



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

12 February 2016
EMA/52102/2016 rev.1
Procedure Management and Committees Support

List of nationally authorised medicinal products

Active substance: topotecan

Procedure no.: PSUSA/00002997/201505



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
Lutecan		51698/12-07-2013 \$ 51697/12-7-2013	Pharmazac Sa	Greece
Ribocamtin	PT/H/0399/001 \$ PT/H/0399/002	82812.00.00 \$ 82813.00.00	Hikma Farmacêutica (Portugal), S.A.	Germany
Topocan		50015/12/20-03-2013	Ariti Sa	Greece
Topoliquid	AT/H/0329/001	1-29714	Ebewe Pharma	Austria
Topotecan Pharmagen		44/091/15-C \$ 44/092/15-C	Pharmagen Cz S.R.O.	Czech Republic
Topotecan	UK/H/2113/001	79509.00.00	Fresenius Kabi Oncology Plc.	Germany
Topotecan	UK/H/2113/002	88336.00.00	Fresenius Kabi Oncology Plc.	Germany
Topotecan Accord	UK/H/1345/001	44743	Accord Healthcare Limited	Sweden
Topotecan Accord	UK/H/4536/001/DC	48501	Accord Healthcare Limited	Denmark
Topotecan Accord	UK/H/4536/001/DC	48501	Accord Healthcare Limited	Denmark
Topotecan 4mg Powder for Concentrate for Solution for Infusion	UK/H/4536/001	MA054/05601	Accord Healthcare Limited	Malta
Topotecan Accord	UK/H/4536/001/DC	OGYI-T-21514/02 \$ OGYI-T-21514/03 \$ OGYI-T-21514/04 \$ OGYI-T-21514/05	Accord Healthcare Limited	Hungary
Topotecan Accord	UK/H/1345/001	PL 20075/0105	Accord Healthcare Limited	United Kingdom
Topotecan Accord	UK/H/4536/001	PA 1390/036/002	Accord Healthcare Limited	Ireland
Topotecan Accord	UK/H/4536/001	PL 20075/0307	Accord Healthcare Limited	United Kingdom
Topotecan Accord	UK/H/1345/01/DC	47358	Accord Healthcare Ab,	Denmark
Topotecan Accord	UK/H/4536/01/DC	11-8165	Accord Healthcare Limited	Norway
Topotecan Accord	UK/H/4536/001	1-31377	Accord Healthcare Limited	Austria

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Topotecan Accord	UK/H/4536/001	1-31377	Accord Healthcare Limited	Austria
Topotecan Accord	UK/H/4536/001	29558	Accord Healthcare Limited	Finland
Topotecan Accord	UK/H/4536/001	29558	Accord Healthcare Limited	Finland
Topotecan Accord	UK/H/4536/001	44/0418/12-S	Accord Healthcare Limited	Slovakia
Topotecan Accord	UK/H/4536/001	44/0418/12-S	Accord Healthcare Limited	Slovakia
Topotecan Accord	UK/H/4536/001	44/322/12-C	Accord Healthcare Limited	Czech Republic
Topotecan Accord	UK/H/4536/001	45706	Accord Healthcare Limited	Sweden
Topotecan Accord	UK/H/4536/001	783112	Accord Healthcare Limited	Estonia
Topotecan Accord	UK/H/4536/001	84489.00.00	Accord Healthcare Limited	Germany
Topotecan Accord	UK/H/4536/001	RVG 109171	Accord Healthcare Limited	Netherlands
Topotecan Accord	UK/H/4536/001	RVG 109171	Accord Healthcare Limited	Netherlands
Topotecan Accord	UK/H/4536/0101	4866/2012/01 \$ 4866/2012/02 \$ 4866/2012/03 \$ 4866/2012/04	Accord Healthcare Limited	Romania
Topotecan Accord	UK/H/4536/01/DC	LT/1/12/2932/001-002 \$ LT/1/12/2932/003-004	Accord Healthcare Limited	Lithuania
Topotecan Accord Healthcare	UK/H/4536/001	BE 422956	Accord Healthcare B.V.	Belgium

