



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

8 February 2018
EMA/88406/2018
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: benserazide / levodopa

Procedure no.: PSUSA/00000330/201706

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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
Madopar "125"	not available	6366	ROCHE A/S	DK
Madopar "125"	not available	13503	ROCHE A/S	DK
Madopar "125" hörð hylki	not available	731657	ROCHE A/S	IS
Madopar "125" töflur	not available	890032	ROCHE A/S	IS
Madopar "250" töflur	not available	812707	ROCHE A/S	IS
Madopar „250“ hörð hylki	not available	731877	ROCHE A/S	IS
Madopar „62,5“ hörð hylki	not available	792435	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
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 cietās kapsulas	not available	00-0724	ROCHE LATVIJA SIA	LV
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 disperģuojamosios 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	UK
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	MA060/00603	ROCHE PRODUCTS LTD	MT
Madopar 100 mg/25 mg Hard Capsules	not available	PL 00031/0073	ROCHE PRODUCTS LTD	UK
Madopar 100 mg/25 mg kietosios kapsulės	not available	LT/1/94/0936/003	UAB "ROCHE LIETUVA"	LT
Madopar 100 mg/25 mg kővakapslid	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 100mg/25mg Dispersible Tablets	not available	PA 50/43/6	ROCHE PRODUCTS LTD	IE
Madopar 12,5/50 kapsler, harde	not available	6694	F. HOFFMANN-LA ROCHE AG	NO
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 125 tablete	not available	HR-H-771762650	ROCHE D.O.O.	HR
Madopar 200 mg + 50 mg compresse divisibili	not available	023142033	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 200 mg + 50 mg comprimidos	not available	8557926	ROCHE FARMACÊUTICA QUÍMICA, LDA.	PT
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	8133/2006/01	ROCHE ROMANIA SRL	RO
Madopar 200 mg/50 mg Hard Capsules	not available	MA060/00604	ROCHE PRODUCTS LTD	MT
Madopar 200 mg/50 mg Hard Capsules	not available	PL 00031/0074	ROCHE PRODUCTS LTD	UK
Madopar 200 mg/50 mg tablete	not available	H/96/00958/003	ROCHE FARMACEVTSKA DRUŽBA D.O.O.	SI
Madopar 200 mg/50 mg tabletēs	not available	96-0643	ROCHE LATVIJA SIA	LV
Madopar 200 mg/50 mg tabletēs	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 tablettá	not available	OGYI-T-1157/01	ROCHE (MAGYARORSZÁG) KFT	HU
Madopar 200 mg/50 mg tabletter	not available	8611	ROCHE OY	FI
Madopar 200mg/50mg Hard Capsules	not available	PA 50/43/2	ROCHE PRODUCTS LTD	IE
Madopar 25/100 kapsler, harde	not available	5967	F. HOFFMANN-LA ROCHE AG	NO
Madopar 250 kapsler, hårde	not available	6367	ROCHE A/S	DK
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

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 250 tablety	not available	27/391/01-C	ROCHE S. R. O.	CZ
Madopar 250, tabletter	not available	11363	ROCHE A/S	DK
Madopar 50 mg/12,5 mg - Kapseln	not available	16.549	ROCHE AUSTRIA GMBH	AT
Madopar 50 mg/12.5 mg Dispersible Tablets	not available	PL 00031/0220	ROCHE PRODUCTS LTD	UK
Madopar 50 mg/12.5 mg Hard Capsules	not available	MA060/00602	ROCHE PRODUCTS LTD	MT
Madopar 50 mg/12.5 mg Hard Capsules	not available	PL 00031/0125	ROCHE PRODUCTS LTD	UK
Madopar 50mg/12.5mg Dispersible Tablets	not available	PA 50/43/5	ROCHE PRODUCTS LTD	IE
Madopar 62,5 kapsler, hårde	not available	9821	ROCHE A/S	DK
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 62,5 rozpustné tablety	not available	27/029/04-C	ROCHE S. R. O.	CZ
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	MA060/00601	ROCHE PRODUCTS LTD	MT
Madopar CR 100 mg/25 mg Prolonged Release Hard Capsules	not available	PL 00031/0227	ROCHE PRODUCTS LTD	UK
Madopar DEPOT 100 mg/25 mg hörð forðahylki	not available	870211	ROCHE A/S	IS

