



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

28 September 2017  
EMA/658413/2017  
Human Medicines Evaluation Division

## List of nationally authorised medicinal products

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

Procedure no.: PSUSA/00009174/201702



<b>Product Name (in authorisation country)</b>	<b>MRP/DCP Authorisation number</b>	<b>National Authorisation Number</b>	<b>MAH of product in the member state</b>	<b>Member State where product is authorised</b>
Feiba 25 U/ml powder and solvent for solution for infusion	AT/H/0343/001	PA 2004/1/1	BAXALTA INNOVATIONS GMBH	IE
Feiba 50 U/ml powder and solvent for solution for infusion	AT/H/0343/002	PA 2004/1/2	BAXALTA INNOVATIONS GMBH	IE
FEIBA NF 500 E Pulver und Lösungsmittel zur Herstellung einer Injektionslösung	not available	PEI.H.03340.01.1	BAXALTA DEUTSCHLAND GMBH	DE
FEIBA NF 1000 E Pulver und Lösungsmittel zur Herstellung einer Injektionslösung	not available	PEI.H.03340.02.1	BAXALTA DEUTSCHLAND GMBH	DE
FEIBA 25 E/ml, poeder en oplosmiddel voor oplossing voor injectie	not available	RVG 17119	BAXALTA INNOVATIONS GMBH	NL
FEIBA 50 E/ml, poeder en oplosmiddel voor oplossing voor injectie	not available	RVG 17120	BAXALTA INNOVATIONS GMBH	NL
Feiba NF 1000 U/20 ml Pó e solvente para solução para perfusão	not available	4451787	BAXALTA INNOVATIONS GMBH	PT
Feiba NF 500 U/20 ml Pó e solvente para solução para perfusão	not available	4451688	BAXALTA INNOVATIONS GMBH	PT
Feiba NF 1000 U/20 ml Pó e solvente para solução para perfusão	not available	3850187	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 500 U powder and solvent for solution for infusion	not available	PL 34078/0002	BAXALTA INNOVATIONS GMBH	UK

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Feiba 1000 U powder and solvent for solution for infusion	not available	PL 34078/0003	BAXALTA INNOVATIONS GMBH	UK
FEIBA NF 500 E	not available	55.953	BAXALTA SPAIN S.L.U	ES
FEIBA NF 1000 E	not available	55.954	BAXALTA SPAIN S.L.U	ES
Feiba 50 Enheter/ml pulver og væske til infusjonsvæske, oppløsning	AT/H/0343/002	09-7025	BAXALTA INNOVATIONS GMBH	NO
Feiba 25 Enheter/ml pulver og væske til infusjonsvæske, oppløsning	AT/H/0343/001	09-7024	BAXALTA INNOVATIONS GMBH	NO
FEIBA 500 U.F./20 ml polvere e solvente per soluzione per infusione	not available	024744043	BAXALTA INNOVATIONS GMBH	IT
FEIBA 1000 U.F./20 ml polvere e solvente per soluzione per infusione	not available	024744056	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 1000 U.F./20 ml polvere e solvente per soluzione per infusione	not available	024744070	BAXALTA INNOVATIONS GMBH	IT
Feiba 500 U powder and solvent for solution for injection	not available	MA 1047/00201	BAXALTA INNOVATIONS GMBH	MT
FEIBA 1000 U, poudre et solvant pour solution injectable	not available	BE124241	BAXALTA INNOVATIONS GMBH	BE
FEIBA 500 U, poudre et solvant pour solution injectable	not available	BE124232	BAXALTA INNOVATIONS GMBH	BE

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FEIBA 25 E./ml - Pulver und Lösungsmittel zur Herstellung einer Infusionslösung	AT/H/0343/001	2-00294	BAXTER AG	AT
FEIBA 50 E./ml - Pulver und Lösungsmittel zur Herstellung einer Infusionslösung	AT/H/0343/002	2-00295	BAXTER AG	AT
ФЕЙБА NF 25 U/ml прах и разтворител за инжекционен разтвор FEIBA NF 25 U/ml U powder and solvent for solution for injection	not available	20150284	BAXALTA INNOVATIONS GMBH	BG
ФЕЙБА NF 50 U/ml прах и разтворител за инжекционен разтвор FEIBA NF 50 U/ml powder and solvent for solution for injection	not available	20150285	BAXALTA INNOVATIONS GMBH	BG
FEIBA NF 500 J. Prášek pro přípravu injekčního roztoku	not available	75/133/80-A/C	BAXALTA INNOVATIONS GMBH	CZ
FEIBA NF 1000 J. Prášek pro přípravu injekčního roztoku	not available	75/133/80-B/C	BAXALTA INNOVATIONS GMBH	CZ
Feiba 500 Ü, süstelahuse pulber ja lahusti	not available	128196	BAXALTA INNOVATIONS GMBH	EE
Feiba 1000 Ü, süstelahuse pulber ja lahusti	not available	128296	BAXALTA INNOVATIONS GMBH	EE

