



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

10 September 2015  
EMA/706456/2015  
Procedure Management and Committees Support

## List of nationally authorised medicinal products

Active substance: 5 fluorouracil (i.v. application)

Procedure no.: PSUSA/00000007/201412



<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>
5 Fu-Cell		47654.00.00	Cell Pharm Gmbh	DE
5 Fu-Cell		47662.00.00	Cell Pharm Gmbh	DE
5-Fluorouracil		44/0150/98-S (1000 mg)	Ebewe Pharma	SK
5-Fluorouracil		44/0150/98-S (250 mg)	Ebewe Pharma	SK
5-Fluorouracil		44/0150/98-S (500 mg)	Ebewe Pharma	SK
5-Fluorouracil		44/0150/98-S (5000 mg)	Ebewe Pharma	SK
5-Fluorouracil "ebewe"		7321/2015/01	Ebewe Pharma	RO
5-Fluorouracil "ebewe"		7321/2015/02	Ebewe Pharma	RO
5-Fluorouracil "ebewe"		7321/2015/03	Ebewe Pharma	RO
5-Fluorouracil "ebewe"		7321/2015/04	Ebewe Pharma	RO

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5-Fluorouracil "ebewe"		7321/2015/05	Ebewe Pharma	RO
5-Fluorouracil "ebewe"		7321/2015/06	Ebewe Pharma	RO
5-Fluorouracil "ebewe"	National authorisation	OGYI-T-7514/01	Ebewe Pharma	HU
5-Fluorouracil "ebewe"	National authorisation	OGYI-T-7514/02	Ebewe Pharma	HU
5-Fluorouracil "ebewe"	National authorisation	OGYI-T-7514/03	Ebewe Pharma	HU
5-Fluorouracil "ebewe"	National authorisation	OGYI-T-7514/04	Ebewe Pharma	HU
5-Fluorouracil "ebewe"	National authorisation	OGYI-T-7514/05	Ebewe Pharma	HU
5-Fluorouracil "ebewe"	National authorisation	OGYI-T-7514/06	Ebewe Pharma	HU
5-Fluorouracil "ebewe"	National authorisation	OGYI-T-7514/07	Ebewe Pharma	HU

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5-Fluorouracil "ebewe"	National authorisation	OGYI-T-7514/08	Ebewe Pharma	HU
5-Fluorouracil "ebewe"	National authorisation	OGYI-T-7514/09	Ebewe Pharma	HU
5-Fluorouracil "ebewe"	National authorisation	OGYI-T-7514/10	Ebewe Pharma	HU
5-Fluorouracil Biosyn		6853369.00.00	Biosyn Arzneimittel Gmbh	DE
5-Fluorouracil "Ebewe"		44/285/99-C	Ebewe Pharma Ges.m.b.H Nfg. KG	CZ
5-Fluorouracil Ebewe	4506	4506	Ebewe Pharma	PL
5-Fluorouracil Ebewe	938.378	1-22397	Ebewe Pharma	AT
5-Fluorouracil Ebewe		245099	Ebewe Pharma	EE
5-Fluorouracil Ebewe	NP/H/0101/001	5363-I-581/14	Ebewe Pharma	SI

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5-Fluorouracil Ebewe	NP/H/0101/001	5363-I-582/14	Ebewe Pharma	SI
5-Fluorouracil Ebewe	NP/H/0101/001	5363-I-583/14	Ebewe Pharma	SI
5-Fluorouracil Ebewe	NP/H/0101/001	5363-I-584/14	Ebewe Pharma	SI
5-Fluorouracil Ebewe	NP/H/0101/001	5363-I-585/14	Ebewe Pharma	SI
5-Fluorouracil Ebewe	NP/H/0101/001	5363-I-586/14	Ebewe Pharma	SI
5-Fluorouracil Ebewe	NP/H/0101/001	5363-I-587/14	Ebewe Pharma	SI
5-Fluorouracil Ebewe	PA 789/5/1	PA 789/5/1	Ebewe Pharma	IE
5-Fluorouracil Ebewe	R-554	20000369	Ebewe Pharma	BG
5-Fluorouracil Hexal	0940482	6940482.00.00	Hexal Ag	DE

