIA	EE
Duodopa 20 mg/ml + 5 mg/ml, gel intestinal	SE/H/0415/001	2010010643	ABBVIE S.A.	LU
Duodopa 20 mg/ml + 5 mg/ml gel intestinal	SE/H/0415/001	66.547	ABBVIE SPAIN S.L.U.	ES
Duodopa 20 mg/ml + 5 mg/ml Gel zur intestinalen Anwendung	SE/H/0415/001	1-25624	ABBVIE GMBH	LI
Duodopa 20 mg/ml + 5 mg/ml intestinalni gel	SE/H/0415/001	HR-H-753613005	ABBVIE D.O.O. (CROATIA)	HR
Duodopa 20 mg/ml + 5 mg/ml gel intestinal	SE/H/0415/001	7217/2014/01	ABBVIE DEUTSCHLAND GMBH&CO KG	RO
Duodopa 20 mg/ml + 5 mg/ml intestinal gel	SE/H/0415/001	19170	ABBVIE OY	FI
Duodopa 20 mg/ml + 5	SE/H/0415/001	BE276814	ABBVIE S.A.	BE

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mg/ml, Gel zur intestinalen Anwendung				
Duodopa 20 mg/ml + 5 mg/ml, Gel zur intestinalen Anwendung	SE/H/0415/001	2010010643	ABBVIE S.A.	LU
Duodopa 20 mg/ml + 5 mg/ml intestinalni gel	SE/H/0415/001	H/05/00514/001	ABBVIE BIOFARMACEVTSKA DRUŽBA D.O.O.	SI
Duodopa 20 mg/ml + 5 mg/ml εντερική γέλη	SE/H/0415/001	19725	ABBVIE PHARMACEUTICALS S.A.	CY
Dopamar	NL/H/0358/002	14852	SANDOZ GMBH	PL
SINEMET DEPOT MITE 25 mg/100 mg FORÐATÖFLUR	not available	910001	MERCK SHARP & DOHME BV	IS
SINEMET 250 mg + 25 mg compresse	not available	023145016	MSD ITALIA S.R.L.	IT
SINEMET 200 mg + 50 mg compresse a rilascio modificato	not available	023145030	MSD ITALIA S.R.L.	IT
SINEMET 100 mg + 25 mg compresse a rilascio modificato	not available	023145042	MSD ITALIA S.R.L.	IT
SINEMET 100 mg + 25 mg compresse	not available	023145028	MSD ITALIA S.R.L.	IT
SINEMET CR 50/200 mg toimeainet prolongeeritult vabastavad tabletid	not available	090394	MERCK SHARP & DOHME OU	EE
Sinemet depot 50 mg/200 mg depottabletter	not available	10211	MERCK SHARP & DOHME BV	FI
SINEMET DEPOT 50 mg/200 mg depottabletit	not available	10211	MERCK SHARP & DOHME BV	FI
SINEMET 25/250 mg/250 mg tabletid	not available	090494	MERCK SHARP & DOHME OU	EE

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SINEMET 25/100 25 mg/100 mg tabletid	not available	380502	MERCK SHARP & DOHME OU	EE
Nakom 250 mg/25 mg tablete	not available	H/92/01076/001	LEK PHARMACEUTICALS D.D. LJUBLJANA	SI
SINEMET® 10 mg/100 mg Tablets	not available	PL 00025/0084	MERCK SHARP & DOHME LTD.	UK
SINEMET® 12.5 mg/50 mg Tablets	not available	PL 00025/0226	MERCK SHARP & DOHME LTD.	UK
SINEMET® Plus 25 mg/100 mg Tablets	not available	PL 00025/0150	MERCK SHARP & DOHME LTD.	UK
SINEMET® 25 mg/250 mg Tablets	not available	PL 00025/0085	MERCK SHARP & DOHME LTD.	UK
Nakom mite 100 mg/25 mg tablete	not available	H/92/01076/002	LEK PHARMACEUTICALS D.D. LJUBLJANA	SI
SINEMET 12,5 mg/50 mg TABLETTER	not available	9753	MERCK SHARP & DOHME BV	FI
SINEMET 25 mg/100 mg TABLETTER	not available	8298	MERCK SHARP & DOHME BV	FI
SINEMET 25 mg/100 mg tabletit	not available	8298	MERCK SHARP & DOHME BV	FI
SINEMET 12,5 mg/50 mg tabletit	not available	9753	MERCK SHARP & DOHME BV	FI
Sinemet 25 mg/250 mg comprimidos	not available	51.794	MERCK SHARP & DOHME DE ESPAÑA, S.A	ES
Sinemet Plus Retard 25 mg/100 mg comprimidos de liberación prolongada	not available	59.872	MERCK SHARP & DOHME DE ESPAÑA, S.A	ES
NACOM® 200 mg/50 mg Retardtabletten Wirkstoffe: Levodopa und Carbidopa	not available	25779.00.00	MSD SHARP & DOHME GMBH	DE
Sinemet Retard 50 mg/200 mg comprimidos de liberación prolongada	not available	59.334	MERCK SHARP & DOHME DE ESPAÑA, S.A	ES

