



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

09 February 2023
EMA/99859/2023
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: benserazide / levodopa

Procedure no.: PSUSA/00000330/202206



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
Madopar "125", kapsler, hårde	not available	6366	ROCHE A/S	DK
Madopar "125", tabletter	not available	13503	ROCHE A/S	DK
Madopar "62,5", kapsler, hårde	not available	9821	ROCHE A/S	DK
Madopar „125“ hörð hylki.	not available	731657 (IS)	ROCHE A/S	IS
Madopar „125“ töflur	not available	890032 (IS)	ROCHE A/S	IS
Madopar „62,5“ hörð hylki	not available	792435 (IS)	ROCHE A/S	IS
Madopar 100 mg + 25 mg capsule rigide	not available	023142019	ROCHE S.P.A.	IT
Madopar 100 mg + 25 mg capsule rigide a rilascio prolungato	not available	023142045	ROCHE S.P.A.	IT
Madopar 100 mg + 25 mg compresse dispersibili	not available	023142058	ROCHE 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
Madopar 100 mg/25 mg - lösliche Tabletten	not available	1-21773	ROCHE AUSTRIA GMBH	AT
Madopar 100 mg/25 mg - Tabletten	not available	1-22672	ROCHE AUSTRIA GMBH	AT
Madopar 100 mg/25 mg depotkapseli	not available	9882	ROCHE OY	FI
Madopar 100 mg/25 mg depotkapslar	not available	9882	ROCHE OY	FI
Madopar 100 mg/25 mg dispergeeruvad tabletid	not available	184197	ROCHE EESTI OÜ	EE
Madopar 100 mg/25 mg disperģējamās tabletes	not available	00-0723	ROCHE LATVIJA SIA	LV
Madopar 100 mg/25 mg disperguojamosios tabletės	not available	LT/1/94/0936/002	UAB "ROCHE LIETUVA"	LT
Madopar 100 mg/25 mg Dispersible Tablets	not available	PL 00031/0221	ROCHE PRODUCTS LTD	XI
Madopar 100 mg/25 mg disperzibilne tablete	not available	H/96/00958/001	ROCHE FARMACEVTSKA DRUŽBA D.O.O.	SI

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
Madopar 100 mg/25 mg diszpergálódó tabletta	not available	OGYI-T-1157/02	ROCHE (MAGYARORSZÁG) KFT	HU
Madopar 100 mg/25 mg Hard Capsules	not available	PL 00031/0073	ROCHE PRODUCTS LTD	XI
Madopar 100 mg/25 mg kietosios kapsulės	not available	LT/1/94/0936/003	UAB "ROCHE LIETUVA"	LT
Madopar 100 mg/25 mg kõvakapslid	not available	403902	ROCHE EESTI OÜ	EE
Madopar 100 mg/25 mg retard kemény kapszula	not available	OGYI-T-1157/03	ROCHE (MAGYARORSZÁG) KFT	HU
Madopar 100 mg/25 mg tablete	not available	H/96/00958/002	ROCHE FARMACEVTSKA DRUŽBA D.O.O.	SI
Madopar 100 mg/25 mg tabletter	not available	9672	ROCHE OY	FI
Madopar 100 mg/25 mg tabletti	not available	9672	ROCHE OY	FI
Madopar 100mg/25mg Dispersible Tablets	not available	PA2307/004/003	ROCHE PRODUCTS (IRELAND) 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
Madopar 12,5/50 kapsler, harde	not available	6694	ROCHE NORGE AS, NORWAY	NO
Madopar 125 mg T Tabletten	not available	6036937.00.01	ROCHE PHARMA AG	DE
Madopar 125 mg tablete	not available	HR-H-771762650	ROCHE D.O.O.	HR
Madopar 125 mg, 100 mg + 25 mg, kapsułki	not available	R/0950	ROCHE POLSKA SP.O.O.	PL
Madopar 125 mg, 100 mg + 25 mg, tabletki do sporządzania zawiesiny doustnej	not available	7487	ROCHE POLSKA SP.O.O.	PL
Madopar 125 mg, dispergeerbare tabletten	not available	RVG 19428	ROCHE NEDERLAND B.V.	NL
Madopar 125 mg, tabletten	not available	RVG 12059	ROCHE NEDERLAND B.V.	NL
Madopar 200 mg + 50 mg compresse divisibili	not available	023142033	ROCHE S.P.A.	IT
Madopar 200 mg + 50 mg comprimidos	not available	8557926	ROCHE FARMACÊUTICA QUÍMICA, 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
Madopar 200 mg + 50 mg comprimidos	not available	8557900	ROCHE FARMACÊUTICA QUÍMICA, LDA.	PT
Madopar 200 mg/50 mg - Tabletten	not available	17.235	ROCHE AUSTRIA GMBH	AT
Madopar 200 mg/50 mg comprimate	not available	13589/2020/01	ROCHE ROMANIA SRL	RO
Madopar 200 mg/50 mg Hard Capsules	not available	PL 00031/0074	ROCHE PRODUCTS LTD	XI
Madopar 200 mg/50 mg tabletes	not available	96-0643	ROCHE LATVIJA SIA	LV
Madopar 200 mg/50 mg tabletės	not available	LT/1/94/0936/001	UAB "ROCHE LIETUVA"	LT
Madopar 200 mg/50 mg tabletid	not available	046594	ROCHE EESTI OÜ	EE
Madopar 200 mg/50 mg tabletta	not available	OGYI-T-1157/01	ROCHE (MAGYARORSZÁG) KFT	HU
Madopar 200 mg/50 mg tabletter	not available	8611	ROCHE OY	FI

