



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

2 September 2016  
EMA/580924/2016  
Procedure Management and Committees Support

## List of nationally authorised medicinal products

Active substance(s): ciclosporin (systemic use)

Procedure No.: PSUSA/00000745/201512



| 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 250 MG/5 ML CONCENTRADO PARA SOLUCIÓN PARA PERFUSIÓN         | DE/H/4002/004                  | 56798                         | NOVARTIS FARMACÉUTICA S.A. (ART57)                 | ES                                       |
| SANDIMMUN 50 mg/ml concentrado para solución para perfusión            | DE/H/4002/004                  | 56800                         | NOVARTIS FARMACÉUTICA S.A. (ART57)                 | ES                                       |
| SANDIMMUN50 MG/ML CONCENTRADO PARA SOLUÇÃO PARA PERFUSÃO               | DE/H/4002/004                  | 8611319                       | NOVARTIS FARMA - PRODUTOS FARMACÉUTICOS S.A. ART57 | PT                                       |
| SANDIMMUN50 MG/ML CONCENTRADO PARA SOLUÇÃO PARA PERFUSÃO               | DE/H/4002/004                  | 8611319                       | NOVARTIS FARMA - PRODUTOS FARMACÉUTICOS S.A. ART57 | PT                                       |
| Sandimmun 50 mg/ml innrennslispykni, lausn                             | DE/H/4002/004                  | 822940                        | NOVARTIS HEALTHCARE A/S (ART57)                    | IS                                       |
| Sandimmun 50 mg/ml konzentrat za raztopino za infundiranje             | DE/H/4002/004                  | 5363-I-363/14                 | NOVARTIS PHARMA GMBH (ART57)                       | SI                                       |
| Sandimmun 50 mg/ml konzentrat za raztopino za infundiranje             | DE/H/4002/004                  | 5363-I-364/14                 | NOVARTIS PHARMA GMBH (ART57)                       | SI                                       |
| SANDIMMUN 250 MG/5 ML SOLUTION À DILUER POUR PERFUSION                 | DE/H/4002/004                  | 1983090382                    | NOVARTIS PHARMA N.V. (ART57)                       | LU                                       |
| Sandimmun 250 mg/5 ml Konzentrat zur Herstellung einer Infusionslösung | DE/H/4002/004                  | 1983090382                    | NOVARTIS PHARMA N.V. (ART57)                       | LU                                       |
| Sandimmun                                                              | DE/H/4002/004                  | 11096                         | NOVARTIS HEALTHCARE A/S (ART57)                    | DK                                       |
| Sandimmun 250 mg/5 ml Konzentrat zur Herstellung einer Infusionslösung | DE/H/4002/004                  | BE124546                      | NOVARTIS PHARMA N.V. (ART57)                       | BE                                       |
| Sandimmun 250 mg/5 ml, concentraat voor oplossing voor infusie         | DE/H/4002/004                  | BE124546                      | NOVARTIS PHARMA N.V. (ART57)                       | BE                                       |
| SANDIMMUN solution pour perfusion                                      | DE/H/4002/004                  | BE124546                      | NOVARTIS PHARMA N.V. (ART57)                       | BE                                       |
| Sandimmun                                                              | DE/H/4002/004                  | 59/123/83-C                   | NOVARTIS, S.R.O. (ART57)                           | CZ                                       |
| Sandimmun 50 mg/ml infuusiokonsentraatti, liuosta varten               | DE/H/4002/004                  | 8569                          | NOVARTIS FINLAND OY (ART57)                        | FI                                       |
| Sandimmun 50 mg/ml infuusiokonsentraatti, liuosta varten               | DE/H/4002/004                  | 8569                          | NOVARTIS FINLAND OY (ART57)                        | FI                                       |
| SANDIMMUN 50 MG/ML KONCENTRÁTUM OLDATOS INFÚZIÓHOZ                     | DE/H/4002/004                  | OGYI-T-4200/06                | NOVARTIS HUNGÁRIA KFT. PHARMA (ART57)              | HU                                       |
| SANDIMMUN 50 MG/ML CONCENTRATE FOR SOLUTION FOR INFUSION               | DE/H/4002/004                  | PA 13/33/3                    | NOVARTIS PHARMACEUTICALS UK LIMITED                | IE                                       |
| SANDIMMUN 50MG SOFT CAPSULES                                           | DE/H/4002/001                  | PA 13/33/6                    | NOVARTIS PHARMACEUTICALS UK LIMITED                | IE                                       |

