



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

4 October 2018  
EMA/382258/2018  
Human Medicines Evaluation Division

## List of nationally authorised medicinal products for maintenance

Active substance(s): human coagulation factor VIII (inhibitor bypassing fraction)

Procedure No.: PSUSA/00009174/201802



| 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 |
|--------------------------------------------------------------------------------|------------------------------|-------------------------------|------------------------------------|------------------------------------------|
| FEIBA 1 000 V milteliai ir tirpiklis injekciniam ar infuziniam tirpalui        | not available                | LT/1/96/1046/003              | BAXALTA INNOVATIONS GMBH           | LT                                       |
| FEIBA 1 000 V milteliai ir tirpiklis injekciniam ar infuziniam tirpalui        | not available                | LT/1/96/1046/004              | BAXALTA INNOVATIONS GMBH           | LT                                       |
| FEIBA 1000 E, poeder en oplosmiddel voor oplossing voor injectie               | not available                | BE124241                      | BAXALTA INNOVATIONS GMBH           | BE                                       |
| FEIBA 1000 E., Pulver und Lösungsmittel zur Herstellung einer Injektionslösung | not available                | BE124241                      | BAXALTA INNOVATIONS GMBH           | BE                                       |
| Feiba 1000 enheter pulver och vätska till injektions-/infusionsvätska, lösning | not available                | 105751                        | BAXALTA INNOVATIONS GMBH           | SE                                       |
| FEIBA 1000 U powder and solvent for solution for infusion                      | not available                | PL 34078/0003                 | BAXALTA INNOVATIONS GMBH           | UK                                       |
| FEIBA 1000 U, poudre et solvant pour solution injectable                       | not available                | BE124241                      | BAXALTA INNOVATIONS GMBH           | BE                                       |
| Feiba 1000 Ü, süstelahuse pulber ja lahusti                                    | not available                | 128296                        | BAXALTA INNOVATIONS GMBH           | EE                                       |
| FEIBA 1000 U.F./20 ml polvere e solvente per soluzione per infusione           | not available                | 024744056                     | BAXALTA INNOVATIONS GMBH           | IT                                       |
| FEIBA 1000 U.F./20 ml polvere e solvente per soluzione per infusione           | not available                | 024744070                     | BAXALTA INNOVATIONS GMBH           | IT                                       |
| FEIBA 1000 U/20 ml, poudre et solvant pour solution injectable                 | not available                | NL20699                       | BAXALTA INNOVATIONS GMBH           | FR                                       |
| FEIBA 1000 U/20 ml, poudre et solvant pour                                     | not available                | NL20699                       | BAXALTA INNOVATIONS GMBH           | 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 |
|---------------------------------------------------------------------------------------------------------------------------------------------|------------------------------|-------------------------------|------------------------------------|------------------------------------------|
| solution injectable                                                                                                                         |                              |                               |                                    |                                          |
| FEIBA 1000 V pulveris un šķīdinātājs infūziju šķīduma pagatavošanai<br>Human Plasma Fractions with Factor VIII Inhibitor Bypassing Activity | not available                | 02-0159                       | BAXALTA INNOVATIONS GMBH           | LV                                       |
| FEIBA 2 500 V milteliai ir tirpiklis injekciniam ar infuziniam tirpalui                                                                     | not available                | LT/1/96/1046/005              | BAXALTA INNOVATIONS GMBH           | LT                                       |
| FEIBA 25 e./ml prašek in vehikel za raztopino za infundiranje                                                                               | AT/H/0343/001                | H/10/00605/002                | BAXALTA INNOVATIONS GMBH           | SI                                       |
| FEIBA 25 e./ml prašek in vehikel za raztopino za infundiranje                                                                               | AT/H/0343/001                | H/10/00605/001                | BAXALTA INNOVATIONS GMBH           | SI                                       |
| FEIBA 25 E./ml Pulver und Lösungsmittel zur Herstellung einer Infusionslösung                                                               | AT/H/0343/001                | 2-00294                       | BAXTER AG                          | AT                                       |
| FEIBA 25 E/ ml, poeder en oplosmiddel voor oplossing voor injectie                                                                          | not available                | RVG 17119                     | BAXALTA INNOVATIONS GMBH           | NL                                       |
| Feiba 25 E/ml Pulver och vätska till infusionsvätska, lösning                                                                               | AT/H/0343/001                | 33278                         | BAXALTA INNOVATIONS GMBH           | FI                                       |
| Feiba 25 E/ml pulver och vätska till infusionsvätska, lösning                                                                               | AT/H/0343/001                | 52769                         | BAXALTA INNOVATIONS GMBH           | SE                                       |
| Feiba 25 Enheter/ml pulver og væske til infusionsvæske, oppløsning                                                                          | AT/H/0343/001                | 09-7024                       | BAXALTA INNOVATIONS GMBH           | NO                                       |
| Feiba 25 U/ml infuusiokuiva-aine ja                                                                                                         | AT/H/0343/001                | 33278                         | BAXALTA INNOVATIONS GMBH           | FI                                       |

