15 September 2022
EMA/837430/2022
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: Ciclosporin (systemic use)

Procedure no.: PSUSA/00000745/202112

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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
Sandimmun - Neoral 10 mg Kapseln	DE/H/4019/001	1-26595	NOVARTIS PHARMA GMBH	AT
Sandimmun - Neoral 100 mg Kapseln	DE/H/4019/004	1-20691	NOVARTIS PHARMA GMBH	AT
Sandimmun - Neoral 100 mg/ml - Trinklösung	DE/H/4019/005	1-20694	NOVARTIS PHARMA GMBH	AT
Sandimmun - Neoral 25 mg Kapseln	DE/H/4019/002	1-20689	NOVARTIS PHARMA GMBH	AT
Sandimmun - Neoral 50 mg Kapseln	DE/H/4019/003	1-20690	NOVARTIS PHARMA GMBH	AT
Sandimmun 50 mg - Konzentrat zur Infusionsbereitung	DE/H/4002/004	17896	NOVARTIS PHARMA GMBH	AT
Neoral-Sandimmun 10 mg capsules molles	DE/H/4019/001	BE196953	NOVARTIS PHARMA N.V.	BE
Neoral-Sandimmun 10 mg Weichkapseln	DE/H/4019/001	BE196953	NOVARTIS PHARMA N.V.	BE
Neoral-Sandimmun 10 mg zachte capsules	DE/H/4019/001	BE196953	NOVARTIS PHARMA N.V.	BE
Neoral-Sandimmun 100 mg capsules molles	DE/H/4019/004	BE170676	NOVARTIS PHARMA N.V.	BE
Neoral-Sandimmun 100 mg Weichkapseln	DE/H/4019/004	BE170676	NOVARTIS PHARMA N.V.	BE
Neoral-Sandimmun 100 mg zachte capsules	DE/H/4019/004	BE170676	NOVARTIS PHARMA N.V.	BE
Neoral-Sandimmun 100 mg/ml drank	DE/H/4019/005	BE170685	NOVARTIS PHARMA N.V.	BE
Neoral-Sandimmun 100 mg/ml Lösung zum Einnehmen	DE/H/4019/005	BE170685	NOVARTIS PHARMA N.V.	BE
Neoral-Sandimmun 100 mg/ml, solution buvable	DE/H/4019/005	BE170685	NOVARTIS PHARMA N.V.	BE
Neoral-Sandimmun 25 mg capsules molles	DE/H/4019/002	BE170642	NOVARTIS PHARMA N.V.	BE
Neoral-Sandimmun 25 mg Weichkapseln	DE/H/4019/002	BE170642	NOVARTIS PHARMA N.V.	BE
Neoral-Sandimmun 25 mg zachte	DE/H/4019/002	BE170642	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
capsules				
Neoral-Sandimmun 50 mg capsules molles	DE/H/4019/003	BE170764	NOVARTIS PHARMA N.V.	BE
Neoral-Sandimmun 50 mg Weichkapseln	DE/H/4019/003	BE170764	NOVARTIS PHARMA N.V.	BE
Neoral-Sandimmun 50 mg zachte capsules	DE/H/4019/003	BE170764	NOVARTIS PHARMA N.V.	BE
Sandimmun 250 mg/5 ml concentraat voor oplossing voor infusie	DE/H/4002/004	BE124546	NOVARTIS PHARMA N.V.	BE
Sandimmun 250 mg/5 ml concentraat voor oplossing voor infusie	DE/H/4002/004	BE477786	NOVARTIS PHARMA N.V.	BE
Sandimmun 250 mg/5 ml Konzentrat zur Herstellung einer Infusionslösung	DE/H/4002/004	BE124546	NOVARTIS PHARMA N.V.	BE
Sandimmun 250 mg/5 ml Konzentrat zur Herstellung einer Infusionslösung	DE/H/4002/004	BE477786	NOVARTIS PHARMA N.V.	BE
Sandimmun 250 mg/5 ml solution à diluer pour perfusion	DE/H/4002/004	BE124546	NOVARTIS PHARMA N.V.	BE
Sandimmun 250 mg/5 ml solution à diluer pour perfusion	DE/H/4002/004	BE477786	NOVARTIS PHARMA N.V.	BE