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| SANDIMMUN 100MG/ML CONCENTRATE FOR ORAL SOLUTION                          | DE/H/4002/005                  | PA 13/33/1                    | NOVARTIS PHARMACEUTICALS UK LIMITED                | IE                                       |
| SANDIMMUN®                                                                | DE/H/4002/004                  | 190030101                     | NOVARTIS (HELLAS) S.A.C.I. (ART57)                 | GR                                       |
| SANDIMMUN®                                                                | DE/H/4002/004                  | 190030201                     | NOVARTIS (HELLAS) S.A.C.I. (ART57)                 | GR                                       |
| SANDIMMUN 50 MG/ML KONCENTRAT ZA OTOPINU ZA INFUZIJU                      | DE/H/4002/004                  | UP/I-530-09/10-02/150         | NOVARTIS HRVATSKA D.O.O. (ART57)                   | HR                                       |
| SANDIMMUN SOFT GELATIN CAPSULES 50 MG                                     | DE/H/4002/001                  | PL 00101/0310                 | NOVARTIS PHARMACEUTICALS UK LIMITED                | UK                                       |
| SANDIMMUN Concentrate for Solution for Infusion 50mg/ml                   | DE/H/4002/004                  | PL 00101/0153                 | NOVARTIS PHARMACEUTICALS UK LIMITED                | UK                                       |
| SANDIMMUN Oral Solution                                                   | DE/H/4002/005                  | PL 00101/0124                 | NOVARTIS PHARMACEUTICALS UK LIMITED                | UK                                       |
| SANDIMMUN 50 MG/ML CONCENTRADO PARA SOLUÇÃO PARA PERFUSÃO                 | DE/H/4002/004                  | 8611301                       | NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A. ART57 | PT                                       |
| SANDIMMUN 50 MG, CAPSULES MOLLES                                          | DE/H/4002/001                  | 3400955856436                 | NOVARTIS PHARMA S.A.S. (ART57)                     | FR                                       |
| SANDIMMUN 50 MG, CAPSULES MOLLES                                          | DE/H/4002/001                  | 3400934630316                 | NOVARTIS PHARMA S.A.S. (ART57)                     | FR                                       |
| SANDIMMUN 50 MG/ML, SOLUTION À DILUER POUR PERFUSION                      | DE/H/4002/004                  | 3400955457961                 | NOVARTIS PHARMA S.A.S. (ART57)                     | FR                                       |
| SANDIMMUN 50 MG/ML, SOLUTION À DILUER POUR PERFUSION                      | DE/H/4002/004                  | 3400955458043                 | NOVARTIS PHARMA S.A.S. (ART57)                     | FR                                       |
| SANDIMMUN 100 mg/ml, solution buvable                                     | DE/H/4002/005                  | 3400934630026                 | NOVARTIS PHARMA S.A.S. (ART57)                     | FR                                       |
| SANDIMMUN 100 mg/ml, solution buvable                                     | DE/H/4002/005                  | 3400955458104                 | NOVARTIS PHARMA S.A.S. (ART57)                     | FR                                       |
| SANDIMMUN 100 mg/ml, solution buvable                                     | DE/H/4002/005                  | 3400955458272                 | NOVARTIS PHARMA S.A.S. (ART57)                     | FR                                       |
| SANDIMMUN 100 mg/ml, solution buvable                                     | DE/H/4002/005                  | 3400955864530                 | NOVARTIS PHARMA S.A.S. (ART57)                     | FR                                       |
| SANDIMMUN 50 mg/ml konsentrat til infusjonsvæske                          | DE/H/4002/004                  | 7073                          | NOVARTIS NORGE AS (ART57)                          | NO                                       |
| SANDIMMUN 50 MG/ML KONCENTRAT DO SPORZĄDZANIA ROZTWORU DO INFUZJI         | DE/H/4002/004                  | R/1198                        | NOVARTIS POLAND SP. Z O. O. (ART57)                | PL                                       |
| SANDIMMUN 50 mg/ml                                                        | DE/H/4002/004                  | 59/0123/83-C/S                | NOVARTIS, S.R.O. (ART57)                           | SK                                       |
| Sandimmun 50 mg - Konzentrat zur Infusionsbereitung                       | DE/H/4002/004                  | 17896                         | NOVARTIS PHARMA GMBH (ART57)                       | AT                                       |
| Sandimmune, concentraat voor oplossing voor intraveneuze infusie 50 mg/ml | DE/H/4002/004                  | RVG 09846                     | NOVARTIS PHARMA B.V. (ART57)                       | NL                                       |

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| SANDIMMUN 25 MG SOFT CAPSULES                                                         | DE/H/4002/002                  | PA 13/33/4                    | NOVARTIS PHARMACEUTICALS UK LIMITED | IE                                       |
| SANDIMMUN 100MG SOFT CAPSULES                                                         | DE/H/4002/003                  | PA 13/33/5                    | NOVARTIS PHARMACEUTICALS UK LIMITED | IE                                       |
| Neoral Oral Solution 100 mg                                                           | DE/H/4019/005                  | PA 13/54/4                    | NOVARTIS PHARMACEUTICALS UK LIMITED | IE                                       |
| Neoral Soft Gelatin Capsules 25 mg                                                    | DE/H/4019/002                  | PA 13/54/1                    | NOVARTIS PHARMACEUTICALS UK LIMITED | IE                                       |
| Neoral Soft Gelatin Capsules 50 mg                                                    | DE/H/4019/003                  | PA 13/54/2                    | NOVARTIS PHARMACEUTICALS UK LIMITED | IE                                       |
| SANDIMMUN NEORAL 25 mg soft capsules / САНДИМУН НЕОРАЛ 25 mg меки капсули             | DE/H/4019/002                  | 20010481                      | NOVARTIS PHARMA GMBH (ART57)        | BG                                       |
| SANDIMMUN NEORAL 50 mg soft capsules / САНДИМУН НЕОРАЛ 50 mg меки капсули             | DE/H/4019/003                  | 20010482                      | NOVARTIS PHARMA GMBH (ART57)        | BG                                       |
| SANDIMMUN NEORAL100 mg/ml oral solution / САНДИМУН НЕОРАЛ 100 mg/ml перорален разтвор | DE/H/4019/005                  | 20010484                      | NOVARTIS PHARMA GMBH (ART57)        | BG                                       |
| Neoral Soft Gelatin Capsules 100 mg                                                   | DE/H/4019/004                  | PA 13/54/3                    | NOVARTIS PHARMACEUTICALS UK LIMITED | IE                                       |
| SANDIMMUN NEORAL 100 mg soft capsules / САНДИМУН НЕОРАЛ 100 mg меки капсули           | DE/H/4019/004                  | 20010483                      | NOVARTIS PHARMA GMBH (ART57)        | BG                                       |
| NEORAL Oral Solution 100mg/ml                                                         | DE/H/4019/005                  | PL 00101/0390                 | NOVARTIS PHARMACEUTICALS UK LIMITED | UK                                       |
| NEORAL Soft Gelatin Capsules                                                          | DE/H/4019/001                  | PL 00101/0483                 | NOVARTIS PHARMACEUTICALS UK LIMITED | UK                                       |
| NEORAL Soft Gelatin Capsules 100 mg                                                   | DE/H/4019/004                  | PL 00101/0389                 | NOVARTIS PHARMACEUTICALS UK LIMITED | UK                                       |
| NEORAL Soft Gelatin Capsules 25 mg                                                    | DE/H/4019/002                  | PL 00101/0387                 | NOVARTIS PHARMACEUTICALS UK LIMITED | UK                                       |
| NEORAL Soft Gelatin Capsules 50 mg                                                    | DE/H/4019/003                  | PL 00101/0388                 | NOVARTIS PHARMACEUTICALS UK LIMITED | UK                                       |
| SANDIMMUN Soft Gelatin Capsules 100mg                                                 | DE/H/4002/003                  | PL 00101/0208                 | NOVARTIS PHARMACEUTICALS UK LIMITED | UK                                       |

