



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

12 April 2018  
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Human Medicines Evaluation Division

## List of nationally authorised medicinal products

Active substance: fludarabine

Procedure no.: PSUSA/00001406/201708

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<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>
Fludarabine Accord Healthcare 25 mg/ml solution à diluer pour solution injectable /pour perfusion	UK/H/5564/001	BE462391	ACCORD HEALTHCARE LIMITED	BE
Fludarabine Accord Healthcare 25 mg/ml Concentraat voor oplossing voor injectie of infusie	UK/H/5564/001	BE462391	ACCORD HEALTHCARE LIMITED	BE
Fludarabine Accord 25 mg/ml, süste- või infusioonilahuse kontsentraat	UK/H/5564/001	855314	ACCORD HEALTHCARE LIMITED	EE
Fludarabin Accord 25 mg/ml koncentrátum oldatos injekcióhoz vagy infúzióhoz	UK/H/5564/001	OGYI-T-22726/01	ACCORD HEALTHCARE LIMITED	HU
Fludarabin Accord 25 mg/ml koncentrátum oldatos injekcióhoz vagy infúzióhoz	UK/H/5564/001	OGYI-T-22726/02	ACCORD HEALTHCARE LIMITED	HU
Fludarabin Accord 25 mg/ml koncentrátum oldatos injekcióhoz vagy infúzióhoz	UK/H/5564/001	OGYI-T-22726/03	ACCORD HEALTHCARE LIMITED	HU
Fludarabine phosphate 25 mg/ml Concentrate for Solution for Injection or Infusion	UK/H/5564/001	PA 1390/096/001	ACCORD HEALTHCARE LIMITED	IE

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Fludarabine Accord 25 mg/ml koncentratas injekciniam ar infuziniam tirpalui	UK/H/5564/001	LT/1/14/3627/001	ACCORD HEALTHCARE LIMITED	LT
Fludarabine Accord 25 mg/ml koncentratas injekciniam ar infuziniam tirpalui	UK/H/5564/001	LT/1/14/3627/002	ACCORD HEALTHCARE LIMITED	LT
Fludarabine Accord 25 mg/ml koncentratas injekciniam ar infuziniam tirpalui	UK/H/5564/001	LT/1/14/3627/003	ACCORD HEALTHCARE LIMITED	LT
Fludarabine Accord 25 mg/ml koncentrats injekciju vai infuziju šķiduma pagatavošanai	UK/H/5564/001	14-0220	ACCORD HEALTHCARE LIMITED	LV
Fludarabine phosphate 25 mg/ml Concentrate for Solution for Injection or Infusion	UK/H/5564/001	MA 054/08401	ACCORD HEALTHCARE LIMITED	MT
Fludarabinefosfaat Accord 25 mg/ml, concentraat voor oplossing voor injectie of infusie	UK/H/5564/001	RVG 114133	ACCORD HEALTHCARE LIMITED	NL
Fludarabine Accord 25 mg/ml Koncentrat till injektions-/infusionsvätska, lösning	UK/H/5564/001	49857	ACCORD HEALTHCARE LIMITED	SE

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Fludarabine phosphate 25 mg/ml Concentrate for Solution for Injection or Infusion	UK/H/5564/001	PL 20075/0379	ACCORD HEALTHCARE LIMITED	UK
Fludarabin Accord 25 mg/ml Konzentrat zur Herstellung einer Injektions oder Infusionslösung	UK/H/5564/001	135927	ACCORD HEALTHCARE LIMITED	AT
Fludarabin Accord 25 mg/ml Konzentrat zur Herstellung einer Injektions-/Infusionslösung	UK/H/5564/001	90741.00.00	ACCORD HEALTHCARE LIMITED	DE
Fludarabina Accord 25mg/ml concentrado para solução injetável ou para perfusão	UK/H/5564/001	5643655	ACCORD HEALTHCARE LIMITED	PT
Fludarabina Accord 25mg/ml concentrado para solução injetável ou para perfusão	UK/H/5564/001	5643663	ACCORD HEALTHCARE LIMITED	PT
Fludarabina Accord 25mg/ml concentrado para solução injetável ou para perfusão	UK/H/5564/001	5643671	ACCORD HEALTHCARE LIMITED	PT

