



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

14 June 2019
EMA/143917/2020
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: human coagulation factor viii / human von willebrand factor

Procedure no.: PSUSA/00001621/201810

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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 |
|---|-------------------------------------|--------------------------------------|---|---|
| Haemate, pulver og solvens til injektions- og infusionsvæske, opløsning | not available | 11799 | CSL BEHRING GMBH | DK |
| Haemate, pulver og solvens til injektions- og infusionsvæske, opløsning | not available | 11799 | CSL BEHRING GMBH | DK |
| Haemate 1000 IU FVIII/2400 IU VWF injektio-/infuusiokuiva-aine ja liuotin, liuosta varten | not available | 23504 | CSL BEHRING GMBH | FI |
| Haemate 250 IU FVIII/600 IU VWF injektio-/infuusiokuiva-aine ja liuotin, liuosta varten | not available | 23502 | CSL BEHRING GMBH | FI |
| Haemate 500 IU FVIII/1200 IU VWF injektio-/infuusiokuiva-aine ja liuotin, liuosta varten | not available | 23502 | CSL BEHRING GMBH | FI |
| Haemate P 500 IU prášok a rozpúšťadlo na injekčný/infúzny roztok | not available | 16/0158/84-C/S | CSL BEHRING GMBH | SK |
| Haemate P 1 000 IU prášok a rozpúšťadlo na injekčný/infúzny roztok | not available | 16/0334/17-S | CSL BEHRING GMBH | SK |

| 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 |
|--|-------------------------------------|--------------------------------------|---|---|
| WILSTART, poudres et solvants pour solution injectable | not available | 34009 564 516 7 8 | LFB BIOMEDICAMENTS | FR |
| Immunate 500 IU FVIII/375 IU vWF prašak i otapalo za otopinu za injekciju | not available | HR-H-927359696 | AGMAR D.O.O. | HR |
| Immunate 1000 IU FVIII/750 IU vWF prašak i otapalo za otopinu za injekciju | not available | HR-H-020604046 | AGMAR D.O.O. | HR |
| Haemate P 500 /1000 Polvere e solvente per soluzione per iniezione o infusione | not available | 026600078 | CSL BEHRING GMBH | IT |
| Haemate P 500 /1000 Polvere e solvente per soluzione per iniezione o infusione | not available | 026600080 | CSL BEHRING GMBH | IT |
| Haemate P 1000 IU Powder and solvent for solution for injection or infusion | not available | PL 15036/0010 | CSL BEHRING GMBH | UK |
| Haemate P 1200 IU VWF/500 IU FVIII prašak i otapalo za otopinu za injekciju/infuziju | not available | HR-H-533693582 | CSL BEHRING GMBH | HR |

| 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 |
|---|-------------------------------------|--------------------------------------|---|---|
| Fanhdi 25 UI/ml Pó e solvente para solução injetável | not available | 3794583 | INSTITUTO GRIFOLS, S.A. | PT |
| Fanhdi 50 UI/ml Pó e solvente para solução injetável. | not available | 3794682 | INSTITUTO GRIFOLS, S.A. | PT |
| Fanhdi 100 UI/ml (1000 UI/10 ml, 1500 UI/15 ml) Pó e solvente para solução injetável | not available | 3794781 | INSTITUTO GRIFOLS, S.A. | PT |
| Fanhdi 100 UI/ml (1000 UI/10 ml, 1500 UI/15 ml) Pó e solvente para solução injetável | not available | 5047378 | INSTITUTO GRIFOLS, S.A. | PT |
| HAEMATE P 2400/1000 UI, polvo y disolvente para solución inyectable o perfusión | not available | 56.868 | CSL BEHRING, S.A | ES |
| HAEMATE P 1200/500 UI, polvo y disolvente para solución inyectable o perfusión | not available | 56.867 | CSL BEHRING, S.A | ES |
| Haemate P 500 i.e./1200 i.e. prašek in vehikel za raztopino za injiciranje/infundiranje | not available | H/93/00718/001 | CSL BEHRING GMBH | SI |

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|---|-------------------------------------|--------------------------------------|---|---|
| Haemate P 500 i.e./1200 i.e. prašek in vehikel za raztopino za injiciranje/infundiranje | not available | H/93/00718/002 | CSL BEHRING GMBH | SI |
| Haemate□P 250 IU/vial / 500 IU/vial / 1000 IU/vial. Κόνις και διαλύτης για παρασκευή ενεσίμου διαλύματος ή διαλύματος προς έγχυση | not available | 15649/08-03-2011 | CSL BEHRING MEPE | GR |
| Haemate□P 250 IU/vial Κόνις και διαλύτης για παρασκευή ενεσίμου διαλύματος ή διαλύματος προς έγχυση | not available | 15646/08-03-2011 | CSL BEHRING MEPE | GR |
| Haemate®P 500 IU/vial Κόνις και διαλύτης για παρασκευή ενεσίμου διαλύματος ή διαλύματος προς έγχυση | not available | 15647/08-03-2011 | CSL BEHRING MEPE | GR |
| Fanhdi 250 NE por és oldószer oldatos injekcióhoz | not available | OGYI-T-4559/01 | INSTITUTO GRIFOLS, S.A. | HU |
| Fanhdi 500 NE por és oldószer oldatos injekcióhoz | not available | OGYI-T-4559/02 | INSTITUTO GRIFOLS, S.A. | HU |

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|--|-------------------------------------|--------------------------------------|---|---|
| Fanhdi 1000 NE por és oldószer oldatos injekcióhoz | not available | OGYI-T-4559/03 | INSTITUTO GRIFOLS, S.A. | HU |
| ALPHANATE 250 UI + 300 UI / 5 ml Polvere e solvente per soluzione per infusione | not available | 033077088 | GRIFOLS ITALIA S.P.A | IT |
| ALPHANATE 500 UI + 600 UI / 5 ml Polvere e solvente per soluzione per infusione | not available | 033077090 | GRIFOLS ITALIA S.P.A | IT |
| ALPHANATE 1000 UI + 1200 UI / 10 ml Polvere e solvente per soluzione per infusione | not available | 033077102 | GRIFOLS ITALIA S.P.A | IT |
| ALPHANATE 1500 UI + 1800 UI / 10 ml Polvere e solvente per soluzione per infusione | not available | 033077114 | GRIFOLS ITALIA S.P.A | IT |
| FANHDI 25 IU/ml, prášek a rozpouštědlo pro injekční roztok | not available | 16/053/97-C | INSTITUTO GRIFOLS, S.A. | CZ |
| FANHDI 50 IU/ml, prášek a rozpouštědlo pro injekční roztok | not available | 16/054/97-C | INSTITUTO GRIFOLS, S.A. | CZ |
| FANHDI 100 IU/ml, prášek a rozpouštědlo pro injekční roztok | not available | 16/055/97-C | INSTITUTO GRIFOLS, S.A. | CZ |

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| Alphanate®, powder for injection | not available | PL 12930/0015 | INSTITUTO GRIFOLS, S.A. | UK |
| Alphanate®, powder for injection | not available | PL 12930/0015 | INSTITUTO GRIFOLS, S.A. | UK |
| Alphanate®, powder for injection | not available | PL 12930/0015 | INSTITUTO GRIFOLS, S.A. | UK |
| Alphanate®, powder for injection | not available | PL 12930/0017 | INSTITUTO GRIFOLS, S.A. | UK |
| Immunate, 250 IE pulver och vätska till injektions-/infusionsvätska, lösning | not available | 11880 | BAXALTA INNOVATIONS GMBH | SE |
| Immunate, 500 IE pulver och vätska till injektions-/infusionsvätska, lösning | not available | 11881 | BAXALTA INNOVATIONS GMBH | SE |
| Immunate, 1000 IE pulver och vätska till injektions-/infusionsvätska, lösning | not available | 11882 | BAXALTA INNOVATIONS GMBH | SE |
| Plitate 250 UI + 300 UI / 10 ml Polvere e solvente per soluzione per infusione | not available | 044564019 | GRIFOLS ITALIA S.P.A | IT |
| Plitate 500 UI + 600 UI / 10 ml Polvere e solvente per soluzione per | not available | 044564021 | GRIFOLS ITALIA S.P.A | IT |

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| infusione | | | | |
| Plitate 1000 UI + 1200 UI / 10 ml Polvere e solvente per soluzione per infusione | not available | 044564033 | GRIFOLS ITALIA S.P.A | IT |
| Plitate 1500 UI + 1800 UI / 15 ml Polvere e solvente per soluzione per infusione | not available | 044564045 | GRIFOLS ITALIA S.P.A | IT |
| Haemate® P 2400/1000 Poudre et solvant pour solution injectable /pour perfusion | not available | BE179024 | CSL BEHRING GMBH | BE |
| Haemate® P 2400/1000 Poeder en oplosmiddel voor oplossing voor injectie of infusie | not available | BE179024 | CSL BEHRING GMBH | BE |
| Haemate® P 600/250 Poudre et solvant pour solution injectable /pour perfusion | not available | BE154481 | CSL BEHRING GMBH | BE |
| Haemate® P 1200/500 Poudre et solvant pour solution injectable /pour perfusion | not available | BE179015 | CSL BEHRING GMBH | BE |