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| SANDIMMUN Soft Gelatin Capsules 25mg            | DE/H/4002/002                  | PL 00101/0207                 | NOVARTIS PHARMACEUTICALS UK LIMITED | UK                                       |
| Sandimmun Neoral 100 mg                         | DE/H/4019/004                  | 59/649/95-C/C                 | NOVARTIS, S.R.O. (ART57)            | CZ                                       |
| Sandimmun Neoral 100 mg/ml                      | DE/H/4019/005                  | 59/665/95-C                   | NOVARTIS, S.R.O. (ART57)            | CZ                                       |
| Sandimmun Neoral 25 mg                          | DE/H/4019/002                  | 59/649/95-A/C                 | NOVARTIS, S.R.O. (ART57)            | CZ                                       |
| Sandimmun Neoral 50 mg                          | DE/H/4019/003                  | 59/649/95-B/C                 | NOVARTIS, S.R.O. (ART57)            | CZ                                       |
| Neoral Sandimmun 10 mg capsule molle            | DE/H/4019/001                  | 1999070021                    | NOVARTIS PHARMA N.V. (ART57)        | LU                                       |
| Neoral-Sandimmun 100 mg capsule molle           | DE/H/4019/004                  | 1993080413                    | NOVARTIS PHARMA N.V. (ART57)        | LU                                       |
| Neoral-Sandimmun 100 mg/ml solution buvable     | DE/H/4019/005                  | 1993080410                    | NOVARTIS PHARMA N.V. (ART57)        | LU                                       |
| Neoral-Sandimmun 25 mg capsule molle            | DE/H/4019/002                  | 1993080411                    | NOVARTIS PHARMA N.V. (ART57)        | LU                                       |
| Neoral-Sandimmun 50 mg capsule molle            | DE/H/4019/003                  | 1993080412                    | NOVARTIS PHARMA N.V. (ART57)        | LU                                       |
| Neoral-Sandimmun 10 mg Weichkapseln             | DE/H/4019/001                  | 1999070021                    | NOVARTIS PHARMA N.V. (ART57)        | LU                                       |
| Neoral-Sandimmun 100 mg Weichkapseln            | DE/H/4019/004                  | 1993080413                    | NOVARTIS PHARMA N.V. (ART57)        | LU                                       |
| Neoral-Sandimmun 100 mg/ml Lösung zum Einnehmen | DE/H/4019/005                  | 1993080410                    | NOVARTIS PHARMA N.V. (ART57)        | LU                                       |
| Neoral-Sandimmun 25 mg Weichkapseln             | DE/H/4019/002                  | 1993080411                    | NOVARTIS PHARMA N.V. (ART57)        | LU                                       |
| Neoral-Sandimmun 50 mg Weichkapseln             | DE/H/4019/003                  | 1993080412                    | NOVARTIS PHARMA N.V. (ART57)        | LU                                       |
| Sandimmun Neoral, 100 mg kapsel                 | DE/H/4019/004                  | 093394                        | NOVARTIS FINLAND OY (ART57)         | EE                                       |
| Sandimmun Neoral, 25 mg kapsel                  | DE/H/4019/002                  | 093194                        | NOVARTIS FINLAND OY (ART57)         | EE                                       |
| Sandimmun Neoral, 50 mg kapsel                  | DE/H/4019/003                  | 093294                        | NOVARTIS FINLAND OY (ART57)         | EE                                       |
| Sandimmun Neoral 10 mg - Kapseln                | DE/H/4019/001                  | 1-26595                       | NOVARTIS PHARMA GMBH (ART57)        | AT                                       |
| Sandimmun Neoral 100 mg - Kapseln               | DE/H/4019/004                  | 1-20691                       | NOVARTIS PHARMA GMBH (ART57)        | AT                                       |
| Sandimmun Neoral 100 mg/ml - Trinklösung        | DE/H/4019/005                  | 1-20694                       | NOVARTIS PHARMA GMBH (ART57)        | AT                                       |
| Sandimmun Neoral 25 mg - Kapseln                | DE/H/4019/002                  | 1-20689                       | NOVARTIS PHARMA GMBH (ART57)        | AT                                       |
| Sandimmun Neoral 50 mg - Kapseln                | DE/H/4019/003                  | 1-20690                       | NOVARTIS PHARMA GMBH (ART57)        | AT                                       |
| NEORAL 100 mg/ml solution buvable               | DE/H/4019/005                  | 3400934633157                 | NOVARTIS PHARMA S.A.S. (ART57)      | FR                                       |
| NEORAL 100 mg/ml solution buvable               | DE/H/4019/005                  | 3400955915379                 | NOVARTIS PHARMA S.A.S. (ART57)      | FR                                       |
| NEORAL 100 mg/ml solution buvable               | DE/H/4019/005                  | 3400955915430                 | NOVARTIS PHARMA S.A.S. (ART57)      | FR                                       |
| neoral 25 mg, capsule molle                     | DE/H/4019/002                  | 3400934630484                 | NOVARTIS PHARMA S.A.S. (ART57)      | FR                                       |
| neoral 25 mg, capsule molle                     | DE/H/4019/002                  | 3400955914600                 | NOVARTIS PHARMA S.A.S. (ART57)      | FR                                       |
| neoral 25 mg, capsule molle                     | DE/H/4019/002                  | 3400955914778                 | NOVARTIS PHARMA S.A.S. (ART57)      | FR                                       |
| NEORAL 50 mg, capsule molle                     | DE/H/4019/003                  | 3400934630545                 | NOVARTIS PHARMA S.A.S. (ART57)      | FR                                       |
| NEORAL 50 mg, capsule molle                     | DE/H/4019/003                  | 3400955914839                 | NOVARTIS PHARMA S.A.S. (ART57)      | FR                                       |

