25 January 2017
EMA/169538/2017
Human Medicines Evaluation Division

# List of nationally authorised medicinal products

Active substance: Budesonide

Procedure no.: PSUSA/00000449/201604

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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 |
|---|---|---|---|---|
| Budesonide Easyhaler 400 Mikrogramm Pulver zur Inhalationspulver | DE/H/0402/003 | BE 266524 | ORION CORPORATION | BE |
| Budesonide Easyhaler 200 Mikrogramm Pulver zur Inhalationspulver | DE/H/0402/002 | BE 266515 | ORION CORPORATION | BE |
| Budesonide Easyhaler 100 Mikrogramm Pulver zur Inhalationspulver | DE/H/0402/001 | BE 266506 | ORION CORPORATION | BE |
| Budesonid Easyhaler 400 mikrogram/dos Inhalationspulver | DE/H/402/03 | 19051 | ORION CORPORATION | FI |
| Budesonid Easyhaler 200 mikrogram/dos Inhalationspulver | DE/H/402/02 | 19050 | ORION CORPORATION | FI |
| Budesonid Easyhaler 100 mikrogram/dos Inhalationspulver | DE/H/402/01 | 19048 | ORION CORPORATION | FI |
| Giona Easyhaler, 400 mikrogrammi/annuses, inhalatsioonipulber | DE/H/0402/003 | 486505 | ORION CORPORATION | EE |
| Giona Easyhaler, 200 mikrogrammi/annuses, inhalatsioonipulber | DE/H/0402/002 | 486205 | ORION CORPORATION | EE |
| Giona Easyhaler 100 mikrogrammi/annuses, inhalatsioonipulber | DE/H/0402/001 | 486305 | ORION CORPORATION | EE |
| Giona® Easyhaler® 100 mikrogramu/deva inhalacijas pulveris | DE/H/0402/001 | 05-0272 | ORION CORPORATION | LV |

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|---|---|---|---|---|
| Giona® Easyhaler® 200 mikrogramu/devā inhalācijas pulveris | DE/H/0402/002 | 05-0273 | ORION CORPORATION | LV |
| Giona® Easyhaler® 400 mikrogramu/deva inhalacijas pulveris | DE/H/0402/003 | 05-0274 | ORION CORPORATION | LV |
| Budesonide Easyhaler 100 µg/dawke, proszek do inhalacji | DE/H/0402/001 | 11779 | ORION CORPORATION | PL |
| Budesonide Easyhaler 200 µg/dawkę, proszek do inhalacji | DE/H/0402/002 | 11780 | ORION CORPORATION | PL |
| Budesonide Easyhaler 400 µg/dawke, proszek do inhalacji | DE/H/0402/003 | 11781 | ORION CORPORATION | PL |
| Giona Easyhaler 400 Prášek k inhalaci | DE/H/0402/003 | 14/171/02-C | ORION CORPORATION | CZ |
| Giona Easyhaler 200 Prášek k inhalaci | DE/H/0402/002 | 14/170/02-C | ORION CORPORATION | CZ |
| Giona Easyhaler 100 Prášek k inhalaci | DE/H/0402/001 | 14/169/02-C | ORION CORPORATION | CZ |
| Giona Easyhaler 400 400 mikrogramov v jednej dávke inhalačného prášku | DE/H/0402/003 | 14/0303/05-S | ORION CORPORATION | SK |
| Giona Easyhaler 200 200 mikrogramov v jednej dávke inhalačného prášku | DE/H/0402/002 | 14/0302/05-S | ORION CORPORATION | SK |
| Giona Easyhaler 100 100 | DE/H/0402/001 | 14/0301/05-S | ORION CORPORATION | SK |

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| mikrogramov v jednej dávke inhalacného prášku | | | | |
| Giona Easyhaler, inhalationspulver | DE/H/0402/001 | 36038 | ORION CORPORATION | DK |
| Giona Easyhaler, inhalationspulver | DE/H/0402/002 | 36039 | ORION CORPORATION | DK |
| Giona Easyhaler, inhalationspulver | DE/H/0402/003 | 36040 | ORION CORPORATION | DK |
| Giona Easyhaler 100 mikrogram/dose inhalasjonspulver | DE/H/0402/001 | 03-2340 | ORION CORPORATION | NO |
| Giona Easyhaler 200 mikrogram/dose inhalasjonspulver | DE/H/0402/002 | 03-2341 | ORION CORPORATION | NO |
| Giona Easyhaler 400 mikrogram/dose inhalasjonspulver | DE/H/0402/003 | 03-2342 | ORION CORPORATION | NO |
| Giona Easyhaler 100 mikrogram/dos, inhalationspulver | DE/H/0402/001 | 20326 | ORION CORPORATION | SE |
| Giona Easyhaler 200 mikrogram/dos, inhalationspulver | DE/H/0402/002 | 20327 | ORION CORPORATION | SE |
| Giona Easyhaler 400 mikrogram/dos, inhalationspulver | DE/H/0402/003 | 20328 | ORION CORPORATION | SE |
| Giona Easyhaler 200 Mikrogramm/Dosis - | DE/H/0402/002 | 1-25360 | ORION CORPORATION | AT |

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| Inhalationspulver | | | | |
| Giona Easyhaler 400 Mikrogramm/Dosis - Inhalationspulver | DE/H/0402/003 | 1-25361 | ORION CORPORATION | AT |
| Easyhaler Budesonide 100 micrograms/dose inhalation powder | DE/H/0402/001 | PL27925/0008 | ORION CORPORATION | UK |
| Easyhaler Budesonide 200 micrograms/dose inhalation powder | DE/H/0402/002 | PL27925/0009 | ORION CORPORATION | UK |
| Easyhaler Budesonide 400 micrograms/dose inhalation powder | DE/H/0402/003 | PL27925/0010 | ORION CORPORATION | UK |
| Budesonide Easyhaler 100 microgrammes, poudre pour inhalation | DE/H/0402/001 | BE 266506 | ORION CORPORATION | BE |
| Budesonide Easyhaler 200 microgrammes, poudre pour inhalation | DE/H/0402/002 | BE 266515 | ORION CORPORATION | BE |
| Budesonide Easyhaler 400 microgrammes, poudre pour inhalation | DE/H/0402/003 | BE 266524 | ORION CORPORATION | BE |
| Budesonide Easyhaler 100 microgram inhalatiepoeder | DE/H/0402/001 | BE 266506 | ORION CORPORATION | BE |
| Budesonide Easyhaler 200 microgram inhalatiepoeder | DE/H/0402/002 | BE 266515 | ORION CORPORATION | BE |

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|---|---|---|---|---|
| Budesonide Easyhaler 400 microgram inhalatiepoeder | DE/H/0402/003 | BE 266524 | ORION CORPORATION | BE |
| BUDESONIDA Easyhaler® 100 microgramos/dosis polvo para inhalación | DE/H/0402/001 | 66.670 | ORION CORPORATION | ES |
| BUDESONIDA Easyhaler® 200 microgramos/dosis polvo para inhalación | DE/H/0402/002 | 66.669 | ORION CORPORATION | ES |
| BUDESONIDA Easyhaler® 400 microgramos/dosis polvo para inhalación | DE/H/0402/003 | 66.671 | ORION CORPORATION | ES |
| Budesonid Orion Easyhaler 100 mikrogramov/odmerek prašek za inhaliranje | DE/H/0402/001 | H/05/00315/003 | ORION CORPORATION | SI |
| Budesonid Orion Easyhaler 200 mikrogramov/odmerek prašek za inhaliranje | DE/H/0402/002 | H/05/00315/007 | ORION CORPORATION | SI |
| Budesonid Orion Easyhaler 400 mikrogramov/odmerek prašek za inhaliranje | DE/H/0402/003 | H/05/00315/011 | ORION CORPORATION | SI |
| Budesonid Easyhaler 0,1 | DE/H/0402/001 | 50235.00.00 | ORION CORPORATION | DE |

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|---|---|---|---|---|
| mg/Dosis Pulver zur Inhalation | | | | |
| Budesonid Easyhaler 0,2 mg/Dosis Pulver zur Inhalation | DE/H/0402/002 | 50234.00.00 | ORION CORPORATION | DE |
| Budesonid Easyhaler 0,4 mg/Dosis Pulver zur Inhalation | DE/H/0402/003 | 50236.00.00 | ORION CORPORATION | DE |
| Budesonid Easyhaler 100 mikrog/annos inhalaatiojauhe | DE/H/0402/001 | 19048 | ORION CORPORATION | FI |
| Budesonid Easyhaler 200 mikrog/annos inhalaatiojauhe | DE/H/0402/002 | 19050 | ORION CORPORATION | FI |
| Budesonid Easyhaler 400 mikrog/annos inhalaatiojauhe | DE/H/0402/003 | 19051 | ORION CORPORATION | FI |
| Giona Easyhaler 100 mikrogramų/dozėje inhaliaciniai milteliai | DE/H/0402/001 | LT/1/05/0399/001 | ORION CORPORATION | LT |
| Giona Easyhaler 100 mikrogramų/dozėje inhaliaciniai milteliai | DE/H/0402/001 | LT/1/05/0399/002 | ORION CORPORATION | LT |
| Giona Easyhaler 100 mikrogramų/dozėje inhaliaciniai milteliai | DE/H/0402/001 | LT/1/05/0399/003 | ORION CORPORATION | LT |
| Giona Easyhaler 100 mikrogramų/dozėje | DE/H/0402/001 | LT/1/05/0399/010 | ORION CORPORATION | LT |

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| inhaliaciniai milteliai | | | | |
| Giona Easyhaler 200 mikrogramų/dozėje inhaliaciniai milteliai | DE/H/0402/002 | LT/1/05/0399/004 | ORION CORPORATION | LT |
| Giona Easyhaler 200 mikrogramų/dozėje inhaliaciniai milteliai | DE/H/0402/002 | LT/1/05/0399/005 | ORION CORPORATION | LT |
| Giona Easyhaler 200 mikrogramų/dozėje inhaliaciniai milteliai | DE/H/0402/002 | LT/1/05/0399/006 | ORION CORPORATION | LT |
| Giona Easyhaler 200 mikrogramų/dozėje inhaliaciniai milteliai | DE/H/0402/002 | LT/1/05/0399/011 | ORION CORPORATION | LT |
| Giona Easyhaler 200 mikrogramų/dozėje inhaliaciniai milteliai | DE/H/0402/002 | LT/1/05/0399/012 | ORION CORPORATION | LT |
| Giona Easyhaler 400 mikrogramų/dozėje inhaliaciniai milteliai | DE/H/0402/003 | LT/1/05/0399/007 | ORION CORPORATION | LT |
| Giona Easyhaler 400 mikrogramų/dozėje inhaliaciniai milteliai | DE/H/0402/003 | LT/1/05/0399/008 | ORION CORPORATION | LT |
| Giona Easyhaler 400 mikrogramų/dozėje inhaliaciniai milteliai | DE/H/0402/003 | LT/1/05/0399/009 | ORION CORPORATION | LT |
| Budesonid Easyhaler 100 mikrogramm/adag inhalációs por | DE/H/0402/001 | OGYI-T-10 492/03 | ORION CORPORATION | HU |

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|---|---|---|---|---|
| Budesonid Easyhaler 100 mikrogramm/adag inhalációs por | DE/H/0402/001 | OGYI-T-10 492/02 | ORION CORPORATION | HU |
| Budesonid Easyhaler 100 mikrogramm/adag inhalációs por | DE/H/0402/001 | OGYI-T-10 492/01 | ORION CORPORATION | HU |
| Budesonid Easyhaler 200 mikrogramm/adag inhalációs por | DE/H/0402/002 | OGYI-T-10 492/06 | ORION CORPORATION | HU |
| Budesonid Easyhaler 200 mikrogramm/adag inhalációs por | DE/H/0402/002 | OGYI-T-10 492/05 | ORION CORPORATION | HU |
| Budesonid Easyhaler 200 mikrogramm/adag inhalációs por | DE/H/0402/002 | OGYI-T-10 492/04 | ORION CORPORATION | HU |
| Budesonid Easyhaler 400 mikrogramm/adag inhalációs por | DE/H/0402/003 | OGYI-T-10 492/09 | ORION CORPORATION | HU |
| Budesonid Easyhaler 400 mikrogramm/adag inhalációs por | DE/H/0402/003 | OGYI-T-10492/08 | ORION CORPORATION | HU |
| Budesonid Easyhaler 400 mikrogramm/adag inhalációs por | DE/H/0402/003 | OGYI-T-10 492/07 | ORION CORPORATION | HU |
| Budesonide Orion 100 Easyhaler, inhalatiepoeder, 100 microgram/dosis | DE/H/0402/001 | RVG 30314 | ORION CORPORATION | NL |

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| Budesonide Orion 200 Easyhaler, inhalatiepoeder, 200 microgram/dosis | DE/H/0402/002 | RVG 30315 | ORION CORPORATION | NL |
| Budesonide Orion 400 Easyhaler, inhalatiepoeder, 400 microgram/dosis | DE/H/0402/003 | RVG 30316 | ORION CORPORATION | NL |
| ENTOCIR 3 mg capsule rigide a rilascio modificato | not available | 34734020 | ASTRAZENECA S.P.A. | IT |
| ENTOCIR 3 mg capsule rigide a rilascio modificato | not available | 34734018 | ASTRAZENECA S.P.A. | IT |
| Novopulmon Novolizer, inhalationspulver 400 mikrogram | DE/H/0907/001 | 40289 | MEDA AS | DK |
| Novopulmon Novolizer 400 mikrogram/dos inhalationspulver | DE/H/0907/001 | 22865 | MEDA OY | FI |
| Novopulmon Meda Novolizer, 400 Mikrogramm/Dosis, Pulver zur Inhalation | DE/H/0907/001/DC | 67865.00.00 | MEDA PHARMA GMBH & CO. KG | DE |
| Novopulmon Novolizer 400 mikrog/annos inhalaatiojauhe | DE/H/0907/001 | 22865 | MEDA OY | FI |
| Novopulmon Novolizer | DE/H/0907/001/DC | 06-4541 | MEDA AS | NO |

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| 400 mikrogram/dose, inhalasjonspulver | | | | |
| Novopulmon Novolizer, 400 mikrogram/dos, inhalationspulver | DE/H/0907/001 | 24747 | MEDA AB | SE |
| Entocort® Kapseln 3 mg, Hartkapseln mit veränderter Wirkstofffreisetzung | not available | 28247.00.01 | TILLOTTS PHARMA GMBH | DE |
| Miflonide® 200 μικρογραμμάρια κόνις για εισπνοή, σκληρό καψάκιο | DK/H/0147/001 | 245990101 | NOVARTIS (HELLAS) S.A.C.I. | GR |
| Miflonide® 200 μικρογραμμάρια κόνις για εισπνοή, σκληρό καψάκιο | DK/H/0147/001 | 245990102 | NOVARTIS (HELLAS) S.A.C.I. | GR |
| Miflonide® 400 μικρογραμμάρια κόνις για εισπνοή, σκληρό καψάκιο | DK/H/0147/002 | 245990201 | NOVARTIS (HELLAS) S.A.C.I. | GR |
| Miflonide® 400 μικρογραμμάρια κόνις για εισπνοή, σκληρό καψάκιο | DK/H/0147/002 | 245990202 | NOVARTIS (HELLAS) S.A.C.I. | GR |
| Miflonide 200 micrograms pó para inalação, cápsulas | DK/H/0147/001 | 2978781 | NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A. | PT |
| Miflonide 200 micrograms pó para inalação, cápsulas | DK/H/0147/001 | 2978880 | NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A. | PT |
| Miflonide 200 | DK/H/0147/001 | 2978989 | NOVARTIS FARMA - | PT |

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| microgramas pó para inalação, cápsulas | | | PRODUTOS FARMACÊUTICOS S.A. | |
| Miflonide 200 microgramas pó para inalação, cápsulas | DK/H/0147/001 | 2979086 | NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A. | PT |
| Miflonide 200 microgramas pó para inalação, cápsulas | DK/H/0147/001 | 2979185 | NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A. | PT |
| Miflonide 200 microgramas pó para inalação, cápsulas | DK/H/0147/001 | 2979284 | NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A. | PT |
| Miflonide 200 microgramas pó para inalação, cápsulas | DK/H/0147/001 | 2979383 | NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A. | PT |
| Miflonide 200 microgramas pó para inalação, cápsulas | DK/H/0147/001 | 2979482 | NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A. | PT |
| Miflonide 200 microgramas pó para inalação, cápsulas | DK/H/0147/001 | 2979581 | NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A. | PT |
| Miflonide 200 microgramas pó para inalação, cápsulas | DK/H/0147/001 | 2979680 | NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A. | PT |
| Miflonide 200 microgramas pó para inalação, cápsulas | DK/H/0147/001 | 2979789 | NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A. | PT |
| Miflonide 200 microgramas pó para | DK/H/0147/001 | 2979888 | NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS | PT |