Сандимун Неорал 100 mg меки капсули	DE/H/4019/004	20010483	NOVARTIS PHARMA GMBH	BG
САНДИМУН НЕОРАЛ 100 mg/ml перорален разтвор	DE/H/4019/005	20010484	NOVARTIS PHARMA GMBH	BG
Сандимун Неорал 25 mg меки капсули	DE/H/4019/002	20010481	NOVARTIS PHARMA GMBH	BG
Сандимун Неорал 50 mg меки капсули	DE/H/4019/003	20010482	NOVARTIS PHARMA GMBH	BG
Sandimmun Neoral 100 mg καψάκια, μαλακά	DE/H/4019/004	18383	NOVARTIS IRELAND LIMITED	CY
Sandimmun Neoral 100 mg/ml πόσιμο διάλυμα	DE/H/4019/005	18413	NOVARTIS IRELAND LIMITED	CY
Sandimmun Neoral 25 mg καψάκια,	DE/H/4019/002	18439	NOVARTIS IRELAND LIMITED	CY

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μαλακά				
Sandimmun Neoral 50 mg καψάκια, μαλακά	DE/H/4019/003	18412	NOVARTIS IRELAND LIMITED	CY
Sandimmun 50 mg/ml koncentrát pro infuzní roztok	DE/H/4002/004	59/123/83-C	NOVARTIS S.R.O.,	CZ
Sandimmun Neoral 100 mg měkké tobolky	DE/H/4019/004	59/649/95-C/C	NOVARTIS S.R.O.,	CZ
Sandimmun Neoral 100 mg/ml perorální roztok	DE/H/4019/005	59/665/95-C	NOVARTIS S.R.O.,	CZ
Sandimmun Neoral 25 mg měkké tobolky	DE/H/4019/002	59/649/95-A/C	NOVARTIS S.R.O.,	CZ
Sandimmun Neoral 50 mg měkké tobolky	DE/H/4019/003	59/649/95-B/C	NOVARTIS S.R.O.,	CZ
Immunosporin® 100 mg Weichkapseln	DE/H/4020/003	41031.02.00	NOVARTIS PHARMA GMBH	DE
Immunosporin® 25 mg Weichkapseln	DE/H/4020/001	41031.00.00	NOVARTIS PHARMA GMBH	DE
Immunosporin® 50 mg Weichkapseln	DE/H/4020/002	41031.01.00	NOVARTIS PHARMA GMBH	DE
Sandimmun® 100 mg Weichkapseln	DE/H/4002/003	26418.02.01	NOVARTIS PHARMA GMBH	DE
Sandimmun® 100 mg/ml Lösung zum Einnehmen	DE/H/4002/005	26418.00.00	NOVARTIS PHARMA GMBH	DE
Sandimmun® 25 mg Weichkapseln	DE/H/4002/002	26418.00.01	NOVARTIS PHARMA GMBH	DE
Sandimmun® 50 mg Weichkapseln	DE/H/4002/001	90481.00.00	NOVARTIS PHARMA GMBH	DE
Sandimmun® 50 mg/ml Konzentrat zur Herstellung einer Infusionslösung	DE/H/4002/004	3123.00.00	NOVARTIS PHARMA GMBH	DE
Sandimmun® 50 mg/ml Konzentrat zur Herstellung einer Infusionslösung	DE/H/4002/004	3123.00.00	NOVARTIS PHARMA GMBH	DE
Sandimmun® Optoral 10 mg Weichkapseln	DE/H/4019/001	34681.03.00	NOVARTIS PHARMA GMBH	DE
Sandimmun® Optoral 10 mg Weichkapseln	DE/H/4019/001	34681.03.00	NOVARTIS PHARMA GMBH	DE
Sandimmun® Optoral 100 mg Weichkapseln	DE/H/4019/004	34681.02.00	NOVARTIS PHARMA GMBH	DE
Sandimmun® Optoral 100 mg	DE/H/4019/004	34681.02.00	NOVARTIS PHARMA GMBH	DE

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Weichkapseln				
Sandimmun® Optoral 100 mg/ml Lösung zum Einnehmen	DE/H/4019/005	29180.00.00	NOVARTIS PHARMA GMBH	DE
Sandimmun® Optoral 100 mg/ml Lösung zum Einnehmen	DE/H/4019/005	29180.00.00	NOVARTIS PHARMA GMBH	DE
Sandimmun® Optoral 25 mg Weichkapseln	DE/H/4019/002	34681.00.00	NOVARTIS PHARMA GMBH	DE
