Amsterdam, 12 May 2023
EMA/301745/2023
Human Medicines Division

List of nationally authorised medicinal products

Active substances: carbidopa / levodopa

Procedure no.: PSUSA/00000548/202210

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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
Co-Careldopa 10 mg / 100 mg tablets	not available	PL 17780/1127	ZENTIVA PHARMA UK LIMITED	XI
Co-Careldopa 12.5 mg / 50 mg tablets	not available	PL 17780/1129	ZENTIVA PHARMA UK LIMITED	XI
Co-Careldopa 25 mg / 100 mg tablets	not available	PL 17780/1130	ZENTIVA PHARMA UK LIMITED	XI
Co-Careldopa 25 mg / 250 mg tablets	not available	PL 17780/1128	ZENTIVA PHARMA UK LIMITED	XI
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	66.547	ABBVIE SPAIN S.L.U.	ES
Duodopa 20 mg/ml + 5 mg/ml gel intestinal	SE/H/0415/001	5135587	ABBVIE, LDA.	PT
Duodopa 20 mg/ml + 5 mg/ml gel intestinal	SE/H/0415/001	12111/2019/01	ABBVIE DEUTSCHLAND GMBH&CO KG	RO
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 Gel zur intestinalen Anwendung	SE/H/0415/001	1-25624	ABBVIE GMBH	AT
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 Gel zur intestinalen Anwendung	SE/H/0415/001	1-25624	ABBVIE GMBH	LI
Duodopa 20 mg/ml + 5 mg/ml intestinal gel	SE/H/0415/001	19170	ABBVIE OY	FI
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 intestinal gel	SE/H/0415/001	19210	ABBVIE AB	SE
Duodopa 20 mg/ml + 5	SE/H/0415/001	PL 41042/0001	ABBVIE LTD (UK)	XI

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
mg/ml intestinal gel				
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 intestinalni gel	SE/H/0415/001	HR-H-753613005	ABBVIE D.O.O. (CROATIA)	HR
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 intestinální gel	SE/H/0415/001	27/391/05-C	ABBVIE S.R.O. (CZECH REPUBLIC)	CZ
Duodopa 20 mg/ml + 5 mg/ml intestināls gels	SE/H/0415/001	05-0485	ABBVIE SIA	LV
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 εντερική γέλη	SE/H/0415/001	19725	ABBVIE PHARMACEUTICALS S.A.	CY
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, gel intestinal	SE/H/0415/001	BE276814	ABBVIE S.A.	BE
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 intestinal	SE/H/0415/001	2010010643	ABBVIE S.A.	LU
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, intestinale gel	SE/H/0415/001	BE276814	ABBVIE S.A.	BE
Duodopa 20/5mg/ml žarnyno	SE/H/0415/001	LT/1/05/0331/001	ABBVIE SIA	LT

