



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

19 September 2024
EMA/224383/2024
Human Medicines Division

List of nationally authorised medicinal products

Active substance(s): 5 fluorouracil (IV use)

Procedure No. PSUSA/00000007/202312



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 Accord 50 mg/ml Injektions- oder Infusionslösung	NL/H/4564/001	1-29257	ACCORD HEALTHCARE B.V.	AT
Fluorouracil Accord 50 mg/ml Injektions- oder Infusionslösung	NL/H/4564/001	1-29257	ACCORD HEALTHCARE B.V.	AT
Fluorouracil Accord 50 mg/ml Injektions- oder Infusionslösung	NL/H/4564/001	1-29257	ACCORD HEALTHCARE B.V.	AT
Fluorouracil Accord 50 mg/ml Injektions- oder Infusionslösung	NL/H/4564/001	1-29257	ACCORD HEALTHCARE B.V.	AT
Fluorouracil Accord 50 mg/ml Injektions- oder Infusionslösung	NL/H/4564/001	1-29257	ACCORD HEALTHCARE B.V.	AT
5-Fluorouracil Ebewe 50 mg/ml - Konzentrat zur Herstellung einer Infusionslösung	not available	1-22397	EBEWE PHARMA	AT
Fluorouracil Accord Healthcare 50 mg/ml, solution pour injection ou perfusion	NL/H/4564/001	BE345615	ACCORD HEALTHCARE B.V.	BE
Fluorouracil Accord Healthcare 50 mg/ml, solution pour injection ou perfusion	NL/H/4564/001	BE415712	ACCORD HEALTHCARE B.V.	BE
Fluorouracil Accord Healthcare 50 mg/ml, solution pour injection ou perfusion	NL/H/4564/001	BE345606	ACCORD HEALTHCARE B.V.	BE
Fluorouracil Accord Healthcare 50 mg/ml, solution pour injection ou perfusion	NL/H/4564/001	BE345624	ACCORD HEALTHCARE B.V.	BE

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 Accord Healthcare 50 mg/ml, solution pour injection ou perfusion	NL/H/4564/001	BE345597	ACCORD HEALTHCARE B.V.	BE
Fluorouracil Accord Healthcare 50 mg/ml oplossing voor injectie of infusie	NL/H/4564/001	BE345615	ACCORD HEALTHCARE B.V.	BE
Fluorouracil Accord Healthcare 50 mg/ml oplossing voor injectie of infusie	NL/H/4564/001	BE415712	ACCORD HEALTHCARE B.V.	BE
Fluorouracil Accord Healthcare 50 mg/ml oplossing voor injectie of infusie	NL/H/4564/001	BE345606	ACCORD HEALTHCARE B.V.	BE
Fluorouracil Accord Healthcare 50 mg/ml oplossing voor injectie of infusie	NL/H/4564/001	BE345624	ACCORD HEALTHCARE B.V.	BE
Fluorouracil Accord Healthcare 50 mg/ml oplossing voor injectie of infusie	NL/H/4564/001	BE345597	ACCORD HEALTHCARE B.V.	BE
Fluracetyl 50 mg/ml, oplossing voor injectie	not available	BE161061	TEVA PHARMA BELGIUM N.V./S.A	BE
Fluracetyl 50 mg/ml, oplossing voor injectie	not available	BE201126	TEVA PHARMA BELGIUM N.V./S.A	BE
Fluracetyl 50mg/ml, solution injectable	not available	BE201126	TEVA PHARMA BELGIUM N.V./S.A	BE
Fluracetyl 50mg/ml, solution injectable	not available	BE161061	TEVA PHARMA BELGIUM N.V./S.A	BE
Fluracetyl 50 mg/ml, Injektionslösung	not available	BE161061	TEVA PHARMA BELGIUM N.V./S.A	BE
Fluracetyl 50 mg/ml, Injektionslösung	not available	BE201126	TEVA PHARMA BELGIUM N.V./S.A	BE
Флуороурацил Акорд 50 mg/ml инъекционен	NL/H/4564/001	20130261	ACCORD HEALTHCARE POLSKA SP. Z O.O.	BG

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
или инфузионен разтвор				
Флуороурацил Акорд 50 mg/ml инжекционен или инфузионен разтвор	NL/H/4564/001	20130261	ACCORD HEALTHCARE POLSKA SP. Z O.O.	BG
Флуороурацил Акорд 50 mg/ml инжекционен или инфузионен разтвор	NL/H/4564/001	20130261	ACCORD HEALTHCARE POLSKA SP. Z O.O.	BG
Флуороурацил Акорд 50 mg/ml инжекционен или инфузионен разтвор	NL/H/4564/001	20130261	ACCORD HEALTHCARE POLSKA SP. Z O.O.	BG
Флуороурацил Акорд 50 mg/ml инжекционен или инфузионен разтвор	NL/H/4564/001	20130261	ACCORD HEALTHCARE POLSKA SP. Z O.O.	BG
5-ФЛУОРОУРАЦИЛ "ЕБЕВЕ" 50 MG/ML КОНЦЕНТРАТ ЗА ИНЖЕКЦИОНЕН И ИНФУЗИОНЕН РАЗТВОР	not available	20000369	EBEWE PHARMA	BG
Fluorouracil Accord 50 mg/ml διάλυμα για ένεση/έγχυση	NL/H/4564/001	021926	ACCORD HEALTHCARE S.L.U.	CY
Fluorouracil Accord 50 mg/ml διάλυμα για ένεση/έγχυση	NL/H/4564/001/E/001	021926	ACCORD HEALTHCARE S.L.U.	CY
Fluorouracil Accord 50 mg/ml διάλυμα για ένεση/έγχυση	NL/H/4564/001/E/001	021926	ACCORD HEALTHCARE S.L.U.	CY
Fluorouracil Accord 50 mg/ml διάλυμα για ένεση/έγχυση	NL/H/4564/001/E/001	021926	ACCORD HEALTHCARE S.L.U.	CY
Fluorouracil Accord 50 mg/ml διάλυμα για ένεση/έγχυση	NL/H/4564/001	021926	ACCORD HEALTHCARE S.L.U.	CY