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| NEORAL 50 mg, capsule molle                  | DE/H/4019/003                  | 3400955915089                 | NOVARTIS PHARMA S.A.S. (ART57)        | FR                                       |
| NEORAL 100 mg, capsule molle                 | DE/H/4019/004                  | 3400934630606                 | NOVARTIS PHARMA S.A.S. (ART57)        | FR                                       |
| NEORAL 100 mg, capsule molle                 | DE/H/4019/004                  | 3400955915140                 | NOVARTIS PHARMA S.A.S. (ART57)        | FR                                       |
| NEORAL 100 mg, capsule molle                 | DE/H/4019/004                  | 3400955915201                 | NOVARTIS PHARMA S.A.S. (ART57)        | FR                                       |
| Sandimmun 100 mg, capsules molles            | DE/H/4002/003                  | 3400934630194                 | NOVARTIS PHARMA S.A.S. (ART57)        | FR                                       |
| Sandimmun 100 mg, capsules molles            | DE/H/4002/003                  | 3400955856665                 | NOVARTIS PHARMA S.A.S. (ART57)        | FR                                       |
| SANDIMMUN 25 mg, capsules molles             | DE/H/4002/002                  | 3400934630255                 | NOVARTIS PHARMA S.A.S. (ART57)        | FR                                       |
| SANDIMMUN 25 mg, capsules molles             | DE/H/4002/002                  | 3400955856375                 | NOVARTIS PHARMA S.A.S. (ART57)        | FR                                       |
| neoral 10 mg, capsule molle                  | DE/H/4019/001                  | 3400934437786                 | NOVARTIS PHARMA S.A.S. (ART57)        | FR                                       |
| neoral 10 mg, capsule molle                  | DE/H/4019/001                  | 3400934437847                 | NOVARTIS PHARMA S.A.S. (ART57)        | FR                                       |
| neoral 10 mg, capsule molle                  | DE/H/4019/001                  | 3400934630774                 | NOVARTIS PHARMA S.A.S. (ART57)        | FR                                       |
| Sandimmun Neoral 100mg/ml belsőleges oldat   | DE/H/4019/005                  | OGYI-T-4200/01                | NOVARTIS HUNGÁRIA KFT. PHARMA (ART57) | HU                                       |
| Sandimmun Neoral 25 mg lágy kapszula         | DE/H/4019/002                  | OGYI-T-4200/03                | NOVARTIS HUNGÁRIA KFT. PHARMA (ART57) | HU                                       |
| Sandimmun Neoral 25 mg mīkstās kapsulas      | DE/H/4019/002                  | 95-0140                       | NOVARTIS FINLAND OY (ART57)           | LV                                       |
| Sandimmun Neoral 50 mg lágy kapszula         | DE/H/4019/003                  | OGYI-T-4200/04                | NOVARTIS HUNGÁRIA KFT. PHARMA (ART57) | HU                                       |
| Sandimmun Neoral 100 mg lágy kapszula        | DE/H/4019/004                  | OGYI-T-4200/05                | NOVARTIS HUNGÁRIA KFT. PHARMA (ART57) | HU                                       |
| Sandimmun Neoral 100 mg mīkstās kapsulas     | DE/H/4019/004                  | 00-1192                       | NOVARTIS FINLAND OY (ART57)           | LV                                       |
| Sandimmun Neoral 10 mg lágy kapszula         | DE/H/4019/001                  | OGYI-T-4200/02                | NOVARTIS HUNGÁRIA KFT. PHARMA (ART57) | HU                                       |
| Sandimmun Neoral 50 mg mīkstās kapsulas      | DE/H/4019/003                  | 00-1191                       | NOVARTIS FINLAND OY (ART57)           | LV                                       |
| Neoral 100 mg/ml, drank                      | DE/H/4019/005                  | RVG 17497                     | NOVARTIS PHARMA B.V. (ART57)          | NL                                       |
| Neoral 25 mg, capsules                       | DE/H/4019/002                  | RVG 17495                     | NOVARTIS PHARMA B.V. (ART57)          | NL                                       |
| SANDIMMUN NEORAL 100 mg/ml mikstur           | DE/H/4019/005                  | 8062                          | NOVARTIS NORGE AS (ART57)             | NO                                       |
| SANDIMMUN NEORAL 25 mg kapsler               | DE/H/4019/002                  | 8060                          | NOVARTIS NORGE AS (ART57)             | NO                                       |
| SANDIMMUN NEORAL 50 mg kapsler               | DE/H/4019/003                  | 95-2610                       | NOVARTIS NORGE AS (ART57)             | NO                                       |
| Sandimmun Neoral, 100 mg/ml, roztwór doustny | DE/H/4019/005                  | R/3369                        | NOVARTIS POLAND SP. Z O. O. (ART57)   | PL                                       |
| Sandimmun Neoral 25 mg kapsułki miękkie      | DE/H/4019/002                  | R/3366                        | NOVARTIS POLAND SP. Z O. O. (ART57)   | PL                                       |
| Sandimmun Neoral 50 mg kapsułki miękkie      | DE/H/4019/003                  | R/3367                        | NOVARTIS POLAND SP. Z O. O. (ART57)   | PL                                       |

