



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

29 September 2016
EMA/661359/2016
Human Medicines Evaluation Division

List of nationally authorised medicinal products

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

Procedure no.: PSUSA/00009174/201602



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	AT/H/0343/001 \$ AT/H/0343/002	2-00294 \$ 2-00295	Baxter Ag	Austria
Feiba		BE124232 \$ BE124241	Baxalta Innovations Gmbh	Belgium
фейба Nf		9700043 \$ 9700044	Baxter Ag	Bulgaria
Feiba		09998	Baxalta Innovations Gmbh	Denmark
Feiba Nf		PEI.H.03340.01.1 \$ PEI.H.03340.02.1	Baxalta Deutschland Gmbh	Germany
Feiba	AT/H/0343/001 \$ AT/H/0343/002	41054/16-06-2010 \$ 41055/16-06-2010	Baxter Hellas	Greece
Feiba	AT/H/0343/001 \$ AT/H/0343/002	PA 2004/1/1 \$ PA 2004/1/2	Baxalta Innovations Gmbh	Ireland
Feiba		024744043 \$ 024744056 \$ 024744068 \$ 024744070	Baxalta Innovations Gmbh	Italy
Feiba		MA 1047/00201	Baxalta Innovations Gmbh	Malta
Feiba		RVG 17119 \$ RVG 17120	Baxalta Innovations Gmbh	Netherlands
Feiba	AT/H/0343/001 \$ AT/H/0343/002	09-7024 \$ 09-7025	Baxalta Innovations Gmbh	Norway
Feiba Nf		R/6691 \$ R/6694	Baxter Polska Sp Z O.O.	Poland
Feiba Nf		3850088 \$ 3850187 \$ 4451688 \$ 4451787 & 5624374 & 5624408	Baxalta Innovations Gmbh	Portugal
Feiba Nf		16/0133/80-CS \$ 16/0225/13-S	Baxter Ag	Slovakia

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Feiba	AT/H/0343/001 \$ AT/H/0343/002	5363-I-985/14 \$ 5363-I-986/14	Baxter D.O.O.	Slovenia
Feiba		55.953 \$ 55.954	Baxalta Spain S.L.U	Spain
Feiba		10575 \$ 10575-1	Baxalta Innovations Gmbh	Sweden
Feiba		PL 34078/0002 \$ PL 34078/0003	Baxalta Innovations Gmbh	United Kingdom
Feiba	AT/H/0343/001 \$ AT/H/0343/002	20150284 \$ 20150285	Baxalta Innovations Gmbh	Bulgaria
Feiba	AT/H/0343/001 \$ AT/H/0343/002	HR-H-24167 6463/01-02 \$ HR-H-68257 3334/01-03	Baxalta Innovations Gmbh	Croatia
Feiba		75/133/80-A/C \$ 75/133/80-B/C	Baxter Ag	Czech Republic
Feiba	AT/H/0343/001 \$ AT/H/0343/002	55683 \$ 55684	Baxalta Innovations Gmbh	Denmark
Feiba		887615 \$ 887715	Baxalta Innovations Gmbh	Estonia
Feiba	AT/H/0343/001 \$ AT/H/0343/002	80118 \$ 80119	Baxalta Innovations Gmbh	Spain
Feiba	AT/H/0343/001 \$ AT/H/0343/002	33278 \$ 33279	Baxalta Innovations Gmbh	Finland
Feiba		NL 19102 \$ NL 20699	Baxalta Innovations Gmbh	France
Feiba		OGYI-T-1804/01 \$ OGYI-T-1804/02	Baxalta Innovations Gmbh	Hungary
Feiba		02-0158 \$ 02-0159	Baxalta Innovations Gmbh	Latvia

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Feiba		LT/1/96/1046/001-005	Baxalta Innovations Gmbh	Lithuania
Feiba	AT/H/0343/001 \$ AT/H/0343/002	8464/2015/01-02 \$ 8464/2015/01-03	Baxalta Innovations Gmbh	Romania
Feiba	AT/H/0343/001 \$ AT/H/0343/002	52769 \$ 52770	Baxalta Innovations Gmbh	Sweden