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| inalação, cápsulas | | | S.A. | |
| Miflonide 200 microgramas pó para inalação, cápsulas | DK/H/0147/001 | 2979987 | NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A. | PT |
| Miflonide 200 microgramas pó para inalação, cápsulas | DK/H/0147/001 | 2980084 | NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A. | PT |
| Miflonide 200 microgramas pó para inalação, cápsulas | DK/H/0147/001 | 2980183 | NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A. | PT |
| Miflonide 200 microgramas pó para inalação, cápsulas | DK/H/0147/001 | 2980282 | NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A. | PT |
| Miflonide 200 microgramas pó para inalação, cápsulas | DK/H/0147/001 | 2980381 | NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A. | PT |
| Miflonide 200 microgramas pó para inalação, cápsulas | DK/H/0147/001 | 2980480 | NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A. | PT |
| Miflonide 200 microgramas pó para inalação, cápsulas | DK/H/0147/001 | 2980589 | NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A. | PT |
| Miflonide 200 microgramas pó para inalação, cápsulas | DK/H/0147/001 | 2980688 | NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A. | PT |
| Miflonide 200 microgramas pó para inalação, cápsulas | DK/H/0147/001 | 2980787 | NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A. | PT |

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| Miflonide 200 microgramas pó para inalação, cápsulas | DK/H/0147/001 | 2980886 | NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A. | PT |
| Miflonide 200 microgramas pó para inalação, cápsulas | DK/H/0147/001 | 2980985 | NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A. | PT |
| Miflonide 200 microgramas pó para inalação, cápsulas | DK/H/0147/001 | 2981082 | NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A. | PT |
| Miflonide 200 microgramas pó para inalação, cápsulas | DK/H/0147/001 | 2981181 | NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A. | PT |
| Miflonide 200 microgramas pó para inalação, cápsulas | DK/H/0147/001 | 2981280 | NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A. | PT |
| Miflonide 200 microgramas pó para inalação, cápsulas | DK/H/0147/001 | 2981389 | NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A. | PT |
| Miflonide 200 microgramas pó para inalação, cápsulas | DK/H/0147/001 | 2981488 | NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A. | PT |
| Miflonide 200 microgramas pó para inalação, cápsulas | DK/H/0147/001 | 2981587 | NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A. | PT |
| Miflonide 200 microgramas pó para inalação, cápsulas | DK/H/0147/001 | 2981686 | NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A. | PT |
| Miflonide 200 | DK/H/0147/001 | 2981785 | NOVARTIS FARMA - | PT |

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| microgramas pó para inalação, cápsulas | | | PRODUTOS FARMACÊUTICOS S.A. | |
| Miflonide 200 microgramas pó para inalação, cápsulas | DK/H/0147/001 | 2981884 | NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A. | PT |
| Miflonide 200 microgramas pó para inalação, cápsulas | DK/H/0147/001 | 2981983 | NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A. | PT |
| Miflonide 200 microgramas pó para inalação, cápsulas | DK/H/0147/001 | 2982080 | NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A. | PT |
| Miflonide 200 microgramas pó para inalação, cápsulas | DK/H/0147/001 | 2982189 | NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A. | PT |
| Miflonide 200 microgramas pó para inalação, cápsulas | DK/H/0147/001 | 2982288 | NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A. | PT |
| MIFLONIDE 200 microgrammi polvere per inalazione, capsule rigide | DK/H/0147/001 | 034413017 | NOVARTIS FARMA S.P.A. | IT |
| MIFLONIDE 200 microgrammi polvere per inalazione, capsule rigide | DK/H/0147/001 | 034413029 | NOVARTIS FARMA S.P.A. | IT |
| MIFLONIDE 200 microgrammi polvere per inalazione, capsule rigide | DK/H/0147/001 | 034413031 | NOVARTIS FARMA S.P.A. | IT |
| MIFLONIDE 200 microgrammi polvere per | DK/H/0147/001 | 034413043 | NOVARTIS FARMA S.P.A. | IT |

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| inalazione, capsule rigide | | | | |
| MIFLONIDE 200 microgrammi polvere per inalazione, capsule rigide | DK/H/0147/001 | 034413056 | NOVARTIS FARMA S.P.A. | IT |
| MIFLONIDE 200 microgrammi polvere per inalazione, capsule rigide | DK/H/0147/001 | 034413068 | NOVARTIS FARMA S.P.A. | IT |
| MIFLONIDE 200 microgrammi polvere per inalazione, capsule rigide | DK/H/0147/001 | 034413070 | NOVARTIS FARMA S.P.A. | IT |
| MIFLONIDE 200 microgrammi polvere per inalazione, capsule rigide | DK/H/0147/001 | 034413082 | NOVARTIS FARMA S.P.A. | IT |
| MIFLONIDE 200 microgrammi polvere per inalazione, capsule rigide | DK/H/0147/001 | 034413094 | NOVARTIS FARMA S.P.A. | IT |
| MIFLONIDE 200 microgrammi polvere per inalazione, capsule rigide | DK/H/0147/001 | 034413106 | NOVARTIS FARMA S.P.A. | IT |
| MIFLONIDE 200 microgrammi polvere per inalazione, capsule rigide | DK/H/0147/001 | 034413118 | NOVARTIS FARMA S.P.A. | IT |
| MIFLONIDE 200 microgrammi polvere per inalazione, capsule rigide | DK/H/0147/001 | 034413120 | NOVARTIS FARMA S.P.A. | IT |
| MIFLONIDE 200 microgrammi polvere per inalazione, capsule rigide | DK/H/0147/001 | 034413132 | NOVARTIS FARMA S.P.A. | IT |

| 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 |
|---|---|---|---|---|
| MIFLONIDE 200 microgrammi polvere per inalazione, capsule rigide | DK/H/0147/001 | 034413144 | NOVARTIS FARMA S.P.A. | IT |
| MIFLONIDE 200 microgrammi polvere per inalazione, capsule rigide | DK/H/0147/001 | 034413157 | NOVARTIS FARMA S.P.A. | IT |
| MIFLONIDE 200 microgrammi polvere per inalazione, capsule rigide | DK/H/0147/001 | 034413169 | NOVARTIS FARMA S.P.A. | IT |
| MIFLONIDE 200 microgrammi polvere per inalazione, capsule rigide | DK/H/0147/001 | 034413171 | NOVARTIS FARMA S.P.A. | IT |
| MIFLONIDE 200 microgrammi polvere per inalazione, capsule rigide | DK/H/0147/001 | 034413183 | NOVARTIS FARMA S.P.A. | IT |
| MIFLONIDE 200 microgrammi polvere per inalazione, capsule rigide | DK/H/0147/001 | 034413195 | NOVARTIS FARMA S.P.A. | IT |
| MIFLONIDE 400 microgrammi polvere per inalazione, capsule rigide | DK/H/0147/002 | 034413207 | NOVARTIS FARMA S.P.A. | IT |
| MIFLONIDE 400 microgrammi polvere per inalazione, capsule rigide | DK/H/0147/002 | 034413219 | NOVARTIS FARMA S.P.A. | IT |
| MIFLONIDE 400 microgrammi polvere per inalazione, capsule rigide | DK/H/0147/002 | 034413221 | NOVARTIS FARMA S.P.A. | IT |
| MIFLONIDE 400 | DK/H/0147/002 | 034413245 | NOVARTIS FARMA S.P.A. | IT |

| 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 |
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| microgrammi polvere per inalazione, capsule rigide | | | | |
| MIFLONIDE 400 microgrammi polvere per inalazione, capsule rigide | DK/H/0147/002 | 034413258 | NOVARTIS FARMA S.P.A. | IT |
| MIFLONIDE 400 microgrammi polvere per inalazione, capsule rigide | DK/H/0147/002 | 034413260 | NOVARTIS FARMA S.P.A. | IT |
| MIFLONIDE 400 microgrammi polvere per inalazione, capsule rigide | DK/H/0147/002 | 034413272 | NOVARTIS FARMA S.P.A. | IT |
| MIFLONIDE 400 microgrammi polvere per inalazione, capsule rigide | DK/H/0147/002 | 034413284 | NOVARTIS FARMA S.P.A. | IT |
| MIFLONIDE 400 microgrammi polvere per inalazione, capsule rigide | DK/H/0147/002 | 034413296 | NOVARTIS FARMA S.P.A. | IT |
| MIFLONIDE 400 microgrammi polvere per inalazione, capsule rigide | DK/H/0147/002 | 034413308 | NOVARTIS FARMA S.P.A. | IT |
| MIFLONIDE 400 microgrammi polvere per inalazione, capsule rigide | DK/H/0147/002 | 034413310 | NOVARTIS FARMA S.P.A. | IT |
| MIFLONIDE 400 microgrammi polvere per inalazione, capsule rigide | DK/H/0147/002 | 034413322 | NOVARTIS FARMA S.P.A. | IT |
| MIFLONIDE 400 microgrammi polvere per | DK/H/0147/002 | 034413334 | NOVARTIS FARMA S.P.A. | IT |

| 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 |
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| inalazione, capsule rigide | | | | |
| MIFLONIDE 400 microgrammi polvere per inalazione, capsule rigide | DK/H/0147/002 | 034413346 | NOVARTIS FARMA S.P.A. | IT |
| MIFLONIDE 400 microgrammi polvere per inalazione, capsule rigide | DK/H/0147/002 | 034413359 | NOVARTIS FARMA S.P.A. | IT |
| MIFLONIDE 400 microgrammi polvere per inalazione, capsule rigide | DK/H/0147/002 | 034413361 | NOVARTIS FARMA S.P.A. | IT |
| MIFLONIDE 400 microgrammi polvere per inalazione, capsule rigide | DK/H/0147/002 | 034413373 | NOVARTIS FARMA S.P.A. | IT |
| MIFLONIDE 400 microgrammi polvere per inalazione, capsule rigide | DK/H/0147/002 | 034413385 | NOVARTIS FARMA S.P.A. | IT |
| Miflonide Breezhaler, 200 mikrogrammi inhalatsioonipulber kõvakapslis | not available | 422103 | NOVARTIS FINLAND OY | EE |
| Miflonide 200 mikrogramų įkvepiamieji milteliai (kietosios kapsulės) | not available | LT/1/02/1570/001 | NOVARTIS FINLAND OY | LT |
| Miflonide 200 mikrogramų įkvepiamieji milteliai (kietosios kapsulės) | not available | LT/1/02/1570/002 | NOVARTIS FINLAND OY | LT |

| 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 |
|---|---|---|---|---|
| Miflonide Breezhaler, 400 mikrogrammi inhalatsioonipulber kõvakapslis | not available | 422203 | NOVARTIS FINLAND OY | EE |
| Miflonide 400 mikrogramų įkvepiamieji milteliai (kietosios kapsulės) | not available | LT/1/02/1570/003 | NOVARTIS FINLAND OY | LT |
| Miflonide 400 mikrogramų įkvepiamieji milteliai (kietosios kapsulės) | not available | LT/1/02/1570/004 | NOVARTIS FINLAND OY | LT |
| MIFLONIDE 200 microgramos polvo para inhalación (cápsula dura) | DK/H/0147/001 | 63.197 | NOVARTIS FARMACÉUTICA S.A. | ES |
| Miflonide 400 microgramos polvo para inhalación (cápsula dura) | DK/H/0147/002 | 63.198 | NOVARTIS FARMACÉUTICA S.A. | ES |
| Miflonide | DK/H/0147/001 | 19532 | NOVARTIS HEALTHCARE A/S | DK |
| Miflonide | DK/H/0147/002 | 19533 | NOVARTIS HEALTHCARE A/S | DK |
| Miflonide® 200 Mikrogramm Hartkapseln mit Pulver zur Inhalation | DK/H/0147/001 | 49491.00.00 | NOVARTIS PHARMA GMBH | DE |
| Miflonide 200 mikrogramm inhalációs por kemény kapszulában | not available | OGYI-T-8674/01 | NOVARTIS HUNGÁRIA KFT. PHARMA | HU |
| Miflonide 200 mikrogramm inhalációs | not available | OGYI-T-8674/02 | 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 |
|---|---|---|---|---|
| por kemény kapszulában | | | | |
| Miflonide® 400 Mikrogramm Hartkapseln mit Pulver zur Inhalation | DK/H/0147/002 | 49491.01.00 | NOVARTIS PHARMA GMBH | DE |
| Miflonide 400 mikrogramm inhalációs por kemény kapszulában | not available | OGYI-T-8674/03 | NOVARTIS HUNGÁRIA KFT. PHARMA | HU |
| Miflonide 400 mikrogramm inhalációs por kemény kapszulában | not available | OGYI-T-8674/04 | NOVARTIS HUNGÁRIA KFT. PHARMA | HU |
| Miflonide 200 Mikrogramm - Hartkapseln mit Pulver zur Inhalation | DK/H/0147/001 | 1-23241 | NOVARTIS PHARMA GMBH | AT |
| Miflonide 200 microgram inhalation powder, hard capsules | not available | 088/02101 | NOVARTIS PHARMACEUTICALS UK LIMITED | MT |
| Miflonide 400 Mikrogramm - Hartkapseln mit Pulver zur Inhalation | DK/H/0147/002 | 1-23242 | NOVARTIS PHARMA GMBH | AT |
| Miflonide 400 microgram inhalation powder, hard capsules | not available | 088/02102 | NOVARTIS PHARMACEUTICALS UK LIMITED | MT |
| MIFLONIL 200 microgrammes, poudre pour inhalation en gélule | not available | 3400935855961 | NOVARTIS PHARMA S.A.S. | FR |
| MIFLONIL 200 | not available | 3400935856043 | NOVARTIS PHARMA S.A.S. | FR |

| Product Name (in authorisation country) | MRP/DCP Authorisation number | National Authorisation Number | MAH of product in the member state | Member State where product is authorised |
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| microgrammes, poudre pour inhalation en gélule | | | | |
| MIFLONIL 200 microgrammes, poudre pour inhalation en gélule | not available | 3400935856104 | NOVARTIS PHARMA S.A.S. | FR |
| MIFLONIL 400 microgrammes, poudre pour inhalation en gélule | not available | 3400935856272 | NOVARTIS PHARMA S.A.S. | FR |
| MIFLONIL 400 microgrammes, poudre pour inhalation en gélule | not available | 3400935856333 | NOVARTIS PHARMA S.A.S. | FR |
| MIFLONIL 400 microgrammes, poudre pour inhalation en gélule | not available | 3400935856562 | NOVARTIS PHARMA S.A.S. | FR |
| MIFLONID 200, prášek k inhalaci v tvrdých tobolkách | not available | 14/232/00-C | NOVARTIS, S.R.O. | CZ |
| MIFLONID 400, prášek k inhalaci v tvrdých tobolkách | not available | 14/233/00-C | NOVARTIS, S.R.O. | CZ |
| Miflonide® 400 microgram inhalation powder, hard capsules | not available | 19506 | NOVARTIS PHARMACEUTICALS UK LIMITED | CY |
| Miflonide® 200 microgram inhalation powder, hard capsules | not available | 19505 | NOVARTIS PHARMACEUTICALS UK LIMITED | CY |
| MIFLONIDE 400 microgrammi polvere per | DK/H/0147/002 | 034413233 | NOVARTIS FARMA S.P.A. | IT |

