



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

21 July 2022
EMA/CMDh/800411/2022
Human Medicines Division

List of nationally authorised medicinal products

Active substance(s): donepezil

Procedure No. PSUSA/00001160/202111



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
ARICEPT 10 mg apvalkotās tabletes	not available	99-0135	PFIZER EUROPE MA EEIG	LV
ARICEPT 10 mg apvalkotās tabletes	not available	99-0135	PFIZER EUROPE MA EEIG	LV
ARICEPT 10 mg compresse orodispersibili	AT/H/0983/004	033254285	PFIZER ITALIA S.R.L.	IT
ARICEPT 10 mg compresse orodispersibili	AT/H/0983/004	033254347	PFIZER ITALIA S.R.L.	IT
ARICEPT 10 mg compresse orodispersibili	AT/H/0983/004	033254350	PFIZER ITALIA S.R.L.	IT
ARICEPT 10 mg compresse orodispersibili	AT/H/0983/004	033254362	PFIZER ITALIA S.R.L.	IT
ARICEPT 10 mg compresse orodispersibili	AT/H/0983/004	033254323	PFIZER ITALIA S.R.L.	IT
ARICEPT 10 mg compresse orodispersibili	AT/H/0983/004	033254311	PFIZER ITALIA S.R.L.	IT
ARICEPT 10 mg compresse orodispersibili	AT/H/0983/004	033254335	PFIZER ITALIA S.R.L.	IT
ARICEPT 10 mg compresse orodispersibili	AT/H/0983/004	033254297	PFIZER ITALIA S.R.L.	IT
ARICEPT 10 mg compresse orodispersibili	AT/H/0983/004	033254309	PFIZER ITALIA S.R.L.	IT
ARICEPT 10 mg compresse orodispersibili	AT/H/0983/004	033254121	PFIZER ITALIA S.R.L.	IT
ARICEPT 10 mg compresse orodispersibili	AT/H/0983/004	033254107	PFIZER ITALIA S.R.L.	IT
ARICEPT 10 mg compresse orodispersibili	AT/H/0983/004	033254145	PFIZER ITALIA S.R.L.	IT
ARICEPT 10 mg compresse orodispersibili	AT/H/0983/004	033254119	PFIZER ITALIA S.R.L.	IT
ARICEPT 10 mg compresse orodispersibili	AT/H/0983/004	033254184	PFIZER ITALIA S.R.L.	IT
ARICEPT 10 mg compresse orodispersibili	AT/H/0983/004	033254160	PFIZER ITALIA S.R.L.	IT
ARICEPT 10 mg	AT/H/0983/004	033254158	PFIZER ITALIA S.R.L.	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
comprimés orodispersibili				
ARICEPT 10 mg comprimés orodispersibili	AT/H/0983/004	033254133	PFIZER ITALIA S.R.L.	IT
ARICEPT 10 mg comprimés rivestite con film	AT/H/0983/002	033254020	PFIZER ITALIA S.R.L.	IT
ARICEPT 10 mg comprimés pelliculés	AT/H/0983/002	BE295644	PFIZER S.A. (BELGIUM)	BE
ARICEPT 10 mg comprimés pelliculés	AT/H/0983/002	BE185805	PFIZER S.A. (BELGIUM)	BE
ARICEPT 10 mg comprimés pelliculés	AT/H/0983/002	2011041096	PFIZER S.A. (BELGIUM)	LU
ARICEPT 10 mg comprimidos revestidos por película	AT/H/0983/002	2574887	LABORATÓRIOS PFIZER, LDA.	PT
ARICEPT 10 mg comprimidos revestidos por película	AT/H/0983/002	2574986	LABORATÓRIOS PFIZER, LDA.	PT
ARICEPT 10 mg film coated tablets	AT/H/0983/002	PA 822/2/2	PFIZER HEALTHCARE IRELAND	IE
Aricept 10 mg filmdragerade tabletter	AT/H/0983/002	12777	PFIZER OY	FI
Aricept 10 mg filmdragerade tabletter	AT/H/0983/002	13568	PFIZER AB	SE
Aricept 10 mg filmom obložene tablete	not available	HR-H-681092208	PFIZER CROATIA D.O.O.	HR
Aricept 10 mg filmom obložene tablete	not available	HR-H-681092208	PFIZER CROATIA D.O.O.	HR
Aricept 10 mg filmomhulde tabletten	AT/H/0983/002	BE185805	PFIZER S.A. (BELGIUM)	BE
Aricept 10 mg filmomhulde tabletten	AT/H/0983/002	BE295644	PFIZER S.A. (BELGIUM)	BE
ARICEPT 10 mg filmsko obložene tablete	not available	H/98/00209/002	PFIZER LUXEMBOURG SARL	SI
ARICEPT 10 mg filmtableta	not available	OGYI-T-6059/02	PFIZER KFT.	HU
ARICEPT 10 mg filmtableta	not available	OGYI-T-6059/02	PFIZER KFT.	HU