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Fludarabina Accord 25 mg/ml concentrado para solución inyectable y para perfusión.	UK/H/5564/001	79829	ACCORD HEALTHCARE S.L.U.	ES
Fludarabina Accord 25 mg/ml Concentrato per soluzione iniettabile o per infusione	UK/H/5564/001	043104013	ACCORD HEALTHCARE LIMITED	IT
Fludarabina Accord 25 mg/ml Concentrato per soluzione iniettabile o per infusione	UK/H/5564/001	043104025	ACCORD HEALTHCARE LIMITED	IT
Fludarabina Accord 25 mg/ml Concentrato per soluzione iniettabile o per infusione	UK/H/5564/001	043104037	ACCORD HEALTHCARE LIMITED	IT
Fludarabine Accord 25 mg/ml koncentrát pro injekční/infuzní roztok	UK/H/5564/001	44/476/15-C	ACCORD HEALTHCARE LIMITED	CZ
Fludarabine Accord 25 mg/ml πυκνό διάλυμα για παρασκευή διαλύματος προς ένεση ή έγχυση	UK/H/5564/001	22209	ACCORD HEALTHCARE LIMITED	CY
Fludarabin Accord 25 mg/ml koncentrat za otopinu za injekciju ili infuziju	UK/H/5564/001	HR-H-663938715	ACCORD HEALTHCARE LIMITED	HR

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 Accord, 25 mg/ml, koncentrat do sporządzania roztworu do wstrzykiwań lub infuzji	UK/H/5564/001	23072	ACCORD HEALTHCARE LIMITED	PL
Fludarabine Accord 25 mg/ml injektio- /infuusiokonsentraatti, liuosta varten	UK/H/5564/001	31752	ACCORD HEALTHCARE LIMITED	FI
Флударабин Акорд 25 mg/ml концентрат за инжекционен или инфузионен разтвор	UK/H/5564/001	20150040	ACCORD HEALTHCARE LIMITED	BG
Fludarabinmedac 25 mg/ml Konzentrat zur Herstellung einer Injektionslösung oder Infusionslösung	NL/H/0805/001	65680.00.00	PHARMACHEMIE B.V	DE
Fludarabine Teva 25 mg/ml, concentraat voor oplossing voor intraveneuze injectie/infusie	NL-H-0805-001	RVG 33728	TEVA NEDERLAND B.V.	NL
Fludarabinphosphat OMNICARE 25 mg/ml Konzentrat zur Herstellung einer Injektionslösung oder Infusionslösung	not available	91843.00.00	OMNICARE PHARMA GMBH	DE

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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
Fludarabine Teva, 25 mg/ml, koncentrat do sporządzania roztworu do wstrzykiwań lub infuzji	NL/H/0715/001	14254	TEVA PHARMACEUTICALS POLSKA SP. Z O.O.	PL
Fludarabina Teva 25mg/ml concentrato per soluzione iniettabile o per infusione	NL/H/0715/001	038033015	TEVA ITALIA S.R.L.	IT
Fludarabinphosphat "Pharmachemie", koncentrat til injektions- og infusionsvæske, opløsning	NL/H/0715/001	38747	PHARMACHEMIE B.V	DK
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
Fludarabina Teva 25 mg/ml, concentrado para solución inyectable y para perfusión EFG	NL/H/0715/001	69052	TEVA PHARMA S.L.U	ES

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Fludarabinphosphat-GRY® 25 mg/ml Konzentrat zur Herstellung einer Injektionslösung oder Infusionslösung	NL/H/0715/001	64929.00.00	TEVA GMBH	DE
FLUDARABINE TEVA 25 mg/ml, solution à diluer pour injectable ou perfusion	NL/H/0715/001	NL32376	TEVA SANTÉ	FR
Fludarabinefosfaat - PCH 25 mg/ml, concentraat voor oplossing voor infusie of injectie	NL/H/0715/001	RVG 33255	PHARMACHEMIE B.V	NL
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 Phosphate 25 mg/ml Concentrate for Solution for Injection or Infusion	NL/H/0715/001	PL 00289/0938	TEVA UK LIMITED	UK
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
Fludara 10 mg plévele dengtos tabletés	not available	LT/1/96/2819/002	GENZYME EUROPE B.V.	LT