| 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 |
|---|---|---|---|---|
| inalazione, capsule rigide | | | | |
| Miflonide 400 microgramas, pó para inalação, cápsulas | DK/H/0147/002 | 2982387 | NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A. | PT |
| Miflonide 400 microgramas, pó para inalação, cápsulas | DK/H/0147/002 | 2982486 | NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A. | PT |
| Miflonide 400 microgramas, pó para inalação, cápsulas | DK/H/0147/002 | 2982585 | NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A. | PT |
| Miflonide 400 microgramas, pó para inalação, cápsulas | DK/H/0147/002 | 2982684 | NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A. | PT |
| Miflonide 400 microgramas, pó para inalação, cápsulas | DK/H/0147/002 | 2982783 | NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A. | PT |
| Miflonide 400 microgramas, pó para inalação, cápsulas | DK/H/0147/002 | 2982882 | NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A. | PT |
| Miflonide 400 microgramas, pó para inalação, cápsulas | DK/H/0147/002 | 2982981 | NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A. | PT |
| Miflonide 400 microgramas, pó para inalação, cápsulas | DK/H/0147/002 | 2983088 | NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A. | PT |
| Miflonide 400 microgramas, pó para inalação, cápsulas | DK/H/0147/002 | 2983187 | 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 |
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| Miflonide 400 microgramas, pó para inalação, cápsulas | DK/H/0147/002 | 2983286 | NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A. | PT |
| Miflonide 400 microgramas, pó para inalação, cápsulas | DK/H/0147/002 | 2983385 | NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A. | PT |
| Miflonide 400 microgramas, pó para inalação, cápsulas | DK/H/0147/002 | 2983484 | NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A. | PT |
| Miflonide 400 microgramas, pó para inalação, cápsulas | DK/H/0147/002 | 2983583 | NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A. | PT |
| Miflonide 400 microgramas, pó para inalação, cápsulas | DK/H/0147/002 | 2983682 | NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A. | PT |
| Miflonide 400 microgramas, pó para inalação, cápsulas | DK/H/0147/002 | 2983781 | NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A. | PT |
| Miflonide 400 microgramas, pó para inalação, cápsulas | DK/H/0147/002 | 2983880 | NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A. | PT |
| Miflonide 400 microgramas, pó para inalação, cápsulas | DK/H/0147/002 | 2983989 | NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A. | PT |
| Miflonide 400 microgramas, pó para inalação, cápsulas | DK/H/0147/002 | 2984086 | NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A. | PT |
| Miflonide 400 | DK/H/0147/002 | 2984185 | NOVARTIS FARMA - | 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 |
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| microgramas, pó para inalação, cápsulas | | | PRODUTOS FARMACÊUTICOS S.A. | |
| Miflonide 400 microgramas, pó para inalação, cápsulas | DK/H/0147/002 | 2984284 | NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A. | PT |
| Miflonide 400 microgramas, pó para inalação, cápsulas | DK/H/0147/002 | 2984383 | NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A. | PT |
| Miflonide 400 microgramas, pó para inalação, cápsulas | DK/H/0147/002 | 2984482 | NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A. | PT |
| Miflonide 400 microgramas, pó para inalação, cápsulas | DK/H/0147/002 | 2984581 | NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A. | PT |
| Miflonide 400 microgramas, pó para inalação, cápsulas | DK/H/0147/002 | 2984680 | NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A. | PT |
| Miflonide 400 microgramas, pó para inalação, cápsulas | DK/H/0147/002 | 2984789 | NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A. | PT |
| Miflonide 400 microgramas, pó para inalação, cápsulas | DK/H/0147/002 | 2984888 | NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A. | PT |
| Miflonide 400 microgramas, pó para inalação, cápsulas | DK/H/0147/002 | 2984987 | NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A. | PT |
| Miflonide 400 microgramas, pó para | DK/H/0147/002 | 2985083 | NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS | 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 |
|---|---|---|---|---|
| inalação, cápsulas | | | S.A. | |
| Miflonide 400 microgramas, pó para inalação, cápsulas | DK/H/0147/002 | 2985182 | NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A. | PT |
| Miflonide 400 microgramas, pó para inalação, cápsulas | DK/H/0147/002 | 2985281 | NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A. | PT |
| Miflonide 400 microgramas, pó para inalação, cápsulas | DK/H/0147/002 | 2985380 | NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A. | PT |
| Miflonide 400 microgramas, pó para inalação, cápsulas | DK/H/0147/002 | 2985489 | NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A. | PT |
| Miflonide 400 microgramas, pó para inalação, cápsulas | DK/H/0147/002 | 2985588 | NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A. | PT |
| Miflonide 400 microgramas, pó para inalação, cápsulas | DK/H/0147/002 | 2985687 | NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A. | PT |
| Miflonide 400 microgramas, pó para inalação, cápsulas | DK/H/0147/002 | 2985786 | NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A. | PT |
| Miflonide 400 microgramas, pó para inalação, cápsulas | DK/H/0147/002 | 2985885 | NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A. | PT |
| Budelin Novolizer 200, 200 µg/dawkę inhalacyjną, proszek do | not available | 10332 | MEDA PHARMA GMBH & CO. KG | PL |

| 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 |
|---|---|---|---|---|
| inhalacji | | | | |
| Budenofalk | not available | 56/359/00-C | DR FALK PHARMA GMBH | CZ |
| Entocort 3 mg hylki með breyttan losunarhraða, hörð | not available | MTNR 940218 (IS) | TILLOTTS PHARMA GMBH | IS |
| Rhinocort Aqua 64 mikrograma/dozi sprej za nos, suspenzija | not available | UP/I-530-09/13-02/120 | ASTRAZENECA D.O.O. | HR |
| Rhinocort Aqua 32 Mikrogramm - Nasal-Pumpspray | not available | 1-23506 | ASTRAZENECA OSTERREICH GMBH | AT |
| Rhinocort Aqua 32 micrograms/dose | not available | 18341 | ASTRAZENECA AB | CY |
| Pulmicort Nasal Aqua | not available | 26797/19.07.2002 | ASTRAZENECA S.A | GR |
| Rhinocort Aqua, næsespray, suspension | not available | 18473 | ASTRAZENECA A/S | DK |
| Rhinocort 32 mcg spray nasale, sospensione | not available | 28935043 | ASTRAZENECA S.P.A. | IT |
| Rhinocort Aqua 32 mikrogramai/dozėje nosies purškalas (suspensija) | not available | 99/6603/5 | ASTRAZENECA AB | LT |
| Rhinocort 32 mcg spray nasale, sospensione | not available | 28935031 | ASTRAZENECA S.P.A. | IT |
| RHINOCORT AQUA 32 microgram./dose, suspension pour | not available | 0173/01050005 | NV ASTRAZENECA SA | LU |

| 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 |
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| pulvérisation nasale | | | | |
| Rhinocort 32 Nevel, neusspray suspensie, 32 microgram per dosis | not available | RVG 23837 | ASTRAZENECA BV | NL |
| Pulmicort Nasal Aqua, 32 microgramas/dose, suspensão para pulverização nasal | not available | 3141488 | ASTRAZENECA PRODUTOS FARMACEUTICOS LDA. | PT |
| Rhinocort Aqua Nasal spray, suspension 32 µg/dose | not available | 4462 | ASTRAZENECA AB | PL |
| RHINOCORT AQUA 32 microgramе/doză spray nazal suspensie | not available | 3022/2002/01 | ASTRAZENECA AB | RO |
| Pulmicort Nasal Aqua, 32 microgramas/dose, suspensão para pulverização nasal | not available | 3141587 | ASTRAZENECA PRODUTOS FARMACEUTICOS LDA. | PT |
| Rhinocort Aqua 64 Mikrogramm - Nasal-Pumpspray | not available | 1-23508 | ASTRAZENECA OSTERREICH GMBH | AT |
| Rhinocort Aqua 32 µg/dávka | not available | 69/0490/97-S | ASTRAZENECA AB | SK |
| Rhinocort Aqua 64 micrograms/dose, nasal spray, suspension | not available | 18340 | ASTRAZENECA AB | CY |
| Rhinocort Aqua, næsespray, suspension | not available | 18474 | ASTRAZENECA A/S | DK |

| Product Name (in authorisation country) | MRP/DCP Authorisation number | National Authorisation Number | MAH of product in the member state | Member State where product is authorised |
|---|---|---|---|---|
| Pulmicort Nasal Aqua | not available | 26798/19.07.2002 | ASTRAZENECA S.A | GR |
| Rhinocort 64 mcg spray nasale, sospensione | not available | 28935056 | ASTRAZENECA S.P.A. | IT |
| Rhinocort Aqua 64 mikrogramai/dozėje nosies purškalas (suspensija) | not available | 99/6604/5 | ASTRAZENECA AB | LT |
| Rhinocort 64 mcg spray nasale, sospensione | not available | 28935068 | ASTRAZENECA S.P.A. | IT |
| RHINOCORT AQUA 64 microgram./dose, suspension pour pulvérisation nasale | not available | 0173/01050067 | NV ASTRAZENECA SA | LU |
| Rhinocort 64 Nevel, neusspray suspensie, 64 microgram per dosis. | not available | RVG 23838 | ASTRAZENECA BV | NL |
| Pulmicort Nasal Aqua, 64 microgramas/dose, suspensão para pulverização nasal | not available | 3141686 | ASTRAZENECA PRODUTOS FARMACEUTICOS LDA. | PT |
| Rhinocort Aqua 64 µg/dávka | not available | 69/0490/97-S | ASTRAZENECA AB | SK |
| Pulmicort Nasal Aqua, 64 microgramas/dose, suspensão para pulverização nasal | not available | 3141785 | ASTRAZENECA PRODUTOS FARMACEUTICOS LDA. | PT |
| Rhinocort Aqua 32 mikrogramm/adag | not available | OGYI-T-8221/01 | ASTRAZENECA KFT. | 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 |
|---|---|---|---|---|
| orrspray | | | | |
| Rhinocort Aqua 64 mikrogramm/adag orrspray | not available | OGYI-T-8222/01 | ASTRAZENECA KFT. | HU |
| Rhinocort Aqua 32 mikrogram/dos nässpray, suspension. | not available | 13176 | ASTRAZENECA AB | SE |
| Rhinocort Aqua 64 mikrogram/dos nässpray, suspension | not available | 13177 | ASTRAZENECA AB | SE |
| RHINOCORT AQUA 32 microgram/dose, neusspray, suspensie | not available | BE220577 | NV ASTRAZENECA SA | BE |
| RHINOCORT AQUA 32 microgram./dose, suspension pour pulvérisation nasale | not available | BE220577 | NV ASTRAZENECA SA | BE |
| RHINOCORT AQUA 64 microgram/dose, neusspray, suspensie | not available | BE220586 | NV ASTRAZENECA SA | BE |
| RHINOCORT AQUA 64 microgram./dose, suspension pour pulvérisation nasale | not available | BE220586 | NV ASTRAZENECA SA | BE |
| Rhinocort® Aqua 32 mikrog/annos nenäsumute, suspensio | not available | 12562 | ASTRAZENECA OY | FI |
| Rhinocort® Aqua 64 | not available | 12563 | ASTRAZENECA OY | FI |

| 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 |
|---|---|---|---|---|
| mikrog/annos nenäsumute, suspensio | | | | |
| RHINOCORT Aqua 64 µg | not available | 69/725/99-C | ASTRAZENECA UK LIMITED | CZ |
| Rhinocort Aqua, 64 mikrogrammi/annuses ninasprei, suspensioon | not available | 331800 | ASTRAZENECA UK LIMITED | EE |
| RHINOCORT TURBOHALER 100, 100 microgram/dosis, snuifpoeder | not available | BE173284 | NV ASTRAZENECA SA | BE |
| RHINOCORT® 64 microgramos suspensión para pulverización nasal. | not available | 64730.0 | ASTRAZENECA FARMACÉUTICA SPAIN, S.A. | ES |
| RHINOCORT® 64 microgrammes/dose, suspension pour pulvérisation nasale | not available | NL 23 495 | ASTRAZENECA S.A.S. | FR |
| Rhinocort Turbuhaler | not available | 14314 | ASTRAZENECA A/S | DK |
| RHINOCORT® AQUA 64 mikrogrami/devā deguna aerosols | not available | 99-0928 | ASTRAZENECA AB | LV |
| Rhinocort 100 Turbuhaler, nasaal inhalatiepoeder 100 microgram/dosis. | not available | RVG 15821 | ASTRAZENECA BV | NL |
| Rhinocort Aqua Nasal spray, suspension 64 µg/dose | not available | 4461 | ASTRAZENECA AB | PL |

| 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 |
|---|---|---|---|---|
| RHINOCORT TURBOHALER 100, 100 microgrammes/dose, poudre nasale | not available | BE173284 | NV ASTRAZENECA SA | BE |
| Rhinocort® Turbuhaler® 100 mikrog/annos nenäjauhe | not available | 10768 | ASTRAZENECA OY | FI |
| Rhinocort® Aqua, 64 micrograms, nasal spray | not available | PL 17901/0074 | ASTRAZENECA UK LIMITED | UK |
| Pulmicort® Turbuhaler® nasal powder | not available | 30429 | ASTRAZENECA S.A | GR |
| Rhinocort® Turbohaler®, 100 micrograms per metered dose, Nasal Powder | not available | PA 970/51/1 | ASTRAZENECA UK LIMITED | IE |
| RHINOCORT TURBOHALER 100, 100 microgrammes/dose, poudre nasale | not available | 0173/06018345 | NV ASTRAZENECA SA | LU |
| Pulmicort Nasal Turbohaler 100 microgramas/dose, pó para inalação | not available | 8630863 | ASTRAZENECA PRODUTOS FARMACEUTICOS LDA. | PT |
| Rhinocort 100 microgrammi/erogazione polvere nasale. | not available | 28935029 | ASTRAZENECA S.P.A. | IT |
| Rhinocort Turbuhaler 100 mikrogram/dos | not available | 11535 | ASTRAZENECA AB | SE |

| 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 |
|---|---|---|---|---|
| näspulver. | | | | |
| Rhinocort® Aqua, 64 micrograms, nasal spray. | not available | 046/01202 A12.21 | ASTRAZENECA UK LIMITED | MT |
| Rhinocort Turbuhaler 100 mikrogramm/adag inhalációs por | not available | OGYI-T 4288/01 | ASTRAZENECA KFT. | HU |
| Rhinocort Turbuhaler 100 mikrog/dose nesepulver | not available | 00/7831 | ASTRAZENECA AS | NO |
| Rhinocort 32 mikrog/dose nesespray | not available | 96-1679 | ASTRAZENECA AS | NO |
| Rhinocort® Hay Fever, 64 micrograms, Nasal Spray | not available | PL 17901/0254 | ASTRAZENECA UK LIMITED | UK |
| Rhinocort 64 mikrog/dose nesespray | not available | 96-1680 | ASTRAZENECA AS | NO |
| Rhinocort Turbuhaler | not available | 910087 | ASTRAZENECA A/S | IS |
| Rhinocort Aqua | not available | 960177 | ASTRAZENECA A/S | IS |
| Rhinocort Aqua | not available | 960178 | ASTRAZENECA A/S | IS |
| Pulmicort Turbuhaler 200 micrograme/doză pulbere de inhalat | not available | 8698/2016/01 | ASTRAZENECA AB | RO |
| Budesonide Allgen 200 CFK-vrije aërosol, aërosoloplossing 200 microgram/dosis | IT/H/0123/001 | RVG 32251 | ALLGEN PHARMACEUTICALS & GENERICS BV | NL |
| Budesonide Allgen 200 CFK-vrije aërosol + JET, | IT/H/0123/001 | RVG 32355 | ALLGEN PHARMACEUTICALS & GENERICS BV | NL |

| Product Name (in authorisation country) | MRP/DCP Authorisation number | National Authorisation Number | MAH of product in the member state | Member State where product is authorised |
|---|---|---|---|---|
| aërosoloplossing 200 microgram/dosis | | | | |
| ENTOCORT klyzma 2 mg | not available | 56/770/97-C | TILLOTTS PHARMA GMBH | CZ |
| Entocort Enema 2 mg comprimidos para suspensão rectal | not available | 3277480 | ASTRAZENECA PRODUTOS FARMACEUTICOS LDA. | PT |
| ENTOCORT® 3 mg, microgranules gastro-résistants en gélule | not available | NL 21 027 | ASTRAZENECA S.A.S. | FR |
| Budesonid Sandoz 32 mikrogram/dose nesespray, suspensjon | DE/H/0933/001 | 06-4631 | SANDOZ A/S | NO |
| Budesonid Sandoz 64 mikrogram/dose nesespray, suspensjon | DE/H/0933/002 | 06-4632 | SANDOZ A/S | NO |
| Budesonid Sandoz 64 Mikrogramm/Sprühstoß - Nasenspray | DE/H/0934/002 | 1-27618 | SANDOZ GMBH | AT |
| Budesonid Sandoz 32 Mikrogramm/Sprühstoß - Nasenspray | DE/H/0934/001 | 1-27617 | SANDOZ GMBH | AT |
| BUDESONIDE SANDOZ 64 microgrammes/dose, suspension pour pulvérisation nasale | DE/H/0933/002 | 34009 398 887 4 3 | SANDOZ | FR |
| BUDESONIDE SANDOZ 64 microgrammes/dose, suspension pour | DE/H/0933/002 | 34009 576 454 1 0 | SANDOZ | FR |

| Product Name (in authorisation country) | MRP/DCP Authorisation number | National Authorisation Number | MAH of product in the member state | Member State where product is authorised |
|---|---|---|---|---|
| pulvérisation nasale | | | | |
| BUDESONIDE SANDOZ 64 microgrammes/dose, suspension pour pulvérisation nasale | DE/H/0933/002 | 34009 398 888 0 4 | SANDOZ | FR |
| Budesonid Sandoz 32 Mikrogramm/Sprühstoß Nasenspray, Suspension | DE/H/0933/001 | 67872.00.00 | HEXAL AG | DE |
| Budes 64 Mikrogramm/Sprühstoß Nasenspray, Suspension | DE/H/0934/002 | 67867.00.00 | HEXAL AG | DE |
| Budesonid Sandoz 64 Mikrogramm/Sprühstoß Nasenspray, Suspension | DE/H/0933/002 | 67873.00.00 | HEXAL AG | DE |
| Budes 32 Mikrogramm/Sprühstoß Nasenspray, Suspension | DE/H/0934/001 | 67866.00.00 | HEXAL AG | DE |
| Budesonid - 1 A Pharma 64 Mikrogramm/Sprühstoß Nasenspray, Suspension | DE/H/0954/002 | 67871.00.00 | 1 A PHARMA GMBH | DE |
| Budesonide 64 micrograms/actuation, Aqueous Nasal Spray | DE/H/0933/002 | PL 04416/0784 | SANDOZ LTD | UK |
| Tafen Nasal 64 µg, 64 mikrogramy/dawkę odmierzoną, aerozol do nosa, zawiesina | DE/H/0933/002 | 16430 | SANDOZ GMBH | PL |