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
Aricept 10 mg Filmtabletten	AT/H/0983/002	BE295644	PFIZER S.A. (BELGIUM)	BE
Aricept 10 mg Filmtabletten	AT/H/0983/002	BE185805	PFIZER S.A. (BELGIUM)	BE
Aricept 10 mg Filmtabletten	AT/H/0983/002	2011041096	PFIZER S.A. (BELGIUM)	LU
Aricept 10 mg filmuhúðaðar töflur.	not available	970077	PFIZER APS	IS
Aricept 10 mg filmuhúðaðar töflur.	not available	970077	PFIZER APS	IS
Aricept 10 mg munsönderfallande tablett	AT/H/0983/004	22918	PFIZER AB	SE
ARICEPT 10 mg potahované tablety	not available	06/122/98-C	PFIZER, SPOL. S R.O.	CZ
ARICEPT 10 mg potahované tablety	not available	06/122/98-C	PFIZER, SPOL. S R.O.	CZ
Aricept 10 mg tabletti, kalvopäällysteinen	AT/H/0983/002	12777	PFIZER OY	FI
ARICEPT 10 mg δισκίο διασπειρόμενο στο στόμα	AT/H/0983/004	81152/24-11-2011	PFIZER HELLAS, A.E.	GR
ARICEPT 10 mg επικαλυμμένα με λεπτό υμένιο δισκία	not available	17825	PFIZER HELLAS, A.E.	CY
ARICEPT 10 mg επικαλυμμένα με λεπτό υμένιο δισκία	not available	17825	PFIZER HELLAS, A.E.	CY
ARICEPT 10 mg επικαλυμμένα με λεπτό υμένιο δισκία	AT/H/0983/002	75519/20-11-2007	PFIZER HELLAS, A.E.	GR
ARICEPT 10 mg, comprimé orodispersible	AT/H/0983/004	NL 32121	LABORATOIRES EISAI S.A	FR
ARICEPT 10 mg, comprimé pelliculé	AT/H/0983/002	NL 22635	LABORATOIRES EISAI S.A	FR
ARICEPT 10mg comprimidos recubiertos con película	not available	61.870	PFIZER, S.L.	ES
ARICEPT 10mg	not available	61.870	PFIZER, S.L.	ES