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gelis				
Duodopa 240 mg/ml + 12 mg/ml oplossing voor infusie	SE/H/0415/003	RVG 128752	ABBVIE B.V.	NL
Duodopa 240 mg/ml + 12 mg/ml solução para perfusão	SE/H/0415/003	5844550	ABBVIE, LDA.	PT
Duodopa 240 mg/ml + 12 mg/ml soluzione per infusione	SE/H/0415/003	036885034	ABBVIE S.R.L.	IT
Duodopa intestinálny gél 20 mg/ml + 5 mg/ml	SE/H/0415/001	27/0389/05-S	ABBVIE S.R.O. (SLOVAKIA)	SK
Duodopa SC 240 mg/ml + 12 mg/ml infuzní roztok	SE/H/0415/003	27/341/21-C	ABBVIE S.R.O. (CZECH REPUBLIC)	CZ
Duodopa, 20 mg/ml + 5 mg/ml intestinaalgeel	SE/H/0415/001	502105	ABBVIE SIA	EE
Duodopa, 20 mg/ml + 5 mg/ml, żel dojelitowy	SE/H/0415/001	11929	ABBVIE SP. Z O.O.	PL
Duodopa, enteralgel	SE/H/0415/001	36377	ABBVIE A/S	DK
Flexilev 5 mg/1,25 mg dispergoituva tabletti annostelulaitteeseen	SE/H/1560/001	33756	SENSIDOSE AB	FI
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
Flexilev, 5 mg + 1,25 mg, tabletka do sporządzania zawiesiny, do dozownika	SE/H/1560/001	24975	SENSIDOSE AB	PL
HALF SINEMET® CR 25 mg/100 mg Prolonged-Release Tablets	not available	PL 00025/0287	ORGANON PHARMA (UK) LIMITED	XI
Levovar 5 mg/1.25 mg dispersible tablet for dose dispenser	SE/H/1560/001	PL 45539/0001	SENSIDOSE AB	XI
NACOM® 100 mg/25 mg Retardtabletten; Wirkstoffe: Levodopa und Carbidopa	not available	27846.00.00	ORGANONHEALTHCARE 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
NACOM® 100 mg/25 mg Tabletten; Wirkstoffe: Levodopa und Carbidopa	not available	3026.00.00	ORGANONHEALTHCARE GMBH	DE
NACOM® 200 mg/50 mg Retardtabletten; Wirkstoffe: Levodopa und Carbidopa	not available	25779.00.00	ORGANONHEALTHCARE GMBH	DE
NACOM® 250 mg/25 mg Tabletten; Wirkstoffe: Levodopa und Carbidopa	not available	6323039.00.00	ORGANONHEALTHCARE GMBH	DE
Nakom 250 mg/25 mg tablete	not available	H/92/01076/001	LEK PHARMACEUTICALS D.D. LJUBLJANA	SI
Nakom mite 100 mg/25 mg tablete	not available	H/92/01076/002	LEK PHARMACEUTICALS D.D. LJUBLJANA	SI
Produodopa 240 mg/ml + 12 mg/ml Infusionslösung	SE/H/0415/003	BE660571	ABBVIE S.A.	BE
Produodopa 240 mg/ml + 12 mg/ml Infusionslösung	SE/H/0415/003	2022110244	ABBVIE S.A.	LU
Produodopa 240 mg/ml + 12 mg/ml infusionsvätska, lösning	SE/H/0415/003	39796	ABBVIE OY	FI
Produodopa 240 mg/ml + 12 mg/ml infusionsvätska, lösning	SE/H/0415/003	62386	ABBVIE AB	SE
Produodopa 240 mg/ml + 12 mg/ml infusjonsvæske, oppløsning	SE/H/0415/003	21-14211	ABBVIE AS	NO
Produodopa 240 mg/ml + 12 mg/ml infuusioneste, liuos	SE/H/0415/003	39796	ABBVIE OY	FI
Produodopa 240 mg/ml + 12 mg/ml oldatos infúzió	SE/H/0415/003	OGYI-T-10543/02	ABBVIE KFT	HU
Produodopa 240 mg/ml + 12 mg/ml oplossing voor infusie	SE/H/0415/003	BE660571	ABBVIE S.A.	BE
Produodopa 240 mg/ml + 12 mg/ml otopina za infuziju	SE/H/0415/003	HR-H-382772882	ABBVIE D.O.O. (CROATIA)	HR
Produodopa 240 mg/ml + 12 mg/ml soluție perfuzabilă	SE/H/0415/003	14682/2022/01	ABBVIE DEUTSCHLAND GMBH&CO KG	RO
Produodopa 240 mg/ml + 12	SE/H/0415/003	PA1824/002/003	ABBVIE LIMITED	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
mg/ml solution for infusion				
