



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

8 March 2018
EMA/113637/2018
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: landiolol

Procedure no.: PSUSA/00010570/201708

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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 |
|---|-------------------------------------|--------------------------------------|---|---|
| Rapibloc, pulver til infusionsvæske, opløsning | NL/H/3368/001 | 55316 | AMOMED PHARMA GMBH | DK |
| Rapibloc, pulver til infusionsvæske, opløsning | NL/H/3368/002 | 55317 | AMOMED PHARMA GMBH | DK |
| Rapibloc, koncentrat til injektionsvæske, opløsning | NL/H/3368/003 | 55318 | AMOMED PHARMA GMBH | DK |
| Raploc, pulver til infusionsvæske, opløsning | NL/H/3368/001 | 15-10508 | AMOMED PHARMA GMBH | NO |
| Raploc, pulver til infusionsvæske, opløsning | NL/H/3368/002 | 15-10509 | AMOMED PHARMA GMBH | NO |
| Raploc, konsentrat til injeksjonsvæske, oppløsning | NL/H/3368/003 | 15-10510 | AMOMED PHARMA GMBH | NO |
| Rapibloc 300 mg Pulver zur Herstellung einer Infusionslösung | NL/H/3368/001 | 94094.00.00 | AMOMED PHARMA GMBH | DE |
| Rapibloc 600 mg Pulver zur Herstellung einer Infusionslösung | NL/H/3368/002 | 94095.00.00 | AMOMED PHARMA GMBH | DE |
| Rapibloc 20 mg/2 ml Konzentrat zur Herstellung einer Injektionslösung | NL/H/3368/003 | 94096.00.00 | AMOMED PHARMA GMBH | DE |
| Raploc 300 mg infusioonilahuse pulber | NL/H/3368/001 | 918316 | AMOMED PHARMA GMBH | EE |

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| Raploc 600 mg infusioonilahuse pulber | NL/H/3368/002 | 918416 | AMOMED PHARMA GMBH | EE |
| Raploc 20 mg/2 ml süstelahuse kontsentraat | NL/H/3368/003 | 918516 | AMOMED PHARMA GMBH | EE |
| Rapibloc 300 mg innrennslisstofn, lausn | NL/H/3368/001 | IS/1/17/009/01 | AMOMED PHARMA GMBH | IS |
| Rapibloc 600 mg innrennslisstofn, lausn | NL/H/3368/002 | IS/1/17/009/02 | AMOMED PHARMA GMBH | IS |
| Rapibloc 20 mg/2 ml stungulyfsþykkni, lausn | NL/H/3368/003 | IS/1/17009/03 | AMOMED PHARMA GMBH | IS |
| Raploc 300 mg miltelíai infuzíníam tirlalui | NL/H/3368/001 | LT/1/17/4047/002 | AMOMED PHARMA GMBH | LT |
| Raploc 600 mg miltelíai infuzíníam tirlalui | NL/H/3368/002 | LT/1/17/4047/003 | AMOMED PHARMA GMBH | LT |
| Raploc 20 mg/2 ml koncentratas injekcíníam tirlalui | NL/H/3368/003 | LT/1/17/4047/001 | AMOMED PHARMA GMBH | LT |
| Rapibloc 300 mg poeder voor oplossing voor infusie | NL/H/3368/001 | RVG 116682 | AMOMED PHARMA GMBH | NL |
| Rapibloc 600 mg poeder voor oplossing voor infusie | NL/H/3368/002 | RVG 116683 | AMOMED PHARMA GMBH | NL |
| Rapibloc 20 mg/2 ml concentraat voor oplossing voor injectie | NL/H/3368/003 | RVG 116684 | AMOMED PHARMA GMBH | NL |
| Rapibloc 300 mg prášok na infúzný roztok | NL/H/3368/001 | 13/0443/16-S | AMOMED PHARMA GMBH | SK |

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| Rapibloc 600 mg prášok na infúzny roztok | NL/H/3368/002 | 13/0443/16-S | AMOMED PHARMA GMBH | SK |
| Rapibloc 20 mg/2 ml injekčný koncentrát | NL/H/3368/003 | 13/0445/16-S | AMOMED PHARMA GMBH | SK |
| Рапиблок 300 mg прах за инфузионен разтвор | NL/H/3368/002 | 20160357 | AMOMED PHARMA GMBH | BG |
| Рапиблок 600 mg прах за инфузионен разтвор | NL/H/3368/001 | 20160358 | AMOMED PHARMA GMBH | BG |
| Рапиблок 20 mg/2 ml концентрат за инжекционен разтвор | NL/H/3368/003 | 20160359 | AMOMED PHARMA GMBH | BG |
| Rapibloc 20 mg/2 ml concentrate for solution for injection | NL/H/3368/003 | MA1169/00103 | AMOMED PHARMA GMBH | MT |
| Rapibloc 300 mg powder for solution for infusion | NL/H/3368/001 | MA1169/00101 | AMOMED PHARMA GMBH | MT |
| Rapibloc 600 mg powder for solution for infusion | NL/H/3368/002 | MA1169/00102 | AMOMED PHARMA GMBH | MT |
| Rapibloc 20 mg/2 ml Konzentrat zur Herstellung einer Injektionslösung | NL/H/3368/003 | 137586 | AMOMED PHARMA GMBH | AT |
| Rapibloc 300 mg Pulver zur Herstellung einer Infusionslösung | NL/H/3368/001 | 137584 | AMOMED PHARMA GMBH | AT |
| Rapibloc 600 mg Pulver zur Herstellung einer Infusionslösung | NL/H/3368/002 | 137585 | AMOMED PHARMA GMBH | AT |