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 Accord 50 mg/ml injekční/infuzní roztok	NL/H/4564/001	44/587/09-C	ACCORD HEALTHCARE POLSKA SP. Z O.O.	CZ
Fluorouracil Accord 50 mg/ml injekční/infuzní roztok	NL/H/4564/001	44/587/09-C	ACCORD HEALTHCARE POLSKA SP. Z O.O.	CZ
Fluorouracil Accord 50 mg/ml injekční/infuzní roztok	NL/H/4564/001	44/587/09-C	ACCORD HEALTHCARE POLSKA SP. Z O.O.	CZ
Fluorouracil Accord 50 mg/ml injekční/infuzní roztok	NL/H/4564/001	44/587/09-C	ACCORD HEALTHCARE POLSKA SP. Z O.O.	CZ
Fluorouracil Accord 50 mg/ml injekční/infuzní roztok	NL/H/4564/001	44/587/09-C	ACCORD HEALTHCARE POLSKA SP. Z O.O.	CZ
5-Fluorouracil Ebewe 50 mg/ml injekční roztok	not available	44/285/99-C	EBEWE PHARMA	CZ
Fluorouracil Accord 50 mg/ml Injektions-/ Infusionslösung	NL/H/4564/001	89351.00.00	ACCORD HEALTHCARE B.V.	DE
Fluorouracil Accord 50 mg/ml Injektions-/ Infusionslösung	NL/H/4564/001	89351.00.00	ACCORD HEALTHCARE B.V.	DE
Fluorouracil Accord 50 mg/ml Injektions-/ Infusionslösung	NL/H/4564/001	89351.00.00	ACCORD HEALTHCARE B.V.	DE
Fluorouracil Accord 50 mg/ml Injektions-/ Infusionslösung	NL/H/4564/001	89351.00.00	ACCORD HEALTHCARE B.V.	DE
Fluorouracil Accord 50 mg/ml Injektions-/ Infusionslösung	NL/H/4564/001	89351.00.00	ACCORD HEALTHCARE B.V.	DE
Fluorouracil Accord 50 mg/ml Injektions-/ Infusionslösung	NL/H/4564/001	89351.00.00	ACCORD HEALTHCARE B.V.	DE
Benda-5 FU 50 mg/ml Injektionslösung	not available	55983.00.00	BENDALIS GMBH	DE
Fluorouracil® HEXAL 50 mg/ml Injektionslösung	not available	84261.00.00	HEXAL AG	DE
Fluorouracil Hikma 50 mg/ml Injektionslösung	not available	6127367.00.00	HIKMA FARMACÊUTICA (PORTUGAL), S.A.	DE

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 Hikma 50 mg/ml Injektionslösung	not available	6127367.00.00	HIKMA FARMACÊUTICA (PORTUGAL), S.A.	DE
Fluorouracil Hikma 50 mg/ml Injektionslösung	not available	6127367.00.00	HIKMA FARMACÊUTICA (PORTUGAL), S.A.	DE
Fluorouracil Hikma 50 mg/ml Injektionslösung	not available	6127367.00.00	HIKMA FARMACÊUTICA (PORTUGAL), S.A.	DE
Fluorouracil Hikma 50 mg/ml Injektionslösung	not available	6127367.00.00	HIKMA FARMACÊUTICA (PORTUGAL), S.A.	DE
Fluorouracil Hikma 50 mg/ml Injektionslösung	not available	6127367.00.00	HIKMA FARMACÊUTICA (PORTUGAL), S.A.	DE
Fluorouracil Hikma 50 mg/ml Injektionslösung	not available	6127367.00.00	HIKMA FARMACÊUTICA (PORTUGAL), S.A.	DE
Fluorouracil Hikma 50 mg/ml Injektionslösung	not available	6127367.00.00	HIKMA FARMACÊUTICA (PORTUGAL), S.A.	DE
Fluorouracil Hikma 50 mg/ml Injektionslösung	not available	6127367.00.00	HIKMA FARMACÊUTICA (PORTUGAL), S.A.	DE
Fluorouracil Hikma 50 mg/ml Injektionslösung	not available	6127367.00.00	HIKMA FARMACÊUTICA (PORTUGAL), S.A.	DE
Fluorouracil PhaRes 50 mg/ml Injektionslösung	not available	98149.00.00	KELIX BIO (MALTA) LIMITED	DE
5-FU medac 50 mg/ml, Injektionslösung	not available	41196.00.00	MEDAC GESELLSCHAFT FÜR KLINISCHE SPEZIALPRÄPARATE MBH (WEDEL)	DE
Fluorouracil PhaRes 50 mg/ml Injektionslösung	not available	89558.00.00	PHARMA RESOURCES GMBH	DE
Fluorouracil-GRY 50 mg/ml Injektionslösung	not available	6117.01.00	TEVA GMBH	DE
Fluorouracil Vitane 50 mg/ml Injektionslösung	not available	91908.00.00	VITANE PHARMA GMBH	DE
Fluorouracil "Accord", injektions-/infusionsvæske, opløsning	NL/H/4564/001	41876	ACCORD HEALTHCARE B.V.	DK
Fluorouracil "Accord", injektions-/infusionsvæske, opløsning	NL/H/4564/001	41876	ACCORD HEALTHCARE B.V.	DK