Produodopa 240 mg/ml + 12 mg/ml solution for infusion	SE/H/0415/003	PLNI 41042/0048	ABBVIE LTD (UK)	XI
Produodopa 240 mg/ml + 12 mg/ml solution pour perfusion	SE/H/0415/003	BE660571	ABBVIE S.A.	BE
Produodopa 240 mg/ml + 12 mg/ml solution pour perfusion	SE/H/0415/003	2022110244	ABBVIE S.A.	LU
Produodopa 240 mg/ml + 12 mg/ml διάλυμα για έγχυση	SE/H/0415/003	023723	ABBVIE PHARMACEUTICALS S.A.	CY
Produodopa, 240 mg/ml + 12 mg/ml infusioonilahus	SE/H/0415/003	1074522	ABBVIE SIA	EE
SINEMET 100 mg + 25 mg compresse	not available	023145028	ORGANON ITALIA S.R.L.	IT
SINEMET 100 mg + 25 mg compresse a rilascio modificato	not available	023145042	ORGANON ITALIA S.R.L.	IT
SINEMET 100 mg/10 mg, comprimé	not available	34009 320 080 5 6	ORGANON_FRANCE	FR
SINEMET 110, tabletten	not available	RVG 06706	N.V. ORGANON	NL
SINEMET 12,5 mg/50 mg tabletit	not available	9753	N.V. ORGANON	FI
Sinemet 12,5 mg/50 mg tablett	not available	10859	N.V. ORGANON	SE
SINEMET 12,5 mg/50 mg TABLETTER	not available	9753	N.V. ORGANON	FI
Sinemet 12,5 mg/50 mg tabletter	not available	7284	N.V. ORGANON	NO
Sinemet 12,5 mg/50 mg töflur	not available	IS/1/15/061/01	N.V. ORGANON	IS
Sinemet 12,5/50, tabletter	not available	12970	N.V. ORGANON	DK
SINEMET 125, tabletten	not available	RVG 08740	N.V. ORGANON	NL
SINEMET 200 mg + 50 mg compresse a rilascio modificato	not available	023145030	ORGANON 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 25 mg/100 mg tabletit	not available	8298	N.V. ORGANON	FI
Sinemet 25 mg/100 mg tablett	not available	10860	N.V. ORGANON	SE
SINEMET 25 mg/100 mg TABLETTER	not available	8298	N.V. ORGANON	FI
Sinemet 25 mg/100 mg tabletter	not available	6575	N.V. ORGANON	NO
Sinemet 25 mg/100 mg-Tabletten	not available	1-18655	ORGANONHEALTHCARE GMBH	AT
Sinemet 25 mg/250 mg comprimidos	not available	51794	ORGANONSALUD, S.L.	ES
Sinemet 25 mg/250 mg-Tabletten	not available	15.715	ORGANONHEALTHCARE GMBH	AT
Sinemet 25/100 25 mg + 100 mg comprimidos	not available	8372524	ORGANONPORTUGAL, SOCIEDADE UNIPESSOAL LDA.	PT
Sinemet 25/100 25 mg + 100 mg comprimidos	not available	8372532	ORGANONPORTUGAL, SOCIEDADE UNIPESSOAL LDA.	PT
SINEMET 25/100 25 mg/100 mg tabletid	not available	380502	N.V. ORGANON	EE
SINEMET 25/100 mg tabletės	not available	LT/1/93/0358/003	N.V. ORGANON	LT
SINEMET 25/100 mg tabletės	not available	LT/1/93/0358/009	N.V. ORGANON	LT
Sinemet 25/250 25 mg + 250 mg comprimidos	not available	8372540	ORGANONPORTUGAL, SOCIEDADE UNIPESSOAL LDA.	PT
Sinemet 25/250 25 mg + 250 mg comprimidos	not available	8372557	ORGANONPORTUGAL, SOCIEDADE UNIPESSOAL LDA.	PT
SINEMET 25/250 25 mg/250 mg tabletid	not available	090494	N.V. ORGANON	EE
SINEMET 25/250 mg tabletės	not available	LT/1/93/0358/001	N.V. ORGANON	LT
SINEMET 25/250 mg tabletės	not available	LT/1/93/0358/002	N.V. ORGANON	LT
SINEMET 250 mg + 25 mg compresse	not available	023145016	ORGANON ITALIA S.R.L.	IT
SINEMET 250 mg/25 mg, comprimé sécable	not available	34009 317 246 3 6	ORGANON_FRANCE	FR
SINEMET 275, tabletten	not available	RVG 06707	N.V. ORGANON	NL
SINEMET 62,5, tabletten	not available	RVG 12858	N.V. ORGANON	NL