| 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 |
|---|---|---|---|---|
| Tafen Nasal 32 µg, 32 mikrogramy/dawkę odmierzoną, aerozol do nosa, zawiesina | DE/H/0933/001 | 16429 | SANDOZ GMBH | PL |
| BUDESONIDE SANDOZ 32 MICROGRAM/DOSIS, NEUSSPRAY, SUSPENSIE | DE/H/0933/001 | RVG 34889 | SANDOZ B.V. | NL |
| BUDESONIDE SANDOZ 64 MICROGRAM/DOSIS, NEUSSPRAY, SUSPENSIE | DE/H/0933/002 | RVG 34890 | SANDOZ B.V. | NL |
| Budesonide Sandoz nevel 50 microgram/dosis, neusspray, suspensie | RVG 107036 | RVG 107036 | SANDOZ B.V. | NL |
| Budesonide Sandoz nevel 100 microgram/dosis, neusspray, suspensie | RVG 107038 | RVG 107038 | SANDOZ B.V. | NL |
| Budesonid "Sandoz" | DE/H/0933/001 | 40505 | SANDOZ A/S | DK |
| Budesonid "Sandoz" | DE/H/0933/002 | 40513 | SANDOZ A/S | DK |
| Desonix 32 mikrogram/dos nässpray, suspension | DE/H/0933/001 | 24924 | SANDOZ A/S | SE |
| Desonix 64 mikrogram/dos nässpray, suspension | DE/H/0933/002 | 24925 | SANDOZ A/S | SE |
| Budes® N 0,2 mg/Dosis Druckgasinhalation, Lösung | not available | 26057.01.00 | HEXAL AG | DE |

| 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 |
|---|---|---|---|---|
| Budesonide Sandoz 0,25 mg/ml, vernevelsuspensie in ampul | DK/H/0703/002 | RVG 32122 | SANDOZ B.V. | NL |
| Budesonide Sandoz 0,5 mg/ml, vernevelsuspensie in ampul | DK/H/0703/003 | RVG 32123 | SANDOZ B.V. | NL |
| Budesonide Sandoz 0,125 mg/ml, vernevelsuspensie in ampul | DK/H/0703/001 | RVG 32121 | SANDOZ B.V. | NL |
| PULMICORT® TURBUHALER® 100 microgramos/inhalación polvo para inhalación | not available | 62.046 | ASTRAZENECA FARMACÉUTICA SPAIN, S.A. | ES |
| PULMICORT® TURBUHALER® 200 microgramos/inhalación polvo para inhalación | not available | 59.254 | ASTRAZENECA FARMACÉUTICA SPAIN, S.A. | ES |
| PULMICORT® TURBUHALER® 400 microgramos/inhalación polvo para inhalación | not available | 59.255 | ASTRAZENECA FARMACÉUTICA SPAIN, S.A. | ES |
| PULMICORT 0,25 mg/ml suspensión para inhalación por nebulizador | not available | 59.298 | ASTRAZENECA FARMACÉUTICA SPAIN, 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 |
|---|---|---|---|---|
| PULMICORT 0,50 mg/ml suspensión para inhalación por nebulizador | not available | 59.297 | ASTRAZENECA FARMACÉUTICA SPAIN, S.A. | ES |
| Budecol ® | not available | 23069 | ASTRAZENECA S.A | GR |
| MIFLO 200 mcg soluzione pressurizzata per inalazione | not available | 035657016 | PROMEDICA S.R.L. | IT |
| MIFLO 200 mcg soluzione pressurizzata per inalazione | not available | 035657028 | PROMEDICA S.R.L. | IT |
| Entocort, 3 mg, kapsułki o przedłużonym uwalnianiu, twarde | not available | 4303 | TILLOTTS PHARMA GMBH | PL |
| Френолин 200 микрограма/ доза прах за инхалация | not available | 20150221 | MEDOCHEMIE LTD. | BG |
| Френолин 400 микрограма/ доза прах за инхалация | not available | 20150222 | MEDOCHEMIE LTD. | BG |
| Entocort 2 mg tafla fyrir endaþarmsdreifu | not available | MTNR 910112 (IS) | TILLOTTS PHARMA GMBH | IS |
| Entocort - Kapseln | not available | 1-21867 | TILLOTTS PHARMA GMBH | AT |
| Entocort 2 mg - Klistiertabletten mit Dispersionsmittel | not available | 1-20720 | TILLOTTS PHARMA GMBH | AT |
| ENTOCORT 3 mg, | not available | BE227823 | NV ASTRAZENECA SA | 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 met gereguleerde afgifte, hard. | | | | |
| ENTOCORT® 3 mg, microgranules gastro-résistants en gélule | not available | NL 21 027 | ASTRAZENECA S.A.S. | FR |
| Entocort Enema 2 mg comprimidos para suspensão rectal | not available | 3277480 | ASTRAZENECA PRODUTOS FARMACEUTICOS LDA. | PT |
| ENTOCORT 3 mg, gélules à libération modifiée | not available | BE227823 | NV ASTRAZENECA SA | BE |
| ENTOCORT ENEMA 2,3 mg, tabletten voor suspensie voor rectaal gebruik | not available | BE164841 | NV ASTRAZENECA SA | BE |
| ENTOCORT ENEMA 2,3 mg, comprimés pour suspension rectale | not available | BE164841 | NV ASTRAZENECA SA | BE |
| ENTOCORT ENEMA 2,3 mg, comprimés pour suspension rectale | not available | 0173/11071197 | NV ASTRAZENECA SA | LU |
| ENTOCORT 3 mg, gélules à libération modifiée. | not available | 0173/11071196 | NV ASTRAZENECA SA | LU |
| Entocort 3 mg cápsulas de libertação modificada | not available | 4459285 | ASTRAZENECA PRODUTOS FARMACEUTICOS LDA. | PT |
| Entocort 3 mg cápsulas de libertação modificada | not available | 4459186 | ASTRAZENECA PRODUTOS FARMACEUTICOS LDA. | PT |
| Entocort 3 mg cápsulas | not available | 4459384 | ASTRAZENECA PRODUTOS | 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 |
|---|---|---|---|---|
| de libertação modificada | | | FARMACEUTICOS LDA. | |
| Entocort 3 mg cápsulas de libertação modificada | not available | 4185385 | ASTRAZENECA PRODUTOS FARMACEUTICOS LDA. | PT |
| Entocort 3 mg cápsulas de libertação modificada | not available | 4459285 | ASTRAZENECA PRODUTOS FARMACEUTICOS LDA. | PT |
| Entocort 3 mg cápsulas de libertação modificada | not available | 4459186 | ASTRAZENECA PRODUTOS FARMACEUTICOS LDA. | PT |
| Entocort 3 mg cápsulas de libertação modificada | not available | 4459384 | ASTRAZENECA PRODUTOS FARMACEUTICOS LDA. | PT |
| Entocort 3 mg cápsulas de libertação modificada | not available | 4185385 | ASTRAZENECA PRODUTOS FARMACEUTICOS LDA. | PT |
| Entocort - Kapseln | not available | 1-21867 | TILLOTTS PHARMA GMBH | AT |
| Ribuvent® 200 Mikrogramm Druckgasinhalation, Lösung | not available | 42626.00.00 | CHIESI GMBH | DE |
| Budenofalk 2mg rektální pěna | not available | 56/716/09-C | DR FALK PHARMA GMBH | CZ |
| Budecol | not available | 5253 | ASTRAZENECA S.A | GR |
| Entocort 3 mg hårda depotkapslar | not available | 12247 | TILLOTTS PHARMA GMBH | SE |
| Bidien 0,025% crema | not available | 026297010 | IDI FARMACEUTICI SRL | IT |
| BIDIEN 0,025% UNGUENTO | not available | 026297022 | IDI FARMACEUTICI SRL | IT |
| BIDIEN 0,025% SOLUZIONE CUTANEA | not available | 026297034 | IDI FARMACEUTICI SRL | IT |

| 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 |
|---|---|---|---|---|
| PULMICORT 0,25 mg/ml, suspension pour inhalation par nébuliseur | not available | 0173/09010118 | NV ASTRAZENECA SA | LU |
| Pulmicort Respules 0,5 mg/ml suspenzija za atomizator | not available | HR-H-217872273-01 | ASTRAZENECA D.O.O. | HR |
| Pulmicort εναιώρημα για εισπνοή με εκνεφωτή 0,125 mg/ml | not available | 5922/95/07.11.1996 | ASTRAZENECA S.A | GR |
| Pulmaxan 0,125 mg/ml sospensione da nebulizzare | not available | 27621046 | ASTRAZENECA S.P.A. | IT |
| PULMICORT, 0,125 MG/ML, ZAWIESINA DO NEBULIZACJI | not available | 4456 | ASTRAZENECA AB | PL |
| Pulmicort 250 Respules, vernevelsuspensie 250 microgram /2 ml | not available | RVG 15730 | ASTRAZENECA BV | NL |
| PULMICORT 0,25 mg/ml, suspension pour inhalation par nébuliseur | not available | BE156046 | NV ASTRAZENECA SA | BE |
| PULMICORT 0,25 mg/ml, vernevelsuspensie | not available | BE156046 | NV ASTRAZENECA SA | BE |
| Pulmicort 0,125 mg/ml suspension för nebulisator | not available | 12351 | ASTRAZENECA AB | SE |
| PULMICORT, 0,25 mg/ml nebuliseeritav | not available | 294299 | ASTRAZENECA AB | EE |

| 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 |
|---|---|---|---|---|
| suspensioon | | | | |
| Пулмикорт 0,25 mg/ml суспензия за пулверизиране | not available | 20030028 | ASTRAZENECA AB | BG |
| Pulmicort Respules 0.25 mg/ml | not available | 14265 | ASTRAZENECA AB | CY |
| Spirocort, inhalationsvæske til nebulisator, suspension | not available | 13556 | ASTRAZENECA A/S | DK |
| PULMICORT □ ml, suspension pour inhalation par nébuliseur en récipient unidose | not available | 337 271.3 | ASTRAZENECA S.A.S. | FR |
| Pulmicort® 0,25 mg/ml sumutinsuspensiot | not available | 10184 | ASTRAZENECA OY | FI |
| Pulmicort εναιώρημα για εισπνοή με εκνεφωτή 0,25 mg/ml | not available | 5921/95/07.11.1996 | ASTRAZENECA S.A | GR |
| Pulmicort® 0,5 mg/2 ml Suspension, Suspension für einen Vernebler | not available | 24713.00.00 | ASTRAZENECA GMBH | DE |
| Pulmaxan 0,25 mg/ml sospensione da nebulizzare | not available | 27621059 | ASTRAZENECA S.P.A. | IT |
| Pulmicort 500 Respules, vernevelsuspensie 500 microgram /2 ml | not available | RVG 14196 | ASTRAZENECA BV | NL |

| Product Name (in authorisation country) | MRP/DCP Authorisation number | National Authorisation Number | MAH of product in the member state | Member State where product is authorised |
|---|---|---|---|---|
| Pulmicort® Respules® 0.5mg. | not available | 046/01405 | ASTRAZENECA AB | MT |
| PULMICORT, 0,250 MG/ML, ZAWIESINA DO NEBULIZACJI | not available | 4457 | ASTRAZENECA AB | PL |
| Pulmicort 0,25mg/ml suspension för nebulisator | not available | 12352 | ASTRAZENECA AB | SE |
| PULMICORT 0,5 mg/ml, suspension pour inhalation par nébuliseur | not available | BE 156037 | NV ASTRAZENECA SA | BE |
| Pulmicort Respules 0.5 mg/ml | not available | 14266 | ASTRAZENECA AB | CY |
| PULMICORT 0,5 mg/ml, vernevelsuspensie | not available | BE156037 | NV ASTRAZENECA SA | BE |
| PULMICORT 1 mg - Suspension zur Inhalation | not available | 1-20319 | ASTRAZENECA OSTERREICH GMBH | AT |
| Spirocort, inhalationsvæske til nebulisator, suspension | not available | 13557 | ASTRAZENECA A/S | DK |
| Pulmicort® 0,5 mg/ml sumutinsuspensiot | not available | 10185 | ASTRAZENECA OY | FI |
| Pulmaxan 0,5 mg/ml sospensione da nebulizzare | not available | 27621061 | ASTRAZENECA S.P.A. | IT |
| Pulmicort 0,5 mg/ml suspensija izsmidzināšanai | not available | 00-1115 | ASTRAZENECA AB | 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 |
|---|---|---|---|---|
| Pulmicort® 1,0 mg/2 ml Suspension, Suspension für einen Vernebler | not available | 24713.01.00 | ASTRAZENECA GMBH | DE |
| Pulmicort ενσιώρημα για εισπνοή με εκνεφωτή 0,5 mg/ml | not available | 5920/95/07.11.1996 | ASTRAZENECA S.A | GR |
| PULMICORT  suspension pour inhalation par nébuliseur en récipient unidose | not available | 337 356.9 | ASTRAZENECA S.A.S. | FR |
| Pulmicort® Respules® 1 mg /2 ml Nebuliser Suspension | not available | PA 970/50/4 | ASTRAZENECA UK LIMITED | IE |
| Pulmicort 1000 Respules, vernevelsuspensie 1000 microgram /2 ml | not available | RVG 14197 | ASTRAZENECA BV | NL |
| PULMICORT 0,5 mg/ml, suspension pour inhalation par nébuliseur | not available | 0173/09010119 | NV ASTRAZENECA SA | LU |
| Pulmicort 1 mg/2 ml suspensão para inalação por nebulização | not available | 8623355; 5216874 | ASTRAZENECA PRODUTOS FARMACEUTICOS LDA. | PT |
| Pulmicort 0,5 mg/ml | not available | 14/0318/00-S | ASTRAZENECA AB | SK |
| PULMICORT, 0,500 MG/ML, ZAWIESINA DO NEBULIZACJI | not available | 4458 | ASTRAZENECA AB | PL |
| Pulmicort 0,5mg/ml suspension för | not available | 12353 | ASTRAZENECA AB | SE |

| 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 |
|---|---|---|---|---|
| nebulisator | | | | |
| PULMICORT ☐ 200 microgrammes/dose, suspension pour inhalation en flacon pressurisé. | not available | NL 16 672 | ASTRAZENECA S.A.S. | FR |
| Pulmicort Turbohaler, 0,1 mg - Dosier-Pulverinhalator | not available | 1-21109 | ASTRAZENECA OSTERREICH GMBH | AT |
| Spirocort Turbuhaler, inhalationspulver | not available | 13820 | ASTRAZENECA A/S | DK |
| PULMICORT TURBUHALER, 100 mikrogrammi/annuses, inhalatsioonipulber | not available | 76794 | ASTRAZENECA UK LIMITED | EE |
| PULMICORT TURBUHALER ENFANT 100 microgrammes/dose, poudre pour inhalation. | not available | NL 18501 | ASTRAZENECA S.A.S. | FR |
| Pulmicort® Turbuhaler® 100 mikrog/annos inhalaatiojauheet | not available | 10933 | ASTRAZENECA OY | FI |
| Pulmicort® Turbuhaler® 100 mcg/dose | not available | 1897704 | ASTRAZENECA S.A | GR |
| Pulmicort Turbuhaler Inhalation powder 100 µg/dose | not available | R/6773 | ASTRAZENECA AB | PL |
| Pulmicort® Turbohaler® | not available | PA 970/50/5 | ASTRAZENECA UK LIMITED | IE |