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5-Fluorouracil Hikma Farmacêutica (Portugal), S.A.		55681.00.00	Hikma Farmacêutica (Portugal), S. A.	DE
5-Fluorouracil Sandoz	RVG 22303	RVG 22303	Sandoz B.V.	NL
5-Fu Hexal	2150734	50732.02.00	Hexal Ag	DE
5-Fu Kohne Pharma Gmbh		74931.00.00	Kohne Pharma Gmbh	DE
Fluorouracil		41196.00.00	Medac Gesellschaft Für Klinische Spezialpräparate Mbh	DE
5-Fu Oncotrade		81692.00.00	Pgd Profusio Haan Gesundheits Gmbh Deutschland	DE
5-Fu Onkovis		83226.00.00	Onkovis Gmbh	DE
Fluorouracil		4778	Medac Gesellschaft Für Klinische Spezialpräparate Mbh	PL
Cinkef-U		2551786	Hospira Portugal Lda	PT

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Cinkef-U		2967982	Hospira Portugal Lda	PT
Cinkef-U		2968089	Hospira Portugal Lda	PT
Cinkef-U		3129780	Hospira Portugal Lda	PT
Eurofluor		67365.00.00	Lapharm Pharmaceutical Products Ltd	DE
Flourouracil-Teva		LT/1/98/0536/001	Teva Pharma B.V. Computerweg 10	LT
Fluoro-Uracil		39.660	Meda Pharma S.A.U.	ES
Fluoro-Uracile MEDA		020352011	Meda Pharma S.P.A.	IT
Fluoro-Uracile MEDA		020352050	Meda Pharma S.P.A.	IT
Fluoro-Uracile MEDA		020352062	Meda Pharma S.P.A.	IT

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Fluoro-Uracile MEDA		020352074	Meda Pharma S.P.A.	IT
Fluoro-Uracile MEDA		020352086	Meda Pharma S.P.A.	IT
Fluorouracil-GRY		6117.01.00	Teva GmbH	DE
Flourouracil-Teva		LT/1/98/0536/002	Teva Pharma B.V. Computerweg 10	LT
Fluorouracil Pliva		UP/I-530-09/09-01/222	Pliva Hrvatska D.O.O.; Prilaz Baruna Filipovica 25, 10000 Zagreb, Croatia	HR
Fluorouracil		AA054/02201	Accord Healthcare Limited	MT
Fluorouracil	UK/H/1185/001/E/001	021926	Accord Healthcare Limited	CY
Fluorouracil Accord	UK/H/1185/001/E/001	12- 9364	Accord Healthcare Limited	NO
Fluorouracil Accord	UK/H/1185/001/E/001	5363-I-1609/13	Accord Healthcare Limited	SI



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Fluorouracil Accord	UK/H/1185/001/E/001	5363-I-1610/13	Accord Healthcare Limited	SI
Fluorouracil Accord	UK/H/1185/001/E/001	5363-I-1611/13	Accord Healthcare Limited	SI
Fluorouracil Accord	UK/H/1185/001/E/001	5363-I-1612/13	Accord Healthcare Limited	SI
Fluorouracil Accord	UK/H/1185/001/E/001	5363-I-1613/13	Accord Healthcare Limited	SI
Fluorouracil Accord	UK/H/1185/001/E/001	5783/2013/01	Accord Healthcare Limited	RO
Fluorouracil Accord	UK/H/1185/001/E/001	5783/2013/02	Accord Healthcare Limited	RO
Fluorouracil Accord	UK/H/1185/001/E/001	5783/2013/03	Accord Healthcare Limited	RO
Fluorouracil Accord	UK/H/1185/001/E/001	5783/2013/04	Accord Healthcare Limited	RO
Fluorouracil Accord	UK/H/1185/001/E/001	5783/2013/05	Accord Healthcare Limited	RO