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SINEMET LP 200 mg/50 mg, comprimé à libération prolongée	not available	34009 334 258 6 9	MSD FRANCE	FR
SINEMET 100 mg/10 mg, comprimé	not available	34009 320 080 5 6	MSD FRANCE	FR
SINEMET 250 mg/25 mg, comprimé sécable	not available	34009 317 246 3 6	MSD FRANCE	FR
SINEMET LP 100 mg/25 mg, comprimé à libération prolongée	not available	34009 335 537 6 0	MSD FRANCE	FR
SINEMET LP 100 mg/25 mg, comprimé à libération prolongée	not available	34009 335 664 8 7	MSD FRANCE	FR
SINEMET LP 100 mg/25 mg, comprimé à libération prolongée	not available	34009 335 543 6 1	MSD FRANCE	FR
SINEMET LP 100 mg/25 mg, comprimé à libération prolongée	not available	34009 335 538 2 1	MSD FRANCE	FR
SINEMET LP 200 mg/50 mg, comprimé à libération prolongée	not available	34009 334 262 3 1	MSD FRANCE	FR
SINEMET LP 200 mg/50 mg, comprimé à libération prolongée	not available	34009 335 692 1 1	MSD FRANCE	FR
SINEMET LP 100 mg/25 mg, comprimé à libération prolongée	not available	34009 335 540 7 1	MSD FRANCE	FR
SINEMET LP 100 mg/25 mg, comprimé à libération prolongée	not available	34009 335 665 4 8	MSD FRANCE	FR
SINEMET LP 200 mg/50 mg, comprimé à libération prolongée	not available	34009 334 259 2 0	MSD FRANCE	FR

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SINEMET LP 100 mg/25 mg, comprimé à libération prolongée	not available	34009 335 539 9 9	MSD FRANCE	FR
SINEMET LP 200 mg/50 mg, comprimé à libération prolongée	not available	34009 334 260 0 2	MSD FRANCE	FR
SINEMET LP 200 mg/50 mg, comprimé à libération prolongée	not available	34009 335 693 8 9	MSD FRANCE	FR
SINEMET LP 200 mg/50 mg, comprimé à libération prolongée	not available	34009 334 261 7 0	MSD FRANCE	FR
SINEMET LP 200 mg/50 mg, comprimé à libération prolongée	not available	34009 334 264 6 0	MSD FRANCE	FR
SINEMET LP 100 mg/25 mg, comprimé à libération prolongée	not available	34009 335 541 3 2	MSD FRANCE	FR
Sinemet 25 mg/100 mg-Tabletten	not available	1-18655	MERCK SHARP & DOHME GES.M.B.H.	AT
Sinemet retard-Tabletten	not available	1-19687	MERCK SHARP & DOHME GES.M.B.H.	AT
Sinemet 25 mg/250 mg-Tabletten	not available	15.715	MERCK SHARP & DOHME GES.M.B.H.	AT
Sinemet 25 mg/100 mg töflur	not available	833135	MERCK SHARP & DOHME BV	IS
Sinemet 12,5 mg/50 mg töflur	not available	IS/1/15/061/01	MERCK SHARP & DOHME BV	IS
NACOM® 250 mg/25 mg Tabletten; Wirkstoffe: Levodopa und Carbidopa	not available	6323039.00.00	MSD SHARP & DOHME GMBH	DE
Dopamar mite	NL/H/0358/001	14851	SANDOZ GMBH	PL
Sinemet 10mg/100mg Tablets	not available	PA 1286/9/3	MERCK SHARP & DOHME IRELAND (HUMAN HEALTH)	IE



