



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

27 October 2016
EMA/735249/2016
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: rocuronium

Procedure no.: PSUSA/00002656/201602



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
Rocuronium Hospira	NL/H/2812/001	135336	Hospira Deutschland Gmbh	Austria
Rocuroniumbromid Kabi	NL/H/1072/001	1-27838	Fresenius Kabi Austria Gmbh	Austria
Esmeron		1-21548	Nv Organon	Austria
Rocuroniumbromid B. Braun	NL/H/1073/001	1-28065	B. Braun Melsungen Ag	Austria
Rocuroniumbromid Hikma	PT/H/1071/001	135383	Hikma Farmacêutica (Portugal), S.A.	Austria
Rocuroniumbromid Tamarang	DE/H/1785/001	1-29074	Tamarang, S.A.	Austria
Rocuroniumbromid Mylan 10 mg/ml Injektionslösung/Infusion slösung	NL/H/2432/001	1-35129 GZ 957570-6404124	Arcana Arzneimittel GmbH	Austria
Esmeron		BE 176522	Nv Organon	Belgium
Esmeron		BE176522 / NAT/H/1624	Nv Organon	Belgium
Rocuronium Bromide Hospira	NL/H/2812/001	BE447733	Hospira Benelux Bvba	Belgium

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Rocuroniumbromide Hospira	NL/H/2812/001	BE447724 \$ BE447733	Hospira Benelux Bvba	Belgium
Rocuroniumbromide Fresenius Kabi	NL/H/1072/001	BE328553 \$ BE328562 \$ BE328571	Fresenius Kabi Nv/Sa	Belgium
Rocuronium B. Braun	NL/H/1073/001	BE328526 \$ BE328535 \$ BE328544	B. Braun Melsungen Ag	Belgium
Rocuronium Sandoz	DE/H/1323/001	BE 335824 \$ BE 335833	Sandoz N.V.	Belgium
есмерон		9700246	Nv Organon	Bulgaria
Esmeron		UP/I-530-09/10-02/455	Merck Sharp & Dohme D.O.O.	Croatia
Esmeron		18110	Nv Organon	Cyprus
Esmeron		63/773/99-C	Nv Organon	Czech Republic
Rocuronium B. Braun	NL/H/1073/001	63/499/08-C	B. Braun Melsungen Ag	Czech Republic

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Esmeron		15661 / dkmk8085001	Nv Organon	Denmark
Rocuronium Hospira	NL/H/2812/001	28675	Hospira Uk Ltd	Denmark
Rocuronium Fresenius Kabi	NL/H/1072/001	41406	Fresenius Kabi Ab	Denmark
Rocuronium Mylan	NL/H/2432/001	49283	Mylan Hospital As	Denmark
Rocuronium "hameln"	NL/H/1071/001	41405	Hameln Pharma Plus Gmbh	Denmark
Esmeron		301100	Nv Organon	Estonia
Esmeron		11528	Nv Organon	Finland
Esmeron		11528	Nv Organon	Finland
Rocuronium B. Braun	NL/H/1073/001	23580	B. Braun Melsungen Ag	Finland

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Rocuronium Hospira	NL/H/2812/001	31261	Hospira Uk Ltd	Finland
Rocuronium Fresenius Kabi	NL/H/1072/001	23579	Fresenius Kabi Ab	Finland
Rocuronium Hameln	NL/H/1071/001	23578	Hameln Pharma Plus Gmbh	Finland
Rocuronium Mylan 10 mg/ml injektio- /infusioneste, liuos	NL/H/2432/001	30055	MYLAN HOSPITAL AS	Finland
Esmeron		34009 559 778 7 2 \$ 34009 559 779 3 3 \$ 34009 564 997 5 5 \$ 34009 571 521 2 3	Msd France	France
Rocuronium B Braun		NL 34772	B. Braun Melsungen Ag	France
Rocuronium Hospira	NL/H/2812/001	34009 550 041 7 2 \$ 34010 550 041 8 9	Hospira France	France
Rocuronium Pfizer	DE/H/3531/001	34009 583 956 9 7 \$ 34009 583 957 5 8 \$ 34009 583 958 1 9 \$ 34009 583 959 8 7 \$ 34009 583 960 6 9 \$ 34009 583 961 2 0 \$ 34009 583 962 9 8 \$ 34009 583 963 5 9	Pfizer Holding France (S.C.A.)	France
Esmeron		30984.00.00 \$ 30984.01.00	Nv Organon	Germany