| 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 |
|---|---|---|---|---|
| 100 micrograms Inhalation Powder | | | | |
| Pulmaxan 100 microgrammi/erogazione, polvere per inalazione | not available | AIC:027621010 | ASTRAZENECA S.P.A. | IT |
| Pulmicort 100 Turbuhaler, inhalatiepoeder 100 microgram/dosis | not available | RVG 14758 | ASTRAZENECA BV | NL |
| Pulmicort® Turbohaler® 100 | not available | 046/01401 | ASTRAZENECA AB | MT |
| Pulmicort Turbuhaler 100 mikrogrami/deva inhalacijas pulveris | not available | 97-0645 | ASTRAZENECA AB | LV |
| Pulmicort Turbuhaler 100 mikrogramov/vdih prašek za inhaliranje | not available | 5363-I-1238/11 | ASTRAZENECA UK LIMITED | SI |
| Pulmicort® Turbohaler® 100 | not available | PL 17901/0162 | ASTRAZENECA UK LIMITED | UK |
| Pulmicort Turbuhaler 100 mikrogram/dos inhalationspulver | not available | 11009 | ASTRAZENECA AB | SE |
| PULMICORT Turbohaler 0,2 mg - Dosier-Pulverinhalator | not available | 1-19463 | ASTRAZENECA OSTERREICH GMBH | AT |
| PULMICORT TURBOHALER 200, poudre pour inhalation | not available | BE159975 | NV ASTRAZENECA SA | 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 |
|---|---|---|---|---|
| Пулмикорт Турбухалер 200 микрограма/доза, прах за инхалация | not available | 9900142 | ASTRAZENECA AB | BG |
| Pulmicort Turbuhaler, 200 micrograms/dose, inhalation powder | not available | 13187 | ASTRAZENECA AB | CY |
| PULMICORT TURBOHALER 200, inhalatiepoeder | not available | BE159975 | NV ASTRAZENECA SA | BE |
| Spirocort Turbuhaler, inhalationspulver | not available | 13395 | ASTRAZENECA A/S | DK |
| PULMICORT TURBUHALER, 200 mikrogrammi/annuses, inhalatsioonipulber | not available | 76894 | ASTRAZENECA UK LIMITED | EE |
| Pulmicort® Turbuhaler® 200 mikrog/annos inhalaatiojauheet | not available | 10114 | ASTRAZENECA OY | FI |
| Pulmicort® Turbohaler® 200 Mikrogramm/Dosis Pulver zur Inhalation | not available | 28528.00.00 | ASTRAZENECA GMBH | DE |
| Pulmicort® Turbuhaler® 200 mcg/dose | not available | 1897705 | ASTRAZENECA S.A | GR |
| Pulmicort® Turbohaler® 200 micrograms Inhalation Powder | not available | PA 970/50/6 | ASTRAZENECA UK LIMITED | IE |
| Pulmaxan 200 microgrammi/erogazione, | not available | AIC:027621022 | ASTRAZENECA S.P.A. | IT |

| 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 |
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| polvere per inalazione | | | | |
| Pulmicort Turbuhaler 200 mikrogrami/devā inhalācijas pulveris | not available | 97-0646 | ASTRAZENECA AB | LV |
| PULMICORT TURBOHALER 200, poudre pour inhalation | not available | 0173/09010120 | NV ASTRAZENECA SA | LU |
| Pulmicort® Turbohaler® 200 | not available | MA 046/01402 | ASTRAZENECA AB | MT |
| Pulmicort 200 Turbuhaler, inhalatiepoeder 200 microgram/dosis | not available | RVG 13698 | ASTRAZENECA BV | NL |
| Pulmicort Turbuhaler Inhalation powder 200 µg/dose | not available | R/6774 | ASTRAZENECA AB | PL |
| Pulmicort Turbohaler 200 microgramas/dose pó para inalação | not available | 8630830 | ASTRAZENECA PRODUTOS FARMACEUTICOS LDA. | PT |
| Pulmicort Turbohaler 200 microgramas/dose pó para inalação | not available | 2685287 | ASTRAZENECA PRODUTOS FARMACEUTICOS LDA. | PT |
| Pulmicort Turbuhaler 200 µg | not available | 14/0005/13-S | ASTRAZENECA AB | SK |
| Pulmicort Turbuhaler 200 mikrogramov/vdih prašek za inhaliranje | not available | 5363-I-1239/11 | ASTRAZENECA UK LIMITED | SI |

| 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 |
|---|---|---|---|---|
| PULMICORT Turbohaler 0,4 mg - Dosier-Pulverinhalator | not available | 1-19464 | ASTRAZENECA OSTERREICH GMBH | AT |
| Pulmicort Turbuhaler 200 mikrogram/dos inhalationspulver | not available | 10888 | ASTRAZENECA AB | SE |
| Pulmicort® Turbohaler® 200 | not available | PL 17901/0163 | ASTRAZENECA UK LIMITED | UK |
| Spirocort Turbuhaler, inhalationspulver | not available | 13396 | ASTRAZENECA A/S | DK |
| Pulmicort® Turbuhaler® 400 mikrog/annos inhalaatiojauheet | not available | 10115 | ASTRAZENECA OY | FI |
| Pulmicort® Turbohaler® 400 µg 400 Mikrogramm/Dosis Pulver zur Inhalation | not available | 28528.01.00 | ASTRAZENECA GMBH | DE |
| Pulmaxan 400 microgrammi/erogazione, polvere per inalazione | not available | AIC:027621034 | ASTRAZENECA S.P.A. | IT |
| Pulmicort® Turbuhaler® 400 mcg/dose | not available | 1897706 | ASTRAZENECA S.A | GR |
| Pulmicort 400 Turbuhaler, inhalatiepoeder 400 microgram/dosis | not available | RVG 13699 | ASTRAZENECA BV | NL |
| Pulmicort® Turbohaler® 400 micrograms | not available | PA 970/50/7 | ASTRAZENECA UK LIMITED | IE |

| 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 |
|---|---|---|---|---|
| Inhalation Powder. | | | | |
| Pulmicort Turbuhaler 400 µg | not available | 14/0006/13-S | ASTRAZENECA AB | SK |
| Pulmicort Turbuhaler 400 mikrogramov/vdih prašek za inhaliranje | not available | 5363-I-1240/11 | ASTRAZENECA UK LIMITED | SI |
| Pulmicort Turbohaler 400 microgramas/dose pó para inalação | not available | 8630889 | ASTRAZENECA PRODUTOS FARMACEUTICOS LDA. | PT |
| Pulmicort® Turbohaler® 400. | not available | PL 17901/0164 | ASTRAZENECA UK LIMITED | UK |
| Pulmicort Turbuhaler 400 mikrogram/dos inhalationspulver | not available | 10889 | ASTRAZENECA AB | SE |
| Pulmicort 0,5 mg/ml szuszpenzió porlasztásra | not available | OGYI-T-4725/08 | ASTRAZENECA KFT. | HU |
| Pulmicort® Respules® 0.5 mg /2 ml Nebuliser Suspension | not available | PA 970/50/3 | ASTRAZENECA UK LIMITED | IE |
| Pulmicort 0,25 mg/ml szuszpenzió porlasztásra | not available | OGYI-T-4725/07 | ASTRAZENECA KFT. | HU |
| Pulmicort® Respules® 0.5 mg, nebuliser suspension | not available | PL 17901/0160 | ASTRAZENECA UK LIMITED | UK |
| Pulmicort® Respules® 1 mg, nebuliser suspension | not available | PL 17901/0161 | ASTRAZENECA UK LIMITED | UK |
| Pulmicort Respules 1 mg, nebuliser suspension | not available | 046/01407 | ASTRAZENECA AB | MT |

| 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 |
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| Pulmicort Turbuhaler 100 mikrogramm/adag adagolt inhalációs por | not available | OGYI-T-4725/04 | ASTRAZENECA KFT. | HU |
| PULMICORT® TURBUHALER® 200 MICROGRAMMES/DOSE, POUDRE POUR INHALATION | not available | NL 16902 | ASTRAZENECA S.A.S. | FR |
| Pulmicort® Topinasal® 64 µg 64 Mikrogramm; Nasenspray, Suspension | not available | 42883.01.00 | ASTRAZENECA GMBH | DE |
| PULMICORT® TURBUHALER® 400 MICROGRAMMES/DOSE, POUDRE POUR INHALATION | not available | NL 16903 | ASTRAZENECA S.A.S. | FR |
| Pulmicort® 0,125 mg/ml inhalasjonsvæske til nebulisator, suspensjon | not available | 94-2765 | ASTRAZENECA AS | NO |
| Pulmicort® Turbuhaler®: 100 mikrog/dose, inhalasjonspulver | not available | 7641 | ASTRAZENECA AS | NO |
| Pulmicort® 0,5 mg/ml inhalasjonsvæske til nebulisator, suspensjon | not available | 94-2767 | ASTRAZENECA AS | NO |
| Pulmicort® 0,25 mg/ml inhalasjonsvæske til nebulisator, suspensjon | not available | 94-2766 | ASTRAZENECA AS | NO |

| 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 |
|---|---|---|---|---|
| Pulmicort® Turbuhaler®: 400 mikrog/dose, inhalasjonspulver | not available | 7432 | ASTRAZENECA AS | NO |
| Pulmicort® Turbuhaler®: 200 mikrog/dose, inhalasjonspulver | not available | 7431 | ASTRAZENECA AS | NO |
| PULMICORT 0,5 mg - Suspension zur Inhalation | not available | 1-20318 | ASTRAZENECA OSTERREICH GMBH | AT |
| Pulmicort 0,125 mg/ml dreifa fyrir eimgjafa | not available | 940301 | ASTRAZENECA A/S | IS |
| Pulmicort Turbuhaler, 100 micrograms/dose, inhalation powder | not available | 13186 | ASTRAZENECA AB | CY |
| Pulmicort 0,25 mg/ml dreifa fyrir eimgjafa | not available | 940302 | ASTRAZENECA A/S | IS |
| Pulmicort 0,5 mg/ml dreifa fyrir eimgjafa | not available | 940303 (IS) | ASTRAZENECA A/S | IS |
| Pulmicort Turbuhaler 100 míkróg/skammt, innöndunarduft | not available | 890213 | ASTRAZENECA A/S | IS |
| Pulmicort Turbuhaler 200 míkróg/skammt, innöndunarduft | not available | 880158 | ASTRAZENECA A/S | IS |
| Pulmicort Turbuhaler 400 míkróg/skammt, innöndunarduft | not available | 880157 | ASTRAZENECA A/S | IS |
| Entocort, kapsler med modificeret udløsning, | not available | 17169 | TILLOTTS PHARMA GMBH | DK |

| Product Name (in authorisation country) | MRP/DCP Authorisation number | National Authorisation Number | MAH of product in the member state | Member State where product is authorised |
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| hårde | | | | |
| Entocort® Enema | not available | PL 45329/0004 | TILLOTTS PHARMA GMBH | UK |
| Cortiment 9 mg depottabletti | NL/H/3168/001 | 32227 | FERRING LÄÄKKEET OY | FI |
| Cortiment 9 mg retard tabletta | NL/H/3168/001 | OGYI-T-22753/01 | FERRING MAGYARORSZÁG GYÓGYSZERKERESKEDELMI KFT. | HU |
| Cortiment 9 mg prolonged release tablets | NL/H/3168/001 | PA 1009/026/001 | FERRING IRELAND LTD. | IE |
| Cortiment 9 mg depottabletter | NL/H/3168/001 | 14-10060 | FERRING LEGEMIDLER AS | NO |
| Cortiment 9 mg, depottablett | NL/H/3168/001 | 51078 | FERRING LÄKEMEDEL AB | SE |
| Cortiment 9 mg, prolonged release tablets | NL/H/3168/001 | PL 03194/0113 | FERRING PHARMACEUTICALS LTD. | UK |
| CortimentMMX 9 mg - Retardtabletten | NL/H/3168/001 | 135913 | FERRING ARZNEIMITTEL GES.M.B.H. | AT |
| Budesonide Ferring 9 mg tabletten met verlengde afgifte. | NL/H/3168/001 | BE466737 | FERRING N.V. | BE |
| Budesonide Ferring 9 mg comprimés à libération prolongée | NL/H/3168/001 | BE466737 | FERRING N.V. | BE |
| Cortiment 9 mg tablety s predĺženým uvoľňovaním | NL/H/3168/001 | 56/0406/14-S | FERRING SLOVAKIA S.R.O. | SK |
| CortimentMMX, 9 mg, | NL/H/3168/001 | 22268 | FERRING GMBH | PL |

| 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 |
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| tabletki o przedluzonym uwalnianiu | | | | |
| Cortiment 9 mg, tableta s prodlouženým uvolňováním | NL/H/3168/001 | 56/006/15-C | FERRING PHARMACEUTICALS CZ S.R.O. | CZ |
| Cortiment 9 mg comprimate cu eliberare prelungită | NL/H/3168/001 | 7403/2015/01 | FERRING GMBH | RO |
| Cortiment 9 mg comprimate cu eliberare prelungită | NL/H/3168/001 | 7403/2015/02 | FERRING GMBH | RO |
| Cortiment 9 mg comprimate cu eliberare prelungită | NL/H/3168/001 | 7403/2015/03 | FERRING GMBH | RO |
| Cortiment 9 mg comprimate cu eliberare prelungită | NL/H/3168/001 | 7403/2015/05 | FERRING GMBH | RO |
| Cortiment 9 mg comprimate cu eliberare prelungită | NL/H/3168/001 | 7403/2015/01 | FERRING GMBH | RO |
| Cortiment 9 mg comprimate cu eliberare prelungită | NL/H/3168/001 | 7403/2015/04 | FERRING GMBH | RO |
| Cortiment®MMX® 9 mg Retardtabletten | NL/H/3168/001 | 92324.00.00 | FERRING ARZNEIMITTEL GMBH | DE |
| Coramen 9 mg, comprimido de libertação prolongada | NL/H/3168/001 | 5626544 | FERRING PORTUGUESA – PRODUTOS FARMACÊUTICOS, | 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 |
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| | | | SOCIEDADE UNIPESSOAL, LDA. | |
| Coramen 9 mg, comprimido de libertação prolongada. | NL/H/3168/001 | 5626510 | FERRING PORTUGUESA – PRODUTOS FARMACÊUTICOS, SOCIEDADE UNIPESSOAL, LDA. | PT |
| Coramen 9 mg, comprimido de libertação prolongada. | NL/H/3168/001 | 5626528 | FERRING PORTUGUESA – PRODUTOS FARMACÊUTICOS, SOCIEDADE UNIPESSOAL, LDA. | PT |
| Coramen 9 mg, comprimido de libertação prolongada. | NL/H/3168/001 | 5626536 | FERRING PORTUGUESA – PRODUTOS FARMACÊUTICOS, SOCIEDADE UNIPESSOAL, LDA. | PT |
| Coramen 9 mg, comprimido de libertação prolongada. | NL/H/3168/001 | 5626502 | FERRING PORTUGUESA – PRODUTOS FARMACÊUTICOS, SOCIEDADE UNIPESSOAL, LDA. | PT |
| Budesonide Ferring 9 mg ilgstošās darbības tabletes | NL/H/3168/001 | 92324.00.00 | FERRING GMBH | LV |
| Budesonide Ferring 9 mg comprimés à libération prolongée | NL/H/3168/001 | 2015040050 | FERRING N.V. | LU |

| 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 |
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| Cortiment, 9 mg, toimeainet prolongeeritult vabastavad tabletid | NL/H/3168/001 | 867315 | FERRING GMBH | EE |
| Budesonide Ferring 9 mg pailginto atpalaidavimo tabletes | NL/H/3168/001 | LT/1/14/3665/001 | FERRING GMBH | LT |
| Budesonide Ferring 9 mg pailginto atpalaidavimo tabletes | NL/H/3168/001 | LT/1/14/3665/002 | FERRING GMBH | LT |
| Budesonide Ferring 9 mg pailginto atpalaidavimo tabletės | NL/H/3168/001 | LT/1/14/3665/003 | FERRING GMBH | LT |
| Budesonide Ferring 9 mg pailginto atpalaidavimo tabletes | NL/H/3168/001 | LT/1/14/3665/004 | FERRING GMBH | LT |
| Budesonide Ferring 9 mg pailginto atpalaidavimo tabletes | NL/H/3168/001 | LT/1/14/3665/005 | FERRING GMBH | LT |
| Budesonide Ferring 9 mg pailginto atpalaidavimo tabletes | NL/H/3168/001 | LT/1/14/3665/006 | FERRING GMBH | LT |
| Budezonid Ferring 9 mg tablete s podaljšanim sproščanjem | NL/H/3168/001 | H/15/01986/006 | FERRING GMBH | SI |
| CortimentMMX 9 mg tablete s produljenim oslobađanjem | NL/H/3168/001 | HR-H-409310460 | FERRING GMBH | HR |
| Cortiment 9 mg, | NL/H/3168/001 | IS/1/15/005/01 | FERRING LÆGEMIDLER A/S | IS |

| 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 |
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| forðatöflur | | | | |
| Кортимент 9 mg таблетки с удължено освобождаване | NL/H/3168/001 | 20150129 | FERRING GMBH | BG |
| Cortiment MMX 9 mg, prolonged release tablets | NL/H/3168/001 | MA832/01201 | FERRING PHARMACEUTICALS LTD. | MT |
| Cortiment 9 mg, δισκία παρατεταμένης αποδέσμευσης | NL/H/3168/001 | 84681 | FERRING HELLAS MEPE | GR |
| Cortiment 9 mg comprimidos de liberación prolongada | NL/H/3168/001 | 79203 | FERRING S.A.U. | ES |
| CORTIMENT 9 mg, compresse a rilascio prolungato | NL/H/3168/001 | 043461019 | FERRING S.P.A. | IT |
| CORTIMENT 9 mg, compresse a rilascio prolungato | NL/H/3168/001 | 043461021 | FERRING S.P.A. | IT |
| CORTIMENT 9 mg, compresse a rilascio prolungato | NL/H/3168/001 | 043461033 | FERRING S.P.A. | IT |
| CORTIMENT 9 mg, compresse a rilascio prolungato | NL/H/3168/001 | 043461045 | FERRING S.P.A. | IT |
| CORTIMENT 9 mg, compresse a rilascio prolungato | NL/H/3168/001 | 043461058 | FERRING S.P.A. | IT |