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 "Accord", injektions- /infusionsvæske, opløsning	NL/H/4564/001	41876	ACCORD HEALTHCARE B.V.	DK
Fluorouracil "Accord", injektions- /infusionsvæske, opløsning	NL/H/4564/001	41876	ACCORD HEALTHCARE B.V.	DK
Fluorouracil "Accord", injektions- /infusionsvæske, opløsning	NL/H/4564/001	41876	ACCORD HEALTHCARE B.V.	DK
Fluorouracil "Pfizer", injektionsvæske, opløsning	not available	14003	PFIZER APS	DK
Fluorouracil Accord 50 mg/ml süste- /infusioonilahus	NL/H/4564/001	648509	ACCORD HEALTHCARE B.V.	EE
Fluorouracil Accord 50 mg/ml süste- /infusioonilahus	NL/H/4564/001	648509	ACCORD HEALTHCARE B.V.	EE
Fluorouracil Accord 50 mg/ml süste- /infusioonilahus	NL/H/4564/001	648509	ACCORD HEALTHCARE B.V.	EE
Fluorouracil Accord 50 mg/ml süste- /infusioonilahus	NL/H/4564/001	648509	ACCORD HEALTHCARE B.V.	EE
Fluorouracil Accord 50 mg/ml süste- /infusioonilahus	NL/H/4564/001	648509	ACCORD HEALTHCARE B.V.	EE
5-Fluorouracil „Ebewe”, 50 mg/ml süste- või infusioonilahus	not available	245099	SANDOZ PHARMACEUTICALS D.D.	EE
Fluorouracilo Accord 50 mg/ml solución inyectable o para perfusión EFG	NL/H/4564/001	71.868	ACCORD HEALTHCARE S.L.U.	ES
Fluorouracilo Accord 50	NL/H/4564/001	71.868	ACCORD HEALTHCARE	ES

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mg/ml solución inyectable o para perfusión EFG			S.L.U.	
Fluorouracilo Accord 50 mg/ml solución inyectable o para perfusión EFG	NL/H/4564/001	71.868	ACCORD HEALTHCARE S.L.U.	ES
Fluorouracilo Accord 50 mg/ml solución inyectable o para perfusión EFG	NL/H/4564/001	71.868	ACCORD HEALTHCARE S.L.U.	ES
Fluorouracilo Accord 50 mg/ml solución inyectable o para perfusión EFG	NL/H/4564/001	71.868	ACCORD HEALTHCARE S.L.U.	ES
Fluorouracil Accord 50 mg/ml injektio-/infuusioneste, liuos	NL/H/4564/001	23977	ACCORD HEALTHCARE B.V.	FI
Fluorouracil Accord 50 mg/ml injektio-/infuusioneste, liuos	NL/H/4564/001	23977	ACCORD HEALTHCARE B.V.	FI
Fluorouracil Accord 50 mg/ml injektio-/infuusioneste, liuos	NL/H/4564/001	23977	ACCORD HEALTHCARE B.V.	FI
Fluorouracil Accord 50 mg/ml injektio-/infuusioneste, liuos	NL/H/4564/001	23977	ACCORD HEALTHCARE B.V.	FI
Fluorouracil Accord 50 mg/ml injektio-/infuusioneste, liuos	NL/H/4564/001	23977	ACCORD HEALTHCARE B.V.	FI
FLUOROURACILE ACCORD 50 mg/ml, solution à diluer pour perfusion	not available	34009 575 181 1 0	ACCORD HEALTHCARE FRANCE SAS	FR
FLUOROURACILE ACCORD 50 mg/ml, solution à diluer pour perfusion	not available	34009 579 845 1 9	ACCORD HEALTHCARE FRANCE SAS	FR

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
FLUOROURACILE ACCORD 50 mg/ml, solution à diluer pour perfusion	not available	34009 575 179 7 7	ACCORD HEALTHCARE FRANCE SAS	FR
FLUOROURACILE ACCORD 50 mg/ml, solution à diluer pour perfusion	not available	34009 575 180 5 9	ACCORD HEALTHCARE FRANCE SAS	FR
FLUOROURACILE ACCORD 50 mg/ml, solution à diluer pour perfusion	not available	34009 575 182 8 8	ACCORD HEALTHCARE FRANCE SAS	FR
FLUOROURACILE PFIZER 50 mg/mL, solution à diluer pour perfusion	not available	34009 560 295 6 3	PFIZER HOLDING FRANCE	FR
FLUOROURACILE PFIZER 50 mg/mL, solution à diluer pour perfusion	not available	34009 572 534 0 0	PFIZER HOLDING FRANCE	FR
FLUOROURACILE PFIZER 50 mg/mL, solution à diluer pour perfusion	not available	34009 564 746 2 2	PFIZER HOLDING FRANCE	FR
FLUOROURACILE PFIZER 50 mg/mL, solution à diluer pour perfusion	not available	34009 572 533 4 9	PFIZER HOLDING FRANCE	FR
FLUOROURACILE PFIZER 50 mg/mL, solution à diluer pour perfusion	not available	34009 572 532 8 8	PFIZER HOLDING FRANCE	FR
FLUOROURACILE PFIZER 50 mg/mL, solution à diluer pour perfusion	not available	34009 564 745 6 1	PFIZER HOLDING FRANCE	FR
FLUOROURACILE PFIZER 50 mg/mL, solution à diluer pour perfusion	not available	34009 572 531 1 0	PFIZER HOLDING FRANCE	FR
FLUOROURACILE PFIZER 50 mg/mL, solution à diluer pour perfusion	not available	34009 572 530 5 9	PFIZER HOLDING FRANCE	FR
FLUOROURACILE PFIZER 50 mg/mL, solution à diluer pour perfusion	not available	34009 550 902 5 0	PFIZER HOLDING FRANCE	FR

