

ANNEX I

LIST OF THE NAMES, PHARMACEUTICAL FORMS, STRENGTHS OF THE MEDICINAL PRODUCTS, ROUTES OF ADMINISTRATION, MARKETING AUTHORISATION HOLDERS IN THE MEMBER STATES

Member State EU/EEA	Marketing authorisation holder	Invented Name	Strength	Pharmaceutical form	Route of administration	Content (concentration)
Austria	Novartis Pharma GmbH Stella-Klein-Löw-Weg 17 AT-1020 Wien Austria	Sandimmun 50 mg – Konzentrat zur Infusionsbereitung	50mg/ml	Concentrate for solution for infusion	Intravenous use	50mg/ml
Belgium	N.V. Novartis Pharma S.A. Medialaan 40, bus 1 B-1800 Vilvoorde Belgium	SANDIMMUN	50mg/ml	Concentrate for solution for infusion	Intravenous use	50 mg/ml
Czech Republic	Novartis s.r.o. Na Pankráci 1724/129 140 00 Prague 4 - Nusle Czech Republic	Sandimmun	50 mg/ml	Concentrate for solution for infusion	Intravenous use	50 mg/ml
Denmark	Novartis Healthcare A/S Lyngbyvej 172 DK-2100 Copenhagen Denmark	Sandimmun	50 mg/ml	Concentrate for solution for infusion	Intravenous use	50 mg/ml
Finland	Novartis Finland OY Metsänneidonkuja 10 FI-02130 Espoo Finland	Sandimmun	50 mg/ml	Concentrate for solution for infusion	Intravenous use	50 mg/ml
France	Novartis Pharma S.A.S. 2-4, rue Lionel Terray 92500 RUEIL-MALMAISON, France	SANDIMMUN	25 mg	Capsule, soft	Oral use	

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France	Novartis Pharma S.A.S. 2-4, rue Lionel Terray 92500 RUEIL-MALMAISON, France	SANDIMMUN	50 mg	Capsule, soft	Oral use	
France	Novartis Pharma S.A.S. 2- 4, rue Lionel Terray 92500 RUEIL-MALMAISON, France	SANDIMMUN	100 mg	Capsule, soft	Oral use	
France	Novartis Pharma S.A.S. 2- 4, rue Lionel Terray 92500 RUEIL-MALMAISON, France	SANDIMMUN	100 mg/ml	Oral solution	Oral use	100 mg/ml
France	Novartis Pharma S.A.S. 2- 4, rue Lionel Terray 92500 RUEIL-MALMAISON, France	SANDIMMUN	50 mg/ml	Solution for infusion	Intravenous use	50 mg/ml
Germany	Novartis Pharma GmbH Roonstrasse 25 D-90429 Nürnberg Germany	Sandimmun 25 mg Weichkapseln	25 mg	Capsule, soft	Oral use	
Germany	Novartis Pharma GmbH Roonstrasse 25 D-90429 Nürnberg Germany	Sandimmun 100 mg Weichkapseln	100 mg	Capsule, soft	Oral use	

Member State EU/EEA	Marketing authorisation holder	Invented Name	Strength	Pharmaceutical form	Route of administration	Content (concentration)
Germany	Novartis Pharma GmbH Roonstrasse 25 D-90429 Nürnberg Germany	Sandimmun 100 mg/ml Lösung zum Einnehmen	100 mg/ml	Oral solution	Oral use	100 mg/ml
Germany	Novartis Pharma GmbH Roonstrasse 25 D-90429 Nürnberg Germany	Sandimmun 50 mg/ml Konzentrat zur Herstellung einer Infusionslösung	50 mg/ml	Concentrate for solution for infusion	Intravenous use	50 mg/ml
Germany	Novartis Pharma GmbH Roonstrasse 25 D-90429 Nürnberg Germany	Immunosporin 25 mg Weichkapseln	25 mg	Capsule, soft	Oral use	
Germany	Novartis Pharma GmbH Roonstrasse 25 D-90429 Nürnberg Germany	Immunosporin 50 mg Weichkapseln	50 mg	Capsule, soft	Oral use	
Germany	Novartis Pharma GmbH Roonstrasse 25 D-90429 Nürnberg Germany	Immunosporin 100 mg Weichkapseln	100 mg	Capsule, soft	Oral use	
Greece	Novartis (Hellas) S.A.C.I. National Road No. 1 (12th Km) Metamorphosis GR-144 51 Athens Greece	SANDIMMUN	250mg/5ml amp	Concentrate for solution for infusion	Intravenous use	50 mg/ml