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FLUDARA 10 mg, comprimé pelliculé	UK/H/0055/002	0321461	GENZYME EUROPE B.V.	LU
Fludara oral 10 mg film-coated tablets	UK/H/0055/002	PL 12375/0040	GENZYME EUROPE B.V.	UK
Fludara oral 10 mg film-coated tablets	UK/H/0055/002	PA 611/4/2	GENZYME EUROPE B.V.	IE
FLUDARA 10 mg, comprimé pelliculé	UK/H/0055/002	358 532-0	GENZYME EUROPE B.V.	FR
FLUDARA 10 mg, comprimé pelliculé	UK/H/0055/002	358 533-7	GENZYME EUROPE B.V.	FR
Fludara 50 mg poudre pour solution injectable ou poudre pour solution pour perfusion	UK/H/0055/001	BE170387	GENZYME EUROPE B.V.	BE
Fludara 50 mg poeder voor oplossing voor injectie of infusie	UK/H/0055/001	BE170387	GENZYME EUROPE B.V.	BE
Fludara 50 mg por oldatos injekcióhoz vagy oldatos infúzióhoz	not available	OGYI-T 8272/03	GENZYME EUROPE B.V.	HU
Fludara 50 mg polvere per soluzione iniettabile o per infusion	UK/H/0055/001	029552015	GENZYME EUROPE B.V.	IT
Fludara 50 mg powder for solution for injection/infusion	not available	MA596/00301	GENZYME EUROPE B.V.	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
Fludara, poeder voor oplossing voor injectie of infusie 50 mg/flacon	UK/H/0055/001	RVG 16849	GENZYME EUROPE B.V.	NL
Fludara 50 mg pó para solução injectável ou para perfusão	UK/H/0055/001	2275782	GENZYME EUROPE B.V.	PT
Fludara 50 mg prašek za raztopino za injiciranje ali infundiranje	not available	H/97/00628/001	GENZYME EUROPE B.V.	SI
Beneflur 50 mg polvo para solución inyectable y para perfusión	UK/H/0055/001	60616	GENZYME EUROPE B.V.	ES
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	UK/H/0055/001	66314/05-10-2010	GENZYME EUROPE B.V.	GR
Флудара oral 10 mg филмирани таблетки	not available	20020574; II-1214/07.12.2007	GENZYME EUROPE B.V.	BG
Fludara 10 mg επικαλυμμένα με λεπτό υμένιο δισκία	not available	20545	GENZYME EUROPE B.V.	CY
Fludara 10 mg, potahované tablety	not available	44/181/01-C	GENZYME EUROPE B.V.	CZ
Fludara, filmovertrukne tabletter	UK/H/0055/002	32647	GENZYME EUROPE 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
Fludara 10 mg tabletti, kalvopäällysteinen	UK/H/0055/002	16553	GENZYME EUROPE B.V.	FI
Fludara 10 mg επικαλυμμένα με λεπτό υμένιο δισκία	UK/H/0055/002	26481/08-04-2013	GENZYME EUROPE B.V.	GR
Fludara 10 mg filtabletta	not available	OGYI-T-8272/01	GENZYME EUROPE B.V.	HU
Fludara 10 mg filtabletta	not available	OGYI-T-8272/02	GENZYME EUROPE B.V.	HU
Fludara 10 mg filmuhúðaðar töflur	UK/H/0055/002	IS/1/01/036/01	GENZYME EUROPE B.V.	IS
Fludara 10 mg compresse rivestite con film	UK/H/0055/002	029552027	GENZYME EUROPE B.V.	IT
Fludara 10 mg compresse rivestite con film	UK/H/0055/002	029552039	GENZYME EUROPE B.V.	IT
Fludara 10 mg apvalkotās tabletes	not available	03-0260	GENZYME EUROPE B.V.	LV
Fludara 10 mg plėvele dengtos tabletės	not available	LT/1/96/2819/001	GENZYME EUROPE B.V.	LT
FLUDARA 10 mg, comprimé pelliculé	UK/H/0055/002	0321458	GENZYME EUROPE B.V.	LU
Fludara oral 10 mg film-coated tablets	not available	MA596/00302	GENZYME EUROPE B.V.	MT
Fludara oraal 10 mg, filmomhulde tabletten	UK/H/0055/002	RVG 26919	GENZYME EUROPE B.V.	NL
Fludara 10 mg tablett, filmdrasjert	UK/H/0055/002	2001-04591	GENZYME EUROPE 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
Fludara Oral, 10 mg, tabletki powlekane	not available	11833	GENZYME EUROPE B.V.	PL
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 oral 10 mg filmom obalené tablety	not available	44/0001/03-S	GENZYME EUROPE B.V.	SK
Fludara 10 mg filmsko obložene tablete	not available	H/97/00628/002	GENZYME EUROPE B.V.	SI
Beneflur10 mg comprimidos recubiertos con película	UK/H/0055/002	64900	GENZYME EUROPE B.V.	ES
Fludara 10 mg filmdragerad tablett	UK/H/0055/002	17317	GENZYME EUROPE B.V.	SE
Fludara 50 mg powder for solution for injection/infusion	UK/H/0055/001	PA 611/4/1	GENZYME EUROPE B.V.	IE
Fludara 50 mg Pulver zur Herstellung einer Injektions- oder Infusionslösung	UK/H/0055/001	30590.00.00	GENZYME EUROPE B.V.	DE
FLUDARA 50 mg, poudre pour solution injectable ou perfusion	UK/H/0055/001	34009 558 544 2 5	GENZYME EUROPE B.V.	FR
Fludara 50 mg powder for solution for injection/infusion	UK/H/0055/001	PL 12375/0039	GENZYME EUROPE B.V.	UK