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| Neoral 100 mg, capsules                   | DE/H/4019/004                  | RVG 17496                     | NOVARTIS PHARMA B.V. (ART57)                       | NL                                       |
| Sandimmun Neoral 100 mg                   | DE/H/4019/004                  | 59/0010/96-S                  | NOVARTIS, S.R.O. (ART57)                           | SK                                       |
| SANDIMMUN NEORAL 100 mg kapsler           | DE/H/4019/004                  | 8061                          | NOVARTIS NORGE AS (ART57)                          | NO                                       |
| Sandimmun Neoral 100 mg kapsułki miękkie  | DE/H/4019/004                  | R/3368                        | NOVARTIS POLAND SP. Z O. O. (ART57)                | PL                                       |
| SANDIMMUN NEORAL 100 mg/ml                | DE/H/4019/005                  | 59/0009/96-S                  | NOVARTIS, S.R.O. (ART57)                           | SK                                       |
| SANDIMMUN NEORAL 25 mg                    | DE/H/4019/002                  | 59/0010/96-S                  | NOVARTIS, S.R.O. (ART57)                           | SK                                       |
| SANDIMMUN NEORAL 50 mg                    | DE/H/4019/003                  | 59/0010/96-S                  | NOVARTIS, S.R.O. (ART57)                           | SK                                       |
| Sandimmun Neoral 10 mg kapsułki miękkie   | DE/H/4019/001                  | 4061                          | NOVARTIS POLAND SP. Z O. O. (ART57)                | PL                                       |
| Sandimmun Neoral capsule moi 25 mg        | DE/H/4019/002                  | 6023/2013/01                  | NOVARTIS PHARMA GMBH (ART57)                       | RO                                       |
| Sandimmun Neoral capsule moi 50 mg        | DE/H/4019/003                  | 6024/2013/01                  | NOVARTIS PHARMA GMBH (ART57)                       | RO                                       |
| Sandimmun Neoral emulsie orala 100mg/ml   | DE/H/4019/005                  | 6025/2013/01                  | NOVARTIS PHARMA GMBH (ART57)                       | RO                                       |
| SANDIMMUN NEORAL 100 mg cápsulas blandas  | DE/H/4019/004                  | 60.320                        | NOVARTIS FARMACÉUTICA S.A. (ART57)                 | ES                                       |
| SANDIMMUN NEORAL 100 mg/ml solución oral  | DE/H/4019/005                  | 56.799                        | NOVARTIS FARMACÉUTICA S.A. (ART57)                 | ES                                       |
| SANDIMMUN NEORAL 25 mg cápsulas blandas   | DE/H/4019/002                  | 60.319                        | NOVARTIS FARMACÉUTICA S.A. (ART57)                 | ES                                       |
| SANDIMMUN NEORAL 50 mg cápsulas blandas   | DE/H/4019/003                  | 60.318                        | NOVARTIS FARMACÉUTICA S.A. (ART57)                 | ES                                       |
| Sandimmun Neoral 100 mg/ml mixtúra, lausn | DE/H/4019/005                  | 940032                        | NOVARTIS HEALTHCARE A/S (ART57)                    | IS                                       |
| Sandimmun Neoral 25 mg mjúk hylki         | DE/H/4019/002                  | 940033                        | NOVARTIS HEALTHCARE A/S (ART57)                    | IS                                       |
| Sandimmun Neoral 50 mg mjúk hylki.        | DE/H/4019/003                  | 940034                        | NOVARTIS HEALTHCARE A/S (ART57)                    | IS                                       |
| Sandimmun Neoral 100 mg mjúk hylki        | DE/H/4019/004                  | 940035                        | NOVARTIS HEALTHCARE A/S (ART57)                    | IS                                       |
| Sandimmun Neoral 100 mg kapseli, pehmeä   | DE/H/4019/004                  | 11609                         | NOVARTIS FINLAND OY (ART57)                        | FI                                       |
| Sandimmun Neoral 100 mg kapslar, mjuka    | DE/H/4019/004                  | 11609                         | NOVARTIS FINLAND OY (ART57)                        | FI                                       |
| Sandimmun Neoral 100 mg/ml oraaliliuos    | DE/H/4019/005                  | 11606                         | NOVARTIS FINLAND OY (ART57)                        | FI                                       |
| Sandimmun Neoral 100 mg/ml oral lösning   | DE/H/4019/005                  | 11606                         | NOVARTIS FINLAND OY (ART57)                        | FI                                       |
| Sandimmun Neoral 25 mg kapseli, pehmeä    | DE/H/4019/002                  | 11607                         | NOVARTIS FINLAND OY (ART57)                        | FI                                       |
| Sandimmun Neoral 25 mg kapslar, mjuka     | DE/H/4019/002                  | 11607                         | NOVARTIS FINLAND OY (ART57)                        | FI                                       |
| Sandimmun Neoral 50 mg kapslar, mjuka     | DE/H/4019/003                  | 11608                         | NOVARTIS FINLAND OY (ART57)                        | FI                                       |
| Sandimmun Neoral 50mg kapseli, pehmeä     | DE/H/4019/003                  | 11608                         | NOVARTIS FINLAND OY (ART57)                        | FI                                       |
| Sandimmun Neoral 25 mg minkštos kapsulės  | DE/H/4019/002                  | LT/1/94/1089/001              | NOVARTIS FINLAND OY (ART57)                        | LT                                       |
| Sandimmun Neoral 50 mg minkštos kapsulės  | DE/H/4019/003                  | LT/1/94/1089/002              | NOVARTIS FINLAND OY (ART57)                        | LT                                       |
| Sandimmun Neoral 100 mg minkštos kapsulės | DE/H/4019/004                  | LT/1/94/1089/003              | NOVARTIS FINLAND OY (ART57)                        | LT                                       |
| Sandimmun Neoral 100 mg Cápsulas moles    | DE/H/4019/004                  | 8742726                       | NOVARTIS FARMA - PRODUTOS FARMACÉUTICOS S.A. ART57 | PT                                       |