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Fluorouracil Accord	UK/H/1185/001/E/001	89351.00.00	Accord Healthcare Limited	DE
Fluorouracil Accord	UK/H/1185/001/E/001	OGYI-T-22502-1	Accord Healthcare Limited	HU
Fluorouracil Accord	UK/H/1185/001/E/001	OGYI-T-22502-2	Accord Healthcare Limited	HU
Fluorouracil Accord	UK/H/1185/001/E/001	OGYI-T-22502-3	Accord Healthcare Limited	HU
Fluorouracil Accord	UK/H/1185/001/E/001	OGYI-T-22502-4	Accord Healthcare Limited	HU
Fluorouracil Accord	UK/H/1185/001/E/001	OGYI-T-22502-5	Accord Healthcare Limited	HU
Fluorouracil Accord	UK/H/1185/01/DC	09-0458	Accord Healthcare Limited	LV
Fluorouracil Accord	UK/H/1185/01/DC	1-29257	Accord Healthcare Limited	AT
Fluorouracil Accord	UK/H/1185/01/DC	16642	Accord Healthcare Limited	PL

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Fluorouracil Accord	UK/H/1185/01/DC	23977	Accord Healthcare Limited	FI
Fluorouracil Accord	UK/H/1185/01/DC	25842	Accord Healthcare Limited	SE
Fluorouracil Accord	UK/H/1185/01/DC	41876	Accord Healthcare Limited	DK
Fluorouracil Accord	UK/H/1185/01/DC	44/0092/11-S	Accord Healthcare Limited	SK
Fluorouracil Accord	UK/H/1185/001/DC	44/587/09-C	Accord Healthcare Limited	CZ
Fluorouracil Accord	UK/H/1185/01/DC	648509	Accord Healthcare Limited	EE
Fluorouracil Accord	UK/H/1185/01/DC	LT/1/10/2109/001	Accord Healthcare Limited	LT
Fluorouracil Accord	UK/H/1185/01/DC	LT/1/10/2109/002	Accord Healthcare Limited	LT
Fluorouracil Accord	UK/H/1185/01/DC	LT/1/10/2109/003	Accord Healthcare Limited	LT

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Fluorouracil Accord	UK/H/1185/01/DC	LT/1/10/2109/004	Accord Healthcare Limited	LT
Fluorouracil Accord	UK/H/1185/01/DC	LT/1/10/2109/005	Accord Healthcare Limited	LT
Fluorouracil	UK/H/1185/01/DC	PA1390/015/001	Accord Healthcare Limited	IE
Fluorouracil	UK/H/1185/01/DC	PL 20075/0078	Accord Healthcare Limited	GB
Fluorouracil Accord	UK/H/1185/01/DC	RVG 100701	Accord Healthcare Limited	NL
Fluorouracil	UK/H/1185/01/DC	S00721	Accord Healthcare Limited	CY
Fluorouracil Accord Healthcare	UK/H/1185/01/DC	BE-345597	Accord Healthcare Limited	BE
Fluorouracil Accord Healthcare	UK/H/1185/01/DC	BE-345606	Accord Healthcare Limited	BE
Fluorouracil Accord Healthcare	UK/H/1185/01/DC	BE-345615	Accord Healthcare Limited	BE

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Fluorouracil Accord Healthcare	UK/H/1185/01/DC	BE-345624	Accord Healthcare Limited	BE
Fluorouracil Accord Healthcare	UK/H/1185/01/DC	BE-415712	Accord Healthcare Limited	BE
Fluorouracil	UK/H/1185/001/E/001	MA054/08101	Accord Healthcare Limited	MT
Fluorouracil Ebewe		99-0207	Ebewe Pharma	LV
Fluorouracil Ebewe		99-0208	Ebewe Pharma	LV
Fluorouracil Ebewe		99-0209	Ebewe Pharma	LV
Fluorouracil Ebewe		LT/1/96/0734/001	Ebewe Pharma	LT
Fluorouracil Ebewe		LT/1/96/0734/002	Ebewe Pharma	LT
Fluorouracil Ebewe		LT/1/96/0734/003	Ebewe Pharma	LT