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			LTD	
SINEMET CR 50mg/200mg Prolonged-release Tablets	not available	PA 1286/009/006	MERCK SHARP & DOHME IRELAND (HUMAN HEALTH) LTD	IE
Sinemet 12.5mg/50mg Tablets	not available	PA 1286/9/2	MERCK SHARP & DOHME IRELAND (HUMAN HEALTH) LTD	IE
Sinemet Plus 25mg/100mg Tablets	not available	PA 1286/9/4	MERCK SHARP & DOHME IRELAND (HUMAN HEALTH) LTD	IE
Sinemet 25mg/250mg Tablets	not available	PA 1286/9/5	MERCK SHARP & DOHME IRELAND (HUMAN HEALTH) LTD	IE
HALF SINEMET CR 25mg/100mg Prolonged-Release Tablets	not available	PA 1286/009/001	MERCK SHARP & DOHME IRELAND (HUMAN HEALTH) LTD	IE
Sinemet 25/100 25 mg + 100 mg comprimidos	not available	8372524	MERCK SHARP & DOHME, LDA.	PT
Sinemet 25/100 25 mg + 100 mg comprimidos	not available	8372532	MERCK SHARP & DOHME, LDA.	PT
Sinemet 25/250 25 mg + 250 mg comprimidos	not available	8372557	MERCK SHARP & DOHME, LDA.	PT
Sinemet 25/250 25 mg + 250 mg comprimidos	not available	8372540	MERCK SHARP & DOHME, LDA.	PT
Sinemet CR 50 + 200 mg comprimidos de libertação prolongada	not available	8372565	MERCK SHARP & DOHME, LDA.	PT
Sinemet CR 50 + 200 mg comprimidos de libertação prolongada	not available	8372573	MERCK SHARP & DOHME, LDA.	PT
СИHEMET 25 mg/250 mg таблетки	not available	20020163	MERCK SHARP & DOHME BULGARIA EOOD	BG
Flexilev 5 mg/1,25 mg, dispergerbara tableter	not available	47278	SENSIDOSE AB	SE

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för dosdispenser				
Flexilev 5 mg/1,25 mg, dispergible tabletter til dosisdispenser	SE/H/1560/001	56874	SENSIDOSE AB	DK
Zuades 5 mg/1,25 mg dispergerbare tabletter til dosedispenser	SE/H/1560/001	15-10951	SENSIDOSE AB	NO
Flexilev 5 mg/1,25 mg dispergoituva tabletti annostelulaitteeseen	SE/H/1560/001	33756	SENSIDOSE AB	FI
Flexilev 5 mg/1,25 mg dreifitafla fyrir skammtara	SE/H/1560/001	IS/1/16/073/01	SENSIDOSE AB	IS
Levovar 5mg/1.25 mg dispersible tablet for dose dispenser	MRP/SE/H/1560/001/MR	PL 45539/0001	SENSIDOSE AB	UK
Suades 5 mg/l ,25 mg Tabletten zur Herstellung einer Suspension zum Einnehmen für einen Dosierspender	SE/H/1560/001	96672.00.00	SENSIDOSE AB	DE
Flexilev 5 mg/1,25 mg disperseeruvad tabletid annustavas dispenseris kasutamiseks	SE/H/1560/001	915516	SENSIDOSE AB	EE
Zuades 5 mg/1,25 mg, disperseerbare tabletten voor dosisdispenser	SE/H/1560/001	RVG 118352	SENSIDOSE AB	NL
Flexilev 5 mg/1,25 mg disperģejamā tablete tablešu izsniegšanas ierīcei (Sensidose AB)	SE/H/1560/001/MR	16-0175	SENSIDOSE AB	LV
Zuades	SE/H/1560/001	2017040154	SENSIDOSE AB	LU
Zuades 5 mg/1,25 mg	SE/H/1560/001	137467	SENSIDOSE AB	AT

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Tabletten zur Herstellung einer Suspension zum Einnehmen für ein Dosiergerät				
Zuades 5 mg/1,25 mg, dispergeerbare tabletten voor dosisdispenser	SE/H/1560/001	BE527111	SENSIDOSE AB	BE
Flexilev, 5 mg + 1,25 mg, tabletka do sporządzania zawiesiny, do dozownika	SE/H/1560/001	24975	SENSIDOSE AB	PL
Flexilev 5 mg/1,25 mg, dispergerbara tabletter för dosdispenser	not available	47278	SENSIDOSE AB	SE
Flexilev 5 mg/1,25 mg, dispergible tabletter til dosisdispenser	SE/H/1560/001	56874	SENSIDOSE AB	DK
Zuades 5 mg/1,25 mg dispergerbare tabletter til dosedispenser	SE/H/1560/001	15-10951	SENSIDOSE AB	NO
Flexilev 5 mg/1,25 mg dispergoituva tabletti annostelulaitteeseen	SE/H/1560/001	33756	SENSIDOSE AB	FI
Flexilev 5 mg/1,25 mg dreifitafla fyrir skammtara	SE/H/1560/001	IS/1/16/073/01	SENSIDOSE AB	IS
Levovar 5mg/1.25 mg dispersible tablet for dose dispenser	MRP/SE/H/1560/001/M R	PL 45539/0001	SENSIDOSE AB	UK
Suades 5 mg/l ,25 mg Tabletten zur Herstellung einer Suspension zum Einnehmen für einen Dosierspender	SE/H/1560/001	96672.00.00	SENSIDOSE AB	DE