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| Sandimmun Neoral 100 mg Cápsulas moles          | DE/H/4019/004                  | 8742742                       | NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A. ART57 | PT                                       |
| Sandimmun Neoral 100 mg/ml Solução oral         | DE/H/4019/005                  | 8611400                       | NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A. ART57 | PT                                       |
| Sandimmun Neoral 25 mg cápsulas moles           | DE/H/4019/002                  | 8742700                       | NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A. ART57 | PT                                       |
| Sandimmun Neoral 25 mg cápsulas moles           | DE/H/4019/002                  | 8742718                       | NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A. ART57 | PT                                       |
| Sandimmun Neoral 50 mg Cápsulas moles           | DE/H/4019/003                  | 3701281                       | NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A. ART57 | PT                                       |
| Sandimmun Neoral 50 mg Cápsulas moles           | DE/H/4019/003                  | 8742767                       | NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A. ART57 | PT                                       |
| NEORAL - SANDIMMUN capsule molles               | DE/H/4019/002                  | BE170642                      | NOVARTIS PHARMA N.V. (ART57)                       | BE                                       |
| NEORAL - SANDIMMUN capsule molles               | DE/H/4019/004                  | BE170676                      | NOVARTIS PHARMA N.V. (ART57)                       | BE                                       |
| NEORAL - SANDIMMUN capsule molles               | DE/H/4019/003                  | BE170764                      | NOVARTIS PHARMA N.V. (ART57)                       | BE                                       |
| NEORAL - SANDIMMUN capsule molles               | DE/H/4019/001                  | BE196953                      | NOVARTIS PHARMA N.V. (ART57)                       | BE                                       |
| Neoral Sandimmun 10 mg, zachte capsule          | DE/H/4019/001                  | BE196953                      | NOVARTIS PHARMA N.V. (ART57)                       | BE                                       |
| Neoral Sandimmun 50 mg, zachte capsule          | DE/H/4019/003                  | BE170764                      | NOVARTIS PHARMA N.V. (ART57)                       | BE                                       |
| Neoral-Sandimmun 100 mg, zachte capsule         | DE/H/4019/004                  | BE170676                      | NOVARTIS PHARMA N.V. (ART57)                       | BE                                       |
| Neoral-Sandimmun 100mg/ml, drinkbare oplossing  | DE/H/4019/005                  | BE170685                      | NOVARTIS PHARMA N.V. (ART57)                       | BE                                       |
| Neoral-Sandimmun 25 mg, zachte capsule          | DE/H/4019/002                  | BE170642                      | NOVARTIS PHARMA N.V. (ART57)                       | BE                                       |
| NEORAL-SANDIMMUN solution injectable/buvable    | DE/H/4019/005                  | BE170685                      | NOVARTIS PHARMA N.V. (ART57)                       | BE                                       |
| Neoral-Sandimmun 100 mg/ml Lösung zum Einnehmen | DE/H/4019/005                  | BE170685                      | NOVARTIS PHARMA N.V. (ART57)                       | BE                                       |
| Neoral-Sandimmun 25 mg Weichkapseln             | DE/H/4019/002                  | BE170642                      | NOVARTIS PHARMA N.V. (ART57)                       | BE                                       |
| Neoral-Sandimmun 50 mg Weichkapseln             | DE/H/4019/003                  | BE170764                      | NOVARTIS PHARMA N.V. (ART57)                       | BE                                       |
| Neoral-Sandimmun 100 mg Weichkapseln            | DE/H/4019/004                  | BE170676                      | NOVARTIS PHARMA N.V. (ART57)                       | BE                                       |
| Neoral-Sandimmun 10 mg Weichkapseln             | DE/H/4019/001                  | BE196953                      | NOVARTIS PHARMA N.V. (ART57)                       | BE                                       |
| Sandimmun Neoral                                | DE/H/4019/002                  | 15804                         | NOVARTIS HEALTHCARE A/S (ART57)                    | DK                                       |
| Sandimmun Neoral                                | DE/H/4019/003                  | 15805                         | NOVARTIS HEALTHCARE A/S (ART57)                    | DK                                       |
| Sandimmun Neoral                                | DE/H/4019/005                  | 15807                         | NOVARTIS HEALTHCARE A/S (ART57)                    | DK                                       |