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| liuotin, liuosta varten                                       |                              |                               |                                    |                                          |
| FEIBA 25 U/ml polvo y disolvente para solución para perfusión | AT/H/0343/001                | 80118                         | BAXALTA INNOVATIONS GMBH           | ES                                       |
| FEIBA 25 U/ml powder and solvent for solution for infusion    | AT/H/0343/001                | PA 2004/1/1                   | BAXALTA INNOVATIONS GMBH           | IE                                       |
| FEIBA 25 U/ml prašak i otapalo za otopinu za infuziju         | AT/H/0343/001                | HR-H-241676463-01             | BAXALTA INNOVATIONS GMBH           | HR                                       |
| FEIBA 25 U/ml prašak i otapalo za otopinu za infuziju         | AT/H/0343/001                | HR-H-241676463-02             | BAXALTA INNOVATIONS GMBH           | HR                                       |
| FEIBA 25 U/ml pulbere și solvent pentru soluție perfuzabilă   | AT/H/0343/001                | 8463/2015/01                  | BAXALTA INNOVATIONS GMBH           | RO                                       |
| FEIBA 25 U/ml pulbere și solvent pentru soluție perfuzabilă   | AT/H/0343/001                | 8463/2015/02                  | BAXALTA INNOVATIONS GMBH           | RO                                       |
| FEIBA 25 U/ml κόνις και διαλύτης για διάλυμα προς έγχυση.     | AT/H/0343/001                | 22343                         | BAXALTA INNOVATIONS GMBH           | CY                                       |
| FEIBA 25 U/ml κόνις και διαλύτης για διάλυμα προς έγχυση.     | AT/H/0343/001                | 67932/16-9-2016               | BAXALTA INNOVATIONS GMBH           | GR                                       |
| FEIBA 25 Ü/ml, infusioonilahuse pulber ja lahusti             | AT/H/0343/001                | 887615                        | BAXALTA INNOVATIONS GMBH           | EE                                       |
| FEIBA 50 e./ml prašek in vehikel za raztopino za infundiranje | AT/H/0343/002                | H/10/00605/004                | BAXALTA INNOVATIONS GMBH           | SI                                       |
| FEIBA 50 e./ml prašek in vehikel za raztopino za infundiranje | AT/H/0343/002                | H/10/00605/005                | BAXALTA INNOVATIONS GMBH           | SI                                       |
| FEIBA 50 e./ml prašek in                                      | AT/H/0343/002                | H/10/00605/003                | BAXALTA INNOVATIONS                | SI                                       |