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
comprimidos recubiertos con película				
Aricept 10mg Filmtabletten Wirkstoff: Donepezilhydrochlorid	AT/H/0983/002/MR	40652.01.00	EISAI GMBH	DE
ARICEPT 5 mg apvalkotās tabletes	not available	99-0134	PFIZER EUROPE MA EEIG	LV
ARICEPT 5 mg apvalkotās tabletes	not available	99-0134	PFIZER EUROPE MA EEIG	LV
ARICEPT 5 mg comprese orodispersibili	AT/H/0983/003	033254210	PFIZER ITALIA S.R.L.	IT
ARICEPT 5 mg comprese orodispersibili	AT/H/0983/003	033254234	PFIZER ITALIA S.R.L.	IT
ARICEPT 5 mg comprese orodispersibili	AT/H/0983/003	033254196	PFIZER ITALIA S.R.L.	IT
ARICEPT 5 mg comprese orodispersibili	AT/H/0983/003	033254246	PFIZER ITALIA S.R.L.	IT
ARICEPT 5 mg comprese orodispersibili	AT/H/0983/003	033254222	PFIZER ITALIA S.R.L.	IT
ARICEPT 5 mg comprese orodispersibili	AT/H/0983/003	033254208	PFIZER ITALIA S.R.L.	IT
ARICEPT 5 mg comprese orodispersibili	AT/H/0983/003	033254259	PFIZER ITALIA S.R.L.	IT
ARICEPT 5 mg comprese orodispersibili	AT/H/0983/003	033254273	PFIZER ITALIA S.R.L.	IT
ARICEPT 5 mg comprese orodispersibili	AT/H/0983/003	033254261	PFIZER ITALIA S.R.L.	IT
ARICEPT 5 mg comprese orodispersibili	AT/H/0983/003	033254071	PFIZER ITALIA S.R.L.	IT
ARICEPT 5 mg comprese orodispersibili	AT/H/0983/003	033254083	PFIZER ITALIA S.R.L.	IT
ARICEPT 5 mg comprese orodispersibili	AT/H/0983/003	033254032	PFIZER ITALIA S.R.L.	IT
ARICEPT 5 mg comprese orodispersibili	AT/H/0983/003	033254172	PFIZER ITALIA S.R.L.	IT
ARICEPT 5 mg comprese orodispersibili	AT/H/0983/003	033254095	PFIZER ITALIA S.R.L.	IT
ARICEPT 5 mg	AT/H/0983/003	033254057	PFIZER ITALIA S.R.L.	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
comprimido orodispersibile				
ARICEPT 5 mg comprimido orodispersibile	AT/H/0983/003	033254044	PFIZER ITALIA S.R.L.	IT
ARICEPT 5 mg comprimido orodispersibile	AT/H/0983/003	033254069	PFIZER ITALIA S.R.L.	IT
ARICEPT 5 mg comprimido rivestito con film	AT/H/0983/001	033254018	PFIZER ITALIA S.R.L.	IT
ARICEPT 5 mg comprimés pelliculés	AT/H/0983/001	BE295653	PFIZER S.A. (BELGIUM)	BE
ARICEPT 5 mg comprimés pelliculés	AT/H/0983/001	BE185814	PFIZER S.A. (BELGIUM)	BE
ARICEPT 5 mg comprimés pelliculés	AT/H/0983/001	2011041097	PFIZER S.A. (BELGIUM)	LU
ARICEPT 5 mg comprimidos revestidos por película	AT/H/0983/001	2574788	LABORATÓRIOS PFIZER, LDA.	PT
ARICEPT 5 mg comprimidos revestidos por película	AT/H/0983/001	2574580	LABORATÓRIOS PFIZER, LDA.	PT
ARICEPT 5 mg comprimidos revestidos por película	AT/H/0983/001	2574689	LABORATÓRIOS PFIZER, LDA.	PT
ARICEPT 5 mg film coated tablets	AT/H/0983/001	PA 822/2/1	PFIZER HEALTHCARE IRELAND	IE
Aricept 5 mg filmtabletten	AT/H/0983/001	12776	PFIZER OY	FI
Aricept 5 mg filmtabletten	AT/H/0983/001	13567	PFIZER AB	SE
Aricept 5 mg filmom obložene tablete	not available	HR-H-615262859	PFIZER CROATIA D.O.O.	HR
Aricept 5 mg filmom obložene tablete	not available	HR-H-615262859	PFIZER CROATIA D.O.O.	HR
Aricept 5 mg filmomhulde tabletten	AT/H/0983/001	BE295653	PFIZER S.A. (BELGIUM)	BE
Aricept 5 mg filmomhulde tabletten	AT/H/0983/001	BE185814	PFIZER S.A. (BELGIUM)	BE
ARICEPT 5 mg filmsko	not available	H/98/00209/001	PFIZER LUXEMBOURG SARL	SI