Member State EU/EEA	Marketing authorisation holder	Invented Name	Strength	Pharmaceutical form	Route of administration	Content (concentration)
Greece	Novartis (Hellas) S.A.C.I. National Road No. 1 (12th Km) Metamorphosis GR-144 51 Athens Greece	SANDIMMUN	50mg/ml amp	Concentrate for solution for infusion	Intravenous use	50 mg/ml
Hungary	Novartis Hungária Kft. Pharma részlege Bartók Béla út 43-47 H-1114 Budapest Hungary	Sandimmun 50 mg/ml koncentrátum oldatos infúzióhoz	50 mg/ml	Concentrate for solution for infusion	Intravenous use	50 mg/ml
Iceland	Novartis Healthcare A/S Edward Thomsens Vej 14 2003 Köbenhavn S Denmark	Sandimmun	50 mg/ml	Concentrate for solution for infusion	Intravenous use	50 mg/ml
Ireland	Novartis Pharmaceuticals UNITED KINGDOM Ltd Frimley Business Park Frimley, Camberley Surrey GU16 7SR United Kingdom	Sandimmun	25mg	Capsule, soft	Oral use	
Ireland	Novartis Pharmaceuticals UNITED KINGDOM Ltd Frimley Business Park Frimley, Camberley Surrey GU16 7SR United Kingdom	Sandimmun	50mg	Capsule, soft	Oral use	

Member State EU/EEA	Marketing authorisation holder	Invented Name	Strength	Pharmaceutical form	Route of administration	Content (concentration)
Ireland	Novartis Pharmaceuticals UNITED KINGDOM Ltd Frimley Business Park Frimley, Camberley Surrey GU16 7SR United Kingdom	Sandimmun	100mg	Capsule, soft	Oral use	
Ireland	Novartis Pharmaceuticals UNITED KINGDOM Ltd Frimley Business Park Frimley, Camberley Surrey GU16 7SR United Kingdom	Sandimmun	100 mg/ml	Oral Solution	Oral use	100 mg/ml
Ireland	Novartis Pharmaceuticals UNITED KINGDOM Ltd Frimley Business Park Frimley, Camberley Surrey GU16 7SR United Kingdom	Sandimmun	50mg/1ml	Concentrate for solution for infusion	Intravenous use	50 mg/ml
Italy	Novartis Europharm Limited Wimblehurst Road Horsham West Sussex, RH12 5AB United Kingdom	SANDIMMUN	25 mg	Capsule, soft	Oral use	
Italy	Novartis Europharm Limited Wimblehurst Road Horsham West Sussex, RH12 5AB United Kingdom	SANDIMMUN	50 mg	Capsule, soft	Oral use	

Member State EU/EEA	Marketing authorisation holder	Invented Name	Strength	Pharmaceutical form	Route of administration	Content (concentration)
Italy	Novartis Europharm Limited Wimblehurst Road Horsham West Sussex, RH12 5AB United Kingdom	SANDIMMUN	100 mg	Capsule, soft	Oral use	
Italy	Novartis Europharm Limited Wimblehurst Road Horsham West Sussex, RH12 5AB United Kingdom	SANDIMMUN	100 mg/ml	Oral solution	Oral use	100 mg/ml
Italy	Novartis Europharm Limited Wimblehurst Road Horsham West Sussex, RH12 5AB United Kingdom	SANDIMMUN	50 mg/ml	Concentrate for solution for infusion	Intravenous use	50 mg/ml
Luxembourg	Novartis Pharma GmbH Roonstrasse 25 D-90429 Nürnberg Germany	Sandimmun 25 mg Weichkapseln	25 mg	Capsule, soft	Oral use	
Luxembourg	Novartis Pharma GmbH Roonstrasse 25 D-90429 Nürnberg Germany	Sandimmun 100 mg Weichkapseln	100 mg	Capsule, soft	Oral use	
Luxembourg	Novartis Pharma GmbH Roonstrasse 25 D-90429 Nürnberg Germany	Sandimmun 100 mg/ml Lösung zum Einnehmen	100 mg/ml	Oral solution	Oral use	100 mg/ml