Sandimmun® Optoral 25 mg Weichkapseln	DE/H/4019/002	34681.00.00	NOVARTIS PHARMA GMBH	DE
Sandimmun® Optoral 50 mg Weichkapseln	DE/H/4019/003	34681.01.00	NOVARTIS PHARMA GMBH	DE
Sandimmun® Optoral 50 mg Weichkapseln	DE/H/4019/003	34681.01.00	NOVARTIS PHARMA GMBH	DE
Sandimmun Neoral, bløde kapsler	DE/H/4019/002	15804	NOVARTIS HEALTHCARE A/S	DK
Sandimmun Neoral, bløde kapsler	DE/H/4019/003	15805	NOVARTIS HEALTHCARE A/S	DK
Sandimmun Neoral, bløde kapsler	DE/H/4019/004	15806	NOVARTIS HEALTHCARE A/S	DK
Sandimmun Neoral, bløde kapsler	DE/H/4019/001	18671	NOVARTIS HEALTHCARE A/S	DK
Sandimmun Neoral, oral opløsning	DE/H/4019/005	15807	NOVARTIS HEALTHCARE A/S	DK
Sandimmun, koncentrat til infusionsvæske, opløsning	DE/H/4002/004	11096	NOVARTIS HEALTHCARE A/S	DK
Sandimmun Neoral, 100 mg pehmekapslid	DE/H/4019/004	093394	SIA NOVARTIS BALTICS	EE
Sandimmun Neoral, 25 mg pehmekapslid	DE/H/4019/002	093194	SIA NOVARTIS BALTICS	EE
Sandimmun Neoral, 50 mg pehmekapslid	DE/H/4019/003	093294	SIA NOVARTIS BALTICS	EE
Sandimmun 250 mg/5 ml concentrado para solución para perfusión	DE/H/4002/004	56.798	NOVARTIS FARMACÉUTICA S.A.	ES
Sandimmun 50 mg/ml concentrado para solución para perfusión	DE/H/4002/004	56.800	NOVARTIS FARMACÉUTICA S.A.	ES
Sandimmun Neoral 100 mg cápsulas blandas	DE/H/4019/004	60.320	NOVARTIS FARMACÉUTICA 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
Sandimmun Neoral 100 mg/ml solución oral	DE/H/4019/005	56.799	NOVARTIS FARMACÉUTICA S.A.	ES
Sandimmun Neoral 25 mg cápsulas blandas	DE/H/4019/002	60.319	NOVARTIS FARMACÉUTICA S.A.	ES
Sandimmun Neoral 50 mg cápsulas blandas	DE/H/4019/003	60.318	NOVARTIS FARMACÉUTICA S.A.	ES
Sandimmun 50 mg/ml infuusiokonsentraatti, liuosta varten	DE/H/4002/004	8569	NOVARTIS FINLAND OY	FI
Sandimmun 50 mg/ml koncentrat till infusionsvätska, lösning	DE/H/4002/004	8569	NOVARTIS FINLAND OY	FI
Sandimmun Neoral 100 mg kapseli, pehmeä	DE/H/4019/004	11609	NOVARTIS FINLAND OY	FI
Sandimmun Neoral 100 mg mjuka kapslar	DE/H/4019/004	11609	NOVARTIS FINLAND OY	FI
Sandimmun Neoral 100 mg/ml oraaliliuos	DE/H/4019/005	11606	NOVARTIS FINLAND OY	FI
Sandimmun Neoral 100 mg/ml oral lösning	DE/H/4019/005	11606	NOVARTIS FINLAND OY	FI
Sandimmun Neoral 25 mg kapseli, pehmeä	DE/H/4019/002	11607	NOVARTIS FINLAND OY	FI
Sandimmun Neoral 25 mg mjuka kapslar	DE/H/4019/002	11607	NOVARTIS FINLAND OY	FI
Sandimmun Neoral 50 mg kapseli, pehmeä	DE/H/4019/003	11608	NOVARTIS FINLAND OY	FI
Sandimmun Neoral 50 mg mjuka kapslar	DE/H/4019/003	11608	NOVARTIS FINLAND OY	FI
NEORAL 10 mg, capsule molle	DE/H/4019/001	34009 344 377 8 6	NOVARTIS PHARMA S.A.S.	FR
NEORAL 10 mg, capsule molle	DE/H/4019/001	34009 344 378 4 7	NOVARTIS PHARMA S.A.S.	FR
NEORAL 10 mg, capsule molle	DE/H/4019/001	34009 346 307 7 4	NOVARTIS PHARMA S.A.S.	FR