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Fluorouracil Ebewe		LT/1/96/0734/004	Ebewe Pharma	LT
Fluorouracil Ebewe		LT/1/96/0734/005	Ebewe Pharma	LT
Fluorouracil Hexal	2184261	84261.00.00	Hexal Ag	DE
Fluorouracil Hospira		034316 0125	Hospira Italia Srl	IT
Fluorouracil Hospira		034316 0245	Hospira Italia Srl	IT
Fluorouracil Hospira		034316 0361	Hospira Italia Srl	IT
Fluorouracil Hospira		034316 0481	Hospira Italia Srl	IT
Fluorouracil Hospira		034316 0511	Hospira Italia Srl	IT
Fluorouracil Hospira		034316 0875	Hospira Italia Srl	IT

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Fluorouracil Hospira		14003	Hospira Nordic Ab	DK
Fluorouracil Hospira		44/255/99-C	Hospira Uk Ltd	CZ
Fluorouracil Hospira		7863	Hospira Nordic Ab	NO
Fluorouracil Hospira		AA734/00101	Hospira Uk Ltd	MT
Fluorouracil Hospira		PA 437/11/01	Hospira Uk Ltd	IE
Fluorouracil Hospira		PL 04515/0088	Hospira Uk Ltd	GB
Fluorouracil Hospira		PL 04515/0024	Hospira Uk Ltd	GB
Fluorouracil Pch		RVG 11900	Pharmachemie B.V.	NL
Fluorouracil PhaRes		89558.00.00	Pharma Resources Gmbh	DE

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Fluorouracil Profusio		84483.00.00	Pgd Profusio Leipzig Gesundheits Gmbh Deutschland	DE
Fluorouracil Teva		11425	Teva Sweden Ab	SE
Fluorouracil – Teva 50 Mg/MI		99-0768	Teva Pharma B.V. Computerweg 10	LV
Fluorouracil-Teva	National authorisation	OGYI-T-4272/01	Teva Gyógyszergyár Zrt	HU
Fluorouracil-Teva	National authorisation	OGYI-T-4272/05	Teva Gyógyszergyár Zrt	HU
Fluorouracil-Teva	National authorisation	OGYI-T-4272/06	Teva Gyógyszergyár Zrt	HU
Fluorouracil-Teva	National authorisation	OGYI-T-4272/07	Teva Gyógyszergyár Zrt	HU
Fluorouracil-Teva	National authorisation	OGYI-T-4272/08	Teva Gyógyszergyár Zrt	HU
Fluorouracil-Teva	National authorisation	OGYI-T-4272/09	Teva Gyógyszergyár Zrt	HU



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Fluorouracil-Teva	National authorisation	OGYI-T-4272/10	Teva Gyógyszergyár Zrt	HU
Fluorouracil-Teva	National authorisation	OGYI-T-4272/11	Teva Gyógyszergyár Zrt	HU
Fluorouracile Accord		575 179-7 OU 34009 575 179 7 7: 5 ML EN FLACON (VERRE). BOÎTE DE 1.	Accord Healthcare France Sas	FR
Fluorouracile Accord		575 180-5 OU 34009 575 180 5 9: 10 ML EN FLACON (VERRE). BOÎTE DE 1.	Accord Healthcare France Sas	FR
Fluorouracile Accord		575 181-1 OU 34009 575 181 1 0: 20 ML EN FLACON (VERRE). BOÎTE DE 1.	Accord Healthcare France Sas	FR
Fluorouracile Accord		575 182-8 OU 34009 575 182 8 8: 100 ML EN FLACON (VERRE). BOÎTE DE 1.	Accord Healthcare France Sas	FR
Fluorouracile Accord		579 845-1 OU 34009 579 845 1 9: 50 ML EN FLACON (VERRE). BOÎTE DE 1.	Accord Healthcare France Sas	FR
Fluorouracile Ahcl	UK/H/1185/01/DC	040593016/M	Accord Healthcare Limited	IT
Fluorouracile Ahcl	UK/H/1185/01/DC	040593028/M	Accord Healthcare Limited	IT

