16 March 2023
EMA/30311/2023
Human Medicines Division

List of nationally authorised medicinal products

Active substance(s): fludarabine

Procedure No. PSUSA/00001406/202208

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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
Beneflur10 mg comprimidos recubiertos con película	NL/H/4467/002	64900	GENZYME EUROPE B.V.	ES
Beneflur10 mg comprimidos recubiertos con película	NL/H/4467/002	64900	GENZYME EUROPE B.V.	ES
Fludara Oral 10 mg comprimate filmate	not available	1229/2008/01	GENZYME EUROPE B.V.	RO
Fludara Oral 10 mg comprimate filmate	not available	1229/2008/02	GENZYME EUROPE B.V.	RO
Fludara 10 mg apvalkotās tabletes	not available	03-0260	GENZYME EUROPE B.V.	LV
Fludara 10 mg apvalkotās tabletes	not available	03-0260	GENZYME EUROPE B.V.	LV
Fludara 10 mg compresse rivestite con film	NL/H/4467/002	029552027	GENZYME EUROPE B.V.	IT
Fludara 10 mg compresse rivestite con film	NL/H/4467/002	029552039	GENZYME EUROPE B.V.	IT
Fludara 10 mg filmdragerad tablett	NL/H/4467/002	16553	GENZYME EUROPE B.V.	FI
Fludara 10 mg filmdragerad tablett	NL/H/4467/002	17317	GENZYME EUROPE B.V.	SE
Fludara 10 mg filmdragerad tablett	NL/H/4467/002	17317	GENZYME EUROPE B.V.	SE
Fludara 10 mg filmdragerad tablett.	NL/H/4467/002	16553	GENZYME EUROPE B.V.	FI
Fludara 10 mg filmsko obložene tablete	not available	H/97/00628/002	GENZYME EUROPE B.V.	SI
Fludara 10 mg filmtabletta	not available	OGYI-T-8272/01	GENZYME EUROPE B.V.	HU
Fludara 10 mg filmtabletta	not available	OGYI-T-8272/02	GENZYME EUROPE B.V.	HU
Fludara 10 mg filmuhúðaðar töflur	NL/H/4467/002	IS/1/01/036/01	GENZYME EUROPE B.V.	IS
Fludara 10 mg filmuhúðaðar töflur	NL/H/4467/002	IS/1/01/036/01	GENZYME EUROPE B.V.	IS
Fludara 10 mg plėvele dengtos tabletės	not available	LT/1/96/2819/002	GENZYME EUROPE B.V.	LT
Fludara 10 mg plėvele dengtos tabletės	not available	LT/1/96/2819/001	GENZYME EUROPE B.V.	LT
Fludara 10 mg potahované tablety	not available	44/181/01-C	GENZYME EUROPE B.V.	CZ
Fludara 10 mg potahované tablety	not available	44/181/01-C	GENZYME EUROPE B.V.	CZ
Fludara 10 mg tablett, filmdrasjert	NL/H/4467/002	2001-04591	GENZYME EUROPE B.V.	NO
Fludara 10 mg tablett, filmdrasjert	NL/H/4467/002	2001-04591	GENZYME EUROPE B.V.	NO
Fludara 10 mg tabletti, kalvopäällysteinen	NL/H/4467/002	16553	GENZYME EUROPE B.V.	FI
Fludara 10 mg tabletti, kalvopäällysteinen	NL/H/4467/002	16553	GENZYME EUROPE B.V.	FI
Fludara 10 mg επικαλυμμένα με λεπτό υμένιο δισκία	not available	20545	GENZYME EUROPE B.V.	CY
Fludara 10 mg επικαλυμμένα με λεπτό υμένιο δισκία	not available	20545	GENZYME EUROPE B.V.	CY
Fludara 10 mg επικαλυμμένα με λεπτό υμένιο δισκία	NL/H/4467/002	26481/08-04-2013	GENZYME EUROPE B.V.	GR
Fludara 10 mg επικαλυμμένα με λεπτό	NL/H/4467/002	26481/08-04-2013	GENZYME EUROPE B.V.	GR