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
diluer pour perfusion				
FLUOROURACILE PFIZER 50 mg/mL, solution à diluer pour perfusion	not available	34009 550 902 4 3	PFIZER HOLDING FRANCE	FR
FLUOROURACILE PFIZER 50 mg/mL, solution à diluer pour perfusion	not available	34009 550 902 3 6	PFIZER HOLDING FRANCE	FR
FLUOROURACILE PFIZER 50 mg/mL, solution à diluer pour perfusion	not available	34009 550 902 2 9	PFIZER HOLDING FRANCE	FR
FLUOROURACILE PFIZER 50 mg/mL, solution à diluer pour perfusion	not available	34009 550 902 6 7	PFIZER HOLDING FRANCE	FR
FLUOROURACILE TEVA 1000 mg/20 ml, solution à diluer pour perfusion	not available	NL22259	TEVA SANTÉ	FR
FLUOROURACILE TEVA 5000 mg/100 ml, solution à diluer pour perfusion	not available	NL22260	TEVA SANTÉ	FR
Fluorouracil/Anabiosis 50 mg/ml διάλυμα για ένεση ή έγχυση	PT/H/1366/001	101128/27-10-2021	ANABIOSIS PC	GR
Uraciflor 250 mg/5 ml ενέσιμο διάλυμα	not available	2480401	MEDICUS A.E	GR
Uraciflor 500 mg/10 ml ενέσιμο διάλυμα	not available	2480402	MEDICUS A.E	GR
Uraciflor 500 mg/10 ml ενέσιμο διάλυμα	not available	2480402	MEDICUS A.E	GR
Uraciflor 250 mg/5 ml ενέσιμο διάλυμα	not available	2480401	MEDICUS A.E	GR
Fluorouracil OPUS 50 mg/ml, διάλυμα για ένεση ή έγχυση	PT/H/1632/001	27258/17/05-06-2018	OPUS-MATERIA LTD	GR
Fluorouracil Pliva 50 mg/ml otopina za injekciju/infuziju	not available	HR-H-111487546	PLIVA HRVATSKA D.O.O.	HR
Fluorouracil Sandoz 50	not available	HR-H-126689750	SANDOZ D.O.O.	HR

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mg/ml otopina za injekciju/infuziju				
Fluorouracil Accord 50 mg/ml oldatos injekció vagy infúzió	NL/H/4564/001/E/001	OGYI-T-22502/01	ACCORD HEALTHCARE POLSKA SP. Z O.O.	HU
Fluorouracil Accord 50 mg/ml oldatos injekció vagy infúzió	NL/H/4564/001	OGYI-T-22502/02	ACCORD HEALTHCARE POLSKA SP. Z O.O.	HU
Fluorouracil Accord 50 mg/ml oldatos injekció vagy infúzió	NL/H/4564/001/E/001	OGYI-T-22502/03	ACCORD HEALTHCARE POLSKA SP. Z O.O.	HU
Fluorouracil Accord 50 mg/ml oldatos injekció vagy infúzió	NL/H/4564/001/E/001	OGYI-T-22502/04	ACCORD HEALTHCARE POLSKA SP. Z O.O.	HU
Fluorouracil Accord 50 mg/ml oldatos injekció vagy infúzió	NL/H/4564/001	OGYI-T-22502/05	ACCORD HEALTHCARE POLSKA SP. Z O.O.	HU
5-Fluorouracil Sandoz 50 mg/ml koncentrátum oldatos infúzióhoz	not available	OGYI-T-7514/01	SANDOZ HUNGÁRIA KFT	HU
5-Fluorouracil Sandoz 50 mg/ml koncentrátum oldatos infúzióhoz	not available	OGYI-T-7514/02	SANDOZ HUNGÁRIA KFT	HU
5-Fluorouracil Sandoz 50 mg/ml koncentrátum oldatos infúzióhoz	not available	OGYI-T-7514/05	SANDOZ HUNGÁRIA KFT	HU
5-Fluorouracil Sandoz 50 mg/ml koncentrátum oldatos infúzióhoz	not available	OGYI-T-7514/06	SANDOZ HUNGÁRIA KFT	HU
5-Fluorouracil Sandoz 50 mg/ml koncentrátum oldatos infúzióhoz	not available	OGYI-T-7514/09	SANDOZ HUNGÁRIA KFT	HU
5-Fluorouracil Sandoz 50 mg/ml koncentrátum oldatos infúzióhoz	not available	OGYI-T-7514/10	SANDOZ HUNGÁRIA KFT	HU
Fluorouracil-Teva 50 mg/ml oldatos injekció	not available	OGYI-T-4272/05	TEVA GYÓGYSZERGYÁR ZRT	HU
Fluorouracil-Teva 50	not available	OGYI-T-4272/11	TEVA GYÓGYSZERGYÁR ZRT	HU

