05 May 2017
EMA/290427/2017
Procedure Management and Committees Support

List of nationally authorised medicinal products

Active substance: oxcarbazepine

Procedure no.: PSUSA/00002235/201608

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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
Timox 300 mg Filmtabletten	DE/H/4778/002	49261.01.00	DESITIN ARZNEIMITTEL GMBH	DE
Timox 600 mg Filmtabletten	DE/H/4778/003	49261.02.00	DESITIN ARZNEIMITTEL GMBH	DE
Timox 150 mg Filmtabletten	DE/H/4778/001	49261.00.00	DESITIN ARZNEIMITTEL GMBH	DE
Timox 60 mg/ml Suspension zum Einnehmen	DE/H/4778/004	52125.00.00	DESITIN ARZNEIMITTEL GMBH	DE
Timox extent 150 mg Tabletten mit veränderter Wirkstofffreisetzung	not available	65230.00.00	DESITIN ARZNEIMITTEL GMBH	DE
Timox extent 300 mg Tabletten mit veränderter Wirkstofffreisetzung	not available	65231.00.00	DESITIN ARZNEIMITTEL GMBH	DE
Timox extent 600 mg Tabletten mit veränderter Wirkstofffreisetzung	not available	65232.00.00	DESITIN ARZNEIMITTEL GMBH	DE
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
Trileptal 150 mg Filmtabletten	DK/H/0168/001	BE208993	NOVARTIS PHARMA N.V.	BE
Trileptal 300 mg Filmtabletten	DK/H/0168/002	BE209002	NOVARTIS PHARMA N.V.	BE
Trileptal 60 mg/ml Suspension zum Einnehmen	DK/H/0168/004	BE227342	NOVARTIS PHARMA N.V.	BE
Trileptal 600 mg Filmtabletten	DK/H/0168/003	BE209011	NOVARTIS PHARMA N.V.	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
Trileptal 300 mg filmom oblozene tablete	DK/H/0168/002	HR-H-309957904-02	NOVARTIS HRVATSKA D.O.O.	HR
Trileptal 300 mg filmom oblozene tablete	DK/H/0168/002	HR-H-309957904-03	NOVARTIS HRVATSKA D.O.O.	HR
Trileptal 300 mg filmom oblozene tablete	DK/H/0168/002	HR-H-309957904-04	NOVARTIS HRVATSKA D.O.O.	HR
Trileptal 300 mg filmom oblozene tablete	DK/H/0168/002	HR-H-309957904-05	NOVARTIS HRVATSKA D.O.O.	HR
Trileptal 600 mg filmom oblozene tablete	DK/H/0168/003	HR-H-007294503-02	NOVARTIS HRVATSKA D.O.O.	HR
Trileptal 600 mg filmom oblozene tablete	DK/H/0168/003	HR-H-007294503-03	NOVARTIS HRVATSKA D.O.O.	HR
Trileptal 600 mg filmom oblozene tablete	DK/H/0168/003	HR-H-007294503-04	NOVARTIS HRVATSKA D.O.O.	HR
Trileptal 600 mg filmom oblozene tablete	DK/H/0168/003	HR-H-007294503-05	NOVARTIS HRVATSKA D.O.O.	HR
TRILEPTAL 300 MG COMPRIMATE FILMATE	not available	9041/2016/01	NOVARTIS PHARMA GMBH	RO
TRILEPTAL 300 MG COMPRIMATE FILMATE	not available	9041/2016/02	NOVARTIS PHARMA GMBH	RO
TRILEPTAL 300 MG COMPRIMATE FILMATE	not available	9041/2016/03	NOVARTIS PHARMA GMBH	RO
