24 April 2025
EMA/185109/2025
Human Medicines Division

List of nationally authorised medicinal products

Active substance(s): Oxcarbazepine

Procedure No. PSUSA/00002235/202408

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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
Apydan extent 150 mg Tabletten mit veränderter Wirkstofffreisetzung	not available	65225.00.00	DESITIN ARZNEIMITTEL GMBH	DE
Apydan extent 300 mg Tabletten mit veränderter Wirkstofffreisetzung	not available	65226.00.00	DESITIN ARZNEIMITTEL GMBH	DE
Apydan extent 600 mg Tabletten mit veränderter Wirkstofffreisetzung	not available	65227.00.00	DESITIN ARZNEIMITTEL GMBH	DE
Timox 60 mg/ml Suspension zum Einnehmen	DE/H/4778/004	52125.00.00	DESITIN ARZNEIMITTEL GMBH	DE
Tolep 300 mg compresse	not available	028304018	NOVARTIS FARMA S.P.A.	IT
Tolep 600 mg compresse	not available	028304020	NOVARTIS FARMA S.P.A.	IT
Trileptal 150 mg comprimidos revestidos por película	DK/H/0168/001	3127081	NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A.	PT
Trileptal 150 mg comprimidos revestidos por película	DK/H/0168/001	3127180	NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A.	PT
Trileptal 150 mg comprimidos revestidos por película	DK/H/0168/001	3127289	NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A.	PT
Trileptal 150 mg comprimidos revestidos por película	DK/H/0168/001	3127388	NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A.	PT
Trileptal 150 mg comprimidos revestidos por película	DK/H/0168/001	3127487	NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A.	PT
Trileptal 150 mg Film-coated tablets	not available	19109	NOVARTIS IRELAND LIMITED	CY
Trileptal 150 mg Film-coated tablets	DK/H/0168/001	PA0896/033/001	NOVARTIS IRELAND LIMITED	IE
Trileptal 150 mg filmdragerade tabletter	DK/H/0168/001	14797	NOVARTIS FINLAND OY	FI
Trileptal 150 mg filmdragerade tabletter	DK/H/0168/001	15781	NOVARTIS SVERIGE AB	SE
Trileptal 150 mg	not available	99-315	NOVARTIS NORGE AS	NO

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filmdrasjerte tabletter				
Trileptal 150 mg filmuhúðaðar töflur.	DK/H/0168/001	IS/1/00/004/01	NOVARTIS HEALTHCARE A/S	IS
Trileptal 150 mg filmuhúðaðar töflur.	DK/H/0168/001	IS/1/00/004/01	NOVARTIS HEALTHCARE A/S	IS
Trileptal 150 mg filmuhúðaðar töflur.	DK/H/0168/001	IS/1/00/004/01	NOVARTIS HEALTHCARE A/S	IS
Trileptal 150 mg filmuhúðaðar töflur.	DK/H/0168/001	IS/1/00/004/01	NOVARTIS HEALTHCARE A/S	IS
Trileptal 150 mg filmuhúðaðar töflur.	DK/H/0168/001	IS/1/00/004/01	NOVARTIS HEALTHCARE A/S	IS
Trileptal 150 mg tabletti, kalvopäällysteinen	DK/H/0168/001	14797	NOVARTIS FINLAND OY	FI
Trileptal 150 mg Επικαλυμμένα με λεπτό υμένιο δισκία	DK/H/0168/001	198880301	NOVARTIS (HELLAS) S.A.C.I.	GR
Trileptal 150 mg Επικαλυμμένα με λεπτό υμένιο δισκία	DK/H/0168/001	198880302	NOVARTIS (HELLAS) S.A.C.I.	GR
TRILEPTAL 150 mg, comprimé pelliculé	DK/H/0168/001	DK/H/0168/001	NOVARTIS PHARMA S.A.S.	FR
TRILEPTAL 150 mg, comprimé pelliculé	DK/H/0168/001	DK/H/0168/001	NOVARTIS PHARMA S.A.S.	FR
TRILEPTAL 150 mg, comprimé pelliculé	DK/H/0168/001	DK/H/0168/001	NOVARTIS PHARMA S.A.S.	FR