NEORAL 100 mg, capsule molle	DE/H/4019/004	34009 346 306 0 6	NOVARTIS PHARMA S.A.S.	FR
NEORAL 100 mg, capsule molle	DE/H/4019/004	34009 559 151 4 0	NOVARTIS PHARMA S.A.S.	FR
NEORAL 100 mg, capsule molle	DE/H/4019/004	34009 559 152 0 1	NOVARTIS PHARMA S.A.S.	FR

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NEORAL 100 mg/ml, solution buvable	DE/H/4019/005	3400934633157	NOVARTIS PHARMA S.A.S.	FR
NEORAL 25 mg, capsule molle	DE/H/4019/002	34009 346 304 8 4	NOVARTIS PHARMA S.A.S.	FR
NEORAL 25 mg, capsule molle	DE/H/4019/002	34009 559 146 0 0	NOVARTIS PHARMA S.A.S.	FR
NEORAL 25 mg, capsule molle	DE/H/4019/002	34009 559 147 7 8	NOVARTIS PHARMA S.A.S.	FR
NEORAL 50 mg, capsule molle	DE/H/4019/003	34009 346 305 4 5	NOVARTIS PHARMA S.A.S.	FR
NEORAL 50 mg, capsule molle	DE/H/4019/003	34009 559 148 3 9	NOVARTIS PHARMA S.A.S.	FR
NEORAL 50 mg, capsule molle	DE/H/4019/003	34009 559 150 8 9	NOVARTIS PHARMA S.A.S.	FR
SANDIMMUN 50 mg/ml, solution à diluer pour perfusion	DE/H/4002/004	34009 554 579-61	NOVARTIS PHARMA S.A.S.	FR
SANDIMMUN 50 mg/ml, solution à diluer pour perfusion	DE/H/4002/004	34009 554 580-43	NOVARTIS PHARMA S.A.S.	FR
Sandimmun Neoral 100 mg μαλακά καψάκια	DE/H/4019/004	223010301	NOVARTIS (HELLAS) S.A.C.I.	GR
Sandimmun Neoral 100 mg μαλακά καψάκια	DE/H/4019/004	223010302	NOVARTIS (HELLAS) S.A.C.I.	GR
Sandimmun Neoral 100 mg/ml πόσιμο διάλυμα	DE/H/4019/005	223010402	NOVARTIS (HELLAS) S.A.C.I.	GR
Sandimmun Neoral 100 mg/ml πόσιμο διάλυμα	DE/H/4019/005	223010401	NOVARTIS (HELLAS) S.A.C.I.	GR
Sandimmun Neoral 25 mg μαλακά καψάκια	DE/H/4019/002	223010101	NOVARTIS (HELLAS) S.A.C.I.	GR
Sandimmun Neoral 25 mg μαλακά καψάκια	DE/H/4019/002	223010102	NOVARTIS (HELLAS) S.A.C.I.	GR
Sandimmun Neoral 50 mg μαλακά καψάκια	DE/H/4019/003	223010201	NOVARTIS (HELLAS) S.A.C.I.	GR
Sandimmun Neoral 50 mg μαλακά καψάκια	DE/H/4019/003	223010202	NOVARTIS (HELLAS) S.A.C.I.	GR
SANDIMMUN®	DE/H/4002/004	190030101	NOVARTIS (HELLAS) S.A.C.I.	GR
SANDIMMUN®	DE/H/4002/004	190030201	NOVARTIS (HELLAS) S.A.C.I.	GR
Sandimmun 50 mg/ml koncentrat za otopinu za infuziju	DE/H/4002/004	HR-H-725462434-01	NOVARTIS HRVATSKA D.O.O.	HR
Sandimmun 50 mg/ml koncentrat za	DE/H/4002/004	HR-H-725462434-	NOVARTIS HRVATSKA D.O.O.	HR

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otopinu za infuziju		02		
Sandimmun Neoral 100 mg meke kapsule	DE/H/4019/004	HR-H-144486729-01	NOVARTIS HRVATSKA D.O.O.	HR
Sandimmun Neoral 100 mg/ml oralna otopina	DE/H/4019/005	HR-H-861000959-01	NOVARTIS HRVATSKA D.O.O.	HR
Sandimmun Neoral 25 mg meke kapsule	DE/H/4019/002	HR-H-141846183-01	NOVARTIS HRVATSKA D.O.O.	HR
Sandimmun Neoral 50 mg meke kapsule	DE/H/4019/003	HR-H-547220134-01	NOVARTIS HRVATSKA D.O.O.	HR