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mg/ml oldatos injekció				
Fluorouracil-Teva 50 mg/ml oldatos injekció	not available	OGYI-T-4272/06	TEVA GYÓGYSZERGYÁR ZRT	HU
Fluorouracil-Teva 50 mg/ml oldatos injekció	not available	OGYI-T-4272/10	TEVA GYÓGYSZERGYÁR ZRT	HU
Fluorouracil-Teva 50 mg/ml oldatos injekció	not available	OGYI-T-4272/01	TEVA GYÓGYSZERGYÁR ZRT	HU
Fluorouracil-Teva 50 mg/ml oldatos injekció	not available	OGYI-T-4272/08	TEVA GYÓGYSZERGYÁR ZRT	HU
Fluorouracil-Teva 50 mg/ml oldatos injekció	not available	OGYI-T-4272/09	TEVA GYÓGYSZERGYÁR ZRT	HU
Fluorouracil-Teva 50 mg/ml oldatos injekció	not available	OGYI-T-4272/07	TEVA GYÓGYSZERGYÁR ZRT	HU
Fluorouracil 50 mg/ml Solution for Injection or Infusion	NL/H/4564/001	PA 2315/091/001	ACCORD HEALTHCARE IRELAND LIMITED	IE
Fluorouracil 50 mg/ml Solution for Injection or Infusion	NL/H/4564/001	PA 2315/091/001	ACCORD HEALTHCARE IRELAND LIMITED	IE
Fluorouracil 50 mg/ml Solution for Injection or Infusion	NL/H/4564/001/DC	PA 2315/091/001	ACCORD HEALTHCARE IRELAND LIMITED	IE
Fluorouracil 50 mg/ml Solution for Injection or Infusion	NL/H/4564/001	PA 2315/091/001	ACCORD HEALTHCARE IRELAND LIMITED	IE
Fluorouracil 50 mg/ml Solution for Injection or Infusion	NL/H/4564/001	PA 2315/091/001	ACCORD HEALTHCARE IRELAND LIMITED	IE
Fluorouracil 25 mg/ml Solution for Injection or Infusion	not available	PA 0822/223/001	PFIZER HEALTHCARE IRELAND	IE
Flúoróúracíl Accord 50 mg/ml, stungulyf/innrennsislyf, lausn	NL/H/4564/001	IS/1/13/080/01	ACCORD HEALTHCARE B.V.	IS
Flúoróúracíl Accord 50 mg/ml, stungulyf/innrennsislyf,	NL/H/4564/001	IS/1/13/080/01	ACCORD HEALTHCARE B.V.	IS

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
lausn				
Flúoróúracíl Accord 50 mg/ml, stungulyf/innrennslislyf, lausn	NL/H/4564/001	IS/1/13/080/01	ACCORD HEALTHCARE B.V.	IS
Flúoróúracíl Accord 50 mg/ml, stungulyf/innrennslislyf, lausn	NL/H/4564/001	IS/1/13/080/01	ACCORD HEALTHCARE B.V.	IS
Flúoróúracíl Accord 50 mg/ml, stungulyf/innrennslislyf, lausn	NL/H/4564/001	IS/1/13/080/01	ACCORD HEALTHCARE B.V.	IS
Fluorouracile AHCL 50 mg/ml, Soluzione per iniezione o infusione	NL/H/4564/001/DC	040593016	ACCORD HEALTHCARE S.L.U.	IT
Fluorouracile AHCL 50 mg/ml, Soluzione per iniezione o infusione	NL/H/4564/001/DC	040593028	ACCORD HEALTHCARE S.L.U.	IT
Fluorouracile AHCL 50 mg/ml, Soluzione per iniezione o infusione	NL/H/4564/001/DC	040593030	ACCORD HEALTHCARE S.L.U.	IT
Fluorouracile AHCL 50 mg/ml, Soluzione per iniezione o infusione	NL/H/4564/001/DC	040593042	ACCORD HEALTHCARE S.L.U.	IT
Fluorouracile AHCL 50 mg/ml, Soluzione per iniezione o infusione	NL/H/4564/001	040593055	ACCORD HEALTHCARE S.L.U.	IT
Fluorouracile Hikma 50 mg/ml soluzione iniettabile per infusione	PT/H/1318/001	044062014	HIKMA FARMACÊUTICA (PORTUGAL), S.A.	IT
Fluorouracile Hikma 50 mg/ml soluzione iniettabile/ per infusione	PT/H/1318/001	044062026	HIKMA FARMACÊUTICA (PORTUGAL), S.A.	IT
Fluorouracile Hikma 50 mg/ml soluzione iniettabile per infusione	PT/H/1318/001	044062038	HIKMA FARMACÊUTICA (PORTUGAL), S.A.	IT
Fluorouracile Hikma 50	PT/H/1318/001	044062040	HIKMA FARMACÊUTICA	IT

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
mg/ml soluzione iniettabile per infusione			(PORTUGAL), S.A.	
Fluorouracile Teva 250 mg/5 ml soluzione per infusione	not available	026542062	TEVA ITALIA S.R.L.	IT
Fluorouracile Teva 5 g/100 ml soluzione per infusione	not available	026542050	TEVA ITALIA S.R.L.	IT
FLUOROURACILE TEVA 500 mg/10 ml soluzione per infusione	not available	026542074	TEVA ITALIA S.R.L.	IT
Fluorouracile Teva 1 g/20 ml soluzione per infusione	not available	026542047	TEVA ITALIA S.R.L.	IT
Fluorouracil Accord 50 mg/ml injekcinis/infuzinis tirpalas	NL/H/4564/001	LT/1/10/2109/005	ACCORD HEALTHCARE B.V.	LT
Fluorouracil Accord 50 mg/ml injekcinis/infuzinis tirpalas	NL/H/4564/001	LT/1/10/2109/001	ACCORD HEALTHCARE B.V.	LT
Fluorouracil Accord 50 mg/ml injekcinis ar infuzinis tirpalas	NL/H/4564/001	LT/1/10/2109/002	ACCORD HEALTHCARE B.V.	LT
Fluorouracil Accord 50 mg/ml injekcinis/infuzinis tirpalas	NL/H/4564/001	LT/1/10/2109/003	ACCORD HEALTHCARE B.V.	LT
Fluorouracil Accord 50 mg/ml injekcinis/infuzinis tirpalas	NL/H/4564/001	LT/1/10/2109/004	ACCORD HEALTHCARE B.V.	LT
Fluracedyl 50mg/ml, solution injectable	not available	1316/06010008	TEVA PHARMA BELGIUM N.V./S.A	LU
Fluracedyl 50mg/ml, solution injectable	not available	1316/06010007	TEVA PHARMA BELGIUM N.V./S.A	LU
Fluorouracil Accord 50	NL/H/4564/001	09-0458	ACCORD HEALTHCARE B.V.	LV