TRILEPTAL 300 MG COMPRIMATE FILMATE	not available	9041/2016/04	NOVARTIS PHARMA GMBH	RO
TRILEPTAL 300 MG COMPRIMATE FILMATE	not available	9041/2016/05	NOVARTIS PHARMA GMBH	RO
TRILEPTAL 600 MG COMPRIMATE FILMATE	not available	9042/2016/01	NOVARTIS PHARMA GMBH	RO
TRILEPTAL 600 MG COMPRIMATE FILMATE	not available	9042/2016/02	NOVARTIS PHARMA GMBH	RO
TRILEPTAL 600 MG COMPRIMATE FILMATE	not available	9042/2016/03	NOVARTIS PHARMA GMBH	RO
TRILEPTAL 600 MG COMPRIMATE FILMATE	not available	9042/2016/04	NOVARTIS PHARMA GMBH	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
TRILEPTAL 600 MG COMPRIMATE FILMATE	not available	9042/2016/05	NOVARTIS PHARMA GMBH	RO
TRILEPTAL® ΕΠΙΚΑΛΥΜΈΝΑ ΜΕ ΛΕΠΤΌ ΥΜΈΝΙΟ ΔΙΣΚΊΑ 150 MG	DK/H/0168/001	198880301	NOVARTIS (HELLAS) S.A.C.I.	GR
TRILEPTAL® ΕΠΙΚΑΛΥΜΈΝΑ ΜΕ ΛΕΠΤΌ ΥΜΈΝΙΟ ΔΙΣΚΊΑ 150 MG	DK/H/0168/001	198880302	NOVARTIS (HELLAS) S.A.C.I.	GR
TRILEPTAL® ΕΠΙΚΑΛΥΜΈΝΑ ΜΕ ΛΕΠΤΌ ΥΜΈΝΙΟ ΔΙΣΚΊΑ 300 MG	DK/H/0168/002	198880401	NOVARTIS (HELLAS) S.A.C.I.	GR
TRILEPTAL® ΕΠΙΚΑΛΥΜΈΝΑ ΜΕ ΛΕΠΤΌ ΥΜΈΝΙΟ ΔΙΣΚΊΑ 300 MG	DK/H/0168/002	198880402	NOVARTIS (HELLAS) S.A.C.I.	GR
TRILEPTAL® ΕΠΙΚΑΛΥΜΈΝΑ ΜΕ ΛΕΠΤΌ ΥΜΈΝΙΟ ΔΙΣΚΊΑ 300 MG	DK/H/0168/002	198880403	NOVARTIS (HELLAS) S.A.C.I.	GR
TRILEPTAL® ΕΠΙΚΑΛΥΜΈΝΑ ΜΕ ΛΕΠΤΌ ΥΜΈΝΙΟ ΔΙΣΚΊΑ 600 MG	DK/H/0168/003	198880501	NOVARTIS (HELLAS) S.A.C.I.	GR
TRILEPTAL® ΕΠΙΚΑΛΥΜΈΝΑ ΜΕ ΛΕΠΤΌ ΥΜΈΝΙΟ ΔΙΣΚΊΑ 600 MG	DK/H/0168/003	198880502	NOVARTIS (HELLAS) S.A.C.I.	GR
TRILEPTAL® ΕΠΙΚΑΛΥΜΈΝΑ ΜΕ ΛΕΠΤΌ ΥΜΈΝΙΟ ΔΙΣΚΊΑ 600 MG	DK/H/0168/003	198880503	NOVARTIS (HELLAS) S.A.C.I.	GR
TRILEPTAL® 60 MG/ML ΠΌΣΙΜΟ ΕΝΑΙΏΡΗΜΑ	DK/H/0168/004	198880601	NOVARTIS (HELLAS) S.A.C.I.	GR
TRILEPTAL 600 MG FILM-COATED TABLETS	not available	18464	NOVARTIS PHARMACEUTICALS UK LIMITED	CY
TRILEPTAL 150 MG FILM-COATED TABLETS	not available	19109	NOVARTIS PHARMACEUTICALS UK LIMITED	CY
TRILEPTAL 300 MG FILM-	not available	18463	NOVARTIS	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
COATED TABLETS			PHARMACEUTICALS UK LIMITED	
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 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 60 mg/ml Suspensão oral	DK/H/0168/004	3732989	NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A.	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
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 150 mg plėvele dengtos tabletės	not available	LT/1/97/1473/001	NOVARTIS FINLAND OY	LT
TRILEPTAL 150 mg tablett, filmdragerad	DK/H/0168/001	14797	NOVARTIS FINLAND OY	FI
Trileptal 150 mg tabletti, kalvopäällysteinen	DK/H/0168/001	14797	NOVARTIS FINLAND OY	FI