Sandimmun 50 mg/ml koncentrátum oldatos infúzióhoz	DE/H/4002/004	OGYI-T-4200/06	NOVARTIS HUNGÁRIA KFT.	HU
Sandimmun Neoral 10 mg lágy kapszula	DE/H/4019/001	OGYI-T-4200/02	NOVARTIS HUNGÁRIA KFT.	HU
Sandimmun Neoral 100 mg lágy kapszula	DE/H/4019/004	OGYI-T-4200/05	NOVARTIS HUNGÁRIA KFT.	HU
Sandimmun Neoral 100mg/ml belsőleges oldat	DE/H/4019/005	OGYI-T-4200/01	NOVARTIS HUNGÁRIA KFT.	HU
Sandimmun Neoral 25 mg lágy kapszula	DE/H/4019/002	OGYI-T-4200/03	NOVARTIS HUNGÁRIA KFT.	HU
Sandimmun Neoral 50 mg lágy kapszula	DE/H/4019/003	OGYI-T-4200/04	NOVARTIS HUNGÁRIA KFT.	HU
Neoral 100 mg Soft Capsules	DE/H/4019/004	PA 0896/024/003	NOVARTIS IRELAND LIMITED	IE
NEORAL 100mg/ml concentrate for oral solution	DE/H/4019/005	PA 0896/024/004	NOVARTIS IRELAND LIMITED	IE
Neoral 25mg Soft Capsules	DE/H/4019/002	PA 0896/024/001	NOVARTIS IRELAND LIMITED	IE
Neoral 50 mg Soft Capsules	DE/H/4019/003	PA 0896/024/002	NOVARTIS IRELAND LIMITED	IE
Sandimmun 100mg Soft Capsules	DE/H/4002/003	PA0896/027/004	NOVARTIS IRELAND LIMITED	IE
Sandimmun 100mg/ml concentrate for oral solution	DE/H/4002/005	PA0896/027/001	NOVARTIS IRELAND LIMITED	IE
Sandimmun 25 mg soft capsules	DE/H/4002/002	PA0896/027/003	NOVARTIS IRELAND LIMITED	IE
Sandimmun 50 mg/ml Concentrate for Solution for Infusion	DE/H/4002/004	PA0896/027/002	NOVARTIS IRELAND LIMITED	IE

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Sandimmun 50mg Soft Capsules	DE/H/4002/001	PA 0896/027/005	NOVARTIS IRELAND LIMITED	IE
Sandimmun 50 mg/ml innrennslisþykkni, lausn	DE/H/4002/004	822940	NOVARTIS HEALTHCARE A/S	IS
Sandimmun Neoral 100 mg mjúk hylki	DE/H/4019/004	940035	NOVARTIS HEALTHCARE A/S	IS
Sandimmun Neoral 100 mg/ml mixtúra, lausn	DE/H/4019/005	940032	NOVARTIS HEALTHCARE A/S	IS
Sandimmun Neoral 25 mg mjúk hylki.	DE/H/4019/002	940033	NOVARTIS HEALTHCARE A/S	IS
Sandimmun Neoral 50 mg mjúk hylki	DE/H/4019/003	940034	NOVARTIS HEALTHCARE A/S	IS
SANDIMMUN 100 mg capsule molli	DE/H/4002/003	025306059	NOVARTIS FARMA S.P.A.	IT
Sandimmun 100 mg/ml soluzione orale	DE/H/4002/005	025306010	NOVARTIS FARMA S.P.A.	IT
SANDIMMUN 25 mg capsule molli	DE/H/4002/002	025306034	NOVARTIS FARMA S.P.A.	IT
SANDIMMUN 50 mg capsule molli	DE/H/4002/001	025306046	NOVARTIS FARMA S.P.A.	IT
SANDIMMUN 50 mg/ml concentrato per soluzione per infusione	DE/H/4002/004	025306022	NOVARTIS FARMA S.P.A.	IT
Sandimmun Neoral 10 mg capsule molli	DE/H/4019/001	029453053	NOVARTIS FARMA S.P.A.	IT
Sandimmun Neoral 100 mg capsule molli	DE/H/4019/004	029453038	NOVARTIS FARMA S.P.A.	IT
SANDIMMUN NEORAL 100 mg/ml Soluzione orale	DE/H/4019/005	029453040	NOVARTIS FARMA S.P.A.	IT
Sandimmun Neoral 25 mg capsule molli	DE/H/4019/002	029453014	NOVARTIS FARMA S.P.A.	IT
Sandimmun Neoral 50 mg capsule molli	DE/H/4019/003	029453026	NOVARTIS FARMA S.P.A.	IT