TRILEPTAL 150 mg, comprimé pelliculé	DK/H/0168/001	34009 353 570 1 4	NOVARTIS PHARMA S.A.S.	FR
TRILEPTAL 150 mg, comprimé pelliculé	DK/H/0168/001	34009 353 571 8 2	NOVARTIS PHARMA S.A.S.	FR
Trileptal 300 mg apvalkotās tabletes.	not available	99-0279	SIA NOVARTIS BALTICS	LV
TRILEPTAL 300 mg comprimate filmate	not available	9041/2016/01	NOVARTIS EUROPHARM LIMITED	RO
TRILEPTAL 300 mg comprimate filmate	not available	9041/2016/02	NOVARTIS EUROPHARM LIMITED	RO
TRILEPTAL 300 mg comprimate filmate	not available	9041/2016/03	NOVARTIS EUROPHARM LIMITED	RO
TRILEPTAL 300 mg	not available	9041/2016/04	NOVARTIS EUROPHARM	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
comprimate filmate			LIMITED	
TRILEPTAL 300 mg comprimate filmate	not available	9041/2016/05	NOVARTIS EUROPHARM LIMITED	RO
Trileptal 300 mg comprimidos recubiertos con película.	DK/H/0168/002	63.093	NOVARTIS FARMACÉUTICA S.A.	ES
Trileptal 300 mg comprimidos revestidos por película	DK/H/0168/002	3127586	NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A.	PT
Trileptal 300 mg comprimidos revestidos por película	DK/H/0168/002	3127685	NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A.	PT
Trileptal 300 mg comprimidos revestidos por película	DK/H/0168/002	3127784	NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A.	PT
Trileptal 300 mg comprimidos revestidos por película	DK/H/0168/002	3127883	NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A.	PT
Trileptal 300 mg comprimidos revestidos por película	DK/H/0168/002	3127982	NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A.	PT
Trileptal 300 mg Film-coated tablets	not available	18463	NOVARTIS IRELAND LIMITED	CY
Trileptal 300 mg Film-coated tablets	DK/H/0168/002	PA0896/033/002	NOVARTIS IRELAND LIMITED	IE
Trileptal 300 mg filmdragerade tabletter	DK/H/0168/002	14798	NOVARTIS FINLAND OY	FI
Trileptal 300 mg filmdragerade tabletter	DK/H/0168/002	15782	NOVARTIS SVERIGE AB	SE
Trileptal 300 mg filmdrasjerte tabletter	not available	99-316	NOVARTIS NORGE AS	NO
Trileptal 300 mg filmom obložene tablete	DK/H/0168/002	HR-H-309957904-02	NOVARTIS HRVATSKA D.O.O.	HR
Trileptal 300 mg filmom obložene tablete	DK/H/0168/002	HR-H-309957904-03	NOVARTIS HRVATSKA D.O.O.	HR
Trileptal 300 mg filmom obložene tablete	DK/H/0168/002	HR-H-309957904-04	NOVARTIS HRVATSKA D.O.O.	HR
Trileptal 300 mg filmom	DK/H/0168/002	HR-H-309957904-05	NOVARTIS HRVATSKA D.O.O.	HR

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
obložene tablete				
Trileptal 300 mg filmom obložene tablete	DK/H/0168/002	HR-H-309957904-01	NOVARTIS HRVATSKA D.O.O.	HR
Trileptal 300 mg filmtabletta	not available	OGYI-T-6308/01	NOVARTIS HUNGÁRIA KFT.	HU
Trileptal 300 mg filmtabletta	not available	OGYI-T-6308/02	NOVARTIS HUNGÁRIA KFT.	HU
Trileptal 300 mg filmuhúðaðar töflur.	DK/H/0168/002	IS/1/00/004/02	NOVARTIS HEALTHCARE A/S	IS
Trileptal 300 mg filmuhúðaðar töflur.	DK/H/0168/002	IS/1/00/004/02	NOVARTIS HEALTHCARE A/S	IS
Trileptal 300 mg filmuhúðaðar töflur.	DK/H/0168/002	IS/1/00/004/02	NOVARTIS HEALTHCARE A/S	IS