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Fluorouracile Ahc	UK/H/1185/01/DC	040593030/M	Accord Healthcare Limited	IT
Fluorouracile Ahc	UK/H/1185/01/DC	040593042/M	Accord Healthcare Limited	IT
Fluorouracile Ebewe	NL 36726	34009 576 145 9 1	Sandoz	FR
Fluorouracile Ebewe	NL 36726	34009 576 146 5 2	Sandoz	FR
Fluorouracile Ebewe	NL 36726	34009 576 147 1 3	Sandoz	FR
Fluorouracile Ebewe	NL 36726	34009 576 148 8 1	Sandoz	FR
Fluorouracile Ebewe	NL 36726	34009 576 149 4 2	Sandoz	FR
Fluorouracile Ebewe	NL 36726	34009 576 150 2 4	Sandoz	FR
Fluorouracile Ebewe	NL 36726	34009 576 151 9 2	Sandoz	FR

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Fluorouracile Ebewe	NL 36726	34009 576 152 5 3	Sandoz	FR
Fluorouracile Ebewe	NL 36726	34009 576 153 1 4	Sandoz	FR
Fluorouracile Ebewe	NL 36726	34009 576 154 8 2	Sandoz	FR
Fluorouracile Sandoz		038332019	Sandoz S.P.A.	IT
Fluorouracile Sandoz		038332021	Sandoz S.P.A.	IT
Fluorouracile Sandoz		038332033	Sandoz S.P.A.	IT
Fluorouracile Sandoz		038332045	Sandoz S.P.A.	IT
Fluorouracile Teva		026542062	Teva Italia S.R.L.	IT
Fluorouracile Teva		026542047	Teva Italia S.R.L.	IT

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Fluorouracile Teva		026542050	Teva Italia S.R.L.	IT
Fluorouracile Teva		026542074	Teva Italia S.R.L.	IT
Fluorouracile Teva		NL22257	Teva Santé	FR
Fluorouracile Teva		NL22258	Teva Santé	FR
Fluorouracile Teva		NL22259	Teva Santé	FR
Fluorouracile Teva		NL22260	Teva Santé	FR
Fluorouracilo Accord	UK/H/1185/01/DC	5229208-5 ML	Accord Healthcare Limited	PT
Fluorouracilo Accord	UK/H/1185/01/DC	5229216-10 ML	Accord Healthcare Limited	PT
Fluorouracilo Accord	UK/H/1185/01/DC	5229224-20 ML	Accord Healthcare Limited	PT

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Fluorouracilo Accord	UK/H/1185/01/DC	5229232-100 ML	Accord Healthcare Limited	PT
Fluorouracilo Accord	UK/H/1185/01/DC	5424361-50 ML	Accord Healthcare Limited	PT
Fluorouracilo Accord	UK/H/1185/01/DC	71868	Accord Healthcare S.L.U.	ES
Fluorouracilo APS		2950087	Generis Farmacêutica, S.A.	PT
Fluorouracilo APS		2950186	Generis Farmacêutica, S.A.	PT
Fluorouracilo APS		3180486	Generis Farmacêutica, S.A.	PT
Fluorouracilo APS		3180585	Generis Farmacêutica, S.A.	PT
Fluorouracilo APS		3180684	Generis Farmacêutica, S.A.	PT
Fluorouracilo APS		3180783	Generis Farmacêutica, S.A.	PT