Sandimmun Neoral 100 mg minkštosios kapsulės	DE/H/4019/004	LT/1/94/1089/003	SIA NOVARTIS BALTICS	LT
Sandimmun Neoral 25 mg minkštosios kapsulės	DE/H/4019/002	LT/1/94/1089/001	SIA NOVARTIS BALTICS	LT
Sandimmun Neoral 50 mg minkštosios kapsulės	DE/H/4019/003	LT/1/94/1089/002	SIA NOVARTIS BALTICS	LT
Neoral-Sandimmun 10 mg capsules molles	DE/H/4019/001	1999070021	NOVARTIS PHARMA N.V.	LU

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Neoral-Sandimmun 10 mg Weichkapseln	DE/H/4019/001	1999070021	NOVARTIS PHARMA N.V.	LU
Neoral-Sandimmun 100 mg capsules molles	DE/H/4019/004	1993080413	NOVARTIS PHARMA N.V.	LU
Neoral-Sandimmun 100 mg Weichkapseln	DE/H/4019/004	1993080413	NOVARTIS PHARMA N.V.	LU
Neoral-Sandimmun 100 mg/ml Lösung zum Einnehmen	DE/H/4019/005	1993080410	NOVARTIS PHARMA N.V.	LU
Neoral-Sandimmun 100 mg/ml, solution buvable	DE/H/4019/005	1993080410	NOVARTIS PHARMA N.V.	LU
Neoral-Sandimmun 25 mg capsules molles	DE/H/4019/002	1993080411	NOVARTIS PHARMA N.V.	LU
Neoral-Sandimmun 25 mg Weichkapseln	DE/H/4019/002	1993080411	NOVARTIS PHARMA N.V.	LU
Neoral-Sandimmun 50 mg capsules molles	DE/H/4019/003	1993080412	NOVARTIS PHARMA N.V.	LU
Neoral-Sandimmun 50 mg Weichkapseln	DE/H/4019/003	1993080412	NOVARTIS PHARMA N.V.	LU
Sandimmun 250 mg/5 ml Konzentrat zur Herstellung einer Infusionslösung	DE/H/4002/004	1983090382	NOVARTIS PHARMA N.V.	LU
Sandimmun 250 mg/5 ml solution à diluer pour perfusion	DE/H/4002/004	1983090382	NOVARTIS PHARMA N.V.	LU
Sandimmun Neoral 100 mg mikstas kapsulas	DE/H/4019/004	00-1192	SIA NOVARTIS BALTICS	LV
Sandimmun Neoral 25 mg mikstas kapsulas	DE/H/4019/002	95-0140	SIA NOVARTIS BALTICS	LV
Sandimmun Neoral 50 mg mīkstās kapsulas	DE/H/4019/003	00-1191	SIA NOVARTIS BALTICS	LV
Sandimmun Neoral 100 mg soft capsules	DE/H/4019/004	MA1249/02703	NOVARTIS IRELAND LIMITED	MT
Sandimmun Neoral 100 mg/ml oral solution	DE/H/4019/005	MA1249/02701	NOVARTIS IRELAND LIMITED	MT

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Sandimmun Neoral 25 mg soft capsules	DE/H/4019/002	MA1249/02702	NOVARTIS IRELAND LIMITED	MT
Neoral 100 mg, capsules	DE/H/4019/004	RVG 17496	NOVARTIS PHARMA B.V.	NL
Neoral 100 mg/ml, drank	DE/H/4019/005	RVG 17497	NOVARTIS PHARMA B.V.	NL
Neoral 25 mg, capsules	DE/H/4019/002	RVG 17495	NOVARTIS PHARMA B.V.	NL
Sandimmune, concentraat voor oplossing voor intraveneuze infusie 50 mg/ml	DE/H/4002/004	RVG 09846	NOVARTIS PHARMA B.V.	NL
Sandimmun 50 mg/ml konsentrat til infusjonsvæske, oppløsning	DE/H/4002/004	7073	NOVARTIS NORGE AS	NO
Sandimmun Neoral 100 mg myke kapsler	DE/H/4019/004	8061	NOVARTIS NORGE AS	NO
Sandimmun Neoral 100 mg/ml mikstur, oppløsning	DE/H/4019/005	00-8062	NOVARTIS NORGE AS	NO
