



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

11 January 2018  
EMA/24886/2018  
Human Medicines Evaluation Division

## List of nationally authorised medicinal products

Active substance: piracetam

Procedure no.: PSUSA/00002429/201704

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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>
Nootropil, 800 mg õhukese polümeerikattega tabletid	not available	161797	UCB PHARMA OY FINLAND (ESPOO FI)	EE
NOOTROPYL 1200 mg, solution buvable en ampoule	not available	34009 330 837 1 7	UCB PHARMA S.A. (COLOMBES FR)	FR
NOOTROPYL 800 mg, comprimé pelliculé	not available	34009 326 861 9 3	UCB PHARMA S.A. (COLOMBES FR)	FR
NOOTROPYL 800 mg, comprimé pelliculé	not available	34009 326 637 1 2	UCB PHARMA S.A. (COLOMBES FR)	FR
GABACET, solution buvable en ampoule	not available	322 018.5	SANOFI-AVENTIS FRANCE	FR
GABACET, solution buvable en ampoule	not available	322 019.1	SANOFI-AVENTIS FRANCE	FR
NOOTROPYL 20 %, solution buvable	not available	34009 320 955 1 3	UCB PHARMA S.A. (COLOMBES FR)	FR
NOOTROPYL 3 g/15 ml, solution injectable en ampoule	not available	34009 346 479 2 5	UCB PHARMA S.A. (COLOMBES FR)	FR
NOOTROPYL 3 g/15 ml, solution injectable en ampoule	not available	34009 551 952 8 3	UCB PHARMA S.A. (COLOMBES FR)	FR
NOOTROPYL 1200 mg, solution buvable en ampoule	not available	34009 330 838 8 5	UCB PHARMA S.A. (COLOMBES FR)	FR

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NOOTROPYL 1200 mg, solution buvable en ampoule	not available	34009 331 441 4 2	UCB PHARMA S.A. (COLOMBES FR)	FR
NOOTROPYL 1200 mg, solution buvable en ampoule	not available	34009 335 267 9 5	UCB PHARMA S.A. (COLOMBES FR)	FR
NOOTROPYL 1200 mg, solution buvable en ampoule	not available	34009 330 837 1 7	UCB PHARMA S.A. (COLOMBES FR)	FR
NOOTROPYL 800 mg, comprimé pelliculé	not available	34009 326 861 9 3	UCB PHARMA S.A. (COLOMBES FR)	FR
NOOTROPYL 800 mg, comprimé pelliculé	not available	34009 326 637 1 2	UCB PHARMA S.A. (COLOMBES FR)	FR
GABACET, solution buvable en ampoule	not available	322 018.5	SANOFI-AVENTIS FRANCE	FR
GABACET, solution buvable en ampoule	not available	322 019.1	SANOFI-AVENTIS FRANCE	FR
NOOTROPYL 20 %, solution buvable	not available	34009 320 955 1 3	UCB PHARMA S.A. (COLOMBES FR)	FR
NOOTROPYL 3 g/15 ml, solution injectable en ampoule	not available	34009 346 479 2 5	UCB PHARMA S.A. (COLOMBES FR)	FR

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NOOTROPYL 3 g/15 ml, solution injectable en ampoule	not available	34009 551 952 8 3	UCB PHARMA S.A. (COLOMBES FR)	FR
NOOTROPYL 1200 mg, solution buvable en ampoule	not available	34009 330 838 8 5	UCB PHARMA S.A. (COLOMBES FR)	FR
NOOTROPYL 1200 mg, solution buvable en ampoule	not available	34009 331 441 4 2	UCB PHARMA S.A. (COLOMBES FR)	FR
NOOTROPYL 1200 mg, solution buvable en ampoule	not available	34009 335 267 9 5	UCB PHARMA S.A. (COLOMBES FR)	FR
NOOTROPIL 800 mg comprimé filmaté	not available	3562/2011/01	UCB PHARMA S.A. (ANDERL BE)	RO
NOOTROPIL 800 mg comprimé filmaté	not available	3562/2011/02	UCB PHARMA S.A. (ANDERL BE)	RO
NOOTROPIL 800 mg comprimé filmaté	not available	3562/2011/03	UCB PHARMA S.A. (ANDERL BE)	RO
NOOTROPIL 1200 mg comprimé filmaté	not available	3563/2011/01	UCB PHARMA S.A. (ANDERL BE)	RO
NOOTROPIL 1200 mg comprimé filmaté	not available	3563/2011/02	UCB PHARMA S.A. (ANDERL BE)	RO