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Topotecan Accord Healthcare	UK/H/4536/001	BE422947 \$ BE422956	Accord Healthcare B.V.	Belgium
Topotecan Ahcl	UK/H/4536/001	040877019/M \$ 040877021/M \$ 040877033/M \$ 040877045/M	Accord Healthcare Limited, UK	Italy
Topotecan Accord Healthcare	UK/H/4536/001 \$ UK/H/4536/01/DC	12-0184	Accord Healthcare Limited	Latvia
Topotecan Atb		3656/2011/01 \$ 3657/2011/01	Antibiotice Sa	Romania
Topotecan Bhardwaj		90951.00.00 \$ 91118.00.00	Pharma Resources Gmbh	Germany
Topotecan Ebewe	AT/H/0327/001	09-6947	Ebewe Pharma	Norway
Topotecan Ebewe	AT/H/0327/001	1-29716	Ebewe Pharma	Austria
Topotecan Ebewe	AT/H/0327/001	18248	Ebewe Pharma	Poland
Topotecan Ebewe	AT/H/0327/001	27823	Ebewe Pharma	Finland
Topotecan Ebewe	AT/H/0327/001	3019/2010/01 \$ 3019/2010/02 \$ 3019/2010/03 \$ 3019/2010/04 \$ 3019/2010/05 \$ 3019/2010/06 \$ 3019/2010/07 \$ 3019/2010/08 \$ 3019/2010/09	Ebewe Pharma	Romania
Topotecan Ebewe	AT/H/0327/001	42896	Ebewe Pharma	Sweden
Topotecan Ebewe	AT/H/0327/001	45500	Ebewe Pharma	Denmark
Topotecan Ebewe	AT/H/0327/001	710410	Ebewe Pharma	Estonia
Topotecan Ebewe	AT/H/0327/001	OGYI-T-21729/01 \$ OGYI-T-21729/02 \$ OGYI-T-21729/03 \$ OGYI-T-21729/04 \$ OGYI-T-21729/05 \$ OGYI-T-21729/06	Ebewe Pharma	Hungary
Topotecan Ebewe	AT/H/0327/001	PL 14510/0060	Ebewe Pharma	United Kingdom
Topotecan Ebewe Pharma	AT/H/0329/001	PL 14510/0062	Ebewe Pharma	United Kingdom
Topotecan Fresenius Kabi	UK/H/2113/001	09-6990	Fresenius Kabi Oncology Plc.	Norway

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Topotecan Fresenius Kabi	UK/H/2113/001	43020	Fresenius Kabi Oncology Plc.	Sweden
Topotecan Fresenius Kabi	UK/H/2113/001	45592	Fresenius Kabi Oncology Plc.	Denmark
Topotecan Fresenius Kabi	UK/H/2113/001	BE381281	Fresenius Kabi Oncology Plc.	Belgium
Topotecan Fresenius Kabi	UK/H/2113/001	RVG 105866	Fresenius Kabi Oncology Plc.	Netherlands
Topotecan Fresenius Kabi	UK/H/2113/002	12-9159	Fresenius Kabi Oncology Plc.	Norway
Topotecan Fresenius Kabi	UK/H/2113/002	30950	Fresenius Kabi Oncology Plc.	Finland
Topotecan Fresenius Kabi	UK/H/2113/002	51182	Fresenius Kabi Oncology Plc.	Denmark
Topotecan Fresenius Kabi	UK/H/2113/002	BE442872 \$ BE442881	Fresenius Kabi Oncology Plc.	Belgium
Topotecan Fresenius Kabi	UK/H/2113/002	RVG 112402	Fresenius Kabi Oncology Plc.	Netherlands
Topotecan Fresenius Kabi Oncology	UK/H/2113/001	PL 18727/0017	Fresenius Kabi Oncology Plc.	United Kingdom
Topotecan Fresenius Kabi Oncology	UK/H/2113/02/DC	MA 911/01001, MA 911/01002	Fresenius Kabi Oncology Plc.	Malta
Topotecan Fresenius Kabi Oncology	UK/H/2113/002	PA 1422/005/002	Fresenius Kabi Oncology Plc.	Ireland
Topotecan Fresenius Kabi Oncology	UK/H/2113/002	PL 18727/0036	Fresenius Kabi Oncology Plc.	United Kingdom
Topotecan Fresenius Kabi Oncology	UK/H/2113/001	PA1422/005/001	Fresenius Kabi Oncology Plc.	Ireland
Topotecan Hexal	AT/H/0330/001	1-29715	Ebewe Pharma	Austria
Topotecan Hexal	AT/H/0330/001	79273.00.00	Hexal Ag	Germany
Topotecan Hikma	PT/H/0399/001 \$ PT/H/0399/002	041872019/M \$ 041872021/M \$ 041872033/M \$ 041872045/M	Hikma Farmacêutica (Portugal), S.A.	Italy
Topotecan Hikma	PT/H/0399/001 \$ PT/H/0399/002	1-31208 \$ 1-31209	Hikma Farmacêutica (Portugal), S.A.	Austria
Topotecan Hikma	PT/H/0399/001 \$ PT/H/0399/002	RVG 107992 \$ RVG 107993	Hikma Farmacêutica (Portugal), S.A.	Netherlands
Topotecan Kabi	UK/H/2113/001	041234016/M \$ 041234028/M	Fresenius Kabi Oncology Plc.	Italy
Topotecan Kabi	UK/H/2113/001	1-30544	Fresenius Kabi Oncology Plc.	Austria
Topotecan Kabi	UK/H/2113/001	18590	Fresenius Kabi Oncology Plc.	Poland