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
υμένιο δισκία				
FLUDARA 10 mg, comprimé pelliculé	NL/H/4467/002	34009 358 532 0 2	GENZYME EUROPE B.V.	FR
FLUDARA 10 mg, comprimé pelliculé	NL/H/4467/002	34009 358 533 7 0	GENZYME EUROPE B.V.	FR
Fludara 50 mg poeder voor oplossing voor injectie of infusie.	NL/H/4467/001	BE170387	GENZYME EUROPE B.V.	BE
Fludara 50 mg polvere per soluzione iniettabile o per infusione.	NL/H/4467/001	029552015	GENZYME EUROPE B.V.	IT
Fludara 50 mg por oldatos injekcióhoz vagy oldatos infúzióhoz	not available	OGYI-T 8272/03	GENZYME EUROPE B.V.	HU
Fludara 50 mg poudre pour solution injectable ou poudre pour solution pour perfusion	NL/H/4467/001	BE170387	GENZYME EUROPE B.V.	BE
Fludara 50 mg powder for solution for injection or infusion	not available	MA596/00301	GENZYME EUROPE B.V.	MT
Fludara 50 mg powder for solution for injection or infusion.	NL/H/4467/001	PA 611/4/1	GENZYME EUROPE B.V.	IE
Fludara 50 mg powder for solution for injection or infusion.	NL/H/4467/001	PL 12375/0039	GENZYME EUROPE B.V.	XI
Fludara 50 mg Pulver zur Herstellung einer Injektions- oder Infusionslösung	NL/H/4467/001	BE170387	GENZYME EUROPE B.V.	BE
Fludara 50 mg Pulver zur Herstellung einer Injektions- oder Infusionslösung.	NL/H/4467/001	30590.00.00	GENZYME EUROPE B.V.	DE
Fludara 50 mg κόνις για ενέσιμο διάλυμα ή για διάλυμα προς έγχυση	not available	18733	GENZYME EUROPE B.V.	CY
Fludara 50 mg κόνις για ενέσιμο διάλυμα ή για διάλυμα προς έγχυση	NL/H/4467/001	66314/05-10-2010	GENZYME EUROPE B.V.	GR
FLUDARA 50 mg, poudre pour solution injectable ou perfusion	NL/H/4467/001	34009 558 544 2 5	GENZYME EUROPE B.V.	FR
Fludara oraal 10 mg, filmomhulde tabletten	NL/H/4467/002	RVG 26919	GENZYME EUROPE B.V.	NL
Fludara oraal 10 mg, filmomhulde tabletten	NL/H/4467/002	RVG 26919	GENZYME EUROPE B.V.	NL
Fludara oral 10 mg filmom obalené tablety	not available	44/0001/03-S	GENZYME EUROPE B.V.	SK
Fludara oral 10 mg filmom obalené tablety	not available	44/0001/03-S	GENZYME EUROPE B.V.	SK