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| Sandimmun Neoral                                                     | DE/H/4019/004                  | 15806                         | NOVARTIS HEALTHCARE A/S (ART57)     | DK                                       |
| Sandimmun Neoral                                                     | DE/H/4019/001                  | 18671                         | NOVARTIS HEALTHCARE A/S (ART57)     | DK                                       |
| Sandimmun Neoral oral solution 100mg/ml                              | DE/H/4019/005                  | 18413                         | NOVARTIS PHARMACEUTICALS UK LIMITED | CY                                       |
| Sandimmun Neoral soft gelatin capsule 25mg                           | DE/H/4019/002                  | 18439                         | NOVARTIS PHARMACEUTICALS UK LIMITED | CY                                       |
| Sandimmun Neoral soft gelatin capsules 100mg                         | DE/H/4019/004                  | 18383                         | NOVARTIS PHARMACEUTICALS UK LIMITED | CY                                       |
| Sandimmun Neoral soft gelatin capsules 50mg                          | DE/H/4019/003                  | 18412                         | NOVARTIS PHARMACEUTICALS UK LIMITED | CY                                       |
| Sandimmun Neoral, καψάκιο μαλακό 100mg                               | DE/H/4019/004                  | 223010301                     | NOVARTIS (HELLAS) S.A.C.I. (ART57)  | GR                                       |
| Sandimmun Neoral, καψάκιο μαλακό 100mg                               | DE/H/4019/004                  | 223010302                     | NOVARTIS (HELLAS) S.A.C.I. (ART57)  | GR                                       |
| Sandimmun Neoral, καψάκιο μαλακό 50mg                                | DE/H/4019/003                  | 223010201                     | NOVARTIS (HELLAS) S.A.C.I. (ART57)  | GR                                       |
| Sandimmun Neoral, καψάκιο μαλακό 50mg                                | DE/H/4019/003                  | 223010202                     | NOVARTIS (HELLAS) S.A.C.I. (ART57)  | GR                                       |
| Sandimmun Neoral, κάψουλες μαλακές 25mg                              | DE/H/4019/002                  | 223010101                     | NOVARTIS (HELLAS) S.A.C.I. (ART57)  | GR                                       |
| Sandimmun Neoral, κάψουλες μαλακές 25mg                              | DE/H/4019/002                  | 223010102                     | NOVARTIS (HELLAS) S.A.C.I. (ART57)  | GR                                       |
| Sandimmun Neoral, πόσιμο διάλυμα 500mg/5ml                           | DE/H/4019/005                  | 223010401                     | NOVARTIS (HELLAS) S.A.C.I. (ART57)  | GR                                       |
| Sandimmun Neoral                                                     | DE/H/4019/005                  | 088/03201                     | NOVARTIS PHARMACEUTICALS UK LIMITED | MT                                       |
| Sandimmun Neoral                                                     | DE/H/4019/002                  | 088/03202                     | NOVARTIS PHARMACEUTICALS UK LIMITED | MT                                       |
| Sandimmun Neoral                                                     | DE/H/4019/004                  | 088/03203                     | NOVARTIS PHARMACEUTICALS UK LIMITED | MT                                       |
| Sandimmun Neoral 100 mg mehke kapsule                                | DE/H/4019/004                  | 5363-I-367/14                 | NOVARTIS PHARMA GMBH (ART57)        | SI                                       |
| Sandimmun Neoral 100 mg/ml peroralna raztopina                       | DE/H/4019/005                  | 5363-I-368/14                 | NOVARTIS PHARMA GMBH (ART57)        | SI                                       |
| Sandimmun Neoral 25 mg mehke kapsule                                 | DE/H/4019/002                  | 5363-I-365/14                 | NOVARTIS PHARMA GMBH (ART57)        | SI                                       |
| Sandimmun Neoral 50 mg mehke kapsule                                 | DE/H/4019/003                  | 5363-I-366/14                 | NOVARTIS PHARMA GMBH (ART57)        | SI                                       |
| Sandimmun® 50 mg/ml Konzentrat zur Herstellung einer Infusionslösung | DE/H/4002/004                  | 3123.00.00                    | NOVARTIS PHARMA GMBH (ART57)        | DE                                       |
| Sandimmun 50 mg Weichkapseln                                         | DE/H/4002/001                  | 90481.00.00                   | NOVARTIS PHARMA GMBH (ART57)        | DE                                       |
| SANDIMMUN NEORAL 25 mg Capsule molli                                 | DE/H/4019/002                  | 029453014                     | NOVARTIS EUROPHARM LIMITED          | IT                                       |
| SANDIMMUN NEORAL 50 mg Capsule molli                                 | DE/H/4019/003                  | 029453026                     | NOVARTIS EUROPHARM LIMITED          | IT                                       |

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| SANDIMMUN NEORAL 100 mg Capsule molli                      | DE/H/4019/004                  | 029453038                     | NOVARTIS EUROPHARM LIMITED          | IT                                       |
| SANDIMMUN NEORAL 10 mg Capsule molli                       | DE/H/4019/001                  | 029453053                     | NOVARTIS EUROPHARM LIMITED          | IT                                       |
| SANDIMMUN 50 mg/ml concentrato per soluzione per infusione | DE/H/4002/004                  | 025306022                     | NOVARTIS EUROPHARM LIMITED          | IT                                       |
| SANDIMMUN 100 mg capsule molli                             | DE/H/4002/003                  | 025306059                     | NOVARTIS EUROPHARM LIMITED          | IT                                       |
| SANDIMMUN 100 mg/ml soluzione orale                        | DE/H/4002/005                  | 025306010                     | NOVARTIS EUROPHARM LIMITED          | IT                                       |
| SANDIMMUN 25 mg capsule molli                              | DE/H/4002/002                  | 025306034                     | NOVARTIS EUROPHARM LIMITED          | IT                                       |
| SANDIMMUN 50 mg capsule molli                              | DE/H/4002/001                  | 025306046                     | NOVARTIS EUROPHARM LIMITED          | IT                                       |
| SANDIMMUN NEORAL 100 mg/ml Soluzione orale                 | DE/H/4019/005                  | 029453040                     | NOVARTIS EUROPHARM LIMITED          | IT                                       |
| Sandimmun Neoral 100 mg/ml oralna otopina                  | DE/H/4019/005                  | UP/I-530-09/10-02/149         | NOVARTIS HRVATSKA D.O.O. (ART57)    | HR                                       |
| Sandimmun Neoral 25 mg meke kapsule                        | DE/H/4019/002                  | UP/I-530-09/10-02/146         | NOVARTIS HRVATSKA D.O.O. (ART57)    | HR                                       |
| Sandimmun Neoral 50 mg meke kapsule                        | DE/H/4019/003                  | UP/I-530-09/10-02/147         | NOVARTIS HRVATSKA D.O.O. (ART57)    | HR                                       |
| Sandimmun Neoral 100 mg meke kapsule                       | DE/H/4019/004                  | UP/I-530-09/10-02/148         | NOVARTIS HRVATSKA D.O.O. (ART57)    | HR                                       |
| Sandimmun Neoral 100 mg mehke kapsule                      | DE/H/4019/004                  | H/92/01394/003                | NOVARTIS PHARMA GMBH (ART57)        | SI                                       |
| Sandimmun Neoral 100 mg/ml peroralna raztopina             | DE/H/4019/005                  | H/92/01394/004                | NOVARTIS PHARMA GMBH (ART57)        | SI                                       |
| Sandimmun Neoral 25 mg mehke kapsule                       | DE/H/4019/002                  | H/92/01394/001                | NOVARTIS PHARMA GMBH (ART57)        | SI                                       |
| Sandimmun Neoral 50 mg mehke kapsule                       | DE/H/4019/003                  | H/92/01394/002                | NOVARTIS PHARMA GMBH (ART57)        | SI                                       |
| Neoral Soft Gelatin Capsules 50 mg                         | DE/H/4019/003                  | PA 13/54/02                   | NOVARTIS PHARMACEUTICALS UK LIMITED | IE                                       |
| Neoral Soft Gelatin Capsules 100 mg                        | DE/H/4019/004                  | PA 13/54/03                   | NOVARTIS PHARMACEUTICALS UK LIMITED | IE                                       |
| Neoral Oral Solution 100 mg                                | DE/H/4019/005                  | PA 13/54/04                   | NOVARTIS PHARMACEUTICALS UK LIMITED | IE                                       |
| Neoral Soft Gelatin Capsules 25 mg                         | DE/H/4019/002                  | PA 13/54/01                   | NOVARTIS PHARMACEUTICALS UK LIMITED | IE                                       |
| Sandimmun 50 mg/ml koncentrat za raztopino za infundiranje | DE/H/4002/004                  | H/92/01964/001                | NOVARTIS PHARMA GMBH (ART57)        | SI                                       |