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| Haemate® P 600/250 Poeder en oplosmiddel voor oplossing voor injectie of infusie | not available | BE154481 | CSL BEHRING GMBH | BE |
| Haemate® P 1200/500 Poeder en oplosmiddel voor oplossing voor injectie of infusie | not available | BE179015 | CSL BEHRING GMBH | BE |
| Haemate P 1000 Proszek i rozpuszczalnik do sporządzania roztworu do wstrzykiwań lub infuzji | not available | 4701 | CSL BEHRING GMBH | PL |
| Haemate P 250 Proszek i rozpuszczalnik do sporządzania roztworu do wstrzykiwan lub infuzji | not available | 4699 | CSL BEHRING GMBH | PL |
| Haemate P 500 Proszek i rozpuszczalnik do sporządzania roztworu do wstrzykiwań lub infuzji | not available | 4700 | CSL BEHRING GMBH | PL |
| Wilate 500 500 UI FVW / 500 UI FVIII pulbere si solvent pentru solutie injectabila | DE/H/0471/003 | 6978/2014/01 | OCTAPHARMA (IP) SPRL | RO |
| Wilate 1000 1000 UI FVW / 1000 UI FVIII pulbere si solvent pentru solutie injectabila | DE/H/0471/004 | 6979/2014/01 | OCTAPHARMA (IP) SPRL | RO |

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| Wilate 500 i.e./500 i.e. prašek in vehikel za raztopino za injiciranje | DE/H/0471/003 | H/10/01666/001 | OCTAPHARMA (IP) SPRL | SI |
| Wilate 1000 i.e./1000 i.e. prašek in vehikel za raztopino za injiciranje | DE/H/0471/004 | H/10/01666/002 | OCTAPHARMA (IP) SPRL | SI |
| Wilate 900 I.E. FVIII und 800 I.E. VWF Pulver und Lösungsmittel zur Herstellung einer Injektionslösung | DE/H/0471/002 | 2-00330 | OCTAPHARMA PHARMAZEUTIKA PRODUKTIONSGESMBH | AT |
| Wilate 450 I.E. FVIII und 400 I.E. VWF Pulver und Lösungsmittel zur Herstellung einer Injektionslösung | DE/H/0471/001 | 2-00329 | OCTAPHARMA PHARMAZEUTIKA PRODUKTIONSGESMBH | AT |
| Wilate 500 I.E. VWF und 500 I.E. FVIII Pulver und Lösungsmittel zur Herstellung einer Injektionslösung | DE/H/0471/003 | 2-00392 | OCTAPHARMA PHARMAZEUTIKA PRODUKTIONSGESMBH | AT |
| Wilate 1000 I.E. VWF und 1000 I.E. FVIII Pulver und Lösungsmittel zur Herstellung einer Injektionslösung | DE/H/0471/004 | 2-00393 | OCTAPHARMA PHARMAZEUTIKA PRODUKTIONSGESMBH | AT |

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|--|-------------------------------------|--------------------------------------|---|---|
| Immunate 250 U.I./5 ml + 190 U.I./5 ml pó e solvente para solução injectável | AT/H/0154/001 | 5620786 | BAXALTA INNOVATIONS GMBH | PT |
| Talate 250 UI / 190 UI polvere e solvente per soluzione iniettabile | AT/H/0154/001 | 037148018 | BAXALTA INNOVATIONS GMBH | IT |
| Talate 500 UI / 375 UI polvere e solvente per soluzione iniettabile | AT/H/0154/002 | 037148020 | BAXALTA INNOVATIONS GMBH | IT |
| Talate 1000 UI / 750 UI polvere e solvente per soluzione iniettabile | AT/H/0154/003 | 037148032 | BAXALTA INNOVATIONS GMBH | IT |
| Immunate 1000 IE FVIII / 750 IE VWF poeder en oplosmiddel voor oplossing voor injectie | AT/H/0154/003 | RVG 32617 | BAXALTA INNOVATIONS GMBH | NL |
| Immunate 500 IE FVIII / 375 IE VWF poeder en oplosmiddel voor oplossing voor injectie | AT/H/0154/002 | RVG 32616 | BAXALTA INNOVATIONS GMBH | NL |
| Immunate 250 IE FVIII / 190 IE VWF poeder en oplosmiddel voor oplossing voor injectie | AT/H/0154/001 | RVG 32615 | BAXALTA INNOVATIONS GMBH | NL |
| Immunate 1000 U.I./10 ml + 750 U.I./10 ml pó e solvente para solução | AT/H/0154/003 | 5620984 | BAXALTA INNOVATIONS GMBH | PT |

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|---|-------------------------------------|--------------------------------------|---|---|
| injectável | | | | |
| Immunate 500 U.I./5 ml + 375 U.I./5 ml pó e solvente para solução injectável | AT/H/0154/002 | 5620885 | BAXALTA INNOVATIONS GMBH | PT |
| WILATE 500, 500 IU VWF/500 IU F VIII powder and solvent for solution for injection | DE/H/0471/003 | 20110733 | OCTAPHARMA (IP) SPRL | BG |
| WILATE 1000, 1000 IU VWF/1000 IU F VIII powder and solvent for solution for injection | DE/H/0471/004 | 20110734 | OCTAPHARMA (IP) SPRL | BG |
| Wilate 500, 500 IU VWF/500 IU FVIII, prášek a rozpouštědlo pro injekční roztok | DE/H/0471/003 | 75/001/12-C | OCTAPHARMA (IP) SPRL | CZ |
| Wilate 1000, 1000 IU VWF/1000 IU FVIII, prášek a rozpouštědlo pro injekční roztok | DE/H/0471/004 | 75/002/12-C | OCTAPHARMA (IP) SPRL | CZ |
| Wilate 500, 500 RÜ VWF/500 RÜ FVIII, süstelahuse pulber ja lahusti | DE/H/0471/003 | 777012 | OCTAPHARMA (IP) SPRL | EE |

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|--|-------------------------------------|--------------------------------------|---|---|
| Wilate 1000, 1000 RÜ VWF/1000 RÜ FVIII, süstelahuse pulber ja lahusti | DE/H/0471/004 | 776912 | OCTAPHARMA (IP) SPRL | EE |
| Wilate, 1000 IU VWF / 1000 IU FVIII, injektiokuiva-aine ja liuotin, liuosta varten | DE/H/0471/004 | 29338 | OCTAPHARMA AB | FI |
| Wilate, 500 IU VWF / 500 IU FVIII, injektiokuiva-aine ja liuotin, liuosta varten | DE/H/0471/003 | 29339 | OCTAPHARMA AB | FI |
| Wilate 1000 NE VWF/1000 NE FVIII por és oldószer oldatos injekcióhoz | DE/H/0471/004 | OGYI-T-21152/04 | OCTAPHARMA (IP) SPRL | HU |
| Wilate 500 NE VWF/500 NE FVIII por és oldószer oldatos injekcióhoz | DE/H/0471/003 | OGYI-T-21152/03 | OCTAPHARMA (IP) SPRL | HU |
| Wilate 500 TV/500 TV milteliai ir tirpiklis injekciniam tirpalui | DE/H/0471/003 | LT/1/09/1830/003 | OCTAPHARMA (IP) SPRL | LT |
| Wilate 1000 TV/1000 TV milteliai ir tirpiklis injekciniam tirpalui | DE/H/0471/004 | LT/1/09/1830/004 | OCTAPHARMA (IP) SPRL | LT |
| Wilate 500 SV / 500 SV pulveris un šķidinatajs injekciju šķiduma pagatavošanai | DE/H/0471/003 | 12-0014 | OCTAPHARMA (IP) SPRL | LV |