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
Fludara oral 10 mg film-coated tablets	NL/H/4467/002	PA 611/4/2	GENZYME EUROPE B.V.	IE
Fludara oral 10 mg film-coated tablets	NL/H/4467/002	PA 611/4/2	GENZYME EUROPE B.V.	IE
Fludara oral 10 mg film-coated tablets	not available	MA596/00302	GENZYME EUROPE B.V.	MT
Fludara oral 10 mg film-coated tablets	not available	MA596/00302	GENZYME EUROPE B.V.	MT
Fludara oral 10 mg film-coated tablets	NL/H/4467/002	PL 12375/0040	GENZYME EUROPE B.V.	XI
Fludara oral 10 mg film-coated tablets	NL/H/4467/002	PL 12375/0040	GENZYME EUROPE B.V.	XI
Fludara Oral, 10 mg, tabletki powlekane	not available	11833	GENZYME EUROPE B.V.	PL
Fludara Oral, 10 mg, tabletki powlekane	not available	11833	GENZYME EUROPE B.V.	PL
Fludara, filmovertrukne tabletter	NL/H/4467/002	32647	GENZYME EUROPE B.V.	DK
Fludara, filmovertrukne tabletter	NL/H/4467/002	32647	GENZYME EUROPE B.V.	DK
Fludara, poeder voor oplossing voor injectie of infusie 50 mg/flacon	NL/H/4467/001	RVG 16849	GENZYME EUROPE B.V.	NL
Fludarabin Accord 25 mg/ml koncentrat za otopinu za injekciju ili infuziju	NL/H/4563/001	HR-H-663938715	ACCORD HEALTHCARE POLSKA SP. Z O.O.	HR
Fludarabin Accord 25 mg/ml koncentrat za raztopino za injiciranje/infundiranje	NL/H/4563/001	H/20/02778/001	ACCORD HEALTHCARE POLSKA SP. Z O.O.	SI
Fludarabin Accord 25 mg/ml koncentrat za raztopino za injiciranje/infundiranje	NL/H/4563/001	H/20/02778/002	ACCORD HEALTHCARE POLSKA SP. Z O.O.	SI
Fludarabin Accord 25 mg/ml koncentrat za raztopino za injiciranje/infundiranje	NL/H/4563/001	H/20/02778/003	ACCORD HEALTHCARE POLSKA SP. Z O.O.	SI
Fludarabin Accord 25 mg/ml koncentrátum oldatos injekcióhoz vagy infúzióhoz	NL/H/4563/001	OGYI-T-22726/01	ACCORD HEALTHCARE POLSKA SP. Z O.O.	HU
Fludarabin Accord 25 mg/ml koncentrátum oldatos injekcióhoz vagy infúzióhoz	NL/H/4563/001	OGYI-T-22726/02	ACCORD HEALTHCARE POLSKA SP. Z O.O.	HU
Fludarabin Accord 25 mg/ml koncentrátum oldatos injekcióhoz vagy infúzióhoz	NL/H/4563/001	OGYI-T-22726/03	ACCORD HEALTHCARE POLSKA SP. Z O.O.	HU
Fludarabin Accord 25 mg/ml Konzentrat zur Herstellung einer Injektions- oder Infusionslösung	NL/H/4563/001	135927	ACCORD HEALTHCARE B.V.	AT
Fludarabin Accord 25 mg/ml Konzentrat zur Herstellung einer Injektions-/Infusionslösung	NL/H/4563/001	90741.00.00	ACCORD HEALTHCARE B.V.	DE
Fludarabin Actavis 25 mg/ml koncentrat till injektions-/infusionsvätska, lösning	SE/H/1834/001	48182	ACTAVIS GROUP PTC EHF.	SE