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
mg/ml šķīdums injekcijām vai infūzijām				
Fluorouracil Accord 50 mg/ml šķīdums injekcijām vai infūzijām	NL/H/4564/001	09-0458	ACCORD HEALTHCARE B.V.	LV
Fluorouracil Accord 50 mg/ml šķīdums injekcijām vai infūzijām	NL/H/4564/001	09-0458	ACCORD HEALTHCARE B.V.	LV
Fluorouracil Accord 50 mg/ml šķīdums injekcijām vai infūzijām	NL/H/4564/001	09-0458	ACCORD HEALTHCARE B.V.	LV
Fluorouracil Accord 50 mg/ml šķīdums injekcijām vai infūzijām	NL/H/4564/001	09-0458	ACCORD HEALTHCARE B.V.	LV
Fluorouracil Accord 50 mg/ml, oplossing voor injectie of infusie	NL/H/4564/001	RVG 100701	ACCORD HEALTHCARE B.V.	NL
Fluorouracil Accord 50 mg/ml, oplossing voor injectie of infusie	NL/H/4564/001	RVG 100701	ACCORD HEALTHCARE B.V.	NL
Fluorouracil Accord 50 mg/ml, oplossing voor injectie of infusie	NL/H/4564/001	RVG 100701	ACCORD HEALTHCARE B.V.	NL
Fluorouracil Accord 50 mg/ml, oplossing voor injectie of infusie	NL/H/4564/001	RVG 100701	ACCORD HEALTHCARE B.V.	NL
Fluorouracil Accord 50 mg/ml, oplossing voor injectie of infusie	NL/H/4564/001	RVG 100701	ACCORD HEALTHCARE B.V.	NL
Fluorouracil Accord 50 mg/ml injekcijas- /infusjonsvæske, oppløsning	NL/H/4564/001	12-9364	ACCORD HEALTHCARE B.V.	NO
Fluorouracil Accord 50 mg/ml injekcijas- /infusjonsvæske, oppløsning	NL/H/4564/001	12-9364	ACCORD HEALTHCARE B.V.	NO
Fluorouracil Accord 50	NL/H/4564/001	12-9364	ACCORD HEALTHCARE B.V.	NO

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
mg/ml injeksjons- /infusjonsvæske, oppløsning				
Fluorouracil Accord 50 mg/ml injeksjons- /infusjonsvæske, oppløsning	NL/H/4564/001	12-9364	ACCORD HEALTHCARE B.V.	NO
Fluorouracil Accord 50 mg/ml injeksjons- /infusjonsvæske, oppløsning	NL/H/4564/001	12-9364	ACCORD HEALTHCARE B.V.	NO
Fluorouracil Accord, 50 mg/ml, roztwór do wstrzykiwań lub infuzji	NL/H/4564/001	16642	ACCORD HEALTHCARE POLSKA SP. Z O.O.	PL
Fluorouracil Accord, 50 mg/ml, roztwór do wstrzykiwań lub infuzji	NL/H/4564/001	16642	ACCORD HEALTHCARE POLSKA SP. Z O.O.	PL
Fluorouracil Accord, 50 mg/ml, roztwór do wstrzykiwań lub infuzji	NL/H/4564/001	16642	ACCORD HEALTHCARE POLSKA SP. Z O.O.	PL
Fluorouracil Accord, 50 mg/ml, roztwór do wstrzykiwań lub infuzji	NL/H/4564/001	16642	ACCORD HEALTHCARE POLSKA SP. Z O.O.	PL
Fluorouracil Accord, 50 mg/ml, roztwór do wstrzykiwań lub infuzji	NL/H/4564/001	16642	ACCORD HEALTHCARE POLSKA SP. Z O.O.	PL
5-FLUOROURACIL- EBEWE, 50 MG/ML, ROZTWÓR DO WSTRZYKIWAŃ I INFUZJI	not available	4506	EBEWE PHARMA	PL
Fluorouracil medac, 50 mg/ml, roztwór do wstrzykiwań	not available	4778	MEDAC GESELLSCHAFT FÜR KLINISCHE SPEZIALPRÄPARATE MBH (WEDEL)	PL
Fluorouracilo Accord 50 mg/ml solução injetável ou para perfusão	NL/H/4564/001	5229208	ACCORD HEALTHCARE S.L.U.	PT