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 125, tabletten	not available	RVG 15175	N.V. ORGANON	NL
SINEMET CR 250, tablets	not available	13225	MERCK SHARP & DOHME BV	CY
SINEMET CR 250, tabletten	not available	RVG 13706	N.V. ORGANON	NL
Sinemet CR 50 + 200 mg comprimidos de libertação prolongada	not available	8372565	ORGANONPORTUGAL, SOCIEDADE UNIPESSOAL LDA.	PT
Sinemet CR 50 + 200 mg comprimidos de libertação prolongada	not available	8372573	ORGANONPORTUGAL, SOCIEDADE UNIPESSOAL LDA.	PT
SINEMET CR 50/200 mg modifikuoto atpalaidavimo tabletės	not available	LT/1/93/0358/004	N.V. ORGANON	LT
SINEMET CR 50/200 mg modifikuoto atpalaidavimo tabletės	not available	LT/1/93/0358/005	N.V. ORGANON	LT
SINEMET CR 50/200 mg toimeainet prolongeeritult vabastavad tabletid	not available	090394	N.V. ORGANON	EE
SINEMET DEPOT 50 mg/200 mg depottabletit	not available	10211	N.V. ORGANON	FI
Sinemet depot 50 mg/200 mg depottabletter	not available	10211	N.V. ORGANON	FI
Sinemet Depot Mite 25 mg/100 mg depottabletter	not available	8106	N.V. ORGANON	NO
SINEMET DEPOT MITE 25 mg/100 mg FORÐATÖFLUR	not available	910001	N.V. ORGANON	IS
Sinemet Depot Mite, depottabletter	not available	14211	N.V. ORGANON	DK
SINEMET LP 100 mg/25 mg, comprimé à libération prolongée	not available	34009 335 537 6 0	ORGANON_FRANCE	FR
SINEMET LP 100 mg/25 mg, comprimé à libération prolongée	not available	34009 335 538 2 1	ORGANON_FRANCE	FR
SINEMET LP 100 mg/25 mg, comprimé à libération prolongée	not available	34009 335 539 9 9	ORGANON_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 335 540 7 1	ORGANON_FRANCE	FR
SINEMET LP 100 mg/25 mg, comprimé à libération prolongée	not available	34009 335 541 3 2	ORGANON_FRANCE	FR
SINEMET LP 100 mg/25 mg, comprimé à libération prolongée	not available	34009 335 543 6 1	ORGANON_FRANCE	FR
SINEMET LP 100 mg/25 mg, comprimé à libération prolongée	not available	34009 335 664 8 7	ORGANON_FRANCE	FR
SINEMET LP 100 mg/25 mg, comprimé à libération prolongée	not available	34009 335 665 4 8	ORGANON_FRANCE	FR
SINEMET LP 200 mg/50 mg, comprimé à libération prolongée	not available	34009 334 258 6 9	ORGANON_FRANCE	FR
SINEMET LP 200 mg/50 mg, comprimé à libération prolongée	not available	34009 334 259 2 0	ORGANON_FRANCE	FR
SINEMET LP 200 mg/50 mg, comprimé à libération prolongée	not available	34009 334 260 0 2	ORGANON_FRANCE	FR
SINEMET LP 200 mg/50 mg, comprimé à libération prolongée	not available	34009 334 261 7 0	ORGANON_FRANCE	FR
SINEMET LP 200 mg/50 mg, comprimé à libération prolongée	not available	34009 334 262 3 1	ORGANON_FRANCE	FR
SINEMET LP 200 mg/50 mg, comprimé à libération prolongée	not available	34009 334 264 6 0	ORGANON_FRANCE	FR
SINEMET LP 200 mg/50 mg, comprimé à libération prolongée	not available	34009 335 692 1 1	ORGANON_FRANCE	FR
SINEMET LP 200 mg/50 mg,	not available	34009 335 693 8 9	ORGANON_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
comprimé à libération prolongée				
Sinemet Plus 25 mg/100 mg comprimidos	not available	55866	ORGANONSALUD, S.L.	ES
Sinemet Plus Retard 25 mg/100 mg comprimidos de liberación prolongada	not available	59872	ORGANONSALUD, S.L.	ES
Sinemet Retard 50 mg/200 mg comprimidos de liberación prolongada	not available	59334	ORGANONSALUD, S.L.	ES
SINEMET® 10 mg/100 mg Tablets	not available	PL 00025/0084	ORGANON PHARMA (UK) LIMITED	XI
SINEMET® 12.5 mg/50 mg Tablets	not available	PL 00025/0226	ORGANON PHARMA (UK) LIMITED	XI
SINEMET® 25 mg/250 mg Tablets	not available	PL 00025/0085	ORGANON PHARMA (UK) LIMITED	XI
SINEMET® CR 50 mg/200 mg Prolonged-Release Tablets	not available	PL 00025/0269	ORGANON PHARMA (UK) LIMITED	XI
SINEMET® Plus 25 mg/100 mg Tablets	not available	PL 00025/0150	ORGANON PHARMA (UK) LIMITED	XI
SIRIO 12.5 mg + 125 mg compresse effervescenti	not available	035625045	CHIESI ITALIA S.P.A.	IT
SIRIO 12.5 mg + 125 mg compresse effervescenti	not available	035625060	CHIESI ITALIA S.P.A.	IT
SIRIO 25 mg + 100 mg compresse effervescenti	not available	035625058	CHIESI ITALIA S.P.A.	IT
SIRIO 25 mg + 100 mg compresse effervescenti	not available	035625072	CHIESI ITALIA S.P.A.	IT
Zuades 5 mg/1,25 mg comprimés dispersibles pour distributeur-doseur	SE/H/1560/001	2017040154	SENSIDOSE AB	LU
Zuades 5 mg/1,25 mg dispergerbare tabletter til dosedispenser	SE/H/1560/001	15-10951	SENSIDOSE AB	NO
Zuades 5 mg/1,25 mg Tabletten zur Herstellung	SE/H/1560/001	137467	SENSIDOSE AB	AT

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
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
Zuades 5 mg/1,25 mg, dispergeerbare tabletten voor dosisdispenser	SE/H/1560/001	RVG 118352	SENSIDOSE AB	NL
Дуодопа 20 mg/ml + 5 mg/ml гел за прилагане в червата	SE/H/0415/001	20060683	ABBVIE DEUTSCHLAND GMBH&CO KG	BG
Продуодопа 240 mg/ml + 12 mg/ml инфузионен разтвор	SE/H/0415/003	BG/MA/MP-60638/19.10.2022	ABBVIE DEUTSCHLAND GMBH&CO KG	BG
СИНЕМЕТ 25 mg/250 mg таблетки	not available	20020163	N.V. ORGANON	BG