



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

21 June 2017
EMA/506182/2017
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: carbidopa / levodopa (except for centrally authorised product)

Procedure no.: PSUSA/00000548/201610



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
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/250 mg comprimidos	not available	51.794	MERCK SHARP & DOHME DE ESPAÑA, S.A	ES
SINEMET DEPOT 50 mg/200 mg depottabletten	not available	10211	MERCK SHARP & DOHME BV	FI
SINEMET DEPOT 50 mg/200 mg depottabletit	not available	10211	MERCK SHARP & DOHME BV	FI
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

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
SINEMET* CR 50 mg/200 mg Prolonged-Release Tablets	not available	PL 0025/0269	MERCK SHARP & DOHME LTD.	UK
HALF SINEMET* CR 25 mg/100 mg Prolonged-Release Tablets	not available	PL 0025/0287	MERCK SHARP & DOHME LTD.	UK
SINEMET® Plus 25 mg/100 mg Tablets	not available	PL 00025/0150	MERCK SHARP & DOHME LTD.	UK
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

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
SINEMET PLUS 25/100 mg Comprimidos	not available	55.866	MERCK SHARP & DOHME DE ESPAÑA, S.A	ES
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 Depot 50 mg/200 mg depottabletter	not available	10930	MERCK SHARP & DOHME BV	SE
Sinemet Depot Mite 25 mg/100 mg depottabletter	not available	11828	MERCK SHARP & DOHME BV	SE
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

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
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
CARBIDOPA LEVODOPA TEVA 10 mg/100 mg, comprimé sécable	not available	NL21348	TEVA SANTÉ	FR
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

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
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	44420/28-6-2010	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
Duodopa 20 mg/ml + 5 mg/ml intestināls 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

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
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, zel 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/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, intestinal gel	SE/H/0415/001	MA 532/00401	ABBVIE LTD (UK)	MT
Duodopa 20 mg/ml + 5 mg/ml gel intestinal	SE/H/0415/001	66.547	ABBVIE SPAIN S.L.U.	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
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 mg/ml, Gel zur intestinalen Anwendung	SE/H/0415/001	BE276814	ABBVIE S.A.	BE
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
Sinemet Depot, depottabletter	not available	13324	MERCK SHARP & DOHME BV	DK

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
Sinemet Depot Mite, depottabletter	not available	14211	MERCK SHARP & DOHME BV	DK
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® 25 mg/250 mg Tablets	not available	PL 00025/0085	MERCK SHARP & DOHME LTD.	UK
Dopamar mite	NL/H/0358/001	14851	SANDOZ GMBH	PL
Dopamar	NL/H/0358/002	14852	SANDOZ GMBH	PL
Nakom® 250 mg/25 mg tablete	not available	5363-I-319/13	LEK PHARMACEUTICALS D.D. LJUBLJANA	SI
Nakom® mite 100 mg/25 mg tablete	not available	5363-I-320/13	LEK PHARMACEUTICALS D.D. LJUBLJANA	SI
Flexilev 5 mg/1,25 mg, dispergerbara tabletter för dosdispenser	not available	47278	SENSIDOSE AB	SE
SINEMET CR 50mg/200mg Prolonged-release Tablets	not available	PA 1286/009/006	MERCK SHARP & DOHME IRELAND (HUMAN HEALTH) LTD	IE

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
HALF SINEMET CR 25mg/100mg Prolonged-Release Tablets	not available	PA 1286/009/001	MERCK SHARP & DOHME IRELAND (HUMAN HEALTH) LTD	IE
SINEMET PLUS RETARD 25/100 mg comprimidos de liberación retardada	not available	59.872	MERCK SHARP & DOHME DE ESPAÑA, S.A	ES
LEVODOPA CARBIDOPA TEVA 250 mg/25 mg, comprimé sécable	not available	NL21349	TEVA SANTÉ	FR
SINEMET RETARD 50/200 mg comprimidos de liberación retardada	not available	59.334	MERCK SHARP & DOHME DE ESPAÑA, S.A	ES
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 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

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
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 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	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

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
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

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
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 ®	not available	69818/11/15-10-2014	VIANEX S.A.	GR
SINEMET ®	not available	84893/15-10-2014	VIANEX S.A.	GR
SINEMET CR 250, tablets	not available	13225	MERCK SHARP & DOHME BV	CY

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
NACOM® 200 mg/50 mg Retardtabletten	not available	25779.00.00	MSD SHARP & DOHME GMBH	DE
SINEMET CR 50/200 mg toimeainet prolongeeritult vabastavad tabletid	not available	090394	MERCK SHARP & DOHME OU	EE
SINEMET 25/250 25 mg/250 mg tabletid	not available	090494	MERCK SHARP & DOHME OU	EE
Sinemet Depot Mite 25 mg/100 mg depottabletter	not available	8106	MERCK SHARP & DOHME BV	NO
SINEMET CR 200/50, 200 mg + 50 mg, tabletki o zmodyfikowanym uwalnianiu	not available	R/0204	MSD POLSKA SP. Z O.O.	PL
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	not available	34009 317 246 3 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
SINEMET LP 100 mg/25 mg, comprimé à libération prolongée	not available	34009 335 537 6 0	MSD FRANCE	FR
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
СИМЕТЕТ 25 mg/250 mg таблетки	not available	20020163	MERCK SHARP & DOHME BULGARIA EOOD	BG
СИМЕТЕТ CR 50 mg/200 mg таблетки с удължено освобождаване	not available	20020164	MERCK SHARP & DOHME BULGARIA EOOD	BG
SINEMET CR 50 mg/200 mg ilgstošās darbības tabletes	not available	94-0232	MERCK SHARP & DOHME LATVIJA SIA	LV
SINEMET 25 mg /250 mg tabletes	not available	95-0244	MERCK SHARP & DOHME LATVIJA SIA	LV

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
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

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
SINEMET LP 200 mg/50 mg, comprimé à libération prolongée	not available	34009 334 259 2 0	MSD FRANCE	FR
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 250 mg + 25 mg compresse	not available	023145016	MSD ITALIA 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
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 25/250 mg tabletės	not available	LT/1/93/0358/002	MERCK SHARP & DOHME, UAB	LT
SINEMET CR 50/200 mg modifikuoto atpalaidavimo tabletės	not available	LT/1/93/0358/005	MERCK SHARP & DOHME, UAB	LT
NACOM® 100 mg/25 mg Retardtabletten	not available	27846.00.00	MSD SHARP & DOHME GMBH	DE
NACOM® 100 mg/25 mg Tabletten	not available	3026.00.00	MSD SHARP & DOHME GMBH	DE
SINEMET 25/100 25 mg/100 mg tabletid	not available	380502	MERCK SHARP & DOHME OU	EE
Sinemet 12,5 mg/50 mg tabletter	not available	7284	MERCK SHARP & DOHME BV	NO

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
Sinemet 25 mg/100 mg tabletter	not available	6575	MERCK SHARP & DOHME BV	NO
SINEMET 25/100 mg tabletès	not available	LT/1/93/0358/006	MERCK SHARP & DOHME, UAB	LT
SINEMET 25/100 mg tabletès	not available	LT/1/93/0358/007	MERCK SHARP & DOHME, UAB	LT
SINEMET 25/250 mg tabletès	not available	LT/1/93/0358/008	MERCK SHARP & DOHME, UAB	LT
Sinemet 25/100	not available	11206	MERCK SHARP & DOHME BV	DK
Sinemet 12,5/50	not available	12970	MERCK SHARP & DOHME BV	DK