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
Madopar 200 mg/50 mg tabletti	not available	8611	ROCHE OY	FI
Madopar 200mg/50mg Hard Capsules	not available	PA2307/004/001	ROCHE PRODUCTS (IRELAND) LIMITED	IE
Madopar 25/100 kapsler, harde	not available	5967	ROCHE NORGE AS, NORWAY	NO
Madopar 250 mg comprimidos	not available	52.146	ROCHE FARMA, S.A.	ES
Madopar 250 mg Tabletten	not available	861.00.01	ROCHE PHARMA AG	DE
Madopar 250 mg, 200 mg + 50 mg, tabletki	not available	R/0951	ROCHE POLSKA SP.O.O.	PL
Madopar 250 mg, tabletten	not available	RVG 11605	ROCHE NEDERLAND B.V.	NL
Madopar 250 tablety	not available	27/391/01-C	ROCHE S. R. O.	CZ
Madopar 50 mg/12,5 mg - Kapseln	not available	16.549	ROCHE AUSTRIA GMBH	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
Madopar 50 mg/12.5 mg Dispersible Tablets	not available	PL 00031/0220	ROCHE PRODUCTS LTD	XI
Madopar 50 mg/12.5 mg Hard Capsules	not available	PL 00031/0125	ROCHE PRODUCTS LTD	XI
Madopar 50mg/12.5mg Dispersible Tablets	not available	PA2307/004/002	ROCHE PRODUCTS (IRELAND) LIMITED	IE
Madopar 62,5 mg, 50 mg + 12,5 mg, kapsułki	not available	R/0949	ROCHE POLSKA SP.O.O.	PL
Madopar 62,5 mg, 50 mg + 12,5 mg, tabletki do sporządzania zawiesiny doustnej	not available	7486	ROCHE POLSKA SP.O.O.	PL
Madopar 62,5 mg, capsules	not available	RVG 08475	ROCHE NEDERLAND B.V.	NL
Madopar CR 100 mg/25 mg - Kapseln	not available	1-19177	ROCHE AUSTRIA GMBH	AT
Madopar CR 100 mg/25 mg Prolonged Release Hard Capsules	not available	PL 00031/0227	ROCHE PRODUCTS LTD	XI
Madopar Depot	not available	13087	ROCHE 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
Madopar Depot 100 mg/25 mg hörð forðahylki.	not available	870211	ROCHE A/S	IS
Madopar Depot 25/100 depotkapsler	not available	7430	ROCHE NORGE AS, NORWAY	NO
Madopar DEPOT Hartkapseln, retardiert	not available	17010.00.00	ROCHE PHARMA AG	DE
Madopar HBS 100 mg + 25 mg cápsulas de libertação prolongada	not available	8402933	ROCHE FARMACÊUTICA QUÍMICA, LDA.	PT
Madopar HBS 100 mg/25 mg ilgstošās darbības cietās kapsulas	not available	96-0353	ROCHE LATVIJA SIA	LV
Madopar HBS 100 mg/25 mg pailginto atpalaidavimo kietosios kapsulės	not available	LT/1/94/0936/004	UAB "ROCHE LIETUVA"	LT
Madopar HBS 100 mg/25 mg toimeainet prolongeeritult vabastavad kõvakapslid	not available	142896	ROCHE EESTI OÜ	EE
Madopar HBS 125 mg, capsules met gereguleerde afgifte	not available	RVG 12489	ROCHE NEDERLAND B.V.	NL
Madopar HBS capsule cu eliberare modificată	not available	13590/2020/02	ROCHE ROMANIA SRL	RO