Trileptal 300 mg filmuhúðaðar töflur.	DK/H/0168/002	IS/1/00/004/02	NOVARTIS HEALTHCARE A/S	IS
Trileptal 300 mg filmuhúðaðar töflur.	DK/H/0168/002	IS/1/00/004/02	NOVARTIS HEALTHCARE A/S	IS
Trileptal 300 mg plėvele dengtos tabletės	not available	LT/1/97/1473/002	SIA NOVARTIS BALTICS	LT
Trileptal 300 mg tabletti, kalvopäällysteinen	DK/H/0168/002	14798	NOVARTIS FINLAND OY	FI
Trileptal 300 mg Επικαλυμμένα με λεπτό υμένιο δισκία	DK/H/0168/002	198880401	NOVARTIS (HELLAS) S.A.C.I.	GR
Trileptal 300 mg Επικαλυμμένα με λεπτό υμένιο δισκία	DK/H/0168/002	198880402	NOVARTIS (HELLAS) S.A.C.I.	GR
Trileptal 300 mg Επικαλυμμένα με λεπτό υμένιο δισκία	DK/H/0168/002	198880403	NOVARTIS (HELLAS) S.A.C.I.	GR
Trileptal 300 mg filmom obalené tablety	not available	21/0336/00-S	NOVARTIS SLOVAKIA S.R.O.	SK
Trileptal 300 mg filmom obalené tablety	not available	21/0336/00-S	NOVARTIS SLOVAKIA S.R.O.	SK
TRILEPTAL 300 mg, comprimé pelliculé	DK/H/0168/002	DK/H/0168/002	NOVARTIS PHARMA S.A.S.	FR
TRILEPTAL 300 mg, comprimé pelliculé	DK/H/0168/002	DK/H/0168/002	NOVARTIS PHARMA S.A.S.	FR
TRILEPTAL 300 mg, comprimé pelliculé	DK/H/0168/002	DK/H/0168/002	NOVARTIS PHARMA S.A.S.	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
TRILEPTAL 300 mg, comprimé pelliculé	DK/H/0168/002	34009 353 572 4 3	NOVARTIS PHARMA S.A.S.	FR
TRILEPTAL 300 mg, comprimé pelliculé	DK/H/0168/002	34009 353 573 0 4	NOVARTIS PHARMA S.A.S.	FR
Trileptal 300 mg, comprimés pelliculés	DK/H/0168/002	BE209002	NOVARTIS PHARMA N.V.	BE
Trileptal 300 mg, filmomhulde tabletten	DK/H/0168/002	BE209002	NOVARTIS PHARMA N.V.	BE
Trileptal 300 mg, filmomhulde tabletten	DK/H/0168/002	RVG 24751	NOVARTIS PHARMA B.V.	NL
Trileptal 300 mg, Filmtabletten	DK/H/0168/002	BE209002	NOVARTIS PHARMA N.V.	BE
Trileptal 60 mg/ml mikstur, suspensjon	not available	00-8131	NOVARTIS NORGE AS	NO
Trileptal 60 mg/ml mixtúra, dreifa.	DK/H/0168/004	IS/1/01/039/01	NOVARTIS HEALTHCARE A/S	IS
Trileptal 60 mg/ml oraalisuspensio	DK/H/0168/004	16570	NOVARTIS FINLAND OY	FI
Trileptal 60 mg/ml oral suspension	DK/H/0168/004	16570	NOVARTIS FINLAND OY	FI
Trileptal 60 mg/ml oral suspension	DK/H/0168/004	17348	NOVARTIS SVERIGE AB	SE
Trileptal 60 mg/ml Oral Suspension.	not available	19494	NOVARTIS IRELAND LIMITED	CY
Trileptal 60 mg/ml Oral Suspension.	DK/H/0168/004	PA0896/033/004	NOVARTIS IRELAND LIMITED	IE
Trileptal 60 mg/ml oralna suspenzija	DK/H/0168/004	HR-H-061545230-01	NOVARTIS HRVATSKA D.O.O.	HR
Trileptal 60 mg/ml Suspensão oral	DK/H/0168/004	3732989	NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A.	PT
Trileptal 60 mg/ml suspensión oral.	DK/H/0168/004	64.398	NOVARTIS FARMACÉUTICA S.A.	ES
Trileptal 60 mg/ml Πόσιμο Εναιώρημα.	DK/H/0168/004	198880601	NOVARTIS (HELLAS) S.A.C.I.	GR
Trileptal 60 mg/ml, suspensie voor oraal gebruik	DK/H/0168/004	BE227342	NOVARTIS PHARMA N.V.	BE
Trileptal 60 mg/ml, suspensie voor oraal gebruik.	DK/H/0168/004	RVG 26830	NOVARTIS PHARMA 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
Trileptal 60 mg/ml, suspension buvable	DK/H/0168/004	BE227342	NOVARTIS PHARMA N.V.	BE
TRILEPTAL 60 mg/ml, suspension buvable	DK/H/0168/004	34009 357 901 2 5	NOVARTIS PHARMA S.A.S.	FR