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| Runrapiq, 20 mg/2 ml, koncentrat do sporządzania roztworu do wstrzykiwań | NL/H/3368/003 | 23882 | AMOMED PHARMA GMBH | PL |
| Runrapiq, 300 mg, proszek do sporządzania roztworu do infuzji | NL/H/3368/001 | 23880 | AMOMED PHARMA GMBH | PL |
| Runrapiq, 600 mg, proszek do sporządzania roztworu do infuzji | NL/H/3368/002 | 23881 | AMOMED PHARMA GMBH | PL |
| RAPIBLOC 20 mg/2 ml, solution à diluer injectable | NL/H/3368/003 | 3400955026914 | AMOMED PHARMA GMBH | FR |
| RAPIBLOC 300 mg, poudre pour solution pour perfusion | NL/H/3368/001 | 3400955026938 | AMOMED PHARMA GMBH | FR |
| RAPIBLOC 600 mg, poudre pour solution pour perfusion | NL/H/3368/002 | 3400955026945 | AMOMED PHARMA GMBH | FR |
| Rapibloc 20 mg/2 ml koncentrat pentru soluție injectabilă | NL/H/3368/003 | 9440/2016/01 | AMOMED PHARMA GMBH | RO |
| Rapibloc 300 mg pulbere pentru soluție perfuzabilă | NL/H/3368/001 | 9438/2016/01 | AMOMED PHARMA GMBH | RO |
| Rapibloc 600 mg pulbere pentru soluție perfuzabilă | NL/H/3368/002 | 9439/2016/01 | AMOMED PHARMA GMBH | RO |

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| Rapibloc 20 mg/2ml koncentrat za raztopino za injiciranje | NL/H/3368/003 | H/16/02273/001 | AMOMED PHARMA GMBH | SI |
| Rapibloc 300 mg prašek za raztopino za infundiranje | NL/H/3368/001 | H/16/02273/002 | AMOMED PHARMA GMBH | SI |
| Rapibloc 600 mg prašek za raztopino za infundiranje | NL/H/3368/002 | H/16/02273/003 | AMOMED PHARMA GMBH | SI |
| Rapibloc 300 mg prášek pro infuzní roztok | NL/H/3368/001 | 58/487/14-C | AOP ORPHAN PHARMACEUTICALS AG | CZ |
| Rapibloc 20 mg/2 ml koncentrát pro injekční roztok | NL/H/3368/003 | 58/486/14-C | AOP ORPHAN PHARMACEUTICALS AG | CZ |
| Rapibloc 600 mg prášek pro infuzní roztok | NL/H/3368/002 | 58/488/14-C | AOP ORPHAN PHARMACEUTICALS AG | CZ |
| Landiobloc 300 mg polvere per soluzione per infusione | NL/H/3368/001 | 044274013 | AOP ORPHAN PHARMACEUTICALS AG | IT |
| Landiobloc 600 mg polvere per soluzione per infusione | NL/H/3368/002 | 044274025 | AOP ORPHAN PHARMACEUTICALS AG | IT |
| Landiobloc 20 mg/2 ml concentrato per soluzione per infusione | NL/H/3368/003 | 044274037 | AOP ORPHAN PHARMACEUTICALS AG | IT |
| Rapibloc 20 mg/2 ml koncentrátum oldatos infúzióhoz | NL/H/3368/003 | OGYI-T-23162/03 | AMOMED PHARMA GMBH | HU |

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| Rapibloc 300 mg por oldatos infúzióhoz | NL/H/3368/001 | OGYI-T-23162/01 | AMOMED PHARMA GMBH | HU |
| Rapibloc 600 mg por oldatos infúzióhoz | NL/H/3368/002 | OGYI-T-23162/02 | AMOMED PHARMA GMBH | HU |
| Rapibloc 10 mg/ml koncentrat till injektionsvätska, lösning | NL/H/3368/003 | 52383 | AMOMED PHARMA GMBH | SE |
| Rapibloc 300 mg/50 ml pulver till infusionsvätska, lösning | NL/H/3368/001 | 52381 | AMOMED PHARMA GMBH | SE |
| Rapibloc 600 mg/50 ml pulver till infusionsvätska, lösning | NL/H/3368/002 | 52382 | AMOMED PHARMA GMBH | SE |
| Raploc 20 mg/2 ml koncentrāts injekciju šķīduma pagatavošanai | NL/H/3368/003 | 17-0021 | AMOMED PHARMA GMBH | LV |
| Raploc 300 mg pulveris infūziju šķīduma pagatavošanai | NL/H/3368/001 | 17-0019 | AMOMED PHARMA GMBH | LV |
| Raploc 600 mg pulveris infūziju šķīduma pagatavošanai | NL/H/3368/002 | 17-0020 | AMOMED PHARMA GMBH | LV |