TRILEPTAL® 300 MG APVALKOTAS TABLETES	not available	99-0279	NOVARTIS FINLAND OY	LV
Trileptal 300 mg plėvele dengtos tabletės	not available	LT/1/97/1473/002	NOVARTIS FINLAND OY	LT
TRILEPTAL 300 mg tablett, filmdragerad	DK/H/0168/002	14798	NOVARTIS FINLAND OY	FI
Trileptal 300 mg tabletti, kalvopäällysteinen	DK/H/0168/002	14798	NOVARTIS FINLAND OY	FI
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® 600 MG APVALKOTAS TABLETES	not available	99-0280	NOVARTIS FINLAND OY	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
Trileptal 600 mg plėvele dengtos tabletės	not available	LT/1/97/1473/003	NOVARTIS FINLAND OY	LT
TRILEPTAL 600 mg tablett, filmdragerad	DK/H/0168/003	14799	NOVARTIS FINLAND OY	FI
Trileptal 600 mg tabletti, kalvopäällysteinen	DK/H/0168/003	14799	NOVARTIS FINLAND OY	FI
Trileptal 300 mg comprimidos recubiertos con película	DK/H/0168/002	63.093	NOVARTIS FARMACÉUTICA S.A.	ES
Trileptal 600 mg comprimidos recubiertos con película	DK/H/0168/003	63.095	NOVARTIS FARMACÉUTICA S.A.	ES
Trileptal	DK/H/0168/001	30413	NOVARTIS HEALTHCARE A/S	DK
Trileptal	DK/H/0168/002	30414	NOVARTIS HEALTHCARE A/S	DK
Trileptal	DK/H/0168/003	30415	NOVARTIS HEALTHCARE A/S	DK
Trileptal, oral suspension	DK/H/0168/004	31743	NOVARTIS HEALTHCARE A/S	DK
Trileptal® 150 mg Filmtabletten	DK/H/0168/001	47357.00.00	NOVARTIS PHARMA GMBH	DE
Trileptal 150 mg, filmomhulde tabletten	DK/H/0168/001	RVG 24750	NOVARTIS PHARMA B.V.	NL
Trileptal 300 mg filmomhulde tabletten	DK/H/0168/002	RVG 24751	NOVARTIS PHARMA B.V.	NL
Trileptal® 300 mg Filmtabletten	DK/H/0168/002	47357.01.00	NOVARTIS PHARMA GMBH	DE
Trileptal 300 mg tabletki powlekane	not available	8256	NOVARTIS POLAND SP. Z O. O.	PL
TRILEPTAL 300 MG FILMTABLETTA	not available	OGYI-T-6308/01	NOVARTIS HUNGÁRIA KFT. PHARMA	HU
TRILEPTAL 300 MG FILMTABLETTA	not available	OGYI-T-6308/02	NOVARTIS HUNGÁRIA KFT. PHARMA	HU

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, suspensie voor oraal gebruik	DK/H/0168/004	RVG 26830	NOVARTIS PHARMA B.V.	NL
Trileptal® 60 mg/ml Suspension zum Einnehmen	DK/H/0168/004	51794.00.00	NOVARTIS PHARMA GMBH	DE
Trileptal 600 mg filmomhulde tabletten	DK/H/0168/003	RVG 24752	NOVARTIS PHARMA B.V.	NL
TRILEPTAL 600 MG FILMTABLETTA	not available	OGYI-T-6308/03	NOVARTIS HUNGÁRIA KFT. PHARMA	HU
TRILEPTAL 600 MG FILMTABLETTA	not available	OGYI-T-6308/04	NOVARTIS HUNGÁRIA KFT. PHARMA	HU
Trileptal® 600 mg Filmtabletten	DK/H/0168/003	47357.02.00	NOVARTIS PHARMA GMBH	DE
Trileptal 600 mg tabletki powlekane	not available	8257	NOVARTIS POLAND SP. Z O. O.	PL