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NOOTROPIL 1200 mg comprimata filmate	not available	3563/2011/03	UCB PHARMA S.A. (ANDERL BE)	RO
NOOTROPIL 1200 mg comprimata filmate	not available	3563/2011/05	UCB PHARMA S.A. (ANDERL BE)	RO
NOOTROPIL 1200 mg comprimata filmate	not available	3563/2011/04	UCB PHARMA S.A. (ANDERL BE)	RO
Piracetam-ELBE-MED® 1 g/5 ml Lösung zur Infusion und Injektion	not available	8481.00.00	HOFMANN & SOMMER GMBH U. CO. KG, CHEMISCH-PHARMAZEUTISCHE FABRIK	DE
Piracetam-ELBE-MED® 1200 mg Tabletten	not available	14819.00.00	HOFMANN & SOMMER GMBH U. CO. KG, CHEMISCH-PHARMAZEUTISCHE FABRIK	DE
Piracetam-ELBE-MED® 800 mg Tabletten	not available	6437.00.01	HOFMANN & SOMMER GMBH U. CO. KG, CHEMISCH-PHARMAZEUTISCHE FABRIK	DE
Piracetam-ELBE-MED® 333,3 mg/ml Lösung zum Einnehmen	not available	6437.00.00	HOFMANN & SOMMER GMBH U. CO. KG, CHEMISCH-PHARMAZEUTISCHE FABRIK	DE
CICLOFALINA® 800 Comprimidos	not available	53.130	KERN PHARMA, S.L.	ES
Nootropil 1 g/5 ml oplossing voor injectie	not available	BE047503	UCB PHARMA S.A. (ANDERL BE)	BE

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Nootropil 3 g/15 ml oplossing voor injectie	not available	BE097282	UCB PHARMA S.A. (ANDERL BE)	BE
Nootropil 800 mg filmomhulde tabletten	not available	BE097291	UCB PHARMA S.A. (ANDERL BE)	BE
Nootropil 12 g/60 ml oplossing voor infusie	not available	BE141583	UCB PHARMA S.A. (ANDERL BE)	BE
Nootropil 1200 mg filmomhulde tabletten	not available	BE141592	UCB PHARMA S.A. (ANDERL BE)	BE
Nootropil 20 % drank	not available	BE242392	UCB PHARMA S.A. (ANDERL BE)	BE
Nootropil 33 % drank	not available	BE249925	UCB PHARMA S.A. (ANDERL BE)	BE
Nootropil 1200 mg comprimés pelliculés	not available	BE141592	UCB PHARMA S.A. (ANDERL BE)	BE
Nootropil 1 g/5 ml solution injectable	not available	BE047503	UCB PHARMA S.A. (ANDERL BE)	BE
Nootropil 3 g/15 ml solution injectable	not available	BE097282	UCB PHARMA S.A. (ANDERL BE)	BE