| 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 |
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| CORTIMENT 9 mg, compresse a rilascio prolungato | NL/H/3168/001 | 43461060 | FERRING S.P.A. | IT |
| Cortiment, depottabletter | NL/H/3168/001 | 56921 | FERRING LÆGEMIDLER A/S | DK |
| Budezonid Ferring 9 mg tablete s podaljšanim sproščanjem | NL/H/3168/001 | H/15/01986/001 | FERRING GMBH | SI |
| Budezonid Ferring 9 mg tablete s podaljšanim sproščanjem | NL/H/3168/001 | H/15/01986/002 | FERRING GMBH | SI |
| Budezonid Ferring 9 mg tablete s podaljšanim sproščanjem | NL/H/3168/001 | H/15/01986/003 | FERRING GMBH | SI |
| Budezonid Ferring 9 mg tablete s podaljšanim sproščanjem | NL/H/3168/001 | H/15/01986/004 | FERRING GMBH | SI |
| Budezonid Ferring 9 mg tablete s podaljšanim sproščanjem | NL/H/3168/001 | H/15/01986/005 | FERRING GMBH | SI |
| CORTIMENT 9 mg, comprimé à libération prolongée | NL/H/3168/001 | 34009 300 557 1 7 | FERRING S.A.S. | FR |
| CORTIMENT 9 mg, comprimé à libération prolongée | NL/H/3168/001 | 34009 300 557 2 4 | FERRING S.A.S. | FR |
| CORTIMENT 9 mg, comprimé à libération prolongée | NL/H/3168/001 | 34009 300 557 3 1 | FERRING S.A.S. | FR |

| Product Name (in authorisation country) | MRP/DCP Authorisation number | National Authorisation Number | MAH of product in the member state | Member State where product is authorised |
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| CORTIMENT 9 mg, comprimé à libération prolongée | NL/H/3168/001 | 34009 550 198 3 1 | FERRING S.A.S. | FR |
| CORTIMENT 9 mg, comprimé à libération prolongée | NL/H/3168/001 | 34009 550 198 4 8 | FERRING S.A.S. | FR |
| CORTIMENT 9 mg, comprimé à libération prolongée | NL/H/3168/001 | 34009 550 198 5 5 | FERRING S.A.S. | FR |
| Cortiment 9 mg, tabletten met verlengde afgifte | NL/H/3168/001 | RVG 110023 | FERRING B.V. | NL |
| OLFEX BUCAL 200 microgramos/inhalación suspensión para inhalación en envase a presión | not available | 59280 | LABORATORIOS BIAL, S.A. | ES |
| OLFEX BUCAL INFANTIL 50 microgramos/inhalación suspensión para inhalación en envase a presión | not available | 59281 | LABORATORIOS BIAL, S.A. | ES |
| ACORSPRAY 200 microgrammes/dose, solution pour inhalation en flacon pressurisé | not available | 369 844-9 | CHIESI S.A.S. | FR |
| ENTOCORT 3 mg, gélules | not available | BE227823 | TILLOTTS PHARMA GMBH | LU |

| 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 |
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| à libération modifiée | | | | |
| ENTOCORT ENEMA 2,3 mg, comprimés pour suspension rectale | not available | BE164841 | TILLOTTS PHARMA GMBH | LU |
| Budesonide Teva 0,50mg/ml vernevelsuspensie | NL/H/2714/002 | BE445840 | TEVA PHARMA BELGIUM N.V./S.A | BE |
| Budesonide Teva 0,125mg/ml vernevelsuspensie | NL/H/2714/001 | BE445822 | TEVA PHARMA BELGIUM N.V./S.A | BE |
| Budesonide Teva 0,25mg/ml vernevelsuspensie | NL/H/2714/002 | BE445982 | TEVA PHARMA BELGIUM N.V./S.A | BE |
| Buderatio 0,25 mg/ml sumutinsuspensio | NL/H/2714/001 | 31007 | TEVA PHARMA B.V. | FI |
| Budesonide Teva Pharma 0.5 mg/2 ml Nebuliser Suspension | NL/H/2714/002 | PA0749/207/002 | TEVA PHARMA B.V. | IE |
| Budesonide Teva Pharma 1 mg/2 ml Nebuliser Suspension | NL/H/2714/003 | PA0749/207/003 | TEVA PHARMA B.V. | IE |
| Budesonide Teva Pharma 0.25 mg/2 ml Nebuliser Suspension | NL/H/2714/001 | PA0749/207/001 | TEVA PHARMA B.V. | IE |
| Budesonide Teva Pharma, 1 mg suspension för nebulisator | NL-H-2714-001-003-DC | 48437 | TEVA PHARMA B.V. | SE |

| 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 |
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| Budesonide Teva 0,5 mg/ml dreifa fyrir eimgjafa | NL/H/2714/002 | IS/1/13/090/03 | TEVA PHARMA B.V. | IS |
| Budesonide Teva Pharma, 0,25 mg suspension för nebulisator | NL-H-2714-001-003-DC | 48435 | TEVA PHARMA B.V. | SE |
| Budesonide Teva Pharma, 0,5 mg suspension för nebulisator | NL-H-2714-001-003-DC | 48436 | TEVA PHARMA B.V. | SE |
| Budesonide "Teva Pharma", inhalationsvæske til nebulisator, suspension | NL/H/2714/002 | 51428 | TEVA PHARMA B.V. | DK |
| Budesonide Teva 0,125 mg/ml dreifa fyrir eimgjafa | NL/H/2714/001 | IS/1/13/090/01 | TEVA PHARMA B.V. | IS |
| Budesonide Teva 0,25 mg/ml dreifa fyrir eimgjafa | NL/H/2714/002 | IS/1/13/090/02 | TEVA PHARMA B.V. | IS |
| Budesonide Teva 0,5 mg/ml sumutinsuspensio | NL/H/2714/002 | 31008 | TEVA PHARMA B.V. | FI |
| Budesonide Teva, 1 mg/2 ml, zawiesina do nebulizacji | NL-H-2714-001-003-DC | 21770 | TEVA PHARMACEUTICALS POLSKA SP. Z O.O. | PL |
| Budesonide Teva, 0,5 mg/2 ml, zawiesina do nebulizacji | NL/H/2714/002 | 21769 | TEVA PHARMACEUTICALS POLSKA SP. Z O.O. | PL |
| Nebbud, 0,25 mg/2 ml, | NL/H/2714/001 | 21768 | TEVA PHARMACEUTICALS | PL |

| 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 |
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| zawiesina do nebulizacji | | | POLSKA SP. Z O.O. | |
| Budesonide Teva 0,125 mg/ml sumutinsuspensio | NL/H/2714/001 | 31006 | TEVA PHARMA B.V. | FI |
| Budesonide Teva Pharma 0.5 mg/2 ml Nebuliser Suspension | NL/H/2714/002 | MA715/04002 | TEVA PHARMA B.V. | MT |
| Budesonide Teva Pharma 0.25 mg/2 ml Nebuliser Suspension | NL/H/2714/001 | MA715/04001 | TEVA PHARMA B.V. | MT |
| Budesonide Teva Pharma 1 mg/2 ml Nebuliser Suspension | NL/H/2714/003 | MA715/04003 | TEVA PHARMA B.V. | MT |
| Budesonide "Teva Pharma", inhalationsvæske til nebulisator, suspension | NL/H/2714/001 | 51426 | TEVA PHARMA B.V. | DK |
| Budesonide "Teva Pharma", inhalationsvæske til nebulisator, suspension | NL/H/2714/001 | 51427 | TEVA PHARMA B.V. | DK |
| Budesonide Teva Steri-Neb 0,25 mg/2 ml, vernevelsuspensie | NL/H/2714/001 | RVG 112503 | TEVA NEDERLAND B.V. | NL |
| Budesonide Teva Steri-Neb 0,5 mg/2 ml, vernevelsuspensie | NL-H-2714-001-003-DC | RVG 112504 | TEVA NEDERLAND B.V. | NL |
| Budesonide Teva Steri-Neb 1,0 mg/2 ml, | NL/H/2714/003 | RVG 112505 | TEVA NEDERLAND B.V. | NL |

| Product Name (in authorisation country) | MRP/DCP Authorisation number | National Authorisation Number | MAH of product in the member state | Member State where product is authorised |
|---|---|---|---|---|
| vernevelsuspensie | | | | |
| Budesonide/Teva 0,5 mg Εναιώρημα για εισπνοή με εκνεφωτή | NL/H/2714/002 | 75324/03-11-2015 | TEVA B.V | GR |
| Budesonide/Teva 1 mg Εναιώρημα για εισπνοή με εκνεφωτή | NL/H/2714/003 | 75326/03-11-2015 | TEVA B.V | GR |
| Budesonide/Teva 0.25 mg Εναιώρημα για εισπνοή με εκνεφωτή | NL/H/2714/001 | 77867/14 | TEVA B.V | GR |
| Budiair®200 Mikrogramm Druckgasinhalation, Lösung | not available | 40593.00.00 | CHIESI GMBH | DE |
| Buparid 0,125 mg/ml, suspension pour inhalation par nébuliseur | DE/3867/001-002/DC | BE461502 | PARI PHARMA GMBH | BE |
| Buparid 0,25 mg/ml, suspension pour inhalation par nébuliseur | DE/H/3867/001 | BE461511 | PARI PHARMA GMBH | BE |
| Buparid 0,5 mg/ml, suspension pour inhalation par nébuliseur | DE/H/3867/002 | BE461520 | PARI PHARMA GMBH | BE |
| Buparid 0,25 mg Suspension für einen Vernebler | DE/H/3867/001 | 89957.00.00 | PARI PHARMA GMBH | DE |
| Buparid 0,5 mg Suspension für einen Vernebler | DE/H/3867/002 | 89958.00.00 | PARI PHARMA GMBH | DE |

| 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 |
|---|---|---|---|---|
| Buparid 1 mg Suspension für einen Vernebler | DE/H/3867/003 | 89959.00.00 | PARI PHARMA GMBH | DE |
| Buparid 0,25 mg Suspension für einen Vernebler | DE/H/3867/001 | 135931 | PARI PHARMA GMBH | AT |
| Buparid 0,5 mg Suspension für einen Vernebler | DE/H/3867/002 | 135929 | PARI PHARMA GMBH | AT |
| Buparid 1 mg Suspension für einen Vernebler | DE/H/3867/003 | 135930 | PARI PHARMA GMBH | AT |
| Buparid 0,25 mg/2ml, suspension pour inhalation par nébuliseur en récipient unidose | DE/H/3867/001 | NL43587 | PARI PHARMA GMBH | FR |
| BUPARID 0,50 mg/2 ml, suspension pour inhalation par nébuliseur en récipient unidose | DE/H/3867/002 | NL43588 | PARI PHARMA GMBH | FR |
| BUPARID 1 mg/2 ml, suspension pour inhalation par nébuliseur en récipient unidose | DE/H/3867/003 | NL43589 | PARI PHARMA GMBH | FR |
| Entocort 3 mg | not available | 56/0003/99-S | TILLOTTS PHARMA GMBH | SK |
| Budecort 200 Novolizer, 200 Mikrogramm, Pulver zur Inhalation | not available | 41480.00.00 | MEDA PHARMA GMBH & CO. KG | DE |
| Budecort 400 Novolizer, 400 Mikrogramm, Pulver | not available | 41480.01.00 | MEDA PHARMA GMBH & CO. KG | DE |

| 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 |
|---|---|---|---|---|
| zur Inhalation | | | | |
| Novopulmon 200 Mikrogramm Novolizer, Pulver zur Inhalation | not available | 54750.00.00 | MEDA PHARMA GMBH & CO. KG | DE |
| Novopulmon 400 Mikrogramm Novolizer, Pulver zur Inhalation | not available | 63050.00.00 | MEDA PHARMA GMBH & CO. KG | DE |
| Budesonid 400 Mikrogramm Novolizer, Pulver zur Inhalation | not available | 63051.00.00 | MEDA PHARMA GMBH & CO. KG | DE |
| Budelin Novolizer 200 µg inhalačný prášok | not available | 14/0079/04-S | MEDA PHARMA SPOL. S R.O. | SK |
| BUDIAIR 200 microgrammi soluzione pressurizzata per inalazione | IT/H/0123/001 | 035656026 | CHIESI FARMACEUTICI S.P.A. | IT |
| BUDIAIR 200 microgrammi soluzione pressurizzata per inalazione | IT/H/0123/001 | 035656014 | CHIESI FARMACEUTICI S.P.A. | IT |
| Aerox Jet 200 mikrogramm túlnyomásos inhalációs oldat | IT/H/0123/001 | OGYI-T-10431/02 | CHIESI PHARMACEUTICALS GMBH | HU |
| Aerox 200 mikrogramm túlnyomásos inhalációs oldat | IT/H/0123/001 | OGYI-T-10431/01 | CHIESI PHARMACEUTICALS GMBH | HU |
| Budiair, 200 | IT/H/0123/001 | 11758 | CHIESI PHARMACEUTICALS | PL |

| 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 |
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| mikrogramów/dawke odmierzona, aerozol inhalacyjny, roztwór | | | GMBH | |
| BUDIAIR Roztok k inhalaci v tlakovém obalu | IT/H/0123/001 | 14/296/05-C | CHIESI PHARMACEUTICALS GMBH | CZ |
| Budiair 200 mikrogramų/dozėje suslėgtas inhaliacinis tirpalas | IT/H/0123/001 | LT/1/05/0378/001 | CHIESI PHARMACEUTICALS GMBH | LT |
| Budiair 200 mikrogramų/dozėje suslėgtas inhaliacinis tirpalas | IT/H/0123/001 | LT/1/05/0378/002 | CHIESI PHARMACEUTICALS GMBH | LT |
| Budiair 200 mikrogramov inhalacijska raztopina pod tlakom | IT/H/0123/001 | 5363-I-600/12 | CHIESI PHARMACEUTICALS GMBH | SI |
| Budiair 200 mikrogramov inhalacijska raztopina pod tlakom | IT/H/0123/001 | 5363-I-601/12 | CHIESI PHARMACEUTICALS GMBH | SI |
| BUDIAIR® 200 μικρογραμμάρια διαλύματος για εισπνοή υπό πίεση | IT/H/0123/001 | 18425/20-3-2006 | CHIESI HELLAS A.E.B.E. | GR |
| Budiair, 200 mikrogrammi/annuses inhalatsiooniaerosool, lahus | IT/H/0123/001 | 490505 | CHIESI PHARMACEUTICALS GMBH | EE |
| Budelin Novolizer 200 | not available | 5363-I-2215/12 | MEDA PHARMA GMBH & CO. | SI |

| 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 |
|---|---|---|---|---|
| mikrogramov/odmerek prašek za inhaliranje, odmerjen | | | KG | |
| Budelin Novolizer 200 mikrogramov/odmerek prašek za inhaliranje, odmerjen | not available | 5363-I-2216/12 | MEDA PHARMA GMBH & CO. KG | SI |
| Budelin Novolizer 200 mikrogramov/odmerek prašek za inhaliranje, odmerjen | not available | 5363-I-2217/12 | MEDA PHARMA GMBH & CO. KG | SI |
| Budelin Novolizer 200 mikrogramov/odmerek prašek za inhaliranje, odmerjen | not available | 5363-I-2218/12 | MEDA PHARMA GMBH & CO. KG | SI |
| Entocort CR 3 mg Capsules | not available | PL 45329/0003 | TILLOTTS PHARMA GMBH | UK |
| Entocort® rektal 2,3 mg, Tabletten und Flüssigkeit zur Herstellung einer Rektalsuspension | not available | 28247.00.00 | TILLOTTS PHARMA GMBH | DE |
| PULMICORT0,5 MG/ML SUSPENZE K ROZPRAŠOVÁNÍ (Z ROZPRAŠOVAČE/NEBULIZÁTORU) | not available | 14/684/97-C | ASTRAZENECA UK LIMITED | CZ |
| PULMICORT TURBUHALER 100 µg Prášek k inhalaci | not available | 14/1161/94-A/C | ASTRAZENECA UK LIMITED | CZ |