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
Fluorouracilo Accord 50 mg/ml solução injetável ou para perfusão	NL/H/4564/001	5229232	ACCORD HEALTHCARE S.L.U.	PT
Fluorouracilo Accord 50 mg/ml solução injectável ou para perfusão	NL/H/4564/001	5229224	ACCORD HEALTHCARE S.L.U.	PT
Fluorouracilo Accord 50 mg/ml solução injetável ou para perfusão	NL/H/4564/001	5229216	ACCORD HEALTHCARE S.L.U.	PT
Fluorouracilo Accord 50 mg/ml solução injectável ou para perfusão	NL/H/4564/001	5424361	ACCORD HEALTHCARE S.L.U.	PT
Fluorouracilo Anabiosis 50 mg/ml, Solução injetável ou para perfusão	PT/H/1366/001	5674866	ANABIOSIS PC	PT
Fluorouracilo Hikma, 50 mg/ml, Solução injetável ou para perfusão	PT/H/1318/001	5672928	HIKMA FARMACÊUTICA (PORTUGAL), S.A.	PT
Fluorouracilo Hikma, 50 mg/ml, Solução injetável ou para perfusão	PT/H/1318/001	5672910	HIKMA FARMACÊUTICA (PORTUGAL), S.A.	PT
Fluorouracilo Hikma, 50 mg/ml, Solução injetável ou para perfusão	PT/H/1318/001	5672936	HIKMA FARMACÊUTICA (PORTUGAL), S.A.	PT
Fluorouracilo Hikma, 50 mg/ml, Solução injetável ou para perfusão	PT/H/1318/001	5672944	HIKMA FARMACÊUTICA (PORTUGAL), S.A.	PT
Fluorouracilo Opus 50 mg/ml Solução injetável ou para perfusão	PT/H/1632/001	PT/H/1632/001	OPUS-MATERIA LTD	PT
Fluorouracilo Teva 50 mg/ml Solução Injectável	not available	2662682	TEVA PHARMA – PRODUTOS FARMACÊUTICOS LDA	PT
Fluorouracilo Teva 50mg/ml Solução Injectável	not available	5012505	TEVA PHARMA – PRODUTOS FARMACÊUTICOS LDA	PT
Fluorouracilo Teva 50	not available	2662880	TEVA PHARMA – PRODUTOS	PT

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
mg/ml Solucao Injectavel			FARMACÊUTICOS LDA	
Fluorouracilo Teva 50 mg/ml Solucao Injectavel	not available	2662781	TEVA PHARMA – PRODUTOS FARMACÊUTICOS LDA	PT
Fluorouracilo Teva 50 mg/ml Solucao Injectavel	not available	2494789	TEVA PHARMA – PRODUTOS FARMACÊUTICOS LDA	PT
Fluorouracil Accord 50 mg/ml soluție injectabilă sau perfuzabilă	NL/H/4564/001/E/001	12866/2019/01	ACCORD HEALTHCARE POLSKA SP. Z O.O.	RO
Fluorouracil Accord 50 mg/ml soluție injectabilă sau perfuzabilă	NL/H/4564/001/E/001	12866/2019/02	ACCORD HEALTHCARE POLSKA SP. Z O.O.	RO
Fluorouracil Accord 50 mg/ml soluție injectabilă sau perfuzabilă	NL/H/4564/001/E/001	12866/2019/03	ACCORD HEALTHCARE POLSKA SP. Z O.O.	RO
Fluorouracil Accord 50 mg/ml soluție injectabilă sau perfuzabilă	NL/H/4564/001/E/001	12866/2019/04	ACCORD HEALTHCARE POLSKA SP. Z O.O.	RO
Fluorouracil Accord 50 mg/ml soluție injectabilă sau perfuzabilă	NL/H/4564/001/E/001	12866/2019/05	ACCORD HEALTHCARE POLSKA SP. Z O.O.	RO
5-Fluorouracil Ebewe 50 mg/ml concentrat pentru soluție injectabilă/perfuzabilă	not available	7321/2015/01	EBEWE PHARMA	RO
5-Fluorouracil Ebewe 50 mg/ml concentrat pentru soluție injectabilă/perfuzabilă	not available	7321/2015/02	EBEWE PHARMA	RO
5-Fluorouracil Ebewe 50 mg/ml concentrat pentru soluție injectabilă/perfuzabilă	not available	7321/2015/04	EBEWE PHARMA	RO
5-Fluorouracil Ebewe 50 mg/ml concentrat pentru soluție	not available	7321/2015/03	EBEWE PHARMA	RO

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
injectabilă/perfuzabilă				
5-Fluorouracil Ebewe 50 mg/ml concentrat pentru soluție injectabilă/perfuzabilă	not available	7321/2015/05	EBEWE PHARMA	RO
5-Fluorouracil Ebewe 50 mg/ml concentrat pentru soluție injectabilă/perfuzabilă	not available	7321/2015/06	EBEWE PHARMA	RO
Fluorouracil Accord 50 mg/ml injektions-/infusionsvätska, lösning	NL/H/4564/001	25842	ACCORD HEALTHCARE B.V.	SE
Fluorouracil Accord 50 mg/ml injektions-/infusionsvätska, lösning	NL/H/4564/001	25842	ACCORD HEALTHCARE B.V.	SE
Fluorouracil Accord 50 mg/ml injektions-/infusionsvätska, lösning	NL/H/4564/001	25842	ACCORD HEALTHCARE B.V.	SE
Fluorouracil Accord 50 mg/ml injektions-/infusionsvätska, lösning	NL/H/4564/001	25842	ACCORD HEALTHCARE B.V.	SE
Fluorouracil Accord 50 mg/ml injektions-/infusionsvätska, lösning	NL/H/4564/001	25842	ACCORD HEALTHCARE B.V.	SE
Fluorouracil Teva 50 mg/ml Injektionsvätska/lösning	not available	11425	TEVA SWEDEN AB	SE
Fluorouracil Accord 50 mg/ml raztopina za injiciranje/infundiranje	NL/H/4564/001	H/13/00639/001	ACCORD HEALTHCARE POLSKA SP. Z O.O.	SI
Fluorouracil Accord 50 mg/ml raztopina za injiciranje/infundiranje	NL/H/4564/001	H/13/00639/002	ACCORD HEALTHCARE POLSKA SP. Z O.O.	SI
Fluorouracil Accord 50 mg/ml raztopina za injiciranje/infundiranje	NL/H/4564/001	H/13/00639/003	ACCORD HEALTHCARE POLSKA SP. Z O.O.	SI
Fluorouracil Accord 50 mg/ml raztopina za	NL/H/4564/001	H/13/00639/004	ACCORD HEALTHCARE POLSKA SP. Z O.O.	SI