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obložene tablete				
ARICEPT 5 mg filmtabletta	not available	OGYI-T-6059/01	PFIZER KFT.	HU
ARICEPT 5 mg filmtabletta	not available	OGYI-T-6059/01	PFIZER KFT.	HU
Aricept 5 mg Filmtabletten	AT/H/0983/001	BE295653	PFIZER S.A. (BELGIUM)	BE
Aricept 5 mg Filmtabletten	AT/H/0983/001	BE185814	PFIZER S.A. (BELGIUM)	BE
Aricept 5 mg Filmtabletten	AT/H/0983/001	2011041097	PFIZER S.A. (BELGIUM)	LU
Aricept 5 mg filmuhúðaðar töflur.	not available	970076	PFIZER APS	IS
Aricept 5 mg filmuhúðaðar töflur.	not available	970076	PFIZER APS	IS
Aricept 5 mg munsönderfallande tablett	AT/H/0983/003	22917	PFIZER AB	SE
ARICEPT 5 mg potahované tablety	not available	06/121/98-C	PFIZER, SPOL. S R.O.	CZ
ARICEPT 5 mg potahované tablety	not available	06/121/98-C	PFIZER, SPOL. S R.O.	CZ
Aricept 5 mg tabletti, kalvopäällysteinen	AT/H/0983/001	12776	PFIZER OY	FI
ARICEPT 5 mg δισκίο διασπειρόμενο στο στόμα	AT/H/0983/003	81151/24-11-2011	PFIZER HELLAS, A.E.	GR
ARICEPT 5 mg επικαλυμμένα με λεπτό υμένιο δισκία	not available	17824	PFIZER HELLAS, A.E.	CY
ARICEPT 5 mg επικαλυμμένα με λεπτό υμένιο δισκία	not available	17824	PFIZER HELLAS, A.E.	CY
ARICEPT 5 mg επικαλυμμένα με λεπτό υμένιο δισκία	AT/H/0983/001	75518/20-11-2007	PFIZER HELLAS, A.E.	GR
ARICEPT 5 mg, comprimé orodispersible	AT/H/0983/003	NL 32120	LABORATOIRES EISAI S.A	FR
ARICEPT 5 mg,	AT/H/0983/001	NL 22634	LABORATOIRES EISAI S.A	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
comprimé pelliculé				
ARICEPT 5mg comprimidos recubiertos con película	not available	61.869	PFIZER, S.L.	ES
ARICEPT 5mg comprimidos recubiertos con película	not available	61.869	PFIZER, S.L.	ES
Aricept 5mg Filmtabletten Wirkstoff: Donepezilhydrochlorid	AT/H/0983/001/MR	40652.00.00	EISAI GMBH	DE
Aricept Evess 10 mg comprimate orodispersabile	not available	7572/2015/01	PFIZER EUROPE MA EEIG	RO
Aricept Evess 10 mg comprimate orodispersabile	not available	7572/2015/02	PFIZER EUROPE MA EEIG	RO
Aricept Evess 10 mg comprimate orodispersabile	not available	7572/2015/01	PFIZER EUROPE MA EEIG	RO
Aricept Evess 10 mg comprimate orodispersabile	not available	7572/2015/02	PFIZER EUROPE MA EEIG	RO
Aricept Evess 10 mg munndreiftöflur	not available	IS/1/05/058/02	PFIZER APS	IS
Aricept Evess 10 mg munndreiftöflur	not available	IS/1/05/058/02	PFIZER APS	IS
Aricept Evess 10 mg munsönderfallande tablett	AT/H/0983/004	21526	PFIZER OY	FI
ARICEPT EVESS 10 mg orodispersible tablet	AT/H/0983/004	PA 822/2/4	PFIZER HEALTHCARE IRELAND	IE
Aricept Evess 10 mg tabletti, suussa hajoava	AT/H/0983/004	21526	PFIZER OY	FI
Aricept Evess 5 mg comprimate orodispersabile	not available	7571/2015/02	PFIZER EUROPE MA EEIG	RO
Aricept Evess 5 mg comprimate	not available	7571/2015/01	PFIZER EUROPE MA EEIG	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
orodispersabile				
Aricept Evess 5 mg comprimate orodispersabile	not available	7571/2015/02	PFIZER EUROPE MA EEIG	RO
Aricept Evess 5 mg comprimate orodispersabile	not available	7571/2015/01	PFIZER EUROPE MA EEIG	RO
Aricept Evess 5 mg munndreifitöflur	not available	IS/1/05/058/01	PFIZER APS	IS
Aricept Evess 5 mg munndreifitöflur	not available	IS/1/05/058/01	PFIZER APS	IS
Aricept Evess 5 mg munsönderfallande tablett	AT/H/0983/003	21525	PFIZER OY	FI
ARICEPT EVESS 5 mg orodispersible tablet	AT/H/0983/003	PA 822/2/3	PFIZER HEALTHCARE IRELAND	IE
Aricept Evess 5 mg tabletti, suussa hajoava	AT/H/0983/003	21525	PFIZER OY	FI
Aricept Evess, smeltetabletter	AT/H/0983/004	38480	PFIZER APS	DK
Aricept Evess, smeltetabletter	AT/H/0983/003	38479	PFIZER APS	DK
ARICEPT FLAS 10 mg comprimidos bucodispersables	not available	68.214	PFIZER, S.L.	ES
ARICEPT FLAS 10 mg comprimidos bucodispersables	not available	68.214	PFIZER, S.L.	ES
ARICEPT FLAS 5 mg comprimidos bucodispersables	not available	68.213	PFIZER, S.L.	ES
ARICEPT FLAS 5 mg comprimidos bucodispersables	not available	68.213	PFIZER, S.L.	ES
Aricept, 10 mg õhukese polümeerikatttega tabletid	not available	322400	PFIZER EUROPE MA EEIG	EE
Aricept, 10 mg õhukese	not available	322400	PFIZER EUROPE MA EEIG	EE