Sandimmun Neoral 25 mg myke kapsler	DE/H/4019/002	8060	NOVARTIS NORGE AS	NO
Sandimmun Neoral 50 mg myke kapsler	DE/H/4019/003	95-2610	NOVARTIS NORGE AS	NO
Sandimmun 50 mg/ml koncentrat do sporządzania roztworu do infuzji	DE/H/4002/004	R/1198	NOVARTIS POLAND SP. Z O. O.	PL
Sandimmun Neoral 10 mg kapsułki miękkie	DE/H/4019/001	4061	NOVARTIS POLAND SP. Z O. O.	PL
Sandimmun Neoral 100 mg kapsułki miękkie	DE/H/4019/004	R/3368	NOVARTIS POLAND SP. Z O. O.	PL
Sandimmun Neoral 100 mg/ml roztwór doustny	DE/H/4019/005	R/3369	NOVARTIS POLAND SP. Z O. O.	PL
Sandimmun Neoral 25 mg kapsułki miękkie	DE/H/4019/002	R/3366	NOVARTIS POLAND SP. Z O. O.	PL
Sandimmun Neoral 50 mg kapsułki miękkie	DE/H/4019/003	R/3367	NOVARTIS POLAND SP. Z O. O.	PL
Sandimmun 50 mg/ml concentrado para solução para perfusão	DE/H/4002/004	8611319	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
Sandimmun 50 mg/ml concentrado para solução para perfusão	DE/H/4002/004	8611301	NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A.	PT
Sandimmun Neoral 100 mg Cápsulas moles	DE/H/4019/004	8742726	NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A.	PT
Sandimmun Neoral 100 mg Cápsulas moles	DE/H/4019/004	8742742	NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A.	PT
Sandimmun Neoral 100 mg/ml Solução oral	DE/H/4019/005	8611400	NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A.	PT
Sandimmun Neoral 25 mg cápsulas moles	DE/H/4019/002	8742700	NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A.	PT
Sandimmun Neoral 25 mg cápsulas moles	DE/H/4019/002	8742718	NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A.	PT
Sandimmun Neoral 50 mg cápsulas moles	DE/H/4019/003	3701281	NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A.	PT
Sandimmun Neoral 50 mg cápsulas moles	DE/H/4019/003	8742767	NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A.	PT
Sandimmun Neoral 100 mg/ml soluţie orală	DE/H/4019/005	6025/2013/01	NOVARTIS PHARMA GMBH	RO
Sandimmun Neoral 25 mg capsule moi	DE/H/4019/002	6023/2013/01	NOVARTIS PHARMA GMBH	RO
Sandimmun Neoral 50 mg capsule moi	DE/H/4019/003	6024/2013/01	NOVARTIS PHARMA GMBH	RO
Ciklosporin IVAX 100 mg mjuka kapslar	not available	19569	TEVA SWEDEN AB	SE
Ciklosporin IVAX 25 mg mjuka kapslar	not available	19567	TEVA SWEDEN AB	SE
Ciklosporin IVAX 50 mg mjuka kapslar	not available	19568	TEVA SWEDEN AB	SE
Sandimmun 50 mg/ml koncentrat till infusionsvätska, lösning	DE/H/4002/004	10263	NOVARTIS SVERIGE AB	SE
Sandimmun Neoral 10 mg mjuka kapslar	DE/H/4019/001	13540	NOVARTIS SVERIGE AB	SE
Sandimmun Neoral 100 mg mjuka kapslar	DE/H/4019/004	12310	NOVARTIS SVERIGE AB	SE
Sandimmun Neoral 100 mg/ml oral lösning	DE/H/4019/005	12311	NOVARTIS SVERIGE AB	SE