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Topotecan Kabi	UK/H/2113/001	1950/11060071	Fresenius Kabi Oncology Plc.	Luxembourg
Topotecan Kabi	UK/H/2113/001	20963	Fresenius Kabi Oncology Plc.	Cyprus
Topotecan Kabi	UK/H/2113/001	3427/2011/01 \$ 3427/2011/02 \$ 3427/2011/03 \$ 3427/2011/04	Fresenius Kabi Oncology Plc.	Romania
Topotecan Kabi	UK/H/2113/002	6043/2013/01 \$ 6043/2013/02 \$ 6043/2013/03 \$ 6043/2013/04	Fresenius Kabi Oncology Plc.	Romania
Topotecan Kabi	UK/H/2113/001	44/0977/10-S	Fresenius Kabi Oncology Plc.	Slovakia
Topotecan Kabi	UK/H/2113/001	44/887/10-C	Fresenius Kabi Oncology Plc.	Czech Republic
Topotecan Kabi	UK/H/2113/001	68156/3-10-2012	Fresenius Kabi Oncology Plc.	Greece
Topotecan Kabi	UK/H/2113/001	714910	Fresenius Kabi Oncology Plc.	Estonia
Topotecan Kabi	UK/H/2113/001	NL 38420	Fresenius Kabi Oncology Plc.	France
Topotecan Kabi	UK/H/2113/001	OGYI-T-21887/01 \$ OGYI-T-21887/02	Fresenius Kabi Oncology Plc.	Hungary
Topotecan Kabi	UK/H/2113/002	021994	Fresenius Kabi Oncology Plc.	Cyprus
Topotecan Kabi	UK/H/2113/002	041234030 \$ 041234042 \$ 041234055 \$ 041234067	Fresenius Kabi Oncology Plc.	Italy
Topotecan Kabi	UK/H/2113/002	135694	Fresenius Kabi Oncology Plc.	Austria
Topotecan Kabi	UK/H/2113/002	14-0038	Fresenius Kabi Oncology Plc.	Latvia
Topotecan Kabi	UK/H/2113/002	21804	Fresenius Kabi Oncology Plc.	Poland
Topotecan Kabi	UK/H/2113/002	44/486/13-C	Fresenius Kabi Oncology Plc.	Czech Republic
Topotecan Kabi	UK/H/2113/002	826513	Fresenius Kabi Oncology Plc.	Estonia
Topotecan Kabi	UK/H/2113/002	95284	Fresenius Kabi Oncology Plc.	Greece
Topotecan Kabi	UK/H/2113/002	LT/1/11/2388/003 \$ LT/1/11/2388/004 \$ LT/1/11/2388/005 \$ LT/1/11/2388/006	Fresenius Kabi Oncology Plc.	Lithuania
Topotecan Kabi	UK/H/2113/002	OGYI-T-21887/03 \$ OGYI-T-21887/04 \$ OGYI-T-21887/05	Fresenius Kabi Oncology Plc.	Hungary
Topotecan Kabi	UK/H/2113/002	OGYI-T-21887/06	Fresenius Kabi Oncology Plc.	Hungary