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Fluorouracilo APS		3180882	Generis Farmacêutica, S.A.	PT
Fluorouracilo Sandoz		5149539	Sandoz Farmaceutica Lda	PT
Fluorouracilo Sandoz		5149547	Sandoz Farmaceutica Lda	PT
Fluorouracilo Sandoz		5149554	Sandoz Farmaceutica Lda	PT
Fluorouracilo Sandoz		5149562	Sandoz Farmaceutica Lda	PT
Fluorouracilo Sandoz		5189568	Sandoz Farmaceutica Lda	PT
Fluorouracilo Teva		2494789	Teva Pharma – Produtos Farmacêuticos Lda	PT
Fluorouracilo Teva		2662682	Teva Pharma – Produtos Farmacêuticos Lda	PT
Fluorouracilo Teva		2662781	Teva Pharma – Produtos Farmacêuticos Lda	PT

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Fluorouracilo Teva		2662880	Teva Pharma – Produtos Farmacêuticos Lda	PT
Fluorouracilo Teva		5012505	Teva Pharma – Produtos Farmacêuticos Lda	PT
Fluoruracil Bhardwaj		89556.00.00	Bhardwaj Pharma Gmbh	DE
Flurablastin		10078	Pfizer Oy	FI
Flurablastin		13103	Pfizer Aps	DK
Flurablastin		890002 (IS)	Pfizer Aps	IS
Fluracedyl		1316/06010007	Teva Pharma Belgium N.V.	LU
Fluracedyl		1316/06010008	Teva Pharma Belgium N.V.	LU
Fluracedyl		BE 161061	Teva Pharma Belgium N.V.	BE

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Fluracedyl		BE 201126	Teva Pharma Belgium N.V.	BE
Fluroblastine		2003037335	Pfizer S.A. (Belgium)	LU
Fluroblastine		2008069813	Pfizer S.A. (Belgium)	LU
Fluroblastine		2008069814	Pfizer S.A. (Belgium)	LU
Fluroblastine		BE119594	Pfizer S.A. (Belgium)	BE
Fluroblastine		BE176687	Pfizer S.A. (Belgium)	BE
Fluroblastine		BE176696	Pfizer S.A. (Belgium)	BE
Flúoróúracíl Accord	UK/H/1185/001/E/001	IS/1/13/080/01	Accord Healthcare Limited	IS
Fluorouracil		PL 11587/0015	Medac Gesellschaft Für Klinische Spezialpräparate Mbh	GB



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
Fluorouracil		PL 11587/0021	Medac Gesellschaft Für Klinische Spezialpräparate Mbh	GB
Ribofluor		6127367.00.00	Hikma Farmacêutica (Portugal), S. A.	DE
флуороурацил акорд	UK/H/1185/001/E/001	20130261	Accord Healthcare Limited	BG
Fluorouracile Pfizer		NL 22191	Pfizer Holding France	FR
Fluorouracilo Sandoz		63.549	Sandoz Farmaceutica Lda	ES
Fluorouracil-Teva	National authorisation	OGYI-T-4272/02	Teva Gyógyszergyár Zrt	HU
Fluorouracil-Teva	National authorisation	OGYI-T-4272/03	Teva Gyógyszergyár Zrt	HU
Fluorouracil-Teva	National authorisation	OGYI-T-4272/04	Teva Gyógyszergyár Zrt	HU
Fluorouracil Pliva		UP/I-530-09/09-01/223	Pliva Hrvatska D.O.O.; Prilaz Baruna Filipovica 25, 10000 Zagreb, Croatia	HR

<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>
Agicil 50 mg/ml Injektions-/Infusionslösung	UK/H/5030/001/DC	135861	Agila Specialties UK Ltd	AT
Agicil 50 mg/ml, solution injectable/infusion	UK/H/5030/001/DC	BE459813 (10 ml)	Agila Specialties UK Ltd	BE
	UK/H/5030/001/DC	BE459822 (20 ml)	Agila Specialties UK Ltd	BE
	UK/H/5030/001/DC	BE459831 (50 ml)	Agila Specialties UK Ltd	BE
	UK/H/5030/001/DC	BE459840 (100 ml)	Agila Specialties UK Ltd	BE
Agicil 50 mg/ml Injektions-/Infusionslösung	UK/H/5030/001/DC	85496.00.00	Agila Specialties UK Ltd	DE
Fluorouracil Agila 50 mg/ml Solution for Injection or infusion	UK/H/5030/001/DC	PA2016/001/001	Agila Specialties UK Ltd	IE
Agicil 50 mg/1 mL, solution injectable/pour perfusion	UK/H/5030/001/DC	2014120344	Agila Specialties UK Ltd	LU
Agicil 50 mg/ml solution for injection/infusion	UK/H/5030/001/DC	MA1054/00101 (10 ml)	Agila Specialties UK Ltd	MT