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Rocuroniumbromid Kabi	NL/H/1072/001	68881.00.00	Fresenius Kabi Deutschland Gmbh	Germany
Rocuroniumbromid Hospira	NL/H/2812/001	89060.00.00	Hospira Deutschland Gmbh	Germany
Rocuronium Inresa		76412.00.00	Inresa Arzneimittel Gmbh	Germany
Rocuronium Tamarang	DE/H/1785/001	70991.00.00	Tamarang, S.A.	Germany
Rocuroniumbromid B. Braun	NL/H/1073/001	68880.00.00	B. Braun Melsungen Ag	Germany
Rocuroniumbromid Hameln	NL/H/1071/001	68879.00.00	Hameln Pharma Plus Gmbh	Germany
Rocuroniumbromid Hexal	DE/H/1323/001	70714.00.00	Hexal Ag	Germany
Rocuroniumbromid Hexal	DE/H/1323/001	70714.00.00	Hexal Ag	Germany
Rocuroniumbromid Hikma	PT/H/1071/001	89258.00.00	Hikma Farmacêutica (Portugal), S.A.	Germany

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Rocuroniumbromid Mylan	NL/H/2432/001	85494.00.00	Mylan Dura Gmbh	Germany
Rocuroniumbromid Pfizer	DE/H/3531/001	76411.00.00	Pfizer Pharma Gmbh	Germany
Rocuroniumbromid Ratiopharm	NL/H/1482/001	75236.00.00	Ratiopharm Gmbh	Germany
Rocuroniumbromid Tamarang	DE/H/2731/001	80998.00.00	Tamarang, S.A.	Germany
Esmeron		41181/10/31-05-2011	Nv Organon	Greece
Rocuronium B. Braun	NL/H/1073/001	34993/15-5-2009	B. Braun Melsungen Ag	Greece
Esmeron		OGYI-T-8863/02 \$ OGYI-T-8863/03	Nv Organon	Hungary
Esmeron		940070	Nv Organon	Iceland
Esmeron		PA 964/1/1	Nv Organon	Ireland

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Rocuronium B. Braun	NL/H/1073/001	PA736/29/19	B. Braun Melsungen Ag	Ireland
Rocuronium Bromide Ibigen	DE/H/2731/001	PA1862/001/001	Ibigen Srl	Ireland
Rocuronium Fresenius Kabi	NL/H/1072/001	PA 566/42/1	Fresenius Kabi Limited	Ireland
Rocuronium Bromide Hospira Uk	NL/H/2812/001	PA 0437/072/001	Hospira Uk Ltd	Ireland
Esmeron		029209032 \$ 029209044 \$ 029209057	Nv Organon	Italy
Rocuronio B. Braun	NL/H/1073/001	039052016 \$ 039052028 \$ 039052030	B. Braun Melsungen Ag	Italy
Rocuronio Hikma,	PT/H/1071/001	042577015	Hikma Farmacêutica (Portugal), S.A.	Italy
Rocuronio Mylan	NL/H/2432/001	041945015	Mylan S.P.A.	Italy
Rocuronio Kabi	NL/H/1072/001	038603015/M \$ 038603027/M \$ 038603039/M \$ 038603041/M \$ 038603054/M \$ 038603066/M	Fresenius Kabi Italia S.R.L.	Italy

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Rocuronio Hospira	NL/H/2812/001	042535017 \$ 042535029	Hospira Italia S.R.L	Italy
Esmeron		04-0203	Nv Organon	Latvia
Esmeron		LT/1/98/0422/001 \$ LT/1/98/0422/002 \$ LT/1/98/0422/003	Nv Organon	Lithuania
Roqurum		LT/1/10/2251/001 \$ LT/1/10/2251/002 \$ LT/1/10/2251/003	Pharmaswiss česká Republika S.R.O.	Lithuania
Esmeron		2001086270 / NAT/H/1624	Nv Organon	Luxembourg
Rocuroniumbromid B. Braun	NL/H/1073/001	0667/11030036	B. Braun Melsungen Ag	Luxembourg
Esmeron		MA 031/00201	Nv Organon	Malta
Esmeron		RVG 16946	Nv Organon	Netherlands
Rocuronium Bromide Sandoz	DE/H/1323/001	RVG 101113	Sandoz B.V.	Netherlands

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Rocuroniumbromide Fresenius Kabi	NL/H/1072/001	RVG 100154	Fresenius Kabi Nederland B.V.	Netherlands
Rocuroniumbromide Hospira	NL/H/2812/001	RVG 113094	Hospira Benelux Bvba	Netherlands
Rocuroniumbromide B. Braun	NL/H/1073/001	RVG 100155	B. Braun Melsungen Ag	Netherlands
Rocuroniumbromide Hameln	NL/H/1071/001	RVG 100151	Hameln Pharma Plus Gmbh	Netherlands
Rocuroniumbromide Ratiopharm	NL/H/1482/001	RVG 103302	Ratiopharm Nederland B.V	Netherlands
Rocuroniumbromide Mylan 10 mg/ml, oplossing voor injectie/infusie	NL/H/2432/001	RVG 110257	Mylan B.V.	Netherlands
Esmeron		8217	NV Organon	Norway
Rocuronium Hospira	NL/H/2812/001	12-9389	Hospira Uk Ltd	Norway
Esmeron		7844 \$ 7845	Nv Organon	Poland