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
Fludarabin Actavis 25 mg/ml koncentrat za raztopino za injiciranje/infundiranje	SE/H/1834/001	H/13/00629/002	ACTAVIS GROUP PTC EHF.	SI
Fludarabin Actavis 25 mg/ml koncentrat za raztopino za injiciranje/infundiranje	SE/H/1834/001	H/13/00629/001	ACTAVIS GROUP PTC EHF.	SI
Fludarabin Actavis 25mg/ml concentrate for solution for injection or infusion	SE/H/1834/001	IS/1/13/061/01	ACTAVIS GROUP PTC EHF.	IS
Fludarabin Actavis 25mg/ml concentrate for solution for injection or infusion	SE/H/1834/001	12-9135	ACTAVIS GROUP PTC EHF.	NO
Fludarabin Aurobindo 25 mg/ml Konzentrat zur Herstellung einer Injektionslösung oder Infusionslösung	DE/H/5605/001	88244.00.00	PUREN PHARMA GMBH & CO. KG	DE
Fludarabin HEXAL® 25 mg/ml Konzentrat zur Herstellung einer Injektions- oder Infusionslösung	not available	74371.00.00	HEXAL AG	DE
Fludarabin Teva 25 mg/ml koncentrat za raztopino za injiciranje ali infundiranje	NL/H/0715/001	H/07/00630/001	TEVA PHARMA B.V.	SI
Fludarabina Accord 25 mg/ml concentrado para solución inyectable y para perfusión.	NL/H/4563/001	79829	ACCORD HEALTHCARE S.L.U.	ES
Fludarabină Accord 25 mg/ml concentrat pentru soluţie injectabilă sau perfuzabilă	NL/H/4563/001/DC	11310/2018/01	ACCORD HEALTHCARE POLSKA SP. Z O.O.	RO
Fludarabină Accord 25 mg/ml concentrat pentru soluţie injectabilă sau perfuzabilă	NL/H/4563/001/DC	11310/2018/02	ACCORD HEALTHCARE POLSKA SP. Z O.O.	RO
Fludarabină Accord 25 mg/ml concentrat pentru soluţie injectabilă sau perfuzabilă	NL/H/4563/001/DC	11310/2018/03	ACCORD HEALTHCARE POLSKA SP. Z O.O.	RO
Fludarabina Accord 25 mg/ml Concentrato per soluzione iniettabile o per infusione	NL/H/4563/001	043104013	ACCORD HEALTHCARE S.L.U.	IT
Fludarabina Accord 25 mg/ml Concentrato per soluzione iniettabile o per infusione	NL/H/4563/001	043104025	ACCORD HEALTHCARE S.L.U.	IT
Fludarabina Accord 25 mg/ml Concentrato per soluzione iniettabile o per infusione	NL/H/4563/001	043104037	ACCORD HEALTHCARE S.L.U.	IT
Fludarabina Accord 25mg/ml concentrado para solução injetável ou para perfusão	NL/H/4563/001	5643655	ACCORD HEALTHCARE S.L.U.	PT
Fludarabina Accord 25mg/ml concentrado para solução injetável ou para perfusão	NL/H/4563/001	5643663	ACCORD HEALTHCARE S.L.U.	PT
Fludarabina Accord 25mg/ml concentrado para solução injetável ou para perfusão	NL/H/4563/001	5643671	ACCORD HEALTHCARE S.L.U.	PT
Fludarabina Aurovitas 25 mg/ml	DE/H/5605/001	77.766	AUROVITAS SPAIN,S.A.U.	ES