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Topotecan Medac	UK/H/3113/001	18922	Medac Gesellschaft Für Klinische Spezialpräparate Mbh (Wedel)	Poland
Topotecan Medac	UK/H/3113/001	34009 579 650 6 8 \$ 34009 579 651 2 9 \$ 34009 579 652 9 7 \$ 34009 579 653 5 8 \$ 34009 579 654 1 9 \$ 34009 579 655 8 7	Medac Gesellschaft Für Klinische Spezialpräparate Mbh (Wedel)	France
Topotecan Medac	UK/H/3113/001	44/0231/11-S	Medac Gesellschaft Für Klinische Spezialpräparate Mbh (Wedel)	Slovak Republic
Topotecan Medac	UK/H/3113/001	44/299/11-C	Medac Gesellschaft Für Klinische Spezialpräparate Mbh (Wedel)	Czech Republic
Topotecan Medac	UK/H/3113/001	79504.00.00	Medac Gesellschaft Für Klinische Spezialpräparate Mbh (Wedel)	Germany
Topotecan Medac	UK/H/3113/001	PL 11587/0059	Medac Gesellschaft Für Klinische Spezialpräparate Mbh (Wedel)	United Kingdom
Topotecan Mylan	UK/H/3114/001	040720017/M \$ 040720029/M \$ 040720031/M \$ 040720043/M \$ 040720056/M \$ 040720068/M \$ 040720070/M \$ 040720082/M \$ 040720094/M	Mylan S.P.A.	Italy
Topotecan Mylan	UK/H/3114/001	1-30299	Arcana Arzneimittel Gmbh	Austria
Topotecan Mylan	UK/H/3114/001	44/0161/11-S	Mylan S.A.S	Slovakia
Topotecan Mylan	UK/H/3114/001	44/297/11-C	Mylan S.A.S	Czech Republic
Topotecan Mylan	UK/H/3114/001	5351812 \$ 5351820 \$ 5351838 \$ 5351846 \$ 5351853 \$ 5351861 \$ 5351879 \$ 5351903 \$ 5353172	Mylan, Lda	Portugal
Topotecan Mylan	UK/H/3114/001	BE384054	Mylan Bvba/Sprl	Belgium
Topotecan Mylan	UK/H/3114/001	BE384054 \$ BE384063 \$ BE384072	Mylan Bvba/Sprl	Belgium
Topotecan Mylan	UK/H/3114/001	BE384063	Mylan Bvba/Sprl	Belgium

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
Topotecan Mylan	UK/H/3114/001	BE384072	Mylan Bvba/Sprl	Belgium
Topotecan Mylan	UK/H/3114/001	NL 38668	Mylan S.A.S	France
Topotecan Mylan	UK/H/3114/001	OGYI-T-21930/01 \$ OGYI-T-21930/02 \$ OGYI-T-21930/03 \$ OGYI-T-21930/04 \$ OGYI-T-21930/05 \$ OGYI-T-21930/06	Mylan S.A.S	Hungary
Topotecan Mylan	UK/H/3114/001	PL 04569/1104	Generics [uk] Limited	United Kingdom
Topotecan Mylan	UK/H/3114/001	RVG 106162	Mylan B.V.	Netherlands
Topotecan Mylan	UK/H/4600/001/DC	20695	Mylan S.A.S	Poland
Topotecan Sandoz	AT/H/0327/001	RVG 105701	Sandoz B.V.	Netherlands
Topotecane Accord	UK/H/4536/001	34009 222 573 7 2; 34009 222 574 3 3; 34009 222 576 6 2; 34009 222 577 2	Accord Healthcare Limited, UK	France
Topotecane Kabi	UK/H/2113/002	NL 42 705	Fresenius Kabi Oncology Plc.	France
Topotecano Azevedos	13/H/0116/001	5607973	Laboratórios Azevedos - Indústria Farmacêutica, S.A.	Portugal
Topotecano Azevedos	13/H/0116/002	5618160	Laboratórios Azevedos - Indústria Farmacêutica, S.A.	Portugal
Topotecano Accord	UK/H/1345/001	5253760	Accord Healthcare Limited	Portugal
Topotecan Accord	UK/H/4536/01/DC	5*1ML-5456819/1*1ML-5456801 \$ 5*4ML-5456835/1*4ML-54568270	Accord Healthcare Limited	Portugal
Topotecano Azevedos	13/H/0116/001	5608005	Laboratórios Azevedos - Indústria Farmacêutica, S.A.	Portugal
Topotecano Azevedos	13/H/0116/002	5618178	Laboratórios Azevedos - Indústria Farmacêutica, S.A.	Portugal
Topotecano Generis	08/H/0417/001	5192075 \$ 5192109 \$ 5192117 \$ 5192125	Generis Farmacêutica, S.A.	Portugal
Topotecano Hikma	PT/H/0399/001	5430509	Hikma Farmacêutica (Portugal), S.A.	Portugal
Topotecano Hikma	PT/H/0399/001 \$ PT/H/0399/002	5430517 \$ 5430525 \$ 5430533	Hikma Farmacêutica (Portugal), S.A.	Portugal