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|---|-------------------------------------|--------------------------------------|---|---|
| Wilate 1000 SV / 1000 SV pulveris un škidinatajs injekciju škiduma pagatavošanai | DE/H/0471/004 | 12-0013 | OCTAPHARMA (IP) SPRL | LV |
| Wilate 500, 500 IU VWF/500 IU FVIII, prášok a rozpúšťadlo na injekčný roztok | DE/H/0471/003 | 16/0779/11-S | OCTAPHARMA (IP) SPRL | SK |
| Wilate 1000, 1000 IU VWF/1000 IU FVIII, prášok a rozpúšťadlo na injekčný roztok | DE/H/0471/004 | 16/0780/11-S | OCTAPHARMA (IP) SPRL | SK |
| Immunate 250 I.E. FVIII/190 I.E. VWF - Pulver und Lösungsmittel zur Herstellung einer Injektionslösung | AT/H/0154/001 | 2-00204 | BAXTER AG | AT |
| Immunate 500 I.E. FVIII/375 I.E. VWF - Pulver und Lösungsmittel zur Herstellung einer Injektionslösung | AT/H/0154/002 | 2-00205 | BAXTER AG | AT |
| Immunate 1000 - I.E. FVIII/750 I.E. VWF Pulver und Lösungsmittel zur Herstellung einer Injektionslösung | AT/H/0154/003 | 2-00206 | BAXTER AG | 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 |
|--|-------------------------------------|--------------------------------------|---|---|
| Immunate Stim Plus 250 IU FVIII/190 IU VWF Prášek a rozpouštědlo pro injekční roztok | AT/H/0154/001 | 75/616/97-C | BAXALTA INNOVATIONS GMBH | CZ |
| Immunate Stim Plus 500 IU FVIII/375 IU VWF Prášek a rozpouštědlo pro injekční roztok | AT/H/0154/002 | 75/617/97-C | BAXALTA INNOVATIONS GMBH | CZ |
| Immunate Stim Plus 1000 IU FVIII/750 IU VWF Prášek a rozpouštědlo pro injekční roztok | AT/H/0154/003 | 75/618/97-C | BAXALTA INNOVATIONS GMBH | CZ |
| IMMUNATE 250 RÜ /190 RÜ, süstelahuse pulber ja lahusti | AT/H/0154/001 | 313200 | BAXALTA INNOVATIONS GMBH | EE |
| IMMUNATE 500 RÜ / 375 RÜ, süstelahuse pulber ja lahusti | AT/H/0154/002 | 313300 | BAXALTA INNOVATIONS GMBH | EE |
| IMMUNATE 1000 RÜ / 750 RÜ, süstelahuse pulber ja lahusti | AT/H/0154/003 | 313400 | BAXALTA INNOVATIONS GMBH | EE |
| Immunate S/D 500 NE FVIII/375 NE VWF por és oldószer oldatos injekcióhoz | AT/H/0154/002 | OGYI-T-5730/02 | BAXALTA INNOVATIONS GMBH | HU |
| Immunate S/D 250 NE FVIII/190 NE VWF por és oldószer oldatos | AT/H/0154/001 | OGYI-T-5730/01 | BAXALTA INNOVATIONS GMBH | HU |

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|---|-------------------------------------|--------------------------------------|---|---|
| injekcióhoz | | | | |
| Immunate S/D 1000 NE FVIII/750 NE VWF por és oldószer oldatos injekcióhoz | AT/H/0154/003 | OGYI-T-5730/03 | BAXALTA INNOVATIONS GMBH | HU |
| Immunate 250 SV/190 SV pulveris un šķīdinātājs injekciju šķīduma pagatavošanai | AT/H/0154/001 | 05-0497 | BAXALTA INNOVATIONS GMBH | LV |
| Immunate 500 SV/375 SV pulveris un šķīdinātājs injekciju šķīduma pagatavošanai | AT/H/0154/002 | 05-0498 | BAXALTA INNOVATIONS GMBH | LV |
| Immunate 1000 SV/750 SV pulveris un šķīdinātājs injekciju šķīduma pagatavošanai | AT/H/0154/003 | 05-0499 | BAXALTA INNOVATIONS GMBH | LV |
| IMMUNATE 250 TV /190 TV milteliai ir tirpiklis injekciniam tirpalui | AT/H/0154/001 | LT/1/05/0493/001 | BAXALTA INNOVATIONS GMBH | LT |
| IMMUNATE 500 TV /375 TV milteliai ir tirpiklis injekciniam tirpalui | AT/H/0154/002 | LT/1/05/0493/002 | BAXALTA INNOVATIONS GMBH | LT |
| IMMUNATE 1000 TV /750 TV milteliai ir tirpiklis injekciniam tirpalui | AT/H/0154/003 | LT/1/05/0493/003 | BAXALTA INNOVATIONS GMBH | LT |

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|---|-------------------------------------|--------------------------------------|---|---|
| Immunate 250 IU FVIII/190 IU VWF powder and solvent for solution for injection | AT/H/0154/001 | MA 162/00701 | BAXTER AG | MT |
| Immunate 500 IU FVIII/375 IU VWF powder and solvent for solution for injection | AT/H/0154/002 | MA 162/00702 | BAXTER AG | MT |
| Immunate 1000 IU FVIII/750 IU VWF powder and solvent for solution for injection | AT/H/0154/003 | MA 162/00703 | BAXTER AG | MT |
| Immunate 250 UI FVIII/190 UI FVW pulbere și solvent pentru soluție injectabilă | AT/H/0154/001 | 5418/2013/01 | BAXALTA INNOVATIONS GMBH | RO |
| WILATE 1000, 1000 IE VWF / 1000 IE FVIII, poeder en oplosmiddel voor oplossing voor injectie. | DE/H/0471/004 | RVG 108854 | OCTAPHARMA GMBH | NL |
| WILATE 500, 500 IE VWF / 500 IE FVIII, poeder en oplosmiddel voor oplossing voor injectie | DE/H/0471/003 | RVG 108853 | OCTAPHARMA GMBH | NL |
| Wilate 500, 500 j.m. VWF / 500 j.m. FVIII, proszek i rozpuszczalnik do sporządzania roztworu do | DE/H/0471/003 | 19708 | OCTAPHARMA (IP) SPRL | PL |

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|--|-------------------------------------|--------------------------------------|---|---|
| wstrzykiwan | | | | |
| Wilate 1000, 1000 j.m. VWF / 1000 j.m. FVIII, proszek i rozpuszczalnik do sporządzania roztworu do wstrzykiwan | DE/H/0471/004 | 19709 | OCTAPHARMA (IP) SPRL | PL |
| Immunate 250 IU FVIII// 190 IU VWF injektiokuiva-aine ja liuotin, liuosta varten | AT/H/0154/001 | 29748 | BAXALTA INNOVATIONS GMBH | FI |
| Immunate 500 IU FVIII/ 375 IU VWF injektiokuiva-aine ja liuotin, liuosta varten | AT/H/0154/002 | 29749 | BAXALTA INNOVATIONS GMBH | FI |
| Immunate 1000 IU FVIII / 750 IU VWF injektiokuiva-aine ja liuotin, liuosta varten | AT/H/0154/003 | 29750 | BAXALTA INNOVATIONS GMBH | FI |
| Wilate 1000, 1000 UI de FVIII + 1000 UI de FvW, pó e solvante para solução injetável | DE/H/0471/004 | 5433933 | OCTAPHARMA PRODUTOS FARMACEUTICOS, LDA. | PT |
| Wilate 500, 500 UI de FVIII + 500 UI de FvW, pó e solvante para solução injetável | DE/H/0471/003 | 5433925 | OCTAPHARMA PRODUTOS FARMACEUTICOS, LDA. | PT |

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|---|-------------------------------------|--------------------------------------|---|---|
| Haemate P 1000 Powder and solvent for solution for injection or infusion | not available | 15649/08-03-2011 | CSL BEHRING GMBH | CY |
| Haemate P 250 IU/500 IU/1000 IU Prášek a rozpouštědlo pro injekční/infuzní roztok | not available | 16/158/84-C | CSL BEHRING GMBH | CZ |
| Haemate P 250 IU/500 IU/1000 IU Prášek a rozpouštědlo pro injekční/infuzní roztok | not available | 16/158/84-C | CSL BEHRING GMBH | CZ |
| Haemate 1000 IU FVIII/2400 IU VWF injektió-/infuusiokuiva-aine ja liuotin, liuosta varten | not available | 23504 | CSL BEHRING GMBH | FI |
| Haemate 250 IU FVIII/600 IU VWF injektió-/infuusiokuiva-aine ja liuotin, liuosta varten | not available | 23502 | CSL BEHRING GMBH | FI |
| Haemate 500 IU FVIII/1200 IU VWF injektió-/infuusiokuiva-aine ja liuotin, liuosta varten | not available | 23502 | CSL BEHRING GMBH | FI |
| Haemate 2400 NE/1000 NE por és oldószer oldatos injekcióhoz vagy infúzióhoz | not available | OGYI-T-4389/02 | CSL BEHRING GMBH | 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 |
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| Haemate 1200 NE/500 NE por és oldószer oldatos injekcióhoz vagy infúzióhoz | not available | OGYI-T-4389/01 | CSL BEHRING GMBH | HU |
| Haemate P 500 /1000 Polvere e solvente per soluzione per iniezione o infusione | not available | 026600078 | CSL BEHRING GMBH | IT |
| Haemate P 500 /1000 Polvere e solvente per soluzione per iniezione o infusione | not available | 026600080 | CSL BEHRING GMBH | IT |
| Haemate® P 1000 IE | not available | RVG 32918 | CSL BEHRING GMBH | NL |
| Haemate® P 250 IE | not available | RVG 32916 | CSL BEHRING GMBH | NL |
| Haemate® P 500 IE | not available | RVG 32917 | CSL BEHRING GMBH | NL |
| Haemate P 1000 Proszek i rozpuszczalnik do sporządzania roztworu do wstrzykiwań lub infuzji | not available | 4701 | CSL BEHRING GMBH | PL |
| Haemate P 250 Proszek i rozpuszczalnik do sporządzania roztworu do | not available | 4699 | CSL BEHRING 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 |
|--|-------------------------------------|--------------------------------------|---|---|
| wstrzykiwan lub infuzji | | | | |
| Haemate P 500 Proszek i rozpuszczalnik do sporządzania roztworu do wstrzykiwań lub infuzji | not available | 4700 | CSL BEHRING GMBH | PL |
| Haemate P 1000 UI + 2400 UI/15 ml Pó e solvente para solução injetável ou para perfusão | not available | 3322088 | CSL BEHRING GMBH | PT |
| Haemate P 500 UI + 1200 UI/10 ml Pó e solvente para solução injetável ou para perfusão | not available | 3321981 | CSL BEHRING GMBH | PT |
| Haemate P 250 UI + 600 UI/5 ml Pó e solvente para solução injetável ou para perfusão | not available | 3321882 | CSL BEHRING GMBH | PT |
| Haemate P 1000 Pulbere si solvent pentru solutie injectabila sau perfuzabila | not available | 7640/2015/01 | CSL BEHRING GMBH | RO |
| HAEMATE P 250 UI pulbere și solvent pentru soluție perfuzabilă/injectabilă | not available | 287/2007/01 | CSL BEHRING GMBH | RO |