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
Madopar HBS capsule cu eliberare modificată	not available	13590/2020/01	ROCHE ROMANIA SRL	RO
Madopar HBS, 100 mg + 25 mg, kapsułki	not available	R/3775	ROCHE POLSKA SP.O.O.	PL
Madopar Quick "125"	not available	18676	ROCHE A/S	DK
Madopar Quick "62,5"	not available	18675	ROCHE A/S	DK
Madopar Quick „62,5“ lausnartöflur	not available	970268 (IS)	ROCHE A/S	IS
Madopar QUICK 100 mg/25 mg liukeneva tabletti	not available	12242	ROCHE OY	FI
Madopar QUICK 100 mg/25 mg lösliga tabletter	not available	12242	ROCHE OY	FI
Madopar Quick„125“ lausnartöflur.	not available	970269 (IS)	ROCHE A/S	IS
Madopar Retard 100 mg/25 mg cápsulas duras de liberación prolongada	not available	62.162	ROCHE FARMA, 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
Madopar Solubile 12,5/50 oppløselige tabletter	not available	8052	ROCHE NORGE AS, NORWAY	NO
Madopar, 200 mg + 50 mg, kapsulki	not available	R/0952	ROCHE POLSKA SP.O.O.	PL
Madopar®	not available	4970/13.06.2018	ROCHE (HELLAS) SA	GR
Madopar® 125 mg Hartkapseln	not available	6036937.00.00	ROCHE PHARMA AG	DE
Madopar® 62,5 mg Hartkapseln	not available	861.00.00	ROCHE PHARMA AG	DE
Madopar® LT Tabletten zur Herstellung einer Suspension zum Einnehmen Levodopa 100 mg Benserazid 25 mg (als Benserazidhydrochlorid)	not available	32582.01.00	ROCHE PHARMA AG	DE
Madopark 100 mg/25 mg tabletter	not available	10828	ROCHE AB - SOLNA	SE
Madopark DEPOT 100 mg/25 mg depotkapslar, hårda	not available	11479	ROCHE AB - SOLNA	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
Madopark Quick 100 mg/25 mg tabletter	not available	12229	ROCHE AB - SOLNA	SE
Madopark Quick mite 50 mg/12,5 mg tabletter	not available	10951	ROCHE AB - SOLNA	SE
Мадопар 100 mg/25 mg диспергиращи се таблетки Madopar 100 mg/25 mg dispersible tablets	not available	9800255	ROCHE BULGARIA EOOD	BG
Мадопар 200 mg/50 mg таблетки Madopar 200 mg/50 mg tablets	not available	20020187	ROCHE BULGARIA EOOD	BG
Modopar 125 (100 mg/25 mg), gélule	not available	34009 317 043 5 5	ROCHE	FR
Modopar 125 (100 mg/25 mg), gélule	not available	34009 317 041 2 6	ROCHE	FR
Modopar 125 (100 mg/25 mg), gélule	not available	34009 317 042 9 4	ROCHE	FR
Modopar 125 (100 mg/25 mg), gélule	not available	34009 300 665 5 3	ROCHE	FR
Modopar 125 (100 mg/25 mg), gélule	not available	34009 300 665 6 0	ROCHE	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
Modopar 125 (100 mg/25 mg), gélule	not available	34009 300 665 7 7	ROCHE	FR
MODOPAR 125 DISPERSIBLE (100 mg/25 mg), comprimé sécable pour suspension buvable	not available	34009 333 131 2 8	ROCHE	FR
MODOPAR 125 DISPERSIBLE (100 mg/25 mg), comprimé sécable pour suspension buvable	not available	34009 300 666 6 9	ROCHE	FR
Modopar 250 (200 mg/50 mg), gélule	not available	34009 317 048 7 4	ROCHE	FR
Modopar 250 (200 mg/50 mg), gélule	not available	34009 317 047 0 6	ROCHE	FR
Modopar 250 (200 mg/50 mg), gélule	not available	34009 317 049 3 5	ROCHE	FR
Modopar 250 (200 mg/50 mg), gélule	not available	34009 300 666 1 4	ROCHE	FR
Modopar 250 (200 mg/50 mg), gélule	not available	34009 300 665 9 1	ROCHE	FR
Modopar 250 (200 mg/50 mg), gélule	not available	34009 300 666 0 7	ROCHE	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
Modopar 62,5 (50 mg/12,5 mg), gélule	not available	34009 324 076 2 0	ROCHE	FR
Modopar 62,5 (50 mg/12,5 mg), gélule	not available	34009 300 665 4 6	ROCHE	FR
Modopar L.P. 125 (100 mg/25 mg), gélule a liberation prolongee	not available	34009 329 854 3 2	ROCHE	FR
Modopar L.P. 125 (100 mg/25 mg), gélule a liberation prolongee	not available	34009 329 852 0 3	ROCHE	FR
Modopar L.P. 125 (100 mg/25 mg), gélule a liberation prolongee	not available	34009 329 853 7 1	ROCHE	FR
Modopar L.P. 125 (100 mg/25 mg), gélule a liberation prolongee	not available	34009 300 666 2 1	ROCHE	FR
Modopar L.P. 125 (100 mg/25 mg), gélule a liberation prolongee	not available	34009 300 666 5 2	ROCHE	FR
MODOPAR L.P. 125 (100 mg/25 mg), gélule à libération prolongée	not available	34009 300 666 3 8	ROCHE	FR
Prolopa 125, 100 mg/25 mg Tabletten zur Herstellung einer Suspension zum Einnehmen	not available	BE182226	N.V. ROCHE S.A.	BE