Trileptal, 60 mg/ml, zawiesina doustna	not available	7471	NOVARTIS POLAND SP. Z O. O.	PL
TRILEPTAL 150 MG TABLETKI POWLEKANE	not available	8255	NOVARTIS POLAND SP. Z O. O.	PL
TRILEPTAL 60 MG/ML ORAL SUSPENSION	not available	088/04301	NOVARTIS PHARMACEUTICALS UK LIMITED	MT
TRILEPTAL 150 MG FILM-COATED TABLETS	not available	088/04302	NOVARTIS PHARMACEUTICALS UK LIMITED	MT
TRILEPTAL 300 MG FILM-COATED TABLETS	not available	088/04303	NOVARTIS PHARMACEUTICALS UK LIMITED	MT
TRILEPTAL 600 MG FILM-COATED TABLETS	not available	088/04304	NOVARTIS PHARMACEUTICALS UK LIMITED	MT
TRILEPTAL 150 MG – FILMTABLETTEN	DK/H/0168/001	1-23489	NOVARTIS PHARMA 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
TRILEPTAL® 150 MG FILM-COATED TABLETS	DK/H/0168/001	PL 00101/0581	NOVARTIS PHARMACEUTICALS UK LIMITED	UK
Trileptal 150 mg filmdragerade tabletter	DK/H/0168/001	15781	NOVARTIS SVERIGE AB	SE
Trileptal 150mg comprimé pelliculé	DK/H/0168/001	3400935357014	NOVARTIS PHARMA S.A.S.	FR
Trileptal 150mg comprimé pelliculé	DK/H/0168/001	3400935357182	NOVARTIS PHARMA S.A.S.	FR
Trileptal 150 mg film-coated tablets	DK/H/0168/001	PA 13/92/1	NOVARTIS PHARMACEUTICALS UK LIMITED	IE
TRILEPTAL 300 MG – FILMTABLETTEN	DK/H/0168/002	1-23490	NOVARTIS PHARMA GMBH	AT
Trileptal 300 mg comprimé pelliculé	DK/H/0168/002	3400935357243	NOVARTIS PHARMA S.A.S.	FR
Trileptal 300 mg comprimé pelliculé	DK/H/0168/002	3400935357304	NOVARTIS PHARMA S.A.S.	FR
TRILEPTAL® 300 MG FILM-COATED TABLETS	DK/H/0168/002	PL 00101/0582	NOVARTIS PHARMACEUTICALS UK LIMITED	UK
Trileptal 300 mg Film-coated tablets	DK/H/0168/002	PA 13/92/2	NOVARTIS PHARMACEUTICALS UK LIMITED	IE
Trileptal 300 mg filmdragerade tabletter	DK/H/0168/002	15782	NOVARTIS SVERIGE AB	SE
TRILEPTAL 60 MG/ML - SUSPENSION ZUM EINNEHMEN	DK/H/0168/004	1-24351	NOVARTIS PHARMA GMBH	AT
Trileptal 60 mg/ml oral suspension	DK/H/0168/004	17348	NOVARTIS SVERIGE AB	SE
TRILEPTAL 600 MG – FILMTABLETTEN	DK/H/0168/003	1-23491	NOVARTIS PHARMA GMBH	AT
TRILEPTAL® 600 MG FILM-COATED TABLETS	DK/H/0168/003	PL 00101/0583	NOVARTIS PHARMACEUTICALS	UK

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
			UK LIMITED	
Trileptal 600 mg filmdragerade tabletter	DK/H/0168/003	15783	NOVARTIS SVERIGE AB	SE
TRILEPTAL 600 MG FILM-COATED TABLETS	DK/H/0168/003	PA 13/92/3	NOVARTIS PHARMACEUTICALS UK LIMITED	IE
Trileptal 600mg, comprimé pelliculé	DK/H/0168/003	3400935357472	NOVARTIS PHARMA S.A.S.	FR
Trileptal 600mg, comprimé pelliculé	DK/H/0168/003	3400935357533	NOVARTIS PHARMA S.A.S.	FR