| 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 |
|--|-------------------------------------|--------------------------------------|---|---|
| HAEMATE P 500 UI pulbere și solvent pentru soluție perfuzabilă/injectabilă | not available | 288/2007/01 | CSL BEHRING GMBH | RO |
| Haemate P 500 i.e./1200 i.e. prašek in vehikel za raztopino za injiciranje/infundiranje | not available | H/93/00718/001 | CSL BEHRING GMBH | SI |
| Haemate P 500 IU prášek a rozpúšťadlo na injekčný/infúzny roztok | not available | 16/0158/84-C/S | CSL BEHRING GMBH | SK |
| Haemate P 1 000 IU prášok a rozpúšťadlo na injekčný/infúzny roztok | not available | 16/0334/17-S | CSL BEHRING GMBH | SK |
| Fanhdi 250 NE por és oldószer oldatos injekcióhoz | not available | OGYI-T-4559/01 | INSTITUTO GRIFOLS, S.A. | HU |
| Fanhdi 500 NE por és oldószer oldatos injekcióhoz | not available | OGYI-T-4559/02 | INSTITUTO GRIFOLS, S.A. | HU |
| Fanhdi 1000 NE por és oldószer oldatos injekcióhoz | not available | OGYI-T-4559/03 | INSTITUTO GRIFOLS, S.A. | HU |
| Фанди 250 IU прах и разтворител за инжекционен разтвор | not available | 9900225 | INSTITUTO GRIFOLS, S.A. | BG |

| 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 |
|---|-------------------------------------|--------------------------------------|---|---|
| Фанди 500 IU прах и разтворител за инжекционен разтвор | not available | 9900224 | INSTITUTO GRIFOLS, S.A. | BG |
| Фанди 1000 IU прах и разтворител за инжекционен разтвор | not available | 9900223 | INSTITUTO GRIFOLS, S.A. | BG |
| Haemate® P Pulver und Lösungsmittel zur Herstellung einer Injektions- oder Infusionslösung | not available | 2-00247 | CSL BEHRING GMBH | AT |
| Haemate® P Pulver und Lösungsmittel zur Herstellung einer Injektions- oder Infusionslösung | not available | 2-00247 | CSL BEHRING GMBH | AT |
| Haemate□P 250 IU/vial / 500 IU/vial / 1000 IU/vial. Κόνις και διαλύτης για παρασκευή ενεσίμου διαλύματος ή διαλύματος προς έγχυση | not available | 15649/08-03-2011 | CSL BEHRING MEPE | GR |
| Haemate□P 250 IU/vial Κόνις και διαλύτης για παρασκευή ενεσίμου διαλύματος ή διαλύματος προς έγχυση | not available | 15646/08-03-2011 | CSL BEHRING MEPE | GR |

| 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 |
|---|-------------------------------------|--------------------------------------|---|---|
| Haemate®P 500 IU/vial Κόνις και διαλύτης για παρασκευή ενεσίμου διαλύματος ή διαλύματος προς έγχυση | not available | 15647/08-03-2011 | CSL BEHRING MEPE | GR |
| Dried Factor VIII Fraction, type 8Y®, 25 IU/mL powder for solution for injection | not available | 18834 | BIO PRODUCTS LABORATORY | CY |
| Dried Factor VIII Fraction, type 8Y®, 25 IU/mL powder for solution for injection | not available | MA049/00201 | BIO PRODUCTS LABORATORY | MT |
| Dried Factor VIII Fraction, type 8Y®, 25 IU/mL powder for solution for injection | not available | 99-1017 | BIO PRODUCTS LABORATORY | LV |
| Immunate 1000 UI FVIII/750 UI FVW pulbere și solvent pentru soluție injectabilă | AT/H/0154/003 | 5420/2013/01 | BAXALTA INNOVATIONS GMBH | RO |
| Immunate 500 UI FVIII/375 UI FVW pulbere și solvent pentru soluție injectabilă | AT/H/0154/002 | 5419/2013/01 | BAXALTA INNOVATIONS GMBH | RO |
| Immunate 1000 IU FVIII/750 IU VWF prášok a rozpúšťadlo na injekčný roztok | AT/H/0154/003 | 16/0142/06-S | BAXALTA INNOVATIONS GMBH | SK |

| 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 |
|---|-------------------------------------|--------------------------------------|---|---|
| Immunate 500 IU FVIII/375 IU VWF prášok a rozpúšťadlo na injekčný roztok | AT/H/0154/002 | 16/0141/06-S | BAXALTA INNOVATIONS GMBH | SK |
| Immunate 250 IU FVIII/190 IU VWF prášok a rozpúšťadlo na injekčný roztok | AT/H/0154/001 | 16/0140/06-S | BAXALTA INNOVATIONS GMBH | SK |
| Fanhdi 25 UI/ml Pó e solvente para solução injetável | not available | 3794583 | INSTITUTO GRIFOLS, S.A. | PT |
| Fanhdi 50 UI/ml Pó e solvente para solução injetável. | not available | 3794682 | INSTITUTO GRIFOLS, S.A. | PT |
| Fanhdi 100 UI/ml (1000 UI/10 ml, 1500 UI/15 ml) Pó e solvente para solução injetável | not available | 3794781 | INSTITUTO GRIFOLS, S.A. | PT |
| Fanhdi 100 UI/ml (1000 UI/10 ml, 1500 UI/15 ml) Pó e solvente para solução injetável | not available | 5047378 | INSTITUTO GRIFOLS, S.A. | PT |
| Immunate 250 i.e. FVIII/190 i.e. VWF prasek in vehikel za raztopino za injiciranje | AT/H/0154/001 | H/11/00769/001 | BAXALTA INNOVATIONS 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 |
|--|-------------------------------------|--------------------------------------|---|---|
| Immunate 500 i.e. FVIII/375 i.e. VWF prasek in vehikel za raztopino za injiciranje | AT/H/0154/002 | H/11/00769/002 | BAXALTA INNOVATIONS GMBH | SI |
| Immunate 1000 i.e. FVIII/750 i.e. VWF prasek in vehikel za raztopino za injiciranje | AT/H/0154/003 | H/11/00769/003 | BAXALTA INNOVATIONS GMBH | SI |
| FANHDI 25 UI/ml, factor VIII de coagulare uman, pulbere si solvent pentru solutie injectabila | not available | 7086/2006/01 | INSTITUTO GRIFOLS, S.A. | RO |
| FANHDI 50 UI/ml, factor VIII de coagulare uman, pulbere si solvent pentru solutie injectabila | not available | 7087/2006/01 | INSTITUTO GRIFOLS, S.A. | RO |
| FANHDI 100 UI/ml, factor VIII de coagulare uman, pulbere și solvent pentru soluție injectabilă | not available | 7088/2006/01 | INSTITUTO GRIFOLS, S.A. | RO |
| IMMUNATE 250 IU FVIII/190 IU VWF, κόνις και διαλύτης για ενέσιμο διάλυμα | AT/H/0154/001 | 20084 | BAXALTA INNOVATIONS GMBH | CY |
| IMMUNATE 1000 IU FVIII/750 IU VWF, κόνις και διαλύτης για ενέσιμο διάλυμα | AT/H/0154/003 | 20086 | BAXALTA INNOVATIONS GMBH | CY |