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
Prolopa 125, 100 mg/25 mg, comprimés dispersibles	not available	BE182226	N.V. ROCHE S.A.	BE
Prolopa 125, 100 mg/25 mg, comprimés dispersibles	not available	2004068272	N.V. ROCHE S.A.	LU
Prolopa 125, 100 mg/25 mg, dispergeerbare tabletten	not available	BE182226	N.V. ROCHE S.A.	BE
Prolopa 125, 100 mg/25 mg, Tabletten zur Herstellung einer Suspension zum Einnehmen	not available	2004068272	N.V. ROCHE S.A.	LU
Prolopa 250, 200 mg/50 mg, comprimés	not available	BE132492	N.V. ROCHE S.A.	BE
Prolopa 250, 200 mg/50 mg, comprimés	not available	2004068273	N.V. ROCHE S.A.	LU
Prolopa 250, 200 mg/50 mg, tabletten	not available	BE132492	N.V. ROCHE S.A.	BE
Prolopa 250, 200 mg/50 mg, Tabletten	not available	BE132492	N.V. ROCHE S.A.	BE
Prolopa 250, 200 mg/50 mg, Tabletten	not available	2004068273	N.V. ROCHE S.A.	LU

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
Prolopa HBS 125, 100 mg/25 mg Hartkapseln, retardiert	not available	BE149475	N.V. ROCHE S.A.	BE
Prolopa HBS 125, 100 mg/25 mg, capsules met verlengde afgifte, hard	not available	BE149475	N.V. ROCHE S.A.	BE
Prolopa HBS 125, 100 mg/25 mg, gélules à libération prolongée	not available	BE149475	N.V. ROCHE S.A.	BE
Prolopa HBS 125, 100 mg/25 mg, gélules à libération prolongée	not available	2004078338	N.V. ROCHE S.A.	LU
Prolopa HBS 125, 100 mg/25 mg, Hartkapseln, retardiert	not available	2004078338	N.V. ROCHE S.A.	LU
Restex 100 mg/25 mg Hartkapseln, retardiert	DE/H/0371/002	44958.00.00	ROCHE PHARMA AG	DE
RESTEX 100 mg/25 mg Retardkapseln	DE/H/0371/002	1-25132	ROCHE AUSTRIA GMBH	AT
RESTEX 100 mg/25 mg Tabletten	DE/H/0371/003	1-25133	ROCHE AUSTRIA GMBH	AT
Restex 100 mg/25 mg Tabletten	DE/H/0371/003	44958.00.02	ROCHE PHARMA AG	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
Мадонар HBS 100 mg/25 mg твърди капсули с удължено освобождаване	not available	20030139	ROCHE BULGARIA EOOD	BG