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Feiba 500 V pulveris un šķidrinātais infūziju šķiduma pagatavošanai Human Plasma Fractions with Factor VIII Inhibitor Bypassing Activity	not available	02-0158	BAXALTA INNOVATIONS GMBH	LV
Feiba 1000 V pulveris un šķidrinātais infūziju šķiduma pagatavošanai Human Plasma Fractions with Factor VIII Inhibitor Bypassing Activity	not available	02-0159	BAXALTA INNOVATIONS GMBH	LV
FEIBA 500 V miltelīši ir tirpklis injekcijām/infūzijām tirpalam	not available	LT/1/96/1046/001	BAXALTA INNOVATIONS GMBH	LT
FEIBA 500 V miltelīši ir tirpklis injekcijām/infūzijām tirpalam	not available	LT/1/96/1046/002	BAXALTA INNOVATIONS GMBH	LT
FEIBA 1000 V miltelīši ir tirpklis injekcijām/infūzijām tirpalam	not available	LT/1/96/1046/003	BAXALTA INNOVATIONS GMBH	LT
FEIBA 1000 V miltelīši ir tirpklis injekcijām/infūzijām tirpalam	not available	LT/1/96/1046/004	BAXALTA INNOVATIONS GMBH	LT
FEIBA NF 500 Prášok a rozpúšťadlo na injekčný alebo infúzny roztok.	not available	16/0133/80-C/S	BAXALTA INNOVATIONS GMBH	SK

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FEIBA 2 500 V milteliai ir tirpiklis injekciniam/infuziniam tirpalui	not available	LT/1/96/1046/005	BAXALTA INNOVATIONS GMBH	LT
FEIBA NF 1000 Prášok a rozpúšťadlo na injekčný alebo infúzny roztok	not available	16/0225/13-S	BAXALTA INNOVATIONS GMBH	SK
FEIBA 25 Ü/ml, infusioonilahuse pulber ja lahusti	not available	887615	BAXALTA INNOVATIONS GMBH	EE
FEIBA 50 Ü/ml, infusioonilahuse pulber ja lahusti	not available	887715	BAXALTA INNOVATIONS GMBH	EE
Feiba 50 E/ml pulver och vätska till infusionsvätska, lösning	AT/H/343/02/01	52770	BAXALTA INNOVATIONS GMBH	SE
Feiba 25 E/ml pulver och vätska till infusionsvätska, lösning	AT/H/343/02/01	52769	BAXALTA INNOVATIONS GMBH	SE
Feiba NF 500 Egység/20ml por és oldószer oldatos injekcióhoz	not available	OGYI-T-1804/01	BAXALTA INNOVATIONS GMBH	HU
Feiba NF 1000 Egység/20ml por és oldószer oldatos injekcióhoz	not available	OGYI-T-1804/02	BAXALTA INNOVATIONS GMBH	HU
Feiba 50 U/ml infuusiokuiva-aine ja liuotin, liuosta varten	AT/H0343/01-02/E/01	33279	BAXALTA INNOVATIONS GMBH	FI
Feiba 25 U/ml infuusiokuiva-aine ja liuotin, liuosta varten	AT/H0343/01-02/E/01	33278	BAXALTA INNOVATIONS GMBH	FI

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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 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 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 50 e./ml prašek in vehikel za raztopino za infundiranje	AT/H/0343/002	H/10/00605/003	BAXALTA INNOVATIONS GMBH	SI
FEIBA 25 U/ml prašak i otapalo za otopinu za infuziju	not available	HR-H-241676463	BAXALTA INNOVATIONS GMBH	HR
FEIBA 50 U/ml prašak i otapalo za otopinu za infuziju	not available	HR-H-682573334	BAXALTA INNOVATIONS GMBH	HR
FEIBA 25 U/ml polvo y disolvente para solución para perfusión.	not available	80118	BAXALTA INNOVATIONS GMBH	ES
FEIBA NF 1000 j., proszek i rozpuszczalnik do sporzadzania roztworu do wstrzykiwan	not available	R/6694	BAXALTA POLAND SP. Z O.O.	PL

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FEIBA NF 500 j., proszek i rozpuszczalnik do sporzadzania roztworu do wstrzykiwan	not available	R/6691	BAXALTA POLAND SP. Z O.O.	PL
FEIBA 25 U/ml κόνις και διαλύτης για διάλυμα προς έγχυση.	AT/H/0343/001	22343	BAXALTA INNOVATIONS GMBH	CY
FEIBA 50 U/ml κόνις και διαλύτης για διάλυμα προς έγχυση.	AT/H/0343/002	22344	BAXALTA INNOVATIONS GMBH	CY