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Sandimmun Neoral 25 mg mjuka kapslar	DE/H/4019/002	12308	NOVARTIS SVERIGE AB	SE
Sandimmun Neoral 50 mg mjuka kapslar	DE/H/4019/003	12309	NOVARTIS SVERIGE AB	SE
Sandimmun 50 mg/ml koncentrat za raztopino za infundiranje	DE/H/4002/004	H/92/01964/001	NOVARTIS PHARMA GMBH	SI
Sandimmun 50 mg/ml koncentrat za raztopino za infundiranje	DE/H/4002/004	H/92/01964/002	NOVARTIS PHARMA GMBH	SI
Sandimmun Neoral 100 mg mehke kapsule	DE/H/4019/004	H/92/01394/003	NOVARTIS PHARMA GMBH	SI
Sandimmun Neoral 100 mg/ml peroralna raztopina	DE/H/4019/005	H/92/01394/004	NOVARTIS PHARMA GMBH	SI
Sandimmun Neoral 25 mg mehke kapsule	DE/H/4019/002	H/92/01394/001	NOVARTIS PHARMA GMBH	SI
Sandimmun Neoral 50 mg mehke kapsule	DE/H/4019/003	H/92/01394/002	NOVARTIS PHARMA GMBH	SI
Sandimmun 50 mg/ml infúzny koncentrát	DE/H/4002/004	59/0123/83-CS	NOVARTIS SLOVAKIA S.R.O.	SK
Sandimmun Neoral 100 mg mäkké kapsuly	DE/H/4019/004	59/0253/18-S	NOVARTIS SLOVAKIA S.R.O.	SK
Sandimmun Neoral 100 mg/ml perorálny roztok	DE/H/4019/005	59/0009/96-S	NOVARTIS SLOVAKIA S.R.O.	SK
Sandimmun Neoral 25 mg mäkké kapsuly	DE/H/4019/002	59/0010/96-S	NOVARTIS SLOVAKIA S.R.O.	SK
Sandimmun Neoral 50 mg mäkké kapsuly	DE/H/4019/003	59/0252/18-S	NOVARTIS SLOVAKIA S.R.O.	SK
Neciclopin 10 mg Soft Gelatin Capsules	DE/H/4019/001	PL 00101/0483	NOVARTIS PHARMACEUTICALS UK LIMITED	XI
Neciclopin 100 mg Soft Gelatin Capsules	DE/H/4019/004	PL 00101/0389	NOVARTIS PHARMACEUTICALS UK LIMITED	XI
Neciclopin 25 mg Soft Gelatin Capsules	DE/H/4019/002	PL 00101/0387	NOVARTIS PHARMACEUTICALS UK LIMITED	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
Neciclopin 50 mg Soft Gelatin Capsules	DE/H/4019/003	PL 00101/0388	NOVARTIS PHARMACEUTICALS UK LIMITED	XI
NEORAL® Oral Solution	DE/H/4019/005	PL 00101/0390	NOVARTIS PHARMACEUTICALS UK LIMITED	XI
NEORAL® Soft Gelatin Capsules 100mg	DE/H/4019/004	PL 00101/0389	NOVARTIS PHARMACEUTICALS UK LIMITED	XI
NEORAL® Soft Gelatin Capsules 10mg	DE/H/4019/001	PL 00101/0483	NOVARTIS PHARMACEUTICALS UK LIMITED	XI
NEORAL® Soft Gelatin Capsules 25mg	DE/H/4019/002	PL 00101/0387	NOVARTIS PHARMACEUTICALS UK LIMITED	XI
NEORAL® Soft Gelatin Capsules 50mg	DE/H/4019/003	PL 00101/0388	NOVARTIS PHARMACEUTICALS UK LIMITED	XI
SANDIMMUN Oral Solution	DE/H/4002/005	PL 00101/0124	NOVARTIS PHARMACEUTICALS UK LIMITED	XI
SANDIMMUN® Concentrate for Solution for Infusion 50mg/ml	DE/H/4002/004	PL 00101/0153	NOVARTIS PHARMACEUTICALS UK LIMITED	XI
SANDIMMUN® Soft Gelatin Capsules 100mg	DE/H/4002/003	PL 00101/0208	NOVARTIS PHARMACEUTICALS UK LIMITED	XI
SANDIMMUN® Soft Gelatin Capsules 25mg	DE/H/4002/002	PL 00101/0207	NOVARTIS PHARMACEUTICALS UK LIMITED	XI
SANDIMMUN® Soft Gelatin Capsules 50 mg	DE/H/4002/001	PL 00101/0310	NOVARTIS PHARMACEUTICALS UK LIMITED	XI