| 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 |
|---|-------------------------------------|--------------------------------------|---|---|
| IMMUNATE 500 IU FVIII/375 IU VWF, κόνις και διαλύτης για ενέσιμο διάλυμα | AT/H/0154/002 | 20085 | BAXALTA INNOVATIONS GMBH | CY |
| Immunate 250 IU FVIII/190 IU VWF Proszek i rozpuszczalnik do sporządzania roztworu do wstrzykiwań | AT/H/0154/001 | 12150 | SHIRE POLSKA SP. Z O. O. | PL |
| Immunate 1000 IU FVIII/750 IU VWF Proszek i rozpuszczalnik do sporządzania roztworu do wstrzykiwań | AT/H/0154/003 | 12151 | SHIRE POLSKA SP. Z O. O. | PL |
| IMMUNATE 500 IU FVIII/375 IU VWF Proszek i rozpuszczalnik do sporządzania roztworu do wstrzykiwan | AT/H/0154/002 | 12154 | SHIRE POLSKA SP. Z O. O. | PL |
| Fanhdi 250 UI + 300 UI /10 ml Polvere e solvente per soluzione per infusione | not available | 033866043 | ISTITUTO GRIFOLS, S.A. | IT |
| Fanhdi 500 UI + 600 UI /10 ml Polvere e solvente per soluzione per infusione | not available | 033866056 | ISTITUTO GRIFOLS, S.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 |
|--|-------------------------------------|--------------------------------------|---|---|
| Fanhdi 1000 UI + 1200 UI /10 ml Polvere e solvente per soluzione per infusione | not available | 033866068 | ISTITUTO GRIFOLS, S.A. | IT |
| Fanhdi 1500 UI + 1800 UI /15 ml Polvere e solvente per soluzione per infusione | not available | 033866070 | ISTITUTO GRIFOLS, S.A. | IT |
| Fanhdi 25 IU/ml, prášek a rozpúšťadlo na injekčný roztok | not available | 16/0427/97-S | ISTITUTO GRIFOLS, S.A. | SK |
| Fanhdi 50 IU/ml, prášek a rozpúšťadlo na injekčný roztok | not available | 16/0169/13-S | ISTITUTO GRIFOLS, S.A. | SK |
| Fanhdi 100 IU/ml, prášek a rozpúšťadlo na injekčný roztok | not available | 16/0170/13-S | ISTITUTO GRIFOLS, S.A. | SK |
| Fanhdi 100 IU/ml, prášek a rozpúšťadlo na injekčný roztok | not available | 16/0250/05-S | ISTITUTO GRIFOLS, S.A. | SK |
| FANHDI 25 IU/ml, prášek a rozpouštědlo pro injekční roztok | not available | 16/053/97-C | ISTITUTO GRIFOLS, S.A. | CZ |
| FANHDI 50 IU/ml, prášek a rozpouštědlo pro injekční roztok | not available | 16/054/97-C | ISTITUTO GRIFOLS, S.A. | 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 |
|--|-------------------------------------|--------------------------------------|---|---|
| FANHDI 100 IU/ml, prášek a rozpouštědlo pro injekční roztok | not available | 16/055/97-C | INSTITUTO GRIFOLS, S.A. | CZ |
| FANHDI, 250 j.m. FVIII + 300 j.m. VWF Proszek i rozpuszczalnik do sporządzania roztworu do wstrzykiwań i infuzji | not available | 7835 | INSTITUTO GRIFOLS, S.A. | PL |
| FANHDI, 500 j.m.FVIII + 600 j.m. VWF Proszek i rozpuszczalnik do sporządzania roztworu do wstrzykiwań i infuzji | not available | 7836 | INSTITUTO GRIFOLS, S.A. | PL |
| FANHDI, 1000 j.m. FVIII + 1200 j.m. VWF Proszek i rozpuszczalnik do sporządzania roztworu do wstrzykiwań i infuzji | not available | 7837 | INSTITUTO GRIFOLS, S.A. | PL |
| IMMUNATE 1000 IU FVIII/750 IU VWF, κόνις και διαλύτης για ενέσιμο διάλυμα | AT/H/0154/003 | 58795/05-09-2011 | BAXALTA INNOVATIONS GMBH | GR |
| IMMUNATE 500 IU FVIII/375 IU VWF, κόνις και διαλύτης για ενέσιμο διάλυμα | AT/H/0154/002 | 58794/05-09-2011 | BAXALTA INNOVATIONS GMBH | GR |

| 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 |
|---|-------------------------------------|--------------------------------------|---|---|
| IMMUNATE 250 IU FVIII/190 IU VWF, κόνις και διαλύτης για ενέσιμο διάλυμα | AT/H/0154/001 | 58793/05-09-2011 | BAXALTA INNOVATIONS GMBH | GR |
| Alphanate® 250, poeder en oplosmiddel voor oplossing voor injectie 50 IE/ml | not available | RVG 17384 | INSTITUTO GRIFOLS, S.A. | NL |
| Alphanate® 500, poeder en oplosmiddel voor oplossing voor injectie 100 IE/ml | not available | RVG 17385 | INSTITUTO GRIFOLS, S.A. | NL |
| Alphanate® 1000, poeder en oplosmiddel voor oplossing voor injectie 100 IE/ml | not available | RVG 17386 | INSTITUTO GRIFOLS, S.A. | NL |
| ALPHANATE 250 UI + 300 UI / 5 ml Polvere e solvente per soluzione per infusione | not available | 033077088 | GRIFOLS ITALIA S.P.A | IT |
| ALPHANATE 500 UI + 600 UI / 5 ml Polvere e solvente per soluzione per infusione | not available | 033077090 | GRIFOLS ITALIA S.P.A | IT |
| ALPHANATE 1000 UI + 1200 UI / 10 ml Polvere e solvente per soluzione per infusione | not available | 033077102 | GRIFOLS ITALIA 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 |
|--|-------------------------------------|--------------------------------------|---|---|
| ALPHANATE 1500 UI + 1800 UI / 10 ml Polvere e solvente per soluzione per infusione | not available | 033077114 | GRIFOLS ITALIA S.P.A | IT |
| Fanhdi 250 IU Κόνις και διαλύτης για ενέσιμο διάλυμα | not available | 43318/14-6-2012 | DEMO ABEE | GR |
| Fanhdi 500 IU Κόνις και διαλύτης για ενέσιμο διάλυμα | not available | 43319/14-6-2012 | DEMO ABEE | GR |
| Fanhdi 1000 IU Κόνις και διαλύτης για ενέσιμο διάλυμα | not available | 43320/14-6-2012 | DEMO ABEE | GR |
| Plitate 250 UI + 300 UI / 10 ml Polvere e solvente per soluzione per infusione | not available | 044564019 | GRIFOLS ITALIA S.P.A | IT |
| Plitate 500 UI + 600 UI / 10 ml Polvere e solvente per soluzione per infusione | not available | 044564021 | GRIFOLS ITALIA S.P.A | IT |
| Plitate 1000 UI + 1200 UI / 10 ml Polvere e solvente per soluzione per infusione | not available | 044564033 | GRIFOLS ITALIA S.P.A | IT |
| Plitate 1500 UI + 1800 UI / 15 ml Polvere e solvente per soluzione per | not available | 044564045 | GRIFOLS ITALIA 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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| infusione | | | | |
| Haemate P 500 i.e./1200 i.e. prašek in vehikel za raztopino za injiciranje/infundiranje | not available | H/93/00718/002 | CSL BEHRING GMBH | SI |
| Immunate 250 IU FVIII / 190 IU VWF pulver och vätska till injektionsvätska, lösning | AT/H/0154/001 | 29748 | BAXALTA INNOVATIONS GMBH | FI |
| Immunate 500 IU FVIII / 375 IU VWF pulver och vätska till injektionsvätska, lösning | AT/H/0154/002 | 29749 | BAXALTA INNOVATIONS GMBH | FI |
| Immunate 1000 IU FVIII / 750 IU VWF pulver och vätska till injektionsvätska, lösning | AT/H/0154/003 | 29750 | BAXALTA INNOVATIONS GMBH | FI |
| Имунейт 250 IU FVIII/190 IU VWF прах и разтворител за инжекционен разтвор | AT/H/0154/001 | 20110551 | BAXALTA INNOVATIONS GMBH | BG |
| Имунейт 500 IU FVIII/375 IU VWF прах и разтворител за инжекционен разтвор | AT/H/0154/002 | 20110552 | BAXALTA INNOVATIONS GMBH | BG |

| 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 |
|---|-------------------------------------|--------------------------------------|---|---|
| Имунейт 1000 IU FVIII/750 IU VWF прах и разтворител за инжекционен разтвор | AT/H/0154/003 | 20110553 | BAXALTA INNOVATIONS GMBH | BG |
| Wilate 1000, 1000 IU VWF/1000 IU FVIII, powder and solvent for solution for injection | DE/H/0471/004 | MA754/01102 | OCTAPHARMA (IP) LTD. | MT |
| Wilate 500, 500 IU VWF/500 IU FVIII, powder and solvent for solution for injection | DE/H/0471/003 | MA754/01101 | OCTAPHARMA (IP) LTD. | MT |
| Wilate 500 "500 UI VWF / 500 UI FVIII - polvere e solvente per soluzione iniettabile" | DE/H/0471/003 | AIC NO.039385036/M | OCTAPHARMA ITALY S.P.A. | IT |
| Wilate 1000 "1000 UI VWF / 1000 UI FVIII - polvere e solvente per soluzione iniettabile" | DE/H/0471/004 | AIC NO.039385048/M | OCTAPHARMA ITALY S.P.A. | IT |
| WILATE 500, 500 IU VWF / 500 IU FVIII , Κ'ΟΝΙΣ ΚΑΙ ΔΙΑΛΥΤΗΣ ΓΙΑ ΕΝΕΣΙΜΟ ΔΙΑΛΥΜΑ | DE/H/0471/003 | 021812 / 01527-03 | OCTAPHARMA (IP) LTD. | CY |
| WILATE 1000, 1000 IU VWF / 1000 IU FVIII, Κ'ΟΝΙΣ ΚΑΙ ΔΙΑΛΥΤΗΣ ΓΙΑ ΕΝΕΣΙΜΟ ΔΙΑΛΥΜΑ | DE/H/0471/004 | 021813 / 01527-04 | OCTAPHARMA (IP) LTD. | CY |