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 10 mg επικαλυμμένα με λεπτό υμένιο δισκία	not available	20545	GENZYME EUROPE B.V.	CY
Флудара орал 10 mg филмирани таблетки	not available	20020574; II-1214/07.12.2007	GENZYME EUROPE B.V.	BG
Fludara oral 10 mg filmom obalené tablety	not available	44/0001/03-S	GENZYME EUROPE B.V.	SK
Fludara 10 mg apvalkotās tabletes	not available	03-0260	GENZYME EUROPE B.V.	LV
Fludara oral 10 mg film- coated tablets	not available	MA596/00302	GENZYME EUROPE B.V.	MT
Fludara Oral, 10 mg, tabletki powlekane	not available	11833	GENZYME EUROPE B.V.	PL
Fludara 10 mg, potahované tablety	not available	44/181/01-C	GENZYME EUROPE B.V.	CZ
Fludara oral 10 mg film- coated tablets	UK/H/0055/002	PL 12375/0040	GENZYME EUROPE B.V.	UK
Fludara 10 mg επικαλυμμένα με λεπτό υμένιο δισκία	UK/H/0055/002	26481/08-04-2013	GENZYME EUROPE B.V.	GR
Fludara 10 mg tablett, filmdrasjert	UK/H/0055/002	2001-04591	GENZYME EUROPE B.V.	NO
Fludara oral 10 mg film- coated tablets	UK/H/0055/002	PA 611/4/2	GENZYME EUROPE B.V.	IE
Fludara, filmovertrukne tabletter	UK/H/0055/002	32647	GENZYME EUROPE B.V.	DK
Fludara 10 mg filmuhúðaðar töflur	UK/H/0055/002	IS/1/01/036/01	GENZYME EUROPE 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
Fludara 10 mg tabletti, kalvopäällysteinen	UK/H/0055/002	16553	GENZYME EUROPE B.V.	FI
Beneflur10 mg comprimidos recubiertos con película	UK/H/0055/002	64900	GENZYME EUROPE B.V.	ES
Fludara oraal 10 mg, filmomhulde tabletten	UK/H/0055/002	RVG 26919	GENZYME EUROPE B.V.	NL
Fludarabin Actavis 25 mg/ml koncentrat till injektions-/infusionsvätska, lösning	UK/H/5290/001	48182	ACTAVIS GROUP PTC EHF.	SE
Fludarabin Actavis 25mg/ml concentrate for solution for injection or infusion	UK/H/5290/001	12-9135	ACTAVIS GROUP PTC EHF.	NO
Fludarabin Actavis 25mg/ml concentrate for solution for injection or infusion	UK/H/5290/001	PA 1380/134/1	ACTAVIS GROUP PTC EHF.	IE
Fludarabine Actavis, 25 mg/ml, süste- või infusioonilahuse kontsentraat	UK/H/5290/001	815413	ACTAVIS GROUP PTC EHF.	EE
FLUDARABINE ACTAVIS 25 MG/ML KONCENTRĀTS INJEKCIJU VAI INFŪZIJU ŠĶĪDUMA PAGATAVOŠANAI	UK/H/5290/001	13-0250	ACTAVIS GROUP PTC EHF.	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
Fludarabine/Actavis 25 mg/ml, πυκνό διάλυμα για παρασκευή ενέσιμου διαλύματος ή διαλύματος προς έγχυση	UK/H/5290/001	95287/1-12-2014	ACTAVIS GROUP PTC EHF.	GR
Fludarabin Actavis 25 mg/ml injektio-/infuusiokonsentraatti, liuosta varten	UK/H/5290/001	32840	ACTAVIS GROUP PTC EHF.	FI
Fludarabinefosfaat Aurobindo 25 mg/ml, concentraat voor oplossing voor injectie of infusie	UK/H/5290/001	RVG 112183	AUROBINDO PHARMA B.V.	NL
Fludarabin Actavis 25 mg/ml koncentrat za raztopino za injiciranje/infundiranje	UK/H/5290/001	H/13/00629/002	ACTAVIS GROUP PTC EHF.	SI
FLUDARABINA AUROBINDO 25 mg/ml concentrato per soluzione iniettabile o per infusione	UK/H/5290/001	042158016	AUROBINDO PHARMA (ITALIA) S.R.L.	IT
FLUDARABINA AUROBINDO 25 mg/ml concentrato per soluzione iniettabile o per infusione	UK/H/5290/001	042158028	AUROBINDO PHARMA (ITALIA) S.R.L.	IT