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| vehikel za raztopino za infundiranje                                          |                              |                               | GMBH                               |                                          |
| FEIBA 50 e./ml prašek in vehikel za raztopino za infundiranje                 | AT/H/0343/002                | H/10/00605/006                | BAXALTA INNOVATIONS GMBH           | SI                                       |
| FEIBA 50 e./ml prašek in vehikel za raztopino za infundiranje                 | AT/H/0343/002                | H/10/00605/007                | BAXALTA INNOVATIONS GMBH           | SI                                       |
| FEIBA 50 E./ml Pulver und Lösungsmittel zur Herstellung einer Infusionslösung | AT/H/0343/002                | 2-00295                       | BAXTER AG                          | AT                                       |
| Feiba 50 E/ml Pulver och vätska till infusionsvätska, lösning                 | AT/H/0343/002                | 33279                         | BAXALTA INNOVATIONS GMBH           | FI                                       |
| Feiba 50 E/ml pulver och vätska till infusionsvätska, lösning                 | AT/H/0343/002                | 52770                         | BAXALTA INNOVATIONS GMBH           | SE                                       |
| FEIBA 50 E/ml, poeder en oplosmiddel voor oplossing voor injectie             | not available                | RVG 17120                     | BAXALTA INNOVATIONS GMBH           | NL                                       |
| Feiba 50 Enheter/ml pulver og væske til infusionsvæske, oppløsning            | AT/H/0343/002                | 09-7025                       | BAXALTA INNOVATIONS GMBH           | NO                                       |
| Feiba 50 U/ml infuusiokuiva-aine ja liuotin, liuosta varten                   | AT/H/0343/002                | 33279                         | BAXALTA INNOVATIONS GMBH           | FI                                       |
| FEIBA 50 U/ml powder and solvent for solution for infusion                    | AT/H/0343/002                | PA 2004/1/2                   | BAXALTA INNOVATIONS GMBH           | IE                                       |
| FEIBA 50 U/ml prašak i otapalo za otopinu za infuziju                         | AT/H/0343/002                | HR-H-682573334-03             | BAXALTA INNOVATIONS GMBH           | HR                                       |
| FEIBA 50 U/ml prašak i                                                        | AT/H/0343/002                | HR-H-682573334-04             | BAXALTA INNOVATIONS                | HR                                       |

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| otapalo za otopinu za infuziju                              |                              |                               | GMBH                               |                                          |
| FEIBA 50 U/ml prašak i otapalo za otopinu za infuziju       | AT/H/0343/002                | HR-H-682573334-01             | BAXALTA INNOVATIONS GMBH           | HR                                       |
| FEIBA 50 U/ml prašak i otapalo za otopinu za infuziju       | AT/H/0343/002                | HR-H-682573334-02             | BAXALTA INNOVATIONS GMBH           | HR                                       |
| FEIBA 50 U/ml prašak i otapalo za otopinu za infuziju       | AT/H/0343/002                | HR-H-682573334-05             | BAXALTA INNOVATIONS GMBH           | HR                                       |
| FEIBA 50 U/ml pulbere i solvent pentru solutie perfuzabi la | AT/H/0343/002                | 8464/2015/01                  | BAXALTA INNOVATIONS GMBH           | RO                                       |
| FEIBA 50 U/ml pulbere i solvent pentru solutie perfuzabi la | AT/H/0343/002                | 8464/2015/02                  | BAXALTA INNOVATIONS GMBH           | RO                                       |
| FEIBA 50 U/ml pulbere i solvent pentru solutie perfuzabi la | AT/H/0343/002                | 8464/2015/03                  | BAXALTA INNOVATIONS GMBH           | RO                                       |
| FEIBA 50 U/ml pulbere i solvent pentru solutie perfuzabi la | AT/H/0343/002                | 8464/2015/04                  | BAXALTA INNOVATIONS GMBH           | RO                                       |
| FEIBA 50 U/ml pulbere i solvent pentru solutie perfuzabi la | AT/H/0343/002                | 8464/2015/05                  | BAXALTA INNOVATIONS GMBH           | RO                                       |
| FEIBA 50 U/ml κόνις και διαλύτης για διάλυμα προς έγχυση.   | AT/H/0343/002                | 22344                         | BAXALTA INNOVATIONS GMBH           | CY                                       |
| FEIBA 50 U/ml κόνις και διαλύτης για διάλυμα προς έγχυση.   | AT/H/0343/002                | 67933/16-9-2016               | BAXALTA INNOVATIONS GMBH           | GR                                       |
| FEIBA 50 Ü/ml, infusioonilahuse pulber ja lahusti           | AT/H/0343/002                | 887715                        | BAXALTA INNOVATIONS GMBH           | EE                                       |