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Rocuronium B. Braun	NL/H/1073/001	16144	B. Braun Melsungen Ag	Poland
Rocuronium Hospira	NL/H/2812/001	21975	Hospira Uk Ltd	Poland
Rocuronium Kabi	NL/H/1072/001	15531	Fresenius Kabi Polska Sp. Z O.O.	Poland
Rocuronium Mylan	NL/H/2432/001	21988	Mylan S.A.S	Poland
Rocuronium Sandoz	DE/H/1323/001	15603	Sandoz Gmbh	Poland
Roqurum		17270	Pharmaswiss česká Republika S.R.O.	Poland
Brometo De Rocurónio B. Braun	NL/H/1073/001	5133475 \$ 5133509 \$ 5133517	B. Braun Melsungen Ag	Portugal
Brometo De Rocurónio Hikma	PT/H/1071/001	5592662	Hikma Farmacêutica (Portugal), S.A.	Portugal
Brometo De Rocurónio Tamarang	DE/H/1785/001	5254776	Tamarang, S.A.	Portugal

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Esmeron		3207081 \$ 5039672 \$ 5053988	Merck Sharp & Dohme, Lda.	Portugal
Brometo De Rocuronio Hospira	NL/H/2812/001	5594866	Hospira Portugal Lda	Portugal
Rocuronio Hospira	NL/H/2812/001	5594874	Hospira Portugal Lda	Portugal
Brometo De Rocurónio Kabi	NL/H/1072/001	5130711 \$ 5130729 \$ 5130737 \$ 5130745 \$ 5130752 \$ 5130760	Fresenius Kabi Pharma Portugal Lda.	Portugal
Esmeron		2988/2010/01 \$ 2988/2010/02 \$ 2988/2010/03	Nv Organon	Romania
Rocuronium Kabi	NL/H/1072/001	4560/2012/01 \$ 4560/2012/02 \$ 4560/2012/03 \$ 4560/2012/04 \$ 4560/2012/05 \$ 4560/2012/06	Fresenius Kabi Romania S.R.L.	Romania
Esmeron		63/0018/01-S	Nv Organon	Slovakia
Rocuronium B. Braun	NL/H/1073/001	63/0392/08-S	B. Braun Melsungen Ag	Slovakia
Rocuronium Hospira	NL/H/2812/001	63/0101/14-S	Hospira Uk Ltd	Slovakia

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Rocuxant	DE/H/1323/001	63/0281/09-S	Sandoz Pharmaceuticals D.D.	Slovakia
Esmeron		H/05/00577/001 \$ H/05/00577/002	Nv Organon	Slovenia
Esmeron		61141	Nv Organon	Spain
Rocuronio Efg B. Braun	NL/H/1073/001	70315	B. Braun Melsungen Ag	Spain
Rocuronio Tamarang	DE/H/1785/001	72862	Tamarang, S.A.	Spain
Rocuronio Hospira	NL/H/2812/001	701708-0 \$ 701708-3	Hospira Productos Farmacéuticos Y Hospitalarios, S.L.	Spain
Rocuronio Kabi	NL/H/1072/001	70.564	Fresenius Kabi España S.A.U.	Spain
Esmeron		12487 \$ 49378 \$ 49883	Merck Sharp & Dohme Bv	Sweden
Rocuronium B. Braun	NL/H/1073/001	25537	B. Braun Melsungen Ag	Sweden

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Rocuronium Hameln	NL/H/1071/001	25535	Hameln Pharma Plus Gmbh	Sweden
Rocuronium Fresenius Kabi	NL/H/1072/001	25536	Fresenius Kabi Ab	Sweden
Rocuronium Hospira	NL/H/2812/001	48940	Hospira Uk Ltd	Sweden
Rocuronium Mylan 10 mg/ml injektions- /infusionsvätska, lösning	NL/H/2432/001	46517 \$ 2011-0807	MYLAN HOSPITAL AS	Sweden
Rocuronium B. Braun	NL/H/1073/001	PL 03551/0111	B. Braun Melsungen Ag	United Kingdom
Rocuronium Bromide Generics [uk]	NL/H/2432/001	PL 04569/1546	Generics [uk] Limited	United Kingdom
Rocuronium Bromide Ibigen	DE/H/2731/001/DC	PL 31745/0029	Ibigen Srl	United Kingdom
Rocuronium Hameln Pharma Plus	NL/H/1071/001	PL 25215/0018	Hameln Pharma Plus Gmbh	United Kingdom
Rocuronium Fresenius Kabi	NL/H/1072/001	PL 08828/0182	Fresenius Kabi Limited	United Kingdom

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Rocuronium Hospira	NL/H/2812/001	PL 04515/0402	Hospira Uk Ltd	United Kingdom
Esmeron		PL 05003/0041	Nv Organon	United Kingdom