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Fludarabina Aurovitas 25 mg/ml concentrado para solución inyectable y para perfusión	UK/H/5290/001	77.766	AUROVITAS SPAIN,S.A.U.	ES
Fludarabin Aurobindo 25 mg/ml Konzentrat zur Herstellung einer Injektionslösung oder Infusionslösung	UK/H/5290/001	88244.00.00	PUREN PHARMA GMBH & CO. KG	DE
Fludarabine Actavis, 25 mg/ml, koncentrat do sporzadzania roztworu do wstrzykiwan/do infuzji	UK/H/5290/001	22516	ACTAVIS GROUP PTC EHF.	PL
Флударабин Актавис 25 mg/ml концентрат за инжекционен или инфузионен разтвор	UK/H/5290/001	20130217	ACTAVIS GROUP PTC EHF.	BG
Fludarabin Actavis 25mg/ml concentrate for solution for injection or infusion	UK/H/5290/001	IS/1/13/061/01	ACTAVIS GROUP PTC EHF.	IS
Fludarabine Actavis 25 mg/ml koncentratas injekciniam/infuziniam tirpalui	UK/H/5290/001	LT/1/13/3338/001-002	ACTAVIS GROUP PTC EHF.	LT



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Fludarabine Actavis 25 mg/ml concentrat pentru solutie injectabila sau perfuzabila	UK/H/5290/001	5735/2013/01-02	ACTAVIS GROUP PTC EHF.	RO
Fludarabine Phosphate 25mg/ml Concentrate for Solution for Injection or Infusion	UK/H/5290/001	PL 30306/0442	ACTAVIS GROUP PTC EHF.	UK
Fludarabinphosphat "Actavis", koncentrat til injektions- og infusionsvæske, opløsning	UK/H/5290/001	51025	ACTAVIS GROUP PTC EHF.	DK
Fludarabinphosphat Actavis 25 mg/ml Konzentrat zur Herstellung einer Injektions- oder Infusionslösung	UK/H/5290/001	1-31896	ACTAVIS GROUP PTC EHF.	AT
Fludarabin Actavis 25 mg/ml koncentrat za raztopino za injiciranje/infundiranje	UK/H/5290/001	H/13/00629/001	ACTAVIS GROUP PTC EHF.	SI
Fludarabine/Teva 25 mg/ml, πυκνό διάλυμα για παρασκευή ενέσιμου διαλύματος ή διαλύματος προς έγχυση	NL/H/0715/001	75649/14	CHEMIPHARM S.G. DE TCHAVES & CIE E.E	GR

<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>
FLUDARABINE EBEWE 25 mg/ml, solution à diluer injectable ou pour perfusion	not available	34009 574 271 7 7	SANDOZ	FR
FLUDARABINE EBEWE 25 mg/ml, solution à diluer injectable ou pour perfusion	not available	34009 574 274 6 7	SANDOZ	FR
FLUDARABINE EBEWE 25 mg/ml, solution à diluer injectable ou pour perfusion	not available	34009 574 272 3 8	SANDOZ	FR
Fludarabine 25 mg/ml - concentrate for solution for injection or infusion	DE/H/0801/001	PL 14510/0009-001	EBEWE PHARMA	UK
Fludarabin HEXAL 25 mg/ml Konzentrat zur Herstellung einer Injektions- oder Infusionslösung	not available	74371.00.00	HEXAL AG	DE