Trileptal 60 mg/ml, Suspension zum Einnehmen	DK/H/0168/004	BE227342	NOVARTIS PHARMA N.V.	BE
Trileptal 600 mg apvalkotās tabletes.	not available	99-0280	SIA NOVARTIS BALTICS	LV
TRILEPTAL 600 mg comprimate filmate	not available	9042/2016/01	NOVARTIS EUROPHARM LIMITED	RO
TRILEPTAL 600 mg comprimate filmate	not available	9042/2016/02	NOVARTIS EUROPHARM LIMITED	RO
TRILEPTAL 600 mg comprimate filmate	not available	9042/2016/03	NOVARTIS EUROPHARM LIMITED	RO
TRILEPTAL 600 mg comprimate filmate	not available	9042/2016/04	NOVARTIS EUROPHARM LIMITED	RO
TRILEPTAL 600 mg comprimate filmate	not available	9042/2016/05	NOVARTIS EUROPHARM LIMITED	RO
Trileptal 600 mg comprimidos recubiertos con película	DK/H/0168/003	63.095	NOVARTIS FARMACÉUTICA S.A.	ES
Trileptal 600 mg comprimidos revestidos por película	DK/H/0168/003	3128089	NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A.	PT
Trileptal 600 mg comprimidos revestidos por película	DK/H/0168/003	3128188	NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A.	PT
Trileptal 600 mg comprimidos revestidos por película	DK/H/0168/003	3128287	NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A.	PT
Trileptal 600 mg comprimidos revestidos por película	DK/H/0168/003	3128386	NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A.	PT
Trileptal 600 mg comprimidos revestidos por película	DK/H/0168/003	3128485	NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A.	PT
Trileptal 600 mg Film-coated tablets	not available	18464	NOVARTIS IRELAND LIMITED	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
Trileptal 600 mg Film-coated tablets	DK/H/0168/003	PA0896/033/003	NOVARTIS IRELAND LIMITED	IE
Trileptal 600 mg filmdragerade tabletter	DK/H/0168/003	14799	NOVARTIS FINLAND OY	FI
Trileptal 600 mg filmdragerade tabletter	DK/H/0168/003	15783	NOVARTIS SVERIGE AB	SE
Trileptal 600 mg filmdrasjerte tabletter	not available	99-317	NOVARTIS NORGE AS	NO
Trileptal 600 mg filmom obložene tablete	DK/H/0168/003	HR-H-007294503-02	NOVARTIS HRVATSKA D.O.O.	HR
Trileptal 600 mg filmom obložene tablete	DK/H/0168/003	HR-H-007294503-03	NOVARTIS HRVATSKA D.O.O.	HR
Trileptal 600 mg filmom obložene tablete	DK/H/0168/003	HR-H-007294503-04	NOVARTIS HRVATSKA D.O.O.	HR
Trileptal 600 mg filmom obložene tablete	DK/H/0168/003	HR-H-007294503-05	NOVARTIS HRVATSKA D.O.O.	HR
Trileptal 600 mg filmom obložene tablete	DK/H/0168/003	HR-H-007294503-01	NOVARTIS HRVATSKA D.O.O.	HR
Trileptal 600 mg filmtabletta	not available	OGYI-T-6308/03	NOVARTIS HUNGÁRIA KFT.	HU
Trileptal 600 mg filmtabletta	not available	OGYI-T-6308/04	NOVARTIS HUNGÁRIA KFT.	HU
Trileptal 600 mg filmuhúðaðar töflur.	DK/H/0168/003	IS/1/00/004/03	NOVARTIS HEALTHCARE A/S	IS
Trileptal 600 mg filmuhúðaðar töflur.	DK/H/0168/003	IS/1/00/004/03	NOVARTIS HEALTHCARE A/S	IS
Trileptal 600 mg filmuhúðaðar töflur.	DK/H/0168/003	IS/1/00/004/03	NOVARTIS HEALTHCARE A/S	IS
Trileptal 600 mg filmuhúðaðar töflur.	DK/H/0168/003	IS/1/00/004/03	NOVARTIS HEALTHCARE A/S	IS
Trileptal 600 mg filmuhúðaðar töflur.	DK/H/0168/003	IS/1/00/004/03	NOVARTIS HEALTHCARE A/S	IS