TRILEPTAL 60 mg/ml, suspension buvable	DK/H/0168/004	3400935790125	NOVARTIS PHARMA S.A.S.	FR
Trileptal Oral Solution 60 mg/ml	DK/H/0168/004	PA 13/92/4	NOVARTIS PHARMACEUTICALS UK LIMITED	IE
Trileptal 60 mg/ml Oral Suspension	not available	19494	NOVARTIS PHARMACEUTICALS UK LIMITED	CY
Trileptal® 60 mg/ml Oral Suspension.	DK/H/0168/004	PL 00101/0631	NOVARTIS PHARMACEUTICALS UK LIMITED	UK
Trileptal 150 mg filmomhulde tabletten	DK/H/0168/001	BE208993	NOVARTIS PHARMA N.V.	BE
Trileptal 150 mg, comprimés pelliculés	DK/H/0168/001	BE208993	NOVARTIS PHARMA N.V.	BE
TRILEPTAL 300 MG FILMOM OBALENÉ TABLETY	not available	21/0336/00-S	NOVARTIS, S.R.O.	SK
Trileptal 60 mg/ml suspensión oral	DK/H/0168/004	64.398	NOVARTIS FARMACÉUTICA S.A.	ES
Trileptal 60 mg/ml, suspensie voor oraal gebruik	DK/H/0168/004	BE227342	NOVARTIS PHARMA N.V.	BE
Trileptal 60 mg/ml,	DK/H/0168/004	BE227342	NOVARTIS PHARMA	BE

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suspension buvable			N.V.	
Trileptal 600 mg filmomhulde tabletten	DK/H/0168/003	BE209011	NOVARTIS PHARMA N.V.	BE
Trileptal 600 mg, comprimés pelliculés	DK/H/0168/003	BE209011	NOVARTIS PHARMA N.V.	BE
Trileptal 150 mg filmuhúðaðar töflur	DK/H/0168/001	IS/1/00/004/01	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 60 mg/ml mixtúra, dreifa	DK/H/0168/004	IS/1/01/039/01	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 150 mg filmdrasjerte tabletter	not available	99-315	NOVARTIS NORGE AS	NO
Trileptal 300 mg filmdrasjerte tabletter	not available	99-316	NOVARTIS NORGE AS	NO
Trileptal 60 mg/ml mikstur, suspensjon	not available	00-8131	NOVARTIS NORGE AS	NO
Trileptal 600 mg filmdrasjerte tabletter	not available	99-317	NOVARTIS NORGE AS	NO
Trileptal 300 mg filmomhulde tabletten	DK/H/0168/002	BE209002	NOVARTIS PHARMA N.V.	BE
Trileptal 300 mg, comprimés pelliculés	DK/H/0168/002	BE209002	NOVARTIS PHARMA N.V.	BE
Trileptal 150 mg õhukese polümeerikattega tabletid	not available	346401	NOVARTIS FINLAND OY	EE
Trileptal 300 mg õhukese polümeerikattega tabletid	not available	346501	NOVARTIS FINLAND OY	EE
Trileptal 600 mg õhukese polümeerikattega tabletid	not available	346601	NOVARTIS FINLAND OY	EE
Trileptal 300 mg filmom oblozene tablete	DK/H/0168/002	HR-H-309957904-01	NOVARTIS HRVATSKA D.O.O.	HR
Trileptal 60 mg/ml oralna	DK/H/0168/004	HR-H-061545230-01	NOVARTIS HRVATSKA	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
suspenzija			D.O.O.	
Trileptal 600 mg filmom oblozene tablete	DK/H/0168/003	HR-H-007294503-01	NOVARTIS HRVATSKA D.O.O.	HR