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Topotecano Kabi	UK/H/2113/001	5344106 \$ 5344114	Fresenius Kabi Oncology Plc.	Portugal
Topotecano Sandoz	AT/H/0327/001	5336342 \$ 5336359 \$ 5336367 \$ 5336375 \$ 5336409 \$ 5336417	Sandoz Farmacêutica Lda.	Portugal
Topotecano Venus		21957	Venus Pharma Gmbh	Cyprus
Topotecano Venus Pharma		5458567	Venus Pharma Gmbh	Portugal
Topotecanum Accord	UK/H/4536/001/DC	20222	Accord Healthcare Limited	Poland
Topotecán Accord	UK/H/1345/001	72892	Accord Healthcare S.L.U.	Spain
Topotecán Accord	UK/H/4536/001	76570	Accord Healthcare S.L.U.	Spain
Topotecán Accord	UK/H/4536/001	76570	Accord Healthcare S.L.U.	Spain
Topotecán Farmalider		78428 \$ 78445	Farmalider S.A	Spain
Topotekan Accord	UK/H/4536/001	5363-I-1457/12 \$ 5363-I-1458/12	Accord Healthcare Limited	Slovenia
Topotekan Kabi	UK/H/2113/001	5363-I-1407/11	Fresenius Kabi Oncology Plc.	Slovenia
Topovin		11878/15-02-2012	Aurora Pharmaceuticals Sa	Greece
topotecan Accord	UK/H/4536/001 \$ UK/H/4536/01/DC	021677	Accord Healthcare Limited	Cyprus
топотекан акорд	UK/H/4536/001	20120329	Accord Healthcare Limited	Bulgaria
топотекан каби	UK/H/2113/001	20120354	Fresenius Kabi Oncology Plc.	Bulgaria
Τοποτεκάνη Accord 1 mg / ml Πυκνό Διάλυμα για έγχυση	UK/H/4536/001/DC	2976701 2976702 2976703 2976704	Accord Healthcare Limited, UK	Greece
Topotecan Thymoorgan		83/15 DMP/21/NNP 84/15 DMP/21/NNP	Promopharm S.A.	Portugal

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Topotecan Kabi 4 mg/ml concentrado para solucion para perfusion	UK/H/2113/001/DC	Awaited	Fresenius Kabi Oncology Plc.	Spain
Topotecan Kabi 1 mg polvo para concentrado para solucion para perfusion	UK/H/2113/002/DC	Awaited	Fresenius Kabi Oncology Plc.	Spain
Topotecan Kabi 1 mg/ml Konzentrat zur Herstellung einer Infusion	UK/H/2113/002/DC	Awaited	Fresenius Kabi Oncology Plc.	Luxembourg
Topotecan Mylan 1mg/ml concentrado para solucion para perfusion	UK/H/3114/001/DC	MA pending	Mylan Pharmaceuticals, S.L.	Spain
Topotecan Mylan Pharmaceuticals 4mg polvo para concentrado para solucion para perfusion EFG	UK/H/4600/001/DC	78022	Mylan Pharmaceuticals, S.L.	Spain
Topotecan 4mg powder for concentrate for solution for infusion	UK/H/4600/001/DC	PL 04569/1531	Generics [UK]Ltd t/a Mylan	United Kingdom
Topotecan Ebewe	AT/H/0327		Ebewe Pharma	Cyprus
Topotecan Accord 1mg/ml concentrate for solution for infusion	UK/H/1345/001/DC	MA054/01601	Accord Healthcare Limited	Malta
Topotecan Alpha-Medical		UP/I-530-09/12-01/715	Alpha-Medical D.O.O.	Croatia
Topotecan Kabi 4 mg prašak za koncentrat za otopinu za infuziju		UP/I-530-09/12-01/636	FRESENIUS KABI D.O.O.	Croatia
Topotecan Cipla	AT/H/0362/001 AT/H/0362/002	1-30603 1-30604	Cipla (Uk) Limited	Austria
Topotecan Cipla	AT/H/0362/001 AT/H/0362/002	3951/2011/01 3952/2011/02	Cipla (Uk) Limited	Romania

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Topotecan Cipla	AT/H/0362/001/DC AT/H/0362/002/DC	20575 20576	Cipla (Uk) Limited	Poland
Topotecan Cipla	AT/H/0362/001/DC \$ AT/H/0362/002/DC	OGYI-T-21932/01 OGYI-T-21932/03	Cipla (Uk) Limited	Hungary
топотекан ципла	AT/H/0362/001/DC \$ AT/H/0362/002/DC	19828 19829	Cipla (Uk) Limited	Bulgaria
Topotecan Haemato		76786.00.00	Haemato Pharm Gmbh	Germany
Topotecan Haemato 1 Mg		76785.00.00	Haemato Pharm Gmbh	Germany