| 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 |
|---|-------------------------------------|--------------------------------------|---|---|
| Haemate 250 IE FVIII /600 IE VWF pulver og væske til injeksjons-/infusjonsvæske, oppløsning | not available | 09-6751 | CSL BEHRING GMBH | NO |
| Haemate 500 IE FVIII /1200 IE VWF pulver og væske til injeksjons-/infusjonsvæske, oppløsning | not available | 09-6752 | CSL BEHRING GMBH | NO |
| Haemate 1000 IE FVIII /2400 IE VWF pulver og væske til injeksjons-/infusjonsvæske, oppløsning | not available | 09-6753 | CSL BEHRING GMBH | NO |
| Fanhdi® 25 IU/ml powder and solvent for solution for injection | not available | PL 12930/0002 | INSTITUTO GRIFOLS, S.A. | UK |
| Fanhdi® 50 IU/ml powder and solvent for solution for injection | not available | PL 12930/0004 | INSTITUTO GRIFOLS, S.A. | UK |
| Fanhdi® 100 IU/ml powder and solvent for solution for injection | not available | PL 12930/0005 | INSTITUTO GRIFOLS, S.A. | UK |
| Dried Factor VIII Fraction, Type 8Y®, 25 IU/mL powder for solution for injection | not available | PL 08801/0021 | BIO PRODUCTS LABORATORY | UK |