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 25/100 depotkapsler	not available	7430	F. HOFFMANN-LA ROCHE AG	NO
Madopar DEPOT, depotkapsler, hårde	not available	13087	ROCHE A/S	DK
Madopar Dispersible 125 mg dispergovateľné tablety	not available	27/0156/00-S	ROCHE SLOVENSKO S.R.O.	SK
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 125 mg tvrdé kapsuly s riadeným uvolnovaním	not available	27/0168/89-C/S	ROCHE SLOVENSKO S.R.O.	SK
Madopar HBS capsule cu eliberare modificată	not available	7678/2006/01	ROCHE ROMANIA SRL	RO
Madopar HBS capsule cu eliberare modificată	not available	7678/2006/02	ROCHE ROMANIA SRL	RO
Madopar HBS tvrdé tobolky s řízeným uvolňováním	not available	27/168/89-C	ROCHE S. R. O.	CZ

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, 100 mg + 25 mg, kapsuļki	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	ROCHE A/S	IS
Madopar QUICK 100 mg/25 mg lösliða tablettar	not available	12242	ROCHE OY	FI
Madopar Quick „125“ lausnartöflur	not available	970269	ROCHE A/S	IS
Madopar RETARD 100/25 mg cápsulas duras de liberación prolongada	not available	62.162	ROCHE FARMA, S.A.	ES
Madopar Solubile 12,5/50 oppløselige tablettar	not available	8052	F. HOFFMANN-LA ROCHE AG	NO
Madopar, 200 mg + 50 mg, kapsuļki	not available	R/0952	ROCHE POLSKA SP.O.O.	PL
Madopar®	not available	85847/15/28.12.2016	ROCHE (HELLAS) SA	GR
MADOPAR® 100 mg/25 mg depotkapseli	not available	9882	ROCHE OY	FI
MADOPAR® 100 mg/25 mg tabletti	not available	9672	ROCHE OY	FI
Madopar® 125 mg Hartkapseln	not available	6036937.00.00	ROCHE PHARMA AG	DE
Madopar® 125 mg T Tabletten	not available	6036937.00.01	ROCHE PHARMA AG	DE
MADOPAR® 200 mg/50 mg tabletti	not available	8611	ROCHE OY	FI
Madopar® 250	not available	52146	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® 250 mg Tabletten Levodopa 200 mg Benserazid 50 mg (als Benserazidhydrochlorid)	not available	861.00.01	ROCHE PHARMA AG	DE
Madopar® 62,5 mg Hartkapseln Levodopa 50 mg Benserazid 12,5 mg (als Benserazidhydrochlorid)	not available	861.00.00	ROCHE PHARMA AG	DE
Madopar® Depot Hartkapseln, retardiert Levodopa 100 mg Benserazid 25 mg (als Benserazidhydrochlorid)	not available	17010.00.00	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
MADOPAR® QUICK 100 mg/25 mg liukeneva tabletti	not available	12242	ROCHE OY	FI
Madopark 100 mg/25 mg tabletter	not available	10828	ROCHE AB	SE
Madopark DEPOT 100 mg/25 mg depotkapslar, hårda	not available	11479	ROCHE AB	SE
Madopark Quick 100 mg/25 mg tabletter	not available	12229	ROCHE AB	SE
Madopark Quick mite 50 mg/12,5 mg tabletter	not available	10951	ROCHE AB	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
Мадопар 100 mg/25 mg диспергиращи се таблетки	not available	9800255	ROCHE BULGARIA EOOD	BG
Мадопар 200 mg/50 mg таблетки	not available	20020187	ROCHE BULGARIA EOOD	BG
Modopar 125 (100 mg/25 mg), gélule	not available	3400931704355	ROCHE	FR
Modopar 125 (100 mg/25 mg), gélule	not available	3400931704126	ROCHE	FR
Modopar 125 (100 mg/25 mg), gélule	not available	3400931704294	ROCHE	FR
Modopar 125 (100 mg/25 mg), gélule	not available	3400930066553	ROCHE	FR