Member State EU/EEA	Marketing authorisation holder	Invented Name	Strength	Pharmaceutical form	Route of administration	Content (concentration)
Luxembourg	Novartis Pharma GmbH Roonstrasse 25 D-90429 Nürnberg Germany	Sandimmun 50 mg/ml Konzentrat zur Herstellung einer Infusionslösung	50 mg/ml	Concentrate for solution for infusion	Intravenous use	50 mg/ml
Netherlands	Novartis Pharma B.V. Raapopseweg 1 6824 DP Arnhem The Netherlands	Sandimmune, concentraat voor oplossing voor intraveneuze infusie 50 mg/ml	50 mg/ml	Concentrate for solution for intravenous infusion	Intravenous use	50 mg/ml
Norway	Novartis Norge AS Nydalen Alle 37A P.O Box 4284 Nydalen, N-0401 Oslo Norway	Sandimmun	50mg/ml	Concentrate for solution for infusion	Intravenous use	50 mg/ml
Poland	Novartis Pharma GmbH Roonstrasse 25 D-90429 Nürnberg Germany	Sandimmun	50 mg/ml	Concentrate for solution for infusion	Intravenous	50 mg/ml
Portugal	Novartis Farma - Produtos Farmacêuticos S.A. Rua do Centro Empresarial, Edifício 8 Quinta da Beloura P-2710-444 Sintra Portugal	Sandimmun	50mg/ml	Concentrate for solution for infusion	Intravenous use	50 mg/ml

Member State EU/EEA	Marketing authorisation holder	Invented Name	Strength	Pharmaceutical form	Route of administration	Content (concentration)
Slovak Republic	Novartis s.r.o. Na Pankráci 1724/129 Prague 140 00 Czech Republic	Sandimmun 50 mg/ml	50 mg/ml	Concentrate for solution for infusion	Intravenous use	50 mg/ml
Slovenia	Novartis Pharma GmbH Roonstrasse 25 D-90429 Nürnberg Germany	Sandimmun 50 mg/ml koncentrat za raztopino za infundiranje	50 mg/ml	Concentrate for solution for infusion	Intravenous use	50 mg/ml
Spain	Novartis Farmacéutica S.A. Gran Via de les Corts Catalanes, 764 E-08013 Barcelona Spain	Sandimmun 50 mg/ml concentrado para solución para perfusión	50 mg/ml	Concentrate for solution for infusion	Intravenous use	50 mg/ml
Spain	Novartis Farmacéutica S.A. Gran Via de les Corts Catalanes, 764 E-08013 Barcelona Spain	Sandimmun 250 mg/5 ml concentrado para solución para perfusión	250 mg/5 ml	Concentrate for solution for infusion	Intravenous use	50 mg/ml
Sweden	Novartis Sverige AB Kemistvägen 1B / Box 1150 SE-183 11 Täby Sweden	Sandimmun	50 mg/ml	Concentrate for solution for infusion	Intravenous use	50 mg/ml
United Kingdom	Novartis Pharmaceuticals UK Ltd Frimley Business Park Frimley, Camberley Surrey GU16 7SR United Kingdom	SANDIMMUN Soft Gelatin Capsules 25mg	25 mg	Capsule, soft	Oral use	

Member State EU/EEA	Marketing authorisation holder	Invented Name	Strength	Pharmaceutical form	Route of administration	Content (concentration)
United Kingdom	Novartis Pharmaceuticals UK Ltd Frimley Business Park Frimley, Camberley Surrey GU16 7SR United Kingdom	SANDIMMUN Soft Gelatin Capsules 50mg	50 mg	Capsule, soft	Oral use	
United Kingdom	Novartis Pharmaceuticals UK Ltd Frimley Business Park Frimley, Camberley Surrey GU16 7SR United Kingdom	SANDIMMUN Soft Gelatin Capsules 100mg	100 mg	Capsule, soft	Oral use	
United Kingdom	Novartis Pharmaceuticals UK Ltd Frimley Business Park Frimley, Camberley Surrey GU16 7SR United Kingdom	SANDIMMUN Oral Solution	100 mg/ml	Oral solution	Oral use	100 mg/ml
United Kingdom	Novartis Pharmaceuticals UK Ltd Frimley Business Park Frimley, Camberley Surrey GU16 7SR United Kingdom	SANDIMMUN Concentrate for Solution for Infusion 50mg/ml	50mg/ml	Concentrate for solution for infusion	Intravenous use	50 mg/ml