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
injiciranje/infundiranje				
Fluorouracil Accord 50 mg/ml raztopina za injiciranje/infundiranje	NL/H/4564/001	H/13/00639/005	ACCORD HEALTHCARE POLSKA SP. Z O.O.	SI
5-Fluorouracil Ebewe 50 mg/ml koncentrat za raztopino za injiciranje/infundiranje	not available	H/04/00102/001	EBEWE PHARMA	SI
5-Fluorouracil Ebewe 50 mg/ml koncentrat za raztopino za injiciranje/infundiranje	not available	H/04/00102/002	EBEWE PHARMA	SI
5-Fluorouracil Ebewe 50 mg/ml koncentrat za raztopino za injiciranje/infundiranje	not available	H/04/00102/003	EBEWE PHARMA	SI
5-Fluorouracil Ebewe 50 mg/ml koncentrat za raztopino za injiciranje/infundiranje	not available	H/04/00102/004	EBEWE PHARMA	SI
Fluorouracil Accord 50 mg/ml injekčný a infúzny roztok	NL/H/4564/001	44/0092/11-S	ACCORD HEALTHCARE POLSKA SP. Z O.O.	SK
Fluorouracil Accord 50 mg/ml injekčný a infúzny roztok	NL/H/4564/001	44/0092/11-S	ACCORD HEALTHCARE POLSKA SP. Z O.O.	SK
Fluorouracil Accord 50 mg/ml injekčný a infúzny roztok	NL/H/4564/001	44/0092/11-S	ACCORD HEALTHCARE POLSKA SP. Z O.O.	SK
Fluorouracil Accord 50 mg/ml injekčný a infúzny roztok	NL/H/4564/001	44/0092/11-S	ACCORD HEALTHCARE POLSKA SP. Z O.O.	SK
Fluorouracil Accord 50 mg/ml injekčný a infúzny roztok	NL/H/4564/001	44/0092/11-S	ACCORD HEALTHCARE POLSKA SP. Z O.O.	SK
Fluorouracil 50 mg/ml Solution for Injection or Infusion	NL/H/4564/001	PL 20075/0078	ACCORD HEALTHCARE LIMITED	XI

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 50 mg/ml Solution for Injection or Infusion	NL/H/4564/001	PL 20075/0078	ACCORD HEALTHCARE LIMITED	XI
Fluorouracil 50 mg/ml Solution for Injection or Infusion	NL/H/4564/001	PL 20075/0078	ACCORD HEALTHCARE LIMITED	XI
Fluorouracil 50 mg/ml Solution for Injection or Infusion	NL/H/4564/001	PL 20075/0078	ACCORD HEALTHCARE LIMITED	XI
Fluorouracil 50 mg/ml Solution for Injection or Infusion	NL/H/4564/001	PL 20075/0078	ACCORD HEALTHCARE LIMITED	XI
Fluorouracil 50 mg/ml Solution for injection/infusion	PT/H/1318/001	PL 15413/0048	HIKMA FARMACÊUTICA (PORTUGAL), S.A.	XI
Fluorouracil 50 mg/ml Solution for injection/infusion	PT/H/1318/001	PL 15413/0048	HIKMA FARMACÊUTICA (PORTUGAL), S.A.	XI
Fluorouracil 50 mg/ml Solution for injection/infusion	PT/H/1318/001	PL 15413/0048	HIKMA FARMACÊUTICA (PORTUGAL), S.A.	XI
Fluorouracil 50 mg/ml Solution for injection/infusion	PT/H/1318/001	PL 15413/0048	HIKMA FARMACÊUTICA (PORTUGAL), S.A.	XI
Fluorouracil 50mg/ml Injection.	not available	PL 04515/0088	HOSPIRA UK LIMITED	XI
Fluorouracil 25mg/ml Injection.	not available	PL 04515/0024	HOSPIRA UK LIMITED	XI
Fluorouracil 50mg/ml Injection.	not available	PL 04515/0088	HOSPIRA UK LIMITED	XI
Fluorouracil 50mg/ml Injection.	not available	PL 04515/0088	HOSPIRA UK LIMITED	XI
Fluorouracil 50mg/ml Injection.	not available	PL 04515/0088	HOSPIRA UK LIMITED	XI
Fluorouracil 50mg/ml Injection.	not available	PL 04515/0088	HOSPIRA UK LIMITED	XI
Fluorouracil 25mg/ml Injection.	not available	PL 04515/0024	HOSPIRA UK LIMITED	XI

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 25mg/ml Injection.	not available	PL 04515/0024	HOSPIRA UK LIMITED	XI
Fluorouracil Injection, 50 mg/ml, solution for injection	not available	PL 11587/0015	MEDAC GESELLSCHAFT FÜR KLINISCHE SPEZIALPRÄPARATE MBH (WEDEL)	XI
Fluorouracil Injection 25 mg/ml, solution for injection	not available	PL 11587/0021	MEDAC GESELLSCHAFT FÜR KLINISCHE SPEZIALPRÄPARATE MBH (WEDEL)	XI