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Nootropil 800 mg comprimés pelliculés	not available	BE097291	UCB PHARMA S.A. (ANDERL BE)	BE
Nootropil 12 g/60 ml solution pour perfusion	not available	BE141583	UCB PHARMA S.A. (ANDERL BE)	BE
Nootropil 20 % solution buvable	not available	BE242392	UCB PHARMA S.A. (ANDERL BE)	BE
Nootropil 33 % solution buvable	not available	BE249925	UCB PHARMA S.A. (ANDERL BE)	BE
Nootropil 1 g/5 ml Injektionslösung	not available	BE047503	UCB PHARMA S.A. (ANDERL BE)	BE
Nootropil 3 g/15 ml Injektionslösung	not available	BE097282	UCB PHARMA S.A. (ANDERL BE)	BE
Nootropil 800 mg Filmtabletten	not available	BE097291	UCB PHARMA S.A. (ANDERL BE)	BE
Nootropil 12 g/60 ml Infusionslösung	not available	BE141583	UCB PHARMA S.A. (ANDERL BE)	BE
Nootropil 1200 mg Filmtabletten	not available	BE141592	UCB PHARMA S.A. (ANDERL BE)	BE

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Nootropil 20% Lösung zum Einnehmen	not available	BE242392	UCB PHARMA S.A. (ANDERL BE)	BE
Nootropil 33% Lösung zum Einnehmen	not available	BE249925	UCB PHARMA S.A. (ANDERL BE)	BE
Nootropil 33%, 333 mg/ml, roztwór doustny	not available	R/1842	UCB PHARMA S.A. (ANDERL BE)	PL
Nootropil, 800 mg, tabletki powlekane	not available	R/1838	UCB PHARMA S.A. (ANDERL BE)	PL
Nootropil, 1200 mg, tabletki powlekane	not available	R/1839	UCB PHARMA S.A. (ANDERL BE)	PL
Nootropil 20%, 200 mg/ml, roztwór doustny	not available	R/1843	UCB PHARMA S.A. (ANDERL BE)	PL
Piracetam-ELBE-MED® 1 g/5 ml Lösung zur Infusion und Injektion	not available	8481.00.00	HOFMANN & SOMMER GMBH U. CO. KG, CHEMISCH-PHARMAZEUTISCHE FABRIK	DE
Piracetam-ELBE-MED® 1200 mg Tabletten	not available	14819.00.00	HOFMANN & SOMMER GMBH U. CO. KG, CHEMISCH-PHARMAZEUTISCHE FABRIK	DE
Piracetam-ELBE-MED® 800 mg Tabletten	not available	6437.00.01	HOFMANN & SOMMER GMBH U. CO. KG, CHEMISCH-PHARMAZEUTISCHE FABRIK	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
Piracetam-ELBE-MED® 333,3 mg/ml Lösung zum Einnehmen	not available	6437.00.00	HOFMANN & SOMMER GMBH U. CO. KG, CHEMISCH- PHARMAZEUTISCHE FABRIK	DE
Nootropil 1200 mg apvalkotās tabletes	not available	99-0317	UCB PHARMA OY (ESPOO FI)	LV
Nootropil 800 mg apvalkotās tabletes	not available	99-0318	UCB PHARMA OY (ESPOO FI)	LV
GERATAM 1200 mg, potahované tablety	not available	06/868/92-B/C	UCB PHARMA S.A. (ANDERL BE)	CZ
GERATAM 800 mg, potahované tablety	not available	06/868/92-A/C	UCB PHARMA S.A. (ANDERL BE)	CZ
GERATAM 3 g, injekční roztok	not available	06/866/92-B/C	UCB PHARMA S.A. (ANDERL BE)	CZ
NOOTROPIL 20% oral solution, perorální roztok	not available	06/867/92-A/C	UCB PHARMA S.A. (ANDERL BE)	CZ
Nootropil 12 g/60 ml soluzione per infusione.	not available	022921074	UCB PHARMA SPA (MILAN IT)	IT
Nootropil 3 g/15 ml soluzione orale e iniettabile per uso endovenoso	not available	022921086	UCB PHARMA SPA (MILAN IT)	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
Nootropil 1200 mg comprese rivestite con film	not available	022921098	UCB PHARMA SPA (MILAN IT)	IT
ΝΟΟΤΡΟΠ®	not available	42558/10/31-