| 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 |
|---|-------------------------------------|--------------------------------------|---|---|
| Fanhdi 250 IU Κόνις και διαλύτης για ενέσιμο διάλυμα | not available | 43318/14-6-2012 | DEMO ABEE | GR |
| Fanhdi 500 IU Κόνις και διαλύτης για ενέσιμο διάλυμα | not available | 43319/14-6-2012 | DEMO ABEE | GR |
| Fanhdi 1000 IU Κόνις και διαλύτης για ενέσιμο διάλυμα | not available | 43320/14-6-2012 | DEMO ABEE | GR |
| Haemate® P 1000 IE | not available | RVG 32918 | CSL BEHRING GMBH | NL |
| Haemate® P 250 IE | not available | RVG 32916 | CSL BEHRING GMBH | NL |
| Haemate® P 500 IE | not available | RVG 32917 | CSL BEHRING GMBH | NL |
| Haemate 2400 NE/1000 NE por és oldószer oldatos injekcióhoz vagy infúzióhoz | not available | OGYI-T-4389/02 | CSL BEHRING GMBH | HU |
| Haemate 1200 NE/500 NE por és oldószer oldatos injekcióhoz vagy infúzióhoz | not available | OGYI-T-4389/01 | CSL BEHRING GMBH | 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 |
|--|-------------------------------------|--------------------------------------|---|---|
| Fanhdi 250 IU Powder and solvent for solution for injection | not available | PA0849/001/001 | INSTITUTO GRIFOLS, S.A. | IE |
| Fanhdi 500 IU Powder and solvent for solution for injection | not available | PA0849/001/002 | INSTITUTO GRIFOLS, S.A. | IE |
| Fanhdi 1000 IU Powder and solvent for solution for injection | not available | PA0849/001/003 | INSTITUTO GRIFOLS, S.A. | IE |
| Alphanate® 250, poeder en oplosmiddel voor oplossing voor injectie 50 IE/ml | not available | RVG 17384 | INSTITUTO GRIFOLS, S.A. | NL |
| Alphanate® 500, poeder en oplosmiddel voor oplossing voor injectie 100 IE/ml | not available | RVG 17385 | INSTITUTO GRIFOLS, S.A. | NL |
| Alphanate® 1000, poeder en oplosmiddel voor oplossing voor injectie 100 IE/ml | not available | RVG 17386 | INSTITUTO GRIFOLS, S.A. | NL |
| Fanhdi® 250 I.E., Trockensubstanz und Lösungsmittel zur Herstellung einer Injektionslösung | not available | 10565A/97-1 | GRIFOLS DEUTSCHLAND 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 |
|--|-------------------------------------|--------------------------------------|---|---|
| Fanhdi® 500 I.E., Trockensubstanz und Lösungsmittel zur Herstellung einer Injektionslösung | not available | 10565A/97-2 | GRIFOLS DEUTSCHLAND GMBH | DE |
| Fanhdi® 1000 I.E., Trockensubstanz und Lösungsmittel zur Herstellung einer Injektionslösung | not available | 10565A/97-3 | GRIFOLS DEUTSCHLAND GMBH | DE |
| Fanhdi® 1500 I.E., Trockensubstanz und Lösungsmittel zur Herstellung einer Injektionslösung | not available | PEI.H.03436.01.1 | GRIFOLS DEUTSCHLAND GMBH | DE |
| Haemate® P 1000 Pulver und Lösungsmittel zur Herstellung einer Injektions- oder Infusionslösung | not available | 2416.02.00 | CSL BEHRING GMBH | DE |
| Haemate® P 250/500/1000 Pulver und Lösungsmittel zur Herstellung einer Injektions- oder Infusionslösung | not available | 2416.00.00 | CSL BEHRING GMBH | DE |
| Haemate® P 250/500/1000 Pulver und Lösungsmittel zur | not available | 2416.01.00 | CSL BEHRING 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 |
|--|-------------------------------------|--------------------------------------|---|---|
| Herstellung einer Injektions- oder Infusionslösung | | | | |
| Haemate® P Pulver und Lösungsmittel zur Herstellung einer Injektions- oder Infusionslösung | not available | 2-00247 | CSL BEHRING GMBH | AT |
| Haemate® P Pulver und Lösungsmittel zur Herstellung einer Injektions- oder Infusionslösung | not available | 2-00247 | CSL BEHRING GMBH | AT |
| Haemate P 250 IU/500 IU/1000 IU Prášek a rozpouštědlo pro injekční/infuzní roztok | not available | 16/158/84-C | CSL BEHRING GMBH | CZ |
| Haemate P 250 IU/500 IU/1000 IU Prášek a rozpouštědlo pro injekční/infuzní roztok | not available | 16/158/84-C | CSL BEHRING GMBH | CZ |
| Haemate P 1000 UI + 2400 UI/15 ml Pó e solvente para solução injetável ou para perfusão | not available | 3322088 | CSL BEHRING GMBH | PT |
| Haemate P 500 UI + 1200 UI/10 ml Pó e solvente para solução injetável ou para perfusão | not available | 3321981 | CSL BEHRING GMBH | 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 |
|---|-------------------------------------|--------------------------------------|---|---|
| Haemate P 250 UI + 600 UI/5 ml Pó e solvente para solução injetável ou para perfusão | not available | 3321882 | CSL BEHRING GMBH | PT |
| Haemate 1000 IE FVIII / 2400 IE VWF pulver och vätska till injektions-/infusionsvätska, lösning | not available | 20660 | CSL BEHRING GMBH | SE |
| Haemate 500 IE FVIII / 1200 IE VWF pulver och vätska till injektions-/infusionsvätska, lösning | not available | 10605 | CSL BEHRING GMBH | SE |
| Wilate 500 500 UI FVW / 500 UI FVIII pulbere si solvent pentru solutie injectabila | DE/H/0471/003 | 6978/2014/01 | OCTAPHARMA (IP) SPRL | RO |
| Wilate 1000 1000 UI FVW / 1000 UI FVIII pulbere si solvent pentru solutie injectabila | DE/H/0471/004 | 6979/2014/01 | OCTAPHARMA (IP) SPRL | RO |
| Wilate 500 i.e./500 i.e. prašek in vehikel za raztopino za injiciranje | DE/H/0471/003 | H/10/01666/001 | OCTAPHARMA (IP) SPRL | SI |
| Wilate 1000 i.e./1000 i.e. prašek in vehikel za raztopino za injiciranje | DE/H/0471/004 | H/10/01666/002 | OCTAPHARMA (IP) SPRL | 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 |
|--|-------------------------------------|--------------------------------------|--|---|
| Wilate 900 I.E. FVIII und 800 I.E. VWF Pulver und Lösungsmittel zur Herstellung einer Injektionslösung | DE/H/0471/002 | 2-00330 | OCTAPHARMA PHARMAZEUTIKA PRODUKTIONSGESMBH | AT |
| Wilate 450 I.E. FVIII und 400 I.E. VWF Pulver und Lösungsmittel zur Herstellung einer Injektionslösung | DE/H/0471/001 | 2-00329 | OCTAPHARMA PHARMAZEUTIKA PRODUKTIONSGESMBH | AT |
| Wilate 500 I.E. VWF und 500 I.E. FVIII Pulver und Lösungsmittel zur Herstellung einer Injektionslösung | DE/H/0471/003 | 2-00392 | OCTAPHARMA PHARMAZEUTIKA PRODUKTIONSGESMBH | AT |
| Wilate 1000 I.E. VWF und 1000 I.E. FVIII Pulver und Lösungsmittel zur Herstellung einer Injektionslösung | DE/H/0471/004 | 2-00393 | OCTAPHARMA PHARMAZEUTIKA PRODUKTIONSGESMBH | AT |
| Wilate 500, 500 UI VWF/500 UI FVIII, poudre et solvant pour solution injectable | DE/H/0471/003 | BE418232 | OCTAPHARMA BENELUX S.A. | BE |
| Wilate 1000, 1000 UI VWF/1000 UI FVIII, poudre et solvant pour solution injectable | DE/H/0471/004 | BE418241 | OCTAPHARMA BENELUX S.A. | 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 |
|--|-------------------------------------|--------------------------------------|---|---|
| WILATE 500, 500 IU VWF/500 IU F VIII powder and solvent for solution for injection | DE/H/0471/003 | 20110733 | OCTAPHARMA (IP) SPRL | BG |
| WILATE 1000, 1000 IU VWF/1000 IU F VIII powder and solvent for solution for injection | DE/H/0471/004 | 20110734 | OCTAPHARMA (IP) SPRL | BG |
| Wilate 500, 500 IU VWF/500 IU FVIII, prášek a rozpouštědlo pro injekční roztok | DE/H/0471/003 | 75/001/12-C | OCTAPHARMA (IP) SPRL | CZ |
| Wilate 1000, 1000 IU VWF/1000 IU FVIII, prášek a rozpouštědlo pro injekční roztok | DE/H/0471/004 | 75/002/12-C | OCTAPHARMA (IP) SPRL | CZ |
| Wilate 500, 500 I.E. VWF/500 I.E. FVIII, Pulver und Lösungsmittel zur Herstellung einer intravenösen Injektionslösung. | DE/H/0471/003 | PEI.H.01918.03.1 | OCTAPHARMA GMBH | DE |
| Wilate 450, 450 I.E. VWF/400 I.E. FVIII, Pulver und Lösungsmittel zur Herstellung einer intravenösen Injektionslösung. | DE/H/0471/001 | PEI.H.01918.01.1 | OCTAPHARMA 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 |
|---|-------------------------------------|--------------------------------------|---|---|
| Wilate 1000, 1000 I.E. VWF/1000 I.E. FVIII, Pulver und Lösungsmittel zur Herstellung einer intravenösen Injektionslösung. | DE/H/0471/004 | PEI.H.01918.04.1 | OCTAPHARMA GMBH | DE |
| Wilate 900, 900 I.E. VWF/800 I.E. FVIII, Pulver und Lösungsmittel zur Herstellung einer intravenösen Injektionslösung | DE/H/0471/002 | PEI.H.01918.02.1 | OCTAPHARMA GMBH | DE |
| Wilnativ, pulver og solvens til injektionsvæske, opløsning | DE/H/0471/003 | MTNR. 47915 | OCTAPHARMA AB | DK |
| Wilnativ, pulver og solvens til injektionsvæske, opløsning | DE/H/0471/004 | MTNR. 47916 | OCTAPHARMA AB | DK |
| Wilate 500, 500 RÜ VWF/500 RÜ FVIII, süstelahuse pulber ja lahusti | DE/H/0471/003 | 777012 | OCTAPHARMA (IP) SPRL | EE |
| Wilate 1000, 1000 RÜ VWF/1000 RÜ FVIII, süstelahuse pulber ja lahusti | DE/H/0471/004 | 776912 | OCTAPHARMA (IP) SPRL | 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 |
|--|-------------------------------------|--------------------------------------|---|---|
| Wilate, 500 UI FvW/500 UI FVIII, polvo y disolvente para solución inyectable | DE/H/0471/003 | 75625 | OCTAPHARMA S.A. | ES |
| Wilate, 1000 UI FvW/1000 UI FVIII, polvo y disolvente para solución inyectable | DE/H/0471/004 | 75648 | OCTAPHARMA S.A. | ES |
| Wilate, 1000 IU VWF / 1000 IU FVIII, injektiokuiva-aine ja liuotin, liuosta varten | DE/H/0471/004 | 29338 | OCTAPHARMA AB | FI |
| Wilate, 500 IU VWF / 500 IU FVIII, injektiokuiva-aine ja liuotin, liuosta varten | DE/H/0471/003 | 29339 | OCTAPHARMA AB | FI |
| Wilate 1000 NE VWF/1000 NE FVIII por és oldószer oldatos injekcióhoz | DE/H/0471/004 | OGYI-T-21152/04 | OCTAPHARMA (IP) SPRL | HU |
| Wilate 500 NE VWF/500 NE FVIII por és oldószer oldatos injekcióhoz | DE/H/0471/003 | OGYI-T-21152/03 | OCTAPHARMA (IP) SPRL | HU |
| Wilate 500 TV/500 TV milteliai ir tirpiklis injekciniam tirpalui | DE/H/0471/003 | LT/1/09/1830/003 | OCTAPHARMA (IP) SPRL | LT |
| Wilate 1000 TV/1000 TV milteliai ir tirpiklis injekciniam tirpalui | DE/H/0471/004 | LT/1/09/1830/004 | OCTAPHARMA (IP) SPRL | 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 |
|--|-------------------------------------|--------------------------------------|---|---|
| Wilate 500 SV / 500 SV pulveris un škidinatajs injekciju škiduma pagatavošanai | DE/H/0471/003 | 12-0014 | OCTAPHARMA (IP) SPRL | LV |
| Wilate 1000 SV / 1000 SV pulveris un škidinatajs injekciju škiduma pagatavošanai | DE/H/0471/004 | 12-0013 | OCTAPHARMA (IP) SPRL | LV |
| Wilate 1000, 1000 IU VWF/1000 IUFVIII, powder and solvent for solution for injection | DE/H/0471/004 | PL 10673/0038 | OCTAPHARMA-LTD | UK |
| Wilate 500, 500 IU VWF/500 IUFVIII, powder and solvent for solution for injection | DE/H/0471/003 | PL 10673/0038 | OCTAPHARMA-LTD | UK |
| Wilate 500, 500 IU VWF/500 IU FVIII, prášok a rozpúšťadlo na injekčný roztok | DE/H/0471/003 | 16/0779/11-S | OCTAPHARMA (IP) SPRL | SK |
| Wilate 1000, 1000 IU VWF/1000 IU FVIII, prášok a rozpúšťadlo na injekčný roztok | DE/H/0471/004 | 16/0780/11-S | OCTAPHARMA (IP) SPRL | SK |
| Wilate 500 IE VWF / 500 IE FVIII pulver og væske til injeksjonsvæske, oppløsning | DE/H/0471/003 | 10-8036 | OCTAPHARMA 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 |
|--|-------------------------------------|--------------------------------------|---|---|
| Wilate 1000 IE VWF / 1000 IE FVIII pulver og væske til injeksjonsvæske, oppløsning | DE/H/0471/004 | 10-8037 | OCTAPHARMA AS | NO |
| WILATE 1000, 1000 IE VWF / 1000 IE FVIII, poeder en oplosmiddel voor oplossing voor injectie. | DE/H/0471/004 | RVG 108854 | OCTAPHARMA GMBH | NL |
| WILATE 500, 500 IE VWF / 500 IE FVIII, poeder en oplosmiddel voor oplossing voor injectie | DE/H/0471/003 | RVG 108853 | OCTAPHARMA GMBH | NL |
| Wilate 500, 500 j.m. VWF / 500 j.m. FVIII, proszek i rozpuszczalnik do sporzadzania roztworu do wstrzykiwan | DE/H/0471/003 | 19708 | OCTAPHARMA (IP) SPRL | PL |
| Wilate 1000, 1000 j.m. VWF / 1000 j.m. FVIII, proszek i rozpuszczalnik do sporzadzania roztworu do wstrzykiwan | DE/H/0471/004 | 19709 | OCTAPHARMA (IP) SPRL | PL |
| Wilate 1000, 1000 UI de FVIII + 1000 UI de FvW, pó e solvente para solução injetável | DE/H/0471/004 | 5433933 | OCTAPHARMA PRODUTOS FARMACEUTICOS, LDA. | 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 |
|--|-------------------------------------|--------------------------------------|---|---|
| Wilate 500, 500 UI de FVIII + 500 UI de FvW, pó e solvente para solução injetável | DE/H/0471/003 | 5433925 | OCTAPHARMA PRODUTOS FARMACEUTICOS, LDA. | PT |
| Wilate 500 IE VWF/500 IE FVIII, pulver och vätska till injektionsvätska, lösning | DE/H/0471/003 | 45431 | OCTAPHARMA AB | SE |
| Wilate 1000 IE VWF/1000 IE FVIII, pulver och vätska till injektionsvätska, lösning | DE/H/0471/004 | 45432 | OCTAPHARMA AB | SE |
| Wilate 500, 500 IU VWF / 500 IU FVIII, prašak i otapalo za otopinu za injekciju | DE/H/0471/003 | HR-H-138328484 | JANA PHARM D.O.O. | HR |
| Wilate 1000, 1000 IU VWF / 1000 IU FVIII, prašak i otapalo za otopinu za injekciju | DE/H/0471/004 | HR-H-758724968 | JANA PHARM D.O.O. | HR |
| EQWILATE 500 UI FVW / 500 UI FVIII, poudre et solvant pour solution injectable | DE/H/0471/003 | 34009 550 450 5 2 | OCTAPHARMA FRANCE | FR |
| EQWILATE 1000 UI FVW / 1000 UI FVIII, poudre et solvant pour solution injectable | DE/H/0471/004 | 34009 550 450 6 9 | OCTAPHARMA FRANCE | 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 |
|---|-------------------------------------|--------------------------------------|---|---|
| Wilate 1000, 1000 IU VWF/1000 IU FVIII, powder and solvent for solution for injection | DE/H/0471/004 | MA754/01102 | OCTAPHARMA (IP) LTD. | MT |
| Wilate 500, 500 IU VWF/500 IU FVIII, powder and solvent for solution for injection | DE/H/0471/003 | MA754/01101 | OCTAPHARMA (IP) LTD. | MT |
| Wilate, 500 IU VWF/500 IU FVIII, powder and solvent for solution for injection | DE/H/0471/003 | PA2219/008/001 | OCTAPHARMA (IP) SPRL | IE |
| Wilate, 1000 IU VWF/1000 IU FVIII, powder and solvent for solution for injection | DE/H/0471/004 | PA2219/008/002 | OCTAPHARMA (IP) SPRL | IE |
| Wilate 500, 500 UI VWF/500 UI FVIII, poudre et solvant pour solution injectable | DE/H/0471/003 | 2012100181 | OCTAPHARMA BENELUX S.A. | LU |
| Wilate 1000, 1000 UI VWF/1000 UI FVIII, poudre et solvant pour solution injectable | DE/H/0471/004 | 2012100182 | OCTAPHARMA BENELUX S.A. | LU |
| Wilate 500 "500 UI VWF / 500 UI FVIII - polvere e solvente per soluzione iniettabile" | DE/H/0471/003 | AIC NO.039385036/M | OCTAPHARMA ITALY 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 |
|--|-------------------------------------|--------------------------------------|---|---|
| Wilate 1000 "1000 UI VWF / 1000 UI FVIII - polvere e solvente per soluzione iniettabile" | DE/H/0471/004 | AIC NO.039385048/M | OCTAPHARMA ITALY S.P.A. | IT |
| WILATE 500, 500 IU VWF / 500 IU FVIII , Κ'ΟΝΙϚ ΚΑΙ ΔΙΑΛΥΤΗϚ ΓΙΑ ΕΝΕΣΙΜΟ ΔΙΑΛΥΜΑ | DE/H/0471/003 | 021812 / 01527-03 | OCTAPHARMA (IP) LTD. | CY |
| WILATE 1000, 1000 IU VWF / 1000 IU FVIII, Κ'ΟΝΙϚ ΚΑΙ ΔΙΑΛΥΤΗϚ ΓΙΑ ΕΝΕΣΙΜΟ ΔΙΑΛΥΜΑ | DE/H/0471/004 | 021813 / 01527-04 | OCTAPHARMA (IP) LTD. | CY |
| FANHDI 25 UI/ml, factor VIII de coagulare uman, pulbere si solvent pentru solutie injectabila | not available | 7086/2006/01 | INSTITUTO GRIFOLS, S.A. | RO |
| FANHDI 50 UI/ml, factor VIII de coagulare uman, pulbere si solvent pentru solutie injectabila | not available | 7087/2006/01 | INSTITUTO GRIFOLS, S.A. | RO |
| FANHDI 100 UI/ml, factor VIII de coagulare uman, pulbere și solvent pentru soluție injectabilă | not available | 7088/2006/01 | INSTITUTO GRIFOLS, S.A. | RO |
| IMMUNATE 500 I.E. Pulver und Lösungsmittel zur Herstellung einer Injektionslösung | not available | 3854.02.00 | SHIRE DEUTSCHLAND 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 |
|--|-------------------------------------|--------------------------------------|---|---|
| IMMUNATE 1000 I.E. Pulver und Lösungsmittel zur Herstellung einer Injektionslösung | not available | 3854.03.00 | SHIRE DEUTSCHLAND GMBH | DE |
| FANHDI, 250 j.m. FVIII + 300 j.m. VWF Proszek i rozpuszczalnik do sporządzania roztworu do wstrzykiwań i infuzji | not available | 7835 | INSTITUTO GRIFOLS, S.A. | PL |
| FANHDI, 500 j.m.FVIII + 600 j.m. VWF Proszek i rozpuszczalnik do sporządzania roztworu do wstrzykiwań i infuzji | not available | 7836 | INSTITUTO GRIFOLS, S.A. | PL |
| FANHDI, 1000 j.m. FVIII + 1200 j.m. VWF Proszek i rozpuszczalnik do sporządzania roztworu do wstrzykiwań i infuzji | not available | 7837 | INSTITUTO GRIFOLS, S.A. | PL |
| Fanhdi 25 UI FVIII/30 UI FVW por ml, polvo y disolvente para solución inyectable | not available | 60601 | INSTITUTO GRIFOLS, S.A. | ES |
| Fanhdi 50 UI FVIII/60 UI FVW por ml, polvo y disolvente para solución inyectable | not available | 60600 | INSTITUTO GRIFOLS, 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 |
|---|-------------------------------------|--------------------------------------|---|---|
| Fanhdi 100 UI FVIII/120 UI FVW por ml, polvo y disolvente para solución inyectable | not available | 60602 | INSTITUTO GRIFOLS, S.A. | ES |
| Fanhdi 25 IU/ml prašak i otapalo za otopinu za injekciju | not available | UP/I-530-09/12-01/329 | INSTITUTO GRIFOLS, S.A. | HR |
| Fanhdi 50 IU/ml prašak i otapalo za otopinu za injekciju | not available | UP/I-530-09/12-01/330 | INSTITUTO GRIFOLS, S.A. | HR |
| Fanhdi 100 IU/ml (1000 IU/10 ml i 1500 IU/15 ml) prašak i otapalo za otopinu za injekciju | not available | UP/I-530-09/12-01/331 | INSTITUTO GRIFOLS, S.A. | HR |
| Haemate P 1000 Pulbere si solvent pentru solutie injectabila sau perfuzabila | not available | 7640/2015/01 | CSL BEHRING GMBH | RO |
| HAEMATE P 250 UI pulbere și solvent pentru soluție perfuzabilă/injectabilă | not available | 287/2007/01 | CSL BEHRING GMBH | RO |
| HAEMATE P 500 UI pulbere și solvent pentru soluție perfuzabilă/injectabilă | not available | 288/2007/01 | CSL BEHRING GMBH | RO |
| Fanhdi 25 IU/ml, prášok a rozpúšťadlo na injekčný roztok | not available | 16/0427/97-S | INSTITUTO GRIFOLS, S.A. | SK |