| 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 |
|---|---|---|---|---|
| PULMICORT TURBUHALER 200 µg Prášek k inhalaci | not available | 14/1161/94-B/C | ASTRAZENECA UK LIMITED | CZ |
| PULMICORT TURBUHALER 400 µg Prášek k inhalaci | not available | 14/1161/94-C/C | ASTRAZENECA UK LIMITED | CZ |
| Entocort, tabletter til rektalvæske, suspension | not available | 14499 | TILLOTTS PHARMA GMBH | DK |
| Budenofalk 2 mg/dosis schuim voor rectaal gebruik | not available | BE451644 | DR. FALK PHARMA BENELUX B.V. | BE |
| Budenofalk 2 mg/dose mousse rectale | not available | BE451644 | DR. FALK PHARMA BENELUX B.V. | BE |
| Budenofalk 3 mg cápsulas de libertação modificada | not available | 3159985 | DR. FALK PHARMA PORTUGAL, SOCIEDADE UNIPESSOAL LDA. | PT |
| Budenofalk 3 mg cápsulas de libertação modificada | not available | 3160082 | DR. FALK PHARMA PORTUGAL, SOCIEDADE UNIPESSOAL LDA. | PT |
| BUDENOFALK, 2 mg/dose, espuma rectal | not available | 5282025 | DR. FALK PHARMA PORTUGAL, SOCIEDADE UNIPESSOAL LDA. | PT |
| BUDENOFALK, 2 mg/dose, espuma rectal | not available | 5282033 | DR. FALK PHARMA PORTUGAL, SOCIEDADE UNIPESSOAL LDA. | PT |
| Budenofalk 3 mg gélules gastro-résistantes | not available | 2007069309 | DR. FALK PHARMA BENELUX B.V. | LU |
| Budenofalk 2 mg/dose mousse rectale | not available | 2016040031 | DR. FALK PHARMA BENELUX B.V. | LU |
| Budo-San 3 mg - Kapseln | not available | 1-22449 | DR FALK 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 |
|---|---|---|---|---|
| Budosan 2 mg pjena za rektum | not available | UP/I-530-09/11-01/09 | WURTH D.O.O. | HR |
| Budosan 3 mg želučanootporne kapsule | not available | UP/I-530-09/12-02/322 | WURTH D.O.O. | HR |
| Budosan 9 mg želučanootporne granule | not available | UP/I-530-09/12-01/295 | WURTH D.O.O. | HR |
| Budenofalk 3 g γαστροανθεκτικά καψάκια σκληρά | not available | 38813/15.10.2008 | GALENICA SA | GR |
| Budenofalk 3 mg maagsapresistente capsules,hard | not available | BE206394 | DR. FALK PHARMA BENELUX B.V. | BE |
| Budenofalk 3 mg gélules gastro-résistantes | not available | BE206394 | DR. FALK PHARMA BENELUX B.V. | BE |
| Budenofalk, maagsapresistente capsules 3 mg | not available | RVG 22557 | DR. FALK PHARMA BENELUX B.V. | NL |
| Буденофалк 3 mg, стомашно-устойчива капсула, твърда | not available | 20000708 | DR FALK PHARMA GMBH | BG |
| Budeno 3mg, Magensaftresistente Hartkapseln | not available | 44333.00.00 | DR FALK PHARMA GMBH | DE |
| Budenofalk 3mg magensaftresistente Hartkapseln | not available | 81258.00.00 | DR FALK PHARMA GMBH | DE |
| BUDENOFALK 3 mg zarnās šķīstošās cietās | not available | 00-1222 | DR FALK PHARMA GMBH | 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 |
|---|---|---|---|---|
| kapsulas | | | | |
| Budenofalk 3mg | not available | 29572.00.00 | DR FALK PHARMA GMBH | DE |
| Budenofalk, 3 mg, kapsułki dojelitowe, twarde | not available | 9439 | DR FALK PHARMA GMBH | PL |
| Budenofalk 3 mg gastrorezistentné kapsuly | not available | 56/0041/00-S | DR FALK PHARMA GMBH | SK |
| Budenofalk, capsule cu pelete gastrorezistente, 3 mg | not available | 6934/2014/01 | DR FALK PHARMA GMBH | RO |
| Budenofalk 3 mg trde gastrorezistentne kapsule | not available | H/02/00314/001 | DR FALK PHARMA GMBH | SI |
| Budenofalk 3 mg skrandyje neirios kietos kapsulės | not available | LT/1/99/0416/001 (PACK SIZE 50) | DR FALK PHARMA GMBH | LT |
| Budenofalk 3 mg skrandyje neirios kietos kapsulės | not available | LT/1/99/0416/002(PACK SIZE 100) | DR FALK PHARMA GMBH | LT |
| Буденофалк 2 mg/изпръскване ректална пяна | not available | 20100339 | DR FALK PHARMA GMBH | BG |
| Budenofalk Rektalschaum | not available | 61241.00.00 | DR FALK PHARMA GMBH | DE |
| Budenofalk 2 mg végbélhab | not available | OGYI-T-8898/03 (PACK SIZE 2) | DR FALK PHARMA GMBH | HU |
| Budenofalk 2 mg végbélhab | not available | OGYI-T-8898/02 (PACK SIZE 1) | DR FALK PHARMA GMBH | HU |
| BUDENOFALK 2 mg/devā | not available | 10-0283 | DR FALK PHARMA GMBH | 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 |
|---|---|---|---|---|
| rektālās putas | | | | |
| Budenofalk 2 mg tiesiosios žarnos putos | not available | LT/1/99/0416/003 (PACK SIZE 1) | DR FALK PHARMA GMBH | LT |
| Budenofalk 2 mg tiesiosios žarnos putos | not available | LT/1/99/0416/004 (PACK SIZE 2) | DR FALK PHARMA GMBH | LT |
| Budenofalk, 2 mg/dawkę, pianka doodbytnicza | not available | 17190 | DR FALK PHARMA GMBH | PL |
| Budenofalk 2 mg/odmerek rektalna pena | not available | H/02/00314/002 (PACK SIZE 1) | DR FALK PHARMA GMBH | SI |
| Budenofalk 2 mg/odmerek rektalna pena | not available | H/02/00314/003 (PACK SIZE 2) | DR FALK PHARMA GMBH | SI |
| Budenofalk rektálna pena | not available | 56/0644/11-S | DR FALK PHARMA GMBH | SK |
| Budenofalk Schuim, 2 mg/dosis schuim voor rectaal gebruik | not available | RVG 102383 | DR. FALK PHARMA BENELUX B.V. | NL |
| Budenofalk 3 mg gyomorsav ellenálló kemény kapszula | not available | OGYI-T-8898/01 | DR FALK PHARMA GMBH | HU |
| Budelin Novolizer 200 mikrograma prašak za inhaliranje | not available | UP/I-530-09/09-02/44 | MEDICAL INTERTRADE D.O.O. | HR |
| Budelin Novolizer 200 mikrograma prašak za inhaliranje | not available | UP/I-530-09/09-02/45 | MEDICAL INTERTRADE D.O.O. | HR |
| MIKICORT 3 mg, gélule | UK/H/0334/001 | 3400935692610 | LABORATOIRES MAYOLY | FR |

| Product Name (in authorisation country) | MRP/DCP Authorisation number | National Authorisation Number | MAH of product in the member state | Member State where product is authorised |
|---|---|---|---|---|
| gastro-résistante | | | SPINDLER | |
| MIKICORT 3 mg, gélule gastro-résistante | UK/H/0334/001 | 3400935692788 | LABORATOIRES MAYOLY SPINDLER | FR |
| MIKICORT 3 mg, gélule gastro-résistante | UK/H/0334/001 | 3400935692849 | LABORATOIRES MAYOLY SPINDLER | FR |
| MIKICORT 3 mg, gélule gastro-résistante | UK/H/0334/001 | 3400935692900 | LABORATOIRES MAYOLY SPINDLER | FR |
| MIKICORT 3 mg, gélule gastro-résistante | UK/H/0334/001 | 34009 356 925 5 9 | LABORATOIRES MAYOLY SPINDLER | FR |
| Budenofalk 3 mg enterokapseli | UK/H/0334/001/MR | 16110 | DR FALK PHARMA GMBH | FI |
| Budenofalk | UK/H/0334/001/MR | 31716 | DR FALK PHARMA GMBH | DK |
| Intesticort 3 mg, Capsula rigida gastroresistente | UK/H/0334/001/MR | 036507010/M (PACK SIZE 90) | DR FALK PHARMA GMBH | IT |
| Intesticort 3 mg, Capsula rigida gastroresistente | UK/H/0334/001/MR | 036507022/M (PACK SIZE 100) | DR FALK PHARMA GMBH | IT |
| Intesticort 3 mg, Capsula rigida gastroresistente | UK/H/0334/001/MR | 036507034/M (PACK SIZE 10) | DR FALK PHARMA GMBH | IT |
| Intesticort 3 mg, Capsula rigida gastroresistente | UK/H/0334/001/MR | 036507046/M (PACK SIZE 50) | DR FALK PHARMA GMBH | IT |
| Intesticort 3 mg, Capsula rigida gastroresistente | UK/H/0334/001/MR | 036507059/M (PACK SIZE 120) | DR FALK PHARMA GMBH | IT |
| Budenofalk 3mg gastro-resistant capsules | UK/H/0334/001/MR | PA 573/2/1 | DR FALK PHARMA GMBH | IE |
| Budenofalk 3 mg enterokapsel, hård | UK/H/0334/001/MR | 16612 | DR FALK PHARMA GMBH | SE |
| Intestifalk 3 mg cápsulas | UK/H/0334/001/MR | 65849 | DR FALK PHARMA GMBH | 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 |
|---|---|---|---|---|
| gastrorresistentes | | | | |
| Budenofalk 3mg gastro-resistant capsules | UK/H/0334/001/MR | PL 08637/0002 | DR FALK PHARMA GMBH | UK |
| Entocort 2 mg/100 ml tablett til rektalvæske, suspensjon | not available | 7835 | TILLOTTS PHARMA GMBH | NO |
| DESO 200 microgrammi soluzione pressurizzata per inalazione | IT/H/0124/001 | 036066013 | MASTER PHARMA S.R.L. | IT |
| DESO 200 microgrammi soluzione pressurizzata per inalazione | IT/H/0124/001 | 036066025 | MASTER PHARMA S.R.L. | IT |
| Ribuspir, 200 mikrogramów/dawkę odmierzoną, aerozol inhalacyjny, roztwór | IT/H/0124/001 | 11758 | CHIESI PHARMACEUTICALS GMBH | PL |
| Budenofalk 2mg/doză, spumă rectală | UK/H/0334/002/MR | 5237/2012/03 (PACK SIZE 1 CLINIC) | DR FALK PHARMA GMBH | RO |
| Budenofalk 2mg/doză, spumă rectală | UK/H/0334/002/MR | 5237/2012/02 (PACK SIZE 2) | DR FALK PHARMA GMBH | RO |
| Budenofalk 2 mg/dose ορθικός αφρός | UK/H/0334/002 | 63033/24-9-2015 | GALENICA SA | GR |
| Intesticort 2mg/dose schiuma rettale | UK/H/0334/002/MR | 036507061 (PACK SIZE 1) | DR FALK PHARMA GMBH | IT |
| Intesticort 2mg/dose schiuma rettale | UK/H/0334/002/MR | 036507085 (PACK SIZE 1 HOSPITAL) | DR FALK PHARMA GMBH | IT |
| Intesticort 2mg/dose schiuma rettale | UK/H/0334/002/MR | 036507073 (PACK SIZE 2) | DR FALK PHARMA GMBH | IT |

| 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 |
|---|---|---|---|---|
| Budo-San 2 mg/Sprühstoß - Rektalschaum | UK/H/0334/002 | 1-28553 | DR FALK PHARMA GMBH | AT |
| Budenofalk 2mg/annos rektaalivaahto | UK/H/0334/002/MR | 25346 | DR FALK PHARMA GMBH | FI |
| Budenofalk, 2 mg/dosis, rektal skum | UK/H/0334/002/MR | 43862 | DR FALK PHARMA GMBH | DK |
| Budenofalk 2mg/dose rectal foam | UK/H/0334/002/MR | PA 573/2/2 | DR FALK PHARMA GMBH | IE |
| Budenofalk 2 mg/dose Mousse rectale | UK/H/0334/002/MR | 2011080008 | DR FALK PHARMA GMBH | LU |
| Budenofalk 2mg/doza, spumă rectală | UK/H/0334/002/MR | 5237/2012/01 (PACK SIZE 1) | DR FALK PHARMA GMBH | RO |
| Budenofalk 2mg/dose rectal foam | UK/H/0334/002/MR | PL 08637/0011 | DR FALK PHARMA GMBH | UK |
| Budenofalk 2 mg/dos rektalskum | UK/H/0334/002/MR | 27882 | DR FALK PHARMA GMBH | SE |
| Intestifalk 2mg / dosis espuma rectal | UK/H/0334/002/MR | 71181 | DR FALK PHARMA GMBH | ES |
| Entocort 2 mg tablett och vätska till rektalsuspension | not available | 11679 | TILLOTTS PHARMA GMBH | SE |
| BUDENA 64 microgramos suspensión para pulverización nasal | not available | 68.584 | LABORATORIO ALDO-UNIÓN, S.L. | ES |
| BUDESONIDA ALDO-UNIÓN 200 microgramos/pulsación | not available | 61.664 | LABORATORIO ALDO-UNIÓN, S.L. | 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 |
|---|---|---|---|---|
| suspensión para inhalación en envase a presión | | | | |
| BUDESONIDA ALDO-UNIÓN 50 microgramos/pulsación suspensión para inhalación en envase a presión | not available | 61.663 | LABORATORIO ALDO-UNIÓN, S.L. | ES |
| Budesonida nasal Aldo-Unión 100 microgramos/dosis suspensión para pulverización nasal | not available | 61670 | LABORATORIO ALDO-UNIÓN, S.L. | ES |
| Entocort 3 mg | not available | 56/1056/97-C | TILLOTTS PHARMA GMBH | CZ |
| Entocord® 3 mg cápsulas de liberación modificada | not available | 61.728 | TILLOTTS PHARMA GMBH | ES |
| Budenofalk Uno 9 mg granule gastrorezistente | UK/H/2778/001/DC | 4227/2012/05 (PACK SIZE 60) | DR FALK PHARMA GMBH | RO |
| Budenofalk Uno 9 mg granule gastrorezistente | UK/H/2778/001/DC | 4227/2012/04 (PACK SIZE 50) | DR FALK PHARMA GMBH | RO |
| Budenofalk Uno 9 mg granule gastrorezistente | UK/H/2778/001/DC | 4227/2012/03 (PACK SIZE 30) | DR FALK PHARMA GMBH | RO |
| Budenofalk Uno 9 mg granule gastrorezistente | UK/H/2778/001/DC | 4227/2012/02 (PACK SIZE 20) | DR FALK PHARMA GMBH | RO |
| Budo-San Uno 9 mg - magensaftresistentes Granulat | UK/H/2778/001 | 1-30410 | DR FALK 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 |
|---|---|---|---|---|
| Budenofalk® Uno 9 mg γαστροανθεκτικά κοκκία | UK/H/2778/001 | 84604/28-11-11 | GALENICA SA | GR |
| Budenofalk 9 mg granulés gastro-résistants | UK/H/2778/001/DC | BE388717 | DR FALK PHARMA GMBH | BE |
| Буденофалк Уно 9 mg стомашно - устойчиви гранули | UK/H/2778/001/DC | 20110149 | DR FALK PHARMA GMBH | BG |
| Budenofalk Uno 9mg enterosolventní granule | UK/H/2778/001/DC | 56/056/11-C | DR FALK PHARMA GMBH | CZ |
| Budenofalk | UK/H/2778/001/DC | 45765 | DR FALK PHARMA GMBH | DK |
| Budenofalk 9mg enterorakeet | UK/H/2778/001/DC | 28000 | DR FALK PHARMA GMBH | FI |
| Budenofalk Uno 9mg magensaftresistentes Granulat | UK/H/2778/001/DC | 79697.00.00 | DR FALK PHARMA GMBH | DE |
| Budenofalk 9 mg gyomorsav ellenálló granulátum | UK/H/2778/001/DC | OGYI-T-8898/04 (PACK SIZE 30) | DR FALK PHARMA GMBH | HU |
| Budenofalk 9 mg gyomorsav ellenálló granulátum | UK/H/2778/001/DC | OGYI-T-8898/05 (PACK SIZE 60) | DR FALK PHARMA GMBH | HU |
| Budenofalk 9mg gastro-resistant granules | UK/H/2778/001/DC | PA 573/2/3 | DR FALK PHARMA GMBH | IE |
| Budenofalk Uno 9 mg zarnās šķīstošās granulas | UK/H/2778/001/DC | 11-0108 | DR FALK PHARMA GMBH | LV |
| Budenofalk 9mg granulés gastro-résistants | UK/H/2778/001/DC | 2011060005 | DR FALK PHARMA GMBH | LU |