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Flexilev 5 mg/1,25 mg dispergeeruvad tabletid annustavas dispenseris kasutamiseks	SE/H/1560/001	915516	SENSIDOSE AB	EE
Zuades 5 mg/1,25 mg, dispergeerbare tabletten voor dosisdispenser	SE/H/1560/001	RVG 118352	SENSIDOSE AB	NL
Flexilev 5 mg/1,25 mg disperģējamā tablete tablešu izsniegšanas ierīcei (Sensidose AB)	SE/H/1560/001/MR	16-0175	SENSIDOSE AB	LV
Zuades	SE/H/1560/001	2017040154	SENSIDOSE AB	LU
Zuades 5 mg/1,25 mg Tabletten zur Herstellung einer Suspension zum Einnehmen für ein Dosiergerät	SE/H/1560/001	137467	SENSIDOSE AB	AT
Zuades 5 mg/1,25 mg, dispergeerbare tabletten voor dosisdispenser	SE/H/1560/001	BE527111	SENSIDOSE AB	BE
Flexilev, 5 mg + 1,25 mg, tabletka do sporządzenia zawiesiny, do dozownika	SE/H/1560/001	24975	SENSIDOSE AB	PL
SINEMET 25/100 mg tabletės	not available	LT/1/93/0358/003	MERCK SHARP & DOHME, UAB	LT
SINEMET 25/250 mg tabletės	not available	LT/1/93/0358/001	MERCK SHARP & DOHME, UAB	LT
SINEMET CR 50/200 mg modifikuoto atpalaidavimo tabletės	not available	LT/1/93/0358/004	MERCK SHARP & DOHME, UAB	LT
SINEMET 25/250 mg tabletės	not available	LT/1/93/0358/002	MERCK SHARP & DOHME, UAB	LT
SINEMET CR 50/200 mg	not available	LT/1/93/0358/005	MERCK SHARP & DOHME,	LT

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modifikuoto atpalaidavimo tabletės			UAB	
SINEMET 25/100 mg tabletės	not available	LT/1/93/0358/009	MERCK SHARP & DOHME, UAB	LT
Sinemet 10mg/100mg Tablets	not available	PA 1286/9/3	MERCK SHARP & DOHME IRELAND (HUMAN HEALTH) LTD	IE
Sinemet 12.5mg/50mg Tablets	not available	PA 1286/9/2	MERCK SHARP & DOHME IRELAND (HUMAN HEALTH) LTD	IE
Sinemet Plus 25mg/100mg Tablets	not available	PA 1286/9/4	MERCK SHARP & DOHME IRELAND (HUMAN HEALTH) LTD	IE
Sinemet 25mg/250mg Tablets	not available	PA 1286/9/5	MERCK SHARP & DOHME IRELAND (HUMAN HEALTH) LTD	IE
SINEMET 110, tabletten	not available	RVG 06706	MERCK SHARP & DOHME BV	NL
SINEMET CR 250, tabletten	not available	RVG 13706	MERCK SHARP & DOHME BV	NL
SINEMET 62,5, tabletten	not available	RVG 12858	MERCK SHARP & DOHME BV	NL
SINEMET CR 125, tabletten	not available	RVG 15175	MERCK SHARP & DOHME BV	NL
SINEMET 125, tabletten	not available	RVG 08740	MERCK SHARP & DOHME BV	NL
SINEMET 275, tabletten	not available	RVG 06707	MERCK SHARP & DOHME BV	NL
Sinemet Plus 25 mg/100 mg comprimidos	not available	55.866	MERCK SHARP & DOHME DE ESPAÑA, S.A	ES
SINEMET CR 200/50, 200 mg + 50 mg, tabletki o zmodyfikowanym uwalniani	not available	R/0204	MSD POLSKA SP. Z O.O.	PL
SINEMET CR 250, tablets	not available	13225	MERCK SHARP & DOHME BV	CY
Sinemet 25/100, tabletter	not available	11206	MERCK SHARP & DOHME BV	DK

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Sinemet 12,5/50, tableter	not available	12970	MERCK SHARP & DOHME BV	DK