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concentrado para solución inyectable y para perfusión				
Fludarabina Teva 25 mg/ml concentrado para solución para perfusión o inyección EFG	NL/H/0715/001	69052	TEVA PHARMA S.L.U.,	ES
Fludarabina Teva, concentrato per soluzione iniettabile o per infusione	NL/H/0715/001	038033015	TEVA ITALIA S.R.L.	IT
Fludarabine - PCH 25 mg/ml, concentraat voor oplossing voor intraveneuze infusie of injectie	NL/H/0715/001	RVG 33255	PHARMACHEMIE BV	NL
Fludarabine 25 mg/ml Concentrate for Solution for Injection or Infusion	NL/H/5179/001	PL 04416/1595	SANDOZ LTD	XI
Fludarabine Accord 25 mg/ml injektio-/infuusiokonsentraatti, liuosta varten	NL/H/4563/001	31752	ACCORD HEALTHCARE B.V.	FI
Fludarabine Accord 25 mg/ml koncentrát pro injekční/infuzní roztok	NL/H/4563/001	44/476/15-C	ACCORD HEALTHCARE POLSKA SP. Z O.O.	CZ
Fludarabine Accord 25 mg/ml Koncentrat till injektions-/infusionsvätska, lösning	NL/H/4563/001	49857	ACCORD HEALTHCARE B.V.	SE
Fludarabine Accord 25 mg/ml koncentratas injekciniam ar infuziniam tirpalui	NL/H/4563/001	LT/1/14/3627/001	ACCORD HEALTHCARE B.V.	LT
Fludarabine Accord 25 mg/ml koncentratas injekciniam ar infuziniam tirpalui	NL/H/4563/001	LT/1/14/3627/002	ACCORD HEALTHCARE B.V.	LT
Fludarabine Accord 25 mg/ml koncentratas injekciniam ar infuziniam tirpalui	NL/H/4563/001	LT/1/14/3627/003	ACCORD HEALTHCARE B.V.	LT
Fludarabine Accord 25 mg/ml p???? d????µa ??a pa?as?e?? d?a??µat?? p??? ??es? ? ????s?	NL/H/4563/001	22209	ACCORD HEALTHCARE S.L.U.	CY
FLUDARABINE ACCORD 25 mg/ml, solution à diluer pour solution injectable/pour perfusion	NL/H/4563/001	34009 301 326 5 4	ACCORD HEALTHCARE FRANCE SAS	FR
FLUDARABINE ACCORD 25 mg/ml, solution à diluer pour solution injectable/pour perfusion	NL/H/4563/001	34009 550 493 0 2	ACCORD HEALTHCARE FRANCE SAS	FR
FLUDARABINE ACCORD 25 mg/ml,	NL/H/4563/001	34009 550 493 1 9	ACCORD HEALTHCARE	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
solution à diluer pour solution injectable/pour perfusion			FRANCE SAS	
Fludarabine Accord 25 mg/ml, süste-/infusioonilahuse kontsentraat.	NL/H/4563/001	855314	ACCORD HEALTHCARE B.V.	EE
Fludarabine Accord Healthcare 25 mg/ml Concentraat voor oplossing voor injectie of infusie	NL/H/4563/001	BE462391	ACCORD HEALTHCARE B.V.	BE
Fludarabine Accord Healthcare 25 mg/ml solution à diluer pour solution injectable /pour perfusion	NL/H/4563/001	BE462391	ACCORD HEALTHCARE B.V.	BE
Fludarabine Accord, 25 mg/ml, koncentrat do sporzadzania roztworu do wstrzykiwan lub infuzji	NL/H/4563/001	23072	ACCORD HEALTHCARE POLSKA SP. Z O.O.	PL
Fludarabine phosphate 25 mg/ml Concentrate for Solution for Injection or Infusion	NL/H/4563/001	PA 2315/035/001	ACCORD HEALTHCARE IRELAND LIMITED	IE
Fludarabine Phosphate 25 mg/ml Concentrate for Solution for Injection or Infusion	NL/H/0715/001	PL 00289/0938	TEVA UK LIMITED	XI
Fludarabine phosphate 25 mg/ml Concentrate for Solution for Injection or Infusion.	NL/H/4563/001	PL 20075/0379	ACCORD HEALTHCARE LIMITED	XI
Fludarabine Phosphate 25mg/ml Concentrate for Solution for Injection / Infusion	UK/H/5290/001	PL 0142/0981	ACCORD-UK LIMITED	XI
Fludarabine Phosphate 25mg/ml Concentrate for Solution for Injection / Infusion	UK/H/5290/001	PL 0142/0981	ACCORD-UK LIMITED	XI
Fludarabine Teva 25 mg/ml concentraat voor oplossing voor injectie of infusie	NL/H/0715/001	BE303721	TEVA PHARMA BELGIUM N.V./S.A	BE
FLUDARABINE TEVA 25 mg/ml KONZENTRAT ZUR HERSTELLUNG EINER INJEKTIONS- ODER INFUSIONSLOESUNG	NL/H/0715/001	BE303721	TEVA PHARMA BELGIUM N.V./S.A	BE
Fludarabine Teva 25 mg/ml solution à diluer pour injection ou perfusion	NL/H/0715/001	BE303721	TEVA PHARMA BELGIUM N.V./S.A	BE
Fludarabine Teva 25 mg/ml solution à diluer pour injection ou perfusion	NL/H/0715/001	2007110015	TEVA PHARMA BELGIUM N.V./S.A	LU

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
FLUDARABINE TEVA 25 mg/ml, solution à diluer pour injectable ou perfusion	NL/H/0715/001	NL32376	TEVA SANTÉ	FR
Fludarabinefosfaat Accord 25 mg/ml, concentraat voor oplossing voor injectie of infusie.	NL/H/4563/001	RVG 114133	ACCORD HEALTHCARE B.V.	NL
Fludarabine-Teva 25 mg/ml, koncentrát pro injekční/infuzní roztok	NL/H/0715/001	44/333/07-C	TEVA PHARMACEUTICALS CR, S.R.O.	CZ
Fludarabinphosphat Actavis KONCENTRAT TIL INJEKTIONS- OG INFUSIONSVÆSKE, OPLØSNING	SE/H/1834/001	51025	ACTAVIS GROUP PTC EHF.	DK
Fludarabinphosphat-GRY® 25 mg/ml Konzentrat zur Herstellung einer Injektionslösung oder Infusionslösung	NL/H/0715/001	64929.00.00	TEVA GMBH	DE
Флударабин Акорд 25 mg/ml концентрат за инжекционен или инфузионен разтвор	NL/H/4563/001	20150040	ACCORD HEALTHCARE POLSKA SP. Z O.O.	BG