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| Sandimmun 50 mg/ml koncentrat za raztopino<br>za infundiranje           | DE/H/4002/004                        | H/92/01964/002                      | NOVARTIS PHARMA GMBH (ART57)       | SI                                             |
| Sandimmun 100 mg/ml Lösung zum Einnehmen                                | DE/H/4002/005                        | 26418.00.00                         | NOVARTIS PHARMA GMBH (ART57)       | DE                                             |
| Sandimmun® 50 mg/ml Konzentrat zur<br>Herstellung einer Infusionslösung | DE/H/4002/004                        | 3123.00.00                          | NOVARTIS PHARMA GMBH (ART57)       | DE                                             |
| SANDIMMUN® 100 MG/ML LÖSUNG ZUM<br>EINNEHMEN                            | DE/H/4019/005                        | 29180.00.00                         | NOVARTIS PHARMA GMBH (ART57)       | DE                                             |
| Immunosporin 100 mg Weichkapseln                                        | DE/H/4020/003                        | 41031.02.00                         | NOVARTIS PHARMA GMBH (ART57)       | DE                                             |
| Immunosporin 25 mg Weichkapseln                                         | DE/H/4020/001                        | 41031.00.00                         | NOVARTIS PHARMA GMBH (ART57)       | DE                                             |
| Immunosporin 50 mg Weichkapseln                                         | DE/H/4020/002                        | 41031.01.00                         | NOVARTIS PHARMA GMBH (ART57)       | DE                                             |
| Sandimmun Optoral 10 mg Weichkapseln                                    | DE/H/4019/001                        | 34681.03.00                         | NOVARTIS PHARMA GMBH (ART57)       | DE                                             |
| Sandimmun Optoral 25 mg Weichkapseln                                    | DE/H/4019/002                        | 34681.00.00                         | NOVARTIS PHARMA GMBH (ART57)       | DE                                             |
| Sandimmun Optoral 50 mg Weichkapseln                                    | DE/H/4019/003                        | 34681.01.00                         | NOVARTIS PHARMA GMBH (ART57)       | DE                                             |
| Sandimmun 50 mg/ml koncentrat till<br>infusionsvätska, lösning          | DE/H/4002/004                        | 10263                               | NOVARTIS SVERIGE AB (ART57)        | SE                                             |
| Sandimmun Neoral 10 mg kapslar, mjuka                                   | DE/H/4019/001                        | 13540                               | NOVARTIS SVERIGE AB (ART57)        | SE                                             |
| Sandimmun Neoral 100 mg kapslar, mjuka                                  | DE/H/4019/004                        | 12310                               | NOVARTIS SVERIGE AB (ART57)        | SE                                             |
| Sandimmun Neoral 100 mg/ml oral lösning                                 | DE/H/4019/005                        | 12311                               | NOVARTIS SVERIGE AB (ART57)        | SE                                             |
| Sandimmun Neoral 25 mg kapslar, mjuka                                   | DE/H/4019/002                        | 12308                               | NOVARTIS SVERIGE AB (ART57)        | SE                                             |
| Sandimmun Neoral 50 mg kapslar, mjuka                                   | DE/H/4019/003                        | 12309                               | NOVARTIS SVERIGE AB (ART57)        | SE                                             |
| Sandimmun 100 mg Weichkapseln                                           | DE/H/4002/003                        | 26418.02.01                         | NOVARTIS PHARMA GMBH (ART57)       | DE                                             |
| Sandimmun 25 mg Weichkapseln                                            | DE/H/4002/002                        | 26418.00.01                         | NOVARTIS PHARMA GMBH (ART57)       | DE                                             |
| Sandimmun Optoral 100 mg Weichkapseln                                   | DE/H/4019/004                        | 34681.02.00                         | NOVARTIS PHARMA GMBH (ART57)       | DE                                             |
| Ciclosporina Mylan 25 mg cápsulas blandas                               | not available                        | 68481                               | MYLAN PHARMACEUTICALS S.L.         | ES                                             |
| Ciklosporin IVAX 50 mg mjuka kapslar                                    | not available                        | 19568                               | TEVA SWEDEN AB                     | SE                                             |
| Ciklosporin IVAX 25 mg mjuka kapslar                                    | not available                        | 19567                               | TEVA SWEDEN AB                     | SE                                             |
| Ciklosporin IVAX 100 mg mjuka kapslar                                   | not available                        | 19569                               | TEVA SWEDEN AB                     | SE                                             |
| Ciklosporin IVAX 50 mg mjuka kapslar                                    | not available                        | 19568                               | TEVA SWEDEN AB                     | SE                                             |