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|-------------------------------------------------------------------------------|-------------------------------------|--------------------------------------|-------------------------------------------|-------------------------------------------------|
| FEIBA 50 U/ml, poudre et solvant pour solution injectable                     | not available                       | 34009 564 515 0 0                    | BAXALTA INNOVATIONS GMBH                  | FR                                              |
| FEIBA 50 U/ml, poudre et solvant pour solution injectable                     | not available                       | 34009 564 515 0 0                    | BAXALTA INNOVATIONS GMBH                  | FR                                              |
| FEIBA 500 E., Pulver und Lösungsmittel zur Herstellung einer Injektionslösung | not available                       | BE124232                             | BAXALTA INNOVATIONS GMBH                  | BE                                              |
| Feiba 500 enheter pulver och vätska till injektions-/infusionsvätska, lösning | not available                       | 10575                                | BAXALTA INNOVATIONS GMBH                  | SE                                              |
| FEIBA 500 U powder and solvent for solution for infusion                      | not available                       | MA 1047/00201                        | BAXALTA INNOVATIONS GMBH                  | MT                                              |
| FEIBA 500 U powder and solvent for solution for infusion                      | not available                       | PL 34078/0002                        | BAXALTA INNOVATIONS GMBH                  | UK                                              |
| FEIBA 500 U, poeder en oplosmiddel vooroplossing voor injectie                | not available                       | BE124232                             | BAXALTA INNOVATIONS GMBH                  | BE                                              |
| FEIBA 500 U, poudre et solvant pour solution injectable                       | not available                       | BE124232                             | BAXALTA INNOVATIONS GMBH                  | BE                                              |
| Feiba 500 Ü, süstelahuse pulber ja lahusti                                    | not available                       | 128196                               | BAXALTA INNOVATIONS GMBH                  | EE                                              |
| FEIBA 500 U.F./20 ml polvere e solvente per soluzione per infusione           | not available                       | 024744043                            | BAXALTA INNOVATIONS GMBH                  | IT                                              |
| FEIBA 500 U.F./20 ml polvere e solvente per soluzione per infusione           | not available                       | 024744068                            | BAXALTA INNOVATIONS GMBH                  | IT                                              |
| FEIBA 500 U/20 ml,                                                            | not available                       | NL19102                              | BAXALTA INNOVATIONS                       | FR                                              |