Trileptal 600 mg plėvele dengtos tabletės	not available	LT/1/97/1473/003	SIA NOVARTIS BALTICS	LT
Trileptal 600 mg tabletti, kalvopäällysteinen	DK/H/0168/003	14799	NOVARTIS FINLAND OY	FI
Trileptal 600 mg Επικαλυμμένα με λεπτό υμένιο δισκία	DK/H/0168/003	198880501	NOVARTIS (HELLAS) S.A.C.I.	GR
Trileptal 600 mg	DK/H/0168/003	198880502	NOVARTIS (HELLAS) S.A.C.I.	GR

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Επικαλυμμένα με λεπτό υμένιο δισκία				
Trileptal 600 mg Επικαλυμμένα με λεπτό υμένιο δισκία	DK/H/0168/003	198880503	NOVARTIS (HELLAS) S.A.C.I.	GR
TRILEPTAL 600 mg, comprimé pelliculé	DK/H/0168/003	DK/H/0168/003	NOVARTIS PHARMA S.A.S.	FR
TRILEPTAL 600 mg, comprimé pelliculé	DK/H/0168/003	DK/H/0168/003	NOVARTIS PHARMA S.A.S.	FR
TRILEPTAL 600 mg, comprimé pelliculé	DK/H/0168/003	DK/H/0168/003	NOVARTIS PHARMA S.A.S.	FR
TRILEPTAL 600 mg, comprimé pelliculé	DK/H/0168/003	34009 353 574 7 2	NOVARTIS PHARMA S.A.S.	FR
TRILEPTAL 600 mg, comprimé pelliculé	DK/H/0168/003	34009 353 575 3 3	NOVARTIS PHARMA S.A.S.	FR
Trileptal 600 mg, comprimés pelliculés	DK/H/0168/003	BE209011	NOVARTIS PHARMA N.V.	BE
Trileptal 600 mg, filmomhulde tabletten	DK/H/0168/003	BE209011	NOVARTIS PHARMA N.V.	BE
Trileptal 600 mg, filmomhulde tabletten	DK/H/0168/003	RVG 24752	NOVARTIS PHARMA B.V.	NL
Trileptal 600 mg, Filmtabletten	DK/H/0168/003	BE209011	NOVARTIS PHARMA N.V.	BE
Trileptal, 300 mg õhukese polümeerikattega tabletid	not available	346501	SIA NOVARTIS BALTICS	EE
Trileptal, 300 mg, tabletki powlekane	not available	8256	NOVARTIS POLAND SP. Z O. O.	PL
Trileptal, 60 mg/mL, zawiesina doustna	not available	7471	NOVARTIS POLAND SP. Z O. O.	PL
Trileptal, 600 mg õhukese polümeerikattega tabletid	not available	346601	SIA NOVARTIS BALTICS	EE
Trileptal, 600 mg, tabletki powlekane	not available	8257	NOVARTIS POLAND SP. Z O. O.	PL
Trileptal, filmovertrukne tabletter	DK/H/0168/001	30413	NOVARTIS HEALTHCARE A/S	DK
Trileptal, filmovertrukne tabletter	DK/H/0168/002	30414	NOVARTIS HEALTHCARE A/S	DK
Trileptal, filmovertrukne	DK/H/0168/003	30415	NOVARTIS HEALTHCARE 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
tabletter				
Trileptal, oral suspension	DK/H/0168/004	31743	NOVARTIS HEALTHCARE A/S	DK
Trileptal® 150 mg – Filmtabletten	DK/H/0168/001	1-23489	NOVARTIS PHARMA GMBH	AT
Trileptal® 300 mg – Filmtabletten	DK/H/0168/002	1-23490	NOVARTIS PHARMA GMBH	AT
Trileptal® 300 mg Filmtabletten	DK/H/0168/002	47357.01.00	NOVARTIS PHARMA GMBH	DE
Trileptal® 60 mg/ml - Suspension zum Einnehmen	DK/H/0168/004	1-24351	NOVARTIS PHARMA GMBH	AT
Trileptal® 60 mg/ml Suspension zum Einnehmen	DK/H/0168/004	51794.00.00	NOVARTIS PHARMA GMBH	DE
Trileptal® 600 mg – Filmtabletten	DK/H/0168/003	1-23491	NOVARTIS PHARMA GMBH	AT
Trileptal® 600 mg Filmtabletten	DK/H/0168/003	47357.02.00	NOVARTIS PHARMA GMBH	DE
Трилептал 300 mg филмирани таблетки	not available	20010387	NOVARTIS EUROPHARM LIMITED	BG
Трилептал 60 mg/ml перорална суспензия	not available	20020486	NOVARTIS EUROPHARM LIMITED	BG
Трилептал 600 mg филмирани таблетки	not available	20010386	NOVARTIS EUROPHARM LIMITED	BG