| 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 |
|--|-------------------------------------|--------------------------------------|---|---|
| Fanhdi 50 IU/ml, prášok a rozpúšťadlo na injekčný roztok | not available | 16/0169/13-S | INSTITUTO GRIFOLS, S.A. | SK |
| Fanhdi 100 IU/ml, prášok a rozpúšťadlo na injekčný roztok | not available | 16/0170/13-S | INSTITUTO GRIFOLS, S.A. | SK |
| Fanhdi 100 IU/ml, prášok a rozpúšťadlo na injekčný roztok | not available | 16/0250/05-S | INSTITUTO GRIFOLS, S.A. | SK |
| Фанди 250 IU прах и разтворител за инжекционен разтвор | not available | 9900225 | INSTITUTO GRIFOLS, S.A. | BG |
| Фанди 500 IU прах и разтворител за инжекционен разтвор | not available | 9900224 | INSTITUTO GRIFOLS, S.A. | BG |
| Фанди 1000 IU прах и разтворител за инжекционен разтвор | not available | 9900223 | INSTITUTO GRIFOLS, S.A. | BG |
| Fanhdi 250 UI + 300 UI /10 ml Polvere e solvente per soluzione per infusione | not available | 033866043 | INSTITUTO GRIFOLS, S.A. | IT |
| Fanhdi 500 UI + 600 UI /10 ml Polvere e solvente per soluzione per infusione | not available | 033866056 | INSTITUTO GRIFOLS, S.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 |
|--|-------------------------------------|--------------------------------------|---|---|
| Fanhdi 1000 UI + 1200 UI /10 ml Polvere e solvente per soluzione per infusione | not available | 033866068 | ISTITUTO GRIFOLS, S.A. | IT |
| Fanhdi 1500 UI + 1800 UI /15 ml Polvere e solvente per soluzione per infusione | not available | 033866070 | ISTITUTO GRIFOLS, S.A. | IT |