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| poudre et solvant pour solution injectable                                                                                                 |                              |                               | GMBH                               |                                          |
| FEIBA 500 U/20 ml, poudre et solvant pour solution injectable                                                                              | not available                | NL19102                       | BAXALTA INNOVATIONS GMBH           | FR                                       |
| FEIBA 500 U/20 ml, poudre et solvant pour solution injectable                                                                              | not available                | NL19102                       | BAXALTA INNOVATIONS GMBH           | FR                                       |
| FEIBA 500 U/20 ml, poudre et solvant pour solution injectable                                                                              | not available                | NL19102                       | BAXALTA INNOVATIONS GMBH           | FR                                       |
| FEIBA 500 V milteliai ir tirpiklis injekciniam ar infuziniam tirpalui                                                                      | not available                | LT/1/96/1046/001              | BAXALTA INNOVATIONS GMBH           | LT                                       |
| FEIBA 500 V milteliai ir tirpiklis injekciniam ar infuziniam tirpalui                                                                      | not available                | LT/1/96/1046/002              | BAXALTA INNOVATIONS GMBH           | LT                                       |
| FEIBA 500 V pulveris un šķīdinātājs infūziju šķīduma pagatavošanai<br>Human Plasma Fractions with Factor VIII Inhibitor Bypassing Activity | not available                | 02-0158                       | BAXALTA INNOVATIONS GMBH           | LV                                       |
| FEIBA NF 1000 E Pulver und Lösungsmittel zur Herstellung einer Injektionslösung                                                            | not available                | PEI.H.03340.02.1              | SHIRE DEUTSCHLAND GMBH             | DE                                       |
| FEIBA NF 1000 j., proszek i rozpuszczalnik do sporzadzania roztworu do wstrzykiwan                                                         | not available                | R/6694                        | SHIRE POLSKA SP. Z O.O.            | PL                                       |
| FEIBA NF 1000 J.Prášek a rozpouštědlo pro injekční roztok                                                                                  | not available                | 75/133/80-B/C                 | BAXALTA INNOVATIONS GMBH           | CZ                                       |
| FEIBA NF 1000 Prášok a                                                                                                                     | not available                | 16/0225/13-S                  | BAXALTA INNOVATIONS                | 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 |
|--------------------------------------------------------------------------------------------|------------------------------|-------------------------------|------------------------------------|------------------------------------------|
| rozpúšťadlo na injekčný alebo infúzny roztok                                               |                              |                               | GMBH                               |                                          |
| Feiba NF 1000 U/20 ml<br>Pó e solvente para<br>solução para perfusão                       | not available                | 4451787                       | BAXALTA INNOVATIONS<br>GMBH        | PT                                       |
| Feiba NF 1000 U/20 ml<br>Pó e solvente para<br>solução para perfusão                       | not available                | 3850187                       | BAXALTA INNOVATIONS<br>GMBH        | PT                                       |
| Feiba NF 25 EgysCg/ml<br>pores oldoszer oldatos<br>injekcioboz                             | not available                | OGYI-T-1804/01                | BAXALTA INNOVATIONS<br>GMBH        | HU                                       |
| Feiba NF 2500 U/50 ml<br>Pó e solvente para<br>solução para perfusão                       | not available                | 5624374                       | BAXALTA INNOVATIONS<br>GMBH        | PT                                       |
| Feiba NF 2500 U/50 ml<br>Pó e solvente para<br>solução para perfusão                       | not available                | 5624408                       | BAXALTA INNOVATIONS<br>GMBH        | PT                                       |
| Feiba NF 50 Egyseg/ml<br>pores oldoszer oldatos<br>injekciohoz                             | not available                | OGYI-T-1804/02                | BAXALTA INNOVATIONS<br>GMBH        | HU                                       |
| Feiba NF 50 Egyseg/ml<br>pores oldoszer oldatos<br>injekciohoz                             | not available                | OGYI-T-1804/03                | BAXALTA INNOVATIONS<br>GMBH        | HU                                       |
| FEIBA NF 500 E Pulver<br>und Lösungsmittel zur<br>Herstellung einer<br>Injektionslösung    | not available                | PEI.H.03340.01.1              | SHIRE DEUTSCHLAND GMBH             | DE                                       |
| FEIBA NF 500 J Prášek a<br>rozpouštědlo pro injekční<br>roztok                             | not available                | 75/133/80-A/C                 | BAXALTA INNOVATIONS<br>GMBH        | CZ                                       |
| FEIBA NF 500 j., proszek<br>i rozpuszczalnik do<br>sporządzania roztworu<br>do wstrzykiwań | not available                | R/6691                        | SHIRE POLSKA SP. Z O.O.            | PL                                       |
| FEIBA NF 500 Prášok a                                                                      | not available                | 16/0133/80-C/S                | BAXALTA INNOVATIONS                | SK                                       |

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|------------------------------------------------------------------------------------------------|------------------------------|-------------------------------|------------------------------------|------------------------------------------|
| rozpúšťadlo na injekčný alebo infúzny roztok.                                                  |                              |                               | GMBH                               |                                          |
| Feiba NF 500 U/20 ml Pó e solvente para solução para perfusão                                  | not available                | 4451688                       | BAXALTA INNOVATIONS GMBH           | PT                                       |
| Feiba NF 500 U/20 ml Pó e solvente para solução para perfusão                                  | not available                | 3850088                       | BAXALTA INNOVATIONS GMBH           | PT                                       |
| Feiba, pulver og solvens til infusionsvæske, opløsning                                         | AT/H/0343/002                | 55684                         | BAXALTA INNOVATIONS GMBH           | DK                                       |
| Feiba, pulver og solvens til infusionsvæske, opløsning                                         | AT/H/0343/001                | 55683                         | BAXALTA INNOVATIONS GMBH           | DK                                       |
| Feiba, pulver og solvens til injektionsog infusionsvæske, opløsning, til intravenøs anvendelse | not available                | 09998                         | BAXALTA INNOVATIONS GMBH           | DK                                       |
| ФЕЙБА 25 U/ml прах и разтворител за инфузионен разтвор                                         | AT/H/0343/001                | 20150284                      | BAXALTA INNOVATIONS GMBH           | BG                                       |
| ФЕЙБА 50 U/ml прах и разтворител за инфузионен разтвор                                         | AT/H/0343/002                | 20150285                      | BAXALTA INNOVATIONS GMBH           | BG                                       |