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
	UK/H/5030/001/DC	MA1054/00102 (20 ml)	Agila Specialties UK Ltd	MT
	UK/H/5030/001/DC	MA1054/00103 (50 ml)	Agila Specialties UK Ltd	MT
	UK/H/5030/001/DC	MA1054/00104 (100 ml)	Agila Specialties UK Ltd	MT
Agicil 50 mg/ml, oplossing	UK/H/5030/001/DC	RVG 110127	Agila Specialties UK Ltd	NL
Agicil	UK/H/5030/001/DC	11-8466	Agila Specialties UK Ltd	NO
Agicil 50 mg/ml, Solução injetável ou para perfusão	UK/H/5030/001/DC	5624069 – 10 vials 50 ml	Agila Specialties UK Ltd	PT
	UK/H/5030/001/DC	5624044 – 1 vial 50 ml	Agila Specialties UK Ltd	PT
	UK/H/5030/001/DC	5624028 – 5 vials 20 ml	Agila Specialties UK Ltd	PT
	UK/H/5030/001/DC	5623970 – 5 vials 10 ml	Agila Specialties UK Ltd	PT

<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>
	UK/H/5030/001/DC	5624010 – 1 vial 20 ml	Agila Specialties UK Ltd	PT
	UK/H/5030/001/DC	5624002 – 10 vials 10 ml	Agila Specialties UK Ltd	PT
	UK/H/5030/001/DC	5624101 – 5 vials 100 ml	Agila Specialties UK Ltd	PT
	UK/H/5030/001/DC	5624077 – 1 vial 100 ml	Agila Specialties UK Ltd	PT
	UK/H/5030/001/DC	5624119 – 10 vials 100 ml	Agila Specialties UK Ltd	PT
	UK/H/5030/001/DC	5624051 – 5 vials 50 ml	Agila Specialties UK Ltd	PT
	UK/H/5030/001/DC	5624036 – 10 vials 20 ml	Agila Specialties UK Ltd	PT
	UK/H/5030/001/DC	5623962 – 1 vial 10 ml	Agila Specialties UK Ltd	PT
Agicil, 50 mg/ml injektions- /infusionsvätska, lösning	UK/H/5030/001/DC	MTnr. 46441	Agila Specialties UK Ltd	SV

<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>
Agicil 50 mg/ml solution for injection /infusion	UK/H/5030/001/DC	PL 04569/1545	Generics (UK) Ltd	GB
Fluorouracil Agila 50 mg/ml stungulyf/innrennsliislyf, lausn	UK/H/4635/001/DC	IS/1/14/072/01	Agila Specialties UK Ltd	IS
Fluorouracil 50 mg/ml solution for injection / infusion	UK/H/4635/001/DC	PL 04569/1544	Generics (UK) Ltd	GB
Fluorouracil Polipharma 50mg/ml	2189557	89557.00.00	S.C. Polipharma Industries S.r.l.	DE
Fluorouracil Ebewe		48450/15-9-2009	Pharmanel Commercial Pharmaceutical S.A.	GR
Fluorouracil/Ebewe 250mg/5ml		48447/15-9-2009	Pharmanel Commercial Pharmaceutical S.A.	GR
Fluorouracil/Ebewe 500mg/10ml		48449/15-9-2009	Pharmanel Commercial Pharmaceutical S.A.	GR
Benda-5 FU		2155983	Bendalis GmbH	DE