Modopar 125 (100 mg/25 mg), gélule	not available	3400930066560	ROCHE	FR
Modopar 125 (100 mg/25 mg), gélule	not available	3400930066577	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	3400930066669	ROCHE	FR
Modopar 250 (200 mg/50 mg), gélule	not available	3400931704874	ROCHE	FR
Modopar 250 (200 mg/50 mg), gélule	not available	3400931704706	ROCHE	FR
Modopar 250 (200 mg/50 mg), gélule	not available	3400931704935	ROCHE	FR
Modopar 250 (200 mg/50 mg), gélule	not available	3400930066614	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 250 (200 mg/50 mg), gélule	not available	3400930066591	ROCHE	FR
Modopar 250 (200 mg/50 mg), gélule	not available	3400930066607	ROCHE	FR
Modopar 62,5 (50 mg/12,5 mg), gélule	not available	3400932407620	ROCHE	FR
Modopar 62,5 (50 mg/12,5 mg), gélule	not available	3400930066546	ROCHE	FR
Modopar L.P. 125 (100 mg/25 mg), gélule a libération prolongée	not available	3400930066621	ROCHE	FR
Modopar L.P. 125 (100 mg/25 mg), gélule a libération prolongée	not available	3400930066638	ROCHE	FR
Modopar L.P. 125 (100 mg/25 mg), gélule a libération prolongée	not available	3400930066652	ROCHE	FR
MODOPAR L.P. 125 100 mg/25 mg, gélule à libération prolongée	not available	3400932985432	ROCHE	FR
MODOPAR L.P. 125 100 mg/25 mg, gélule à libération prolongée	not available	3400932985203	ROCHE	FR
MODOPAR L.P. 125 100 mg/25 mg, gélule à libération prolongée	not available	3400932985371	ROCHE	FR
Prolopa 125, 100 mg/25 mg, capsules, hard	not available	BE054083	N.V. ROCHE S.A.	BE
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	0178/04068272	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 125, 100 mg/25 mg, dispergeerbare tabletten	not available	BE182226	N.V. ROCHE S.A.	BE
Prolopa 125, 100 mg/25 mg, gélules	not available	BE054083	N.V. ROCHE S.A.	BE
Prolopa 125, 100 mg/25 mg, gélules	not available	0178/86070194	N.V. ROCHE S.A.	LU
Prolopa 125, 100 mg/25 mg, Hartkapseln	not available	BE054083	N.V. ROCHE S.A.	BE
Prolopa 125, 100 mg/25 mg, Hartkapseln	not available	0178/86070194	N.V. ROCHE S.A.	LU
Prolopa 125, 100 mg/25 mg, Tabletten zur Herstellung einer Suspension zum Einnehmen	not available	BE182226	N.V. ROCHE S.A.	BE
Prolopa 125, 100 mg/25 mg, Tabletten zur Herstellung einer Suspension zum Einnehmen	not available	0178/04068272	N.V. ROCHE S.A.	LU
Prolopa 250 comprimés	not available	0178/04068273	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, 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	0178/04068273	N.V. ROCHE S.A.	LU
Prolopa HBS 125, 100 mg/25 mg, capsules met verlengde afgifte, hard	not available	BE149475	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 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	0178/04078338	N.V. ROCHE S.A.	LU
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, Hartkapseln, retardiert	not available	0178/04078338	N.V. ROCHE S.A.	LU
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
Restex® 100 mg/25 mg Hartkapseln, retardiert	DE/H/0371/002	44958.00.00	ROCHE PHARMA AG	DE
Мадопар HBS 100 mg/25 mg твърди капсули с удължено освобождаване	not available	20030139	ROCHE BULGARIA EOOD	BG