| 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 |
|---|---|---|---|---|
| Budenofalk 9mg maagsapresistent granulaat | UK/H/2778/001/DC | RVG 106117 | DR FALK PHARMA GMBH | NL |
| Budenofalk Uno 9 mg skrandyje neirios granulės | UK/H/2778/001/DC | LT/1/12/3103/005 (PACK SIZE 60) | DR FALK PHARMA GMBH | LT |
| Budenofalk Uno 9 mg skrandyje neirios granulės | UK/H/2778/001/DC | LT/1/12/3103/004 (PACK SIZE 50) | DR FALK PHARMA GMBH | LT |
| Budenofalk Uno 9 mg skrandyje neirios granulės | UK/H/2778/001/DC | LT/1/12/3103/003 (PACK SIZE 30) | DR FALK PHARMA GMBH | LT |
| Budenofalk Uno 9 mg skrandyje neirios granulės | UK/H/2778/001/DC | LT/1/12/3103/002 (PACK SIZE 20) | DR FALK PHARMA GMBH | LT |
| Budenofalk Uno 9 mg skrandyje neirios granulės | UK/H/2778/001/DC | LT/1/12/3103/001 (PACK SIZE 15) | DR FALK PHARMA GMBH | LT |
| Budenofalk 9mg enterogranulat | UK/H/2778/001/DC | 09-7087 | DR FALK PHARMA GMBH | NO |
| Budenofalk Uno 9 mg granule gastrorezistente | UK/H/2778/001/DC | 4227/2012/01 (PACK SIZE 15) | DR FALK PHARMA GMBH | RO |
| Budenofalk 9 mg gastrorezistentný granulát | UK/H/2778/001/DC | 56/0071/11-S | DR FALK PHARMA GMBH | SK |
| Budenofalk 9mg gastrorezistentna zrnca | UK/H/2778/001/DC | 5363-I-958/11 (PACK SIZE 60) | DR FALK PHARMA GMBH | SI |
| Budenofalk 9mg | UK/H/2778/001/DC | 5363-I-957/11 (PACK SIZE 50) | DR FALK PHARMA GMBH | SI |

| 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 |
|---|---|---|---|---|
| gastrorezistentna zrnca | | | | |
| Budenofalk 9mg gastrorezistentna zrnca | UK/H/2778/001/DC | 5363-I-956/11 (PACK SIZE 30) | DR FALK PHARMA GMBH | SI |
| Budenofalk 9mg gastrorezistentna zrnca | UK/H/2778/001/DC | 5363-I-955/11 (PACK SIZE 20) | DR FALK PHARMA GMBH | SI |
| Budenofalk 9mg gastrorezistentna zrnca | UK/H/2778/001/DC | 5363-I-954/11 (PACK SIZE 15) | DR FALK PHARMA GMBH | SI |
| Budenofalk OD 9 mg granulado gastrorresistente | UK/H/2778/001/DC | 5354915 (PACK SIZE 20) | DR FALK PHARMA GMBH | PT |
| Budenofalk OD 9 mg granulado gastrorresistente | UK/H/2778/001/DC | 5354923 (PACK SIZE 60) | DR FALK PHARMA GMBH | PT |
| Budenofalk Uno 9mg gastro-resistant granules | UK/H/2778/001/DC | PL 08637/0020 | DR FALK PHARMA GMBH | UK |
| Intestifalk Uno 9 mg granulado gastrorresistente | UK/H/2778/001/DC | 75467 | DR FALK PHARMA GMBH | ES |
| Budenofalk 9 mg enterogranulat | UK/H/2778/001/DC | 43176 | DR FALK PHARMA GMBH | SE |
| Entocort® 2 mg tabletti ja liuotin peräruiskesuspensiota varten | not available | 11323 | TILLOTTS PHARMA GMBH | FI |
| Entocort® CR 3 mg Gastro-resistant Capsules, Hard | not available | PA2018/003/001 | TILLOTTS PHARMA GMBH | IE |

| 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 |
|---|---|---|---|---|
| Entocort 2 mg - Klistiertabletten mit Dispersionsmittel | not available | 1-20720 | TILLOTTS PHARMA GMBH | AT |
| RIBUJET, 200 microgramos/dosis, Solución para inhalación en envase a presión | not available | 60.500 | CHIESI ESPAÑA S.A. | ES |
| Larbex® 0,5 mg/2 ml Steri-Neb® Suspension für einen Vernebler | DE/H/1272/001 | 70568.00.00 | TEVA GMBH | DE |
| Budesonid Teva | DE-H-1272-001-DC | 41947 | TEVA DENMARK A/S | DK |
| Budesonide Teva 0,25 mg/ml sumutinsuspensio | DE/H/1272/001 | 24021 | TEVA SWEDEN AB | FI |
| Kabud, 0,25 mg/ml, zawiesina do nebulizacji | DE/H/1272/001 | 17546 | TEVA PHARMACEUTICALS POLSKA SP. Z O.O. | PL |
| Budesonide Teva 0.5mg/2mL Nebuliser suspension | DE/H/1272/001 | MA715/02301 | TEVA PHARMA B.V. | MT |
| Larbex Steri-Neb 0,5 mg/2 ml, vernevelsuspensie | DE/H/1272/001 | RVG 100826 | TEVA NEDERLAND B.V. | NL |
| Entocort depotkapsler 3 mg | not available | 94-3348 | TILLOTTS PHARMA GMBH | NO |
| Entocort® 3 mg depotkapseli, kova | not available | 11949 | TILLOTTS PHARMA GMBH | FI |
| Novolizer® Budesonid Meda 400 Mikrogramm, Pulver zur Inhalation | DE/H/0367/002 | 1-26081 | MEDA 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 |
|---|---|---|---|---|
| Budelin® Novolizer® 200 micrograms per actuation inhalation powder | DE/H/0367/001 | PL 15142/0054 | MEDA PHARMACEUTICALS LTD | UK |
| Budelin® Novolizer® 400 micrograms per actuation inhalation powder | DE/H/0367/002 | PL 15142/0055 | MEDA PHARMACEUTICALS LTD | UK |
| Novopulmon Novolizer 200 mikrogram/dos inhalationspulver | DE/H/0367/001 | 17906 | MEDA OY | FI |
| Novolizer Budesonide 200 Mikrogramm/Dosis, Pulver zur Inhalation | DE/H/0367/001 | BE255132 | S.A. MEDA PHARMA N.V. | BE |
| Novolizer Budesonide 400 Mikrogramm/Dosis, Pulver zur Inhalation | DE/H/0367/002 | BE291602 | S.A. MEDA PHARMA N.V. | BE |
| Novolizer Budesonide 200 Mikrogramm/Dosis, Pulver zur Inhalation | DE/H/0367/001 | 2005/040026 | S.A. MEDA PHARMA N.V. | LU |
| Novolizer Budesonide 400 Mikrogramm/Dosis, Pulver zur Inhalation | DE/H/0367/002 | 2007/070019 | S.A. MEDA PHARMA N.V. | LU |
| Novopulmon 200 Novolizer, Pulver zur Inhalation | DE/H/0367/001 | 36323.00.00 | MEDA PHARMA GMBH & CO. KG | DE |
| Novopulmon 400 Novolizer, Pulver zur Inhalation | DE/H/0367/002 | 36323.00.01 | MEDA PHARMA GMBH & CO. KG | DE |
| Budesonida Novolizer 200 | DE/H/0367/001 | 4454880 | MEDA PHARMA – PRODUTOS | 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 |
|---|---|---|---|---|
| microgramas pó para inalação | | | FARMACÊUTICOS, S.A. | |
| Budesonida Novolizer 200 microgramas pó para inalação | DE/H/0367/001 | 4454989 | MEDA PHARMA – PRODUTOS FARMACÊUTICOS, S.A. | PT |
| Budesonida Novolizer 200 microgramas pó para inalação | DE/H/0367/001 | 4455085 | MEDA PHARMA – PRODUTOS FARMACÊUTICOS, S.A. | PT |
| Budesonida Novolizer 200 microgramas pó para inalação | DE/H/0367/001 | 4455382 | MEDA PHARMA – PRODUTOS FARMACÊUTICOS, S.A. | PT |
| Budesonida Novolizer 200 microgramas pó para inalação | DE/H/0367/001 | 4455184 | MEDA PHARMA – PRODUTOS FARMACÊUTICOS, S.A. | PT |
| Budesonida Novolizer 200 microgramas pó para inalação | DE/H/0367/001 | 4455283 | MEDA PHARMA – PRODUTOS FARMACÊUTICOS, S.A. | PT |
| Budesonida Novolizer 400 microgramas pó para inalação | DE/H/0367/002 | 5567383 | MEDA PHARMA – PRODUTOS FARMACÊUTICOS, S.A. | PT |
| Budesonida Novolizer 400 microgramas pó para inalação | DE/H/0367/002 | 5567482 | MEDA PHARMA – PRODUTOS FARMACÊUTICOS, S.A. | PT |
| Budesonide Novolizer 200 microgram, inhalatiepoeder | DE/H/0367/001 | RVG 28795 | MEDA PHARMA B.V. | NL |
| Budesonide Novolizer 400 microgram, | DE/H/0367/002 | RVG 32454 | MEDA PHARMA B.V. | NL |

| Product Name (in authorisation country) | MRP/DCP Authorisation number | National Authorisation Number | MAH of product in the member state | Member State where product is authorised |
|---|---|---|---|---|
| inhalatiepoeder | | | | |
| Novolizer® Budesonid Meda 200 Mikrogramm, Pulver zur Inhalation | DE/H/0367/001 | 1-25536 | MEDA PHARMA GMBH | AT |
| NOVOLIZER BUDESONIDE 400 microgrammes/dose, poudre pour inhalation | DE/H/0367/002 | 2007/070019 | S.A. MEDA PHARMA N.V. | LU |
| Novolizer Budesonide 400 micrograms inhalation powder | DE/H/0367/002 | PA1332/14/2 | MEDA HEALTH SALES IRELAND LIMITED | IE |
| Novolizer Budesonide 400 microgram/dosis, inhalatiepoeder. | DE/H/0367/002 | BE291602 | S.A. MEDA PHARMA N.V. | BE |
| Novolizer Budesonide 200 microgram/dosis, inhalatiepoeder. | DE/H/0367/001 | BE255132 | S.A. MEDA PHARMA N.V. | BE |
| Novolizer Budesonide 200 micrograms inhalation powder | DE/H/0367/001 | PA1332/14/1 | MEDA HEALTH SALES IRELAND LIMITED | IE |
| NOVOLIZER BUDESONIDE 200 microgrammes/dose, poudre pour inhalation | DE/H/0367/001 | 2005/040026 | S.A. MEDA PHARMA N.V. | LU |
| NOVOLIZER BUDESONIDE 400 microgrammes/dose, poudre pour inhalation | DE/H/0367/002 | BE291602 | S.A. MEDA 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 |
|---|---|---|---|---|
| Novopulm Novolizer 200 microgramos polvo para inhalación | DE/H/0367/001 | 65536 | MEDA PHARMA S.A.U. | ES |
| NOVOLIZER BUDESONIDE 200 microgrammes/dose, poudre pour inhalation | DE/H/0367/001 | BE255132 | S.A. MEDA PHARMA N.V. | BE |
| Novopulmon Novolizer 200 mikrog/annos inhalaatiojauhe | DE/H/0367/001 | 17906 | MEDA OY | FI |
| Novopulm Novolizer 400 microgramos polvo para inhalación. | DE/H/0367/002 | 67103 | MEDA PHARMA S.A.U. | ES |
| NOVOPULMON NOVOLIZER 200 microgrammes/dose, poudre pour inhalation | DE/H/0367/001 | 362 937-1 | MEDA PHARMA SAS | FR |
| NOVOPULMON NOVOLIZER 200 microgrammes/dose, poudre pour inhalation | DE/H/0367/001 | 362 938-8 | MEDA PHARMA SAS | FR |
| NOVOPULMON NOVOLIZER 200 microgrammes/dose, poudre pour inhalation | DE/H/0367/001 | 362 939-4 | MEDA PHARMA SAS | FR |
| NOVOPULMON NOVOLIZER 200 microgrammes/dose, | DE/H/0367/001 | 362 940-2 | MEDA PHARMA SAS | FR |

| Product Name (in authorisation country) | MRP/DCP Authorisation number | National Authorisation Number | MAH of product in the member state | Member State where product is authorised |
|---|---|---|---|---|
| poudre pour inhalation | | | | |
| NOVOPULMON NOVOLIZER 200 microgrammes/dose, poudre pour inhalation | DE/H/0367/001 | 362 941-9 | MEDA PHARMA SAS | FR |
| Novopulmon Novolizer200 mikrogram/dose inhalasjonspulver | DE/H/0367/01-02/MR | 02-1578 | MEDA AS | NO |
| Novopulmon Novolizer 200 mikrogram/dos inhalationspulver | DE/H/0367/001 | 19126 | MEDA AB | SE |
| NOVOPULMON NOVOLIZER 400 microgrammes/dose, poudre pour inhalation | DE/H/0367/002 | 369 845-5 | MEDA PHARMA SAS | FR |
| NOVOPULMON NOVOLIZER 200 microgrammes/dose, poudre pour inhalation | DE/H/0367/001 | 564 974-5 | MEDA PHARMA SAS | FR |
| NOVOPULMON NOVOLIZER 400 microgrammes/dose, poudre pour inhalation | DE/H/0367/002 | 369 846-1 | MEDA PHARMA SAS | FR |
| NOVOPULMON NOVOLIZER 400 microgrammes/dose, poudre pour inhalation | DE/H/0367/002 | 369 847 8 | MEDA PHARMA SAS | FR |

| Product Name (in authorisation country) | MRP/DCP Authorisation number | National Authorisation Number | MAH of product in the member state | Member State where product is authorised |
|---|---|---|---|---|
| NOVOPULMON NOVOLIZER 400 microgrammes/dose, poudre pour inhalation | DE/H/0367/002 | 369 848-4 | MEDA PHARMA SAS | FR |
| Budesonide Viatris Novolizer 200 microgrammi polvere per inalazione | DE/H/0367/001 | 036004012 | MEDA PHARMA S.P.A. | IT |
| Budesonide Viatris Novolizer 200 microgrammi polvere per inalazione | DE/H/0367/001 | 036004036 | MEDA PHARMA S.P.A. | IT |
| NOVOPULMON NOVOLIZER 400 microgrammes/dose, poudre pour inhalation | DE/H/0367/002 | 369 849-0 | MEDA PHARMA SAS | FR |
| NOVOPULMON NOVOLIZER 400 microgrammes/dose, poudre pour inhalation | DE/H/0367/002 | 369 850-9 | MEDA PHARMA SAS | FR |
| NOVOPULMON NOVOLIZER 400 microgrammes/dose, poudre pour inhalation | DE/H/0367/002 | 567 424-6 | MEDA PHARMA SAS | FR |
| Budesonide Viatris Novolizer 200 microgrammi polvere per inalazione | DE/H/0367/001 | 036004024 | MEDA PHARMA S.P.A. | IT |

| 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 |
|---|---|---|---|---|
| NOVOPULMON NOVOLIZER 400 microgrammes/dose, poudre pour inhalation | DE/H/0367/002 | 567 425-2 | MEDA PHARMA SAS | FR |
| Budesonide Viatris Novolizer 200 microgrammi polvere per inalazione | DE/H/0367/001 | 036004051 | MEDA PHARMA S.P.A. | IT |
| Budesonide Viatris Novolizer 200 microgrammi polvere per inalazione | DE/H/0367/001 | 036004048 | MEDA PHARMA S.P.A. | IT |
| Budesonide Viatris Novolizer 200 microgrammi polvere per inalazione | DE/H/0367/001 | 036004063 | MEDA PHARMA S.P.A. | IT |
| Budesonide Viatris Novolizer 400 microgrammi polvere per inalazione | DE/H/0367/002 | 036004075 | MEDA PHARMA S.P.A. | IT |
| Budesonide Viatris Novolizer 400 microgrammi polvere per inalazione | DE/H/0367/002 | 036004087 | MEDA PHARMA S.P.A. | IT |
| Budesonide Viatris Novolizer 400 microgrammi polvere per inalazione | DE/H/0367/002 | 036004099 | MEDA PHARMA S.P.A. | IT |

| 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 |
|---|---|---|---|---|
| Budesonide Viatris Novolizer 400 microgrammi polvere per inalazione | DE/H/0367/002 | 036004101 | MEDA PHARMA S.P.A. | IT |
| Budesonide Viatris Novolizer 400 microgrammi polvere per inalazione | DE/H/0367/002 | 036004113 | MEDA PHARMA S.P.A. | IT |
| Budesonide Viatris Novolizer 400 microgrammi polvere per inalazione | DE/H/0367/002 | 036004125 | MEDA PHARMA S.P.A. | IT |
| Budesonide Viatris Novolizer 400 microgrammi polvere per inalazione | DE/H/0367/002 | 036004137 | MEDA PHARMA S.P.A. | IT |
| Budesonide Viatris Novolizer 400 microgrammi polvere per inalazione | DE/H/0367/002 | 036004149 | MEDA PHARMA S.P.A. | IT |
| Novopulmon Novolizer, inhalationspulver 200 mikrogram | DE/H/0367/001 | 34539 | MEDA AS | DK |
| Budesonide Apotex nevel 50, 50 microgram/dosis, neusspray, suspensie | not available | RVG 24012 | APOTEX EUROPE B.V. | NL |
| Budesonide Apotex nevel 100, 100 | not available | RVG 24013 | APOTEX EUROPE B.V. | NL |

| Product Name (in authorisation country) | MRP/DCP Authorisation number | National Authorisation Number | MAH of product in the member state | Member State where product is authorised |
|---|---|---|---|---|
| microgram/dosis, neusspray, suspensie | | | | |