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
polümeerikattega tabletid				
Aricept, 10 mg, comprimidos orodispersíveis	AT/H/0983/004	5716188	LABORATÓRIOS PFIZER, LDA.	PT
Aricept, 10 mg, comprimidos orodispersíveis	AT/H/0983/004	5716089	LABORATÓRIOS PFIZER, LDA.	PT
Aricept, 10 mg, comprimidos orodispersíveis	AT/H/0983/004	5716287	LABORATÓRIOS PFIZER, LDA.	PT
Aricept, 10 mg, comprimidos orodispersíveis	AT/H/0983/004	5709787	LABORATÓRIOS PFIZER, LDA.	PT
Aricept, 10 mg, tabletki powlekane	not available	7529	PFIZER EUROPE MA EEIG	PL
Aricept, 10 mg, tabletki powlekane	not available	7529	PFIZER EUROPE MA EEIG	PL
Aricept, 5 mg õhukese polümeerikattega tabletid	not available	322300	PFIZER EUROPE MA EEIG	EE
Aricept, 5 mg õhukese polümeerikattega tabletid	not available	322300	PFIZER EUROPE MA EEIG	EE
Aricept, 5 mg, comprimidos orodispersíveis	AT/H/0983/003	5709688	LABORATÓRIOS PFIZER, LDA.	PT
Aricept, 5 mg, comprimidos orodispersíveis	AT/H/0983/003	5715784	LABORATÓRIOS PFIZER, LDA.	PT
Aricept, 5 mg, comprimidos orodispersíveis	AT/H/0983/003	5715982	LABORATÓRIOS PFIZER, LDA.	PT
Aricept, 5 mg, comprimidos orodispersíveis	AT/H/0983/003	5715883	LABORATÓRIOS PFIZER, LDA.	PT
Aricept, 5 mg, tabletki powlekane	not available	7528	PFIZER EUROPE MA EEIG	PL

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
Aricept, 5 mg, tabletki powlekane	not available	7528	PFIZER EUROPE MA EEIG	PL
Aricept, tabletter, filmovertukne	AT/H/0983/001	18797	PFIZER APS	DK
Aricept, tabletter, filmovertukne	AT/H/0983/002	18798	PFIZER APS	DK
Aricept® 10 mg - Filmtabletten	AT/H/0983/002	1-22057	PFIZER CORPORATION AUSTRIA GESELLSCHAFT M.B.H.	AT
Aricept® 10 mg filmdrasjerte tabletter	not available	96-3401	PFIZER AS	NO
Aricept® 10 mg filmdrasjerte tabletter	not available	96-3401	PFIZER AS	NO
Aricept® 5 mg - Filmtabletten	AT/H/0983/001	1-22056	PFIZER CORPORATION AUSTRIA GESELLSCHAFT M.B.H.	AT
Aricept® 5 mg filmdrasjerte tabletter	not available	96-3400	PFIZER AS	NO
Aricept® 5 mg filmdrasjerte tabletter	not available	96-3400	PFIZER AS	NO
Aricept® Evess 10 mg - Schmelztabletten	AT/H/0983/004	1-26554	PFIZER CORPORATION AUSTRIA GESELLSCHAFT M.B.H.	AT
Aricept® Evess 5 mg - Schmelztabletten	AT/H/0983/003	1-26553	PFIZER CORPORATION AUSTRIA GESELLSCHAFT M.B.H.	AT
Donepezil hydrochloride 10 mg film-coated tablets	not available	PL 36687/0279	TORRENT PHARMA (UK) LTD.	XI
Donepezil hydrochloride 10mg film-coated tablets	not available	PL 20416/0486	CRESCENT PHARMA LIMITED	XI
Donepezil hydrochloride 5 mg film-coated tablets	not available	PL 36687/0278	TORRENT PHARMA (UK) LTD.	XI
Donepezil hydrochloride 5mg film-coated tablets	not available	PL 20416/485	CRESCENT PHARMA LIMITED	XI
Oromentis 2 mg/ml Πόσιμο διάλυμα	EL/H/0214/001	100816/18-10-2018	ELPEN PHARMACEUTICAL CO. INC.	GR
Pezimax 1 mg/ml	ES/H/0759/001	84746	NEURAXPHARM SPAIN,	ES

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solución oral			S.L.U.	
Pezimax 2 mg/ml solución oral	ES/H/0759/002	84747	NEURAXPHARM SPAIN, S.L.U.	ES
Solidra 2 mg/ml soluzione orale	ES/H/0759/002	047043017	NEURAXPHARM ITALY SPA	IT
АРИСЕПТ 10 mg филмирани таблетки	not available	9800178	PFIZER EUROPE MA EEIG	BG
АРИСЕПТ 10 mg филмирани таблетки	not available	9800178	PFIZER EUROPE MA EEIG	BG
АРИСЕПТ 5 mg филмирани таблетки	not available	9800177	PFIZER EUROPE MA EEIG	BG
АРИСЕПТ 5 mg филмирани таблетки	not available	9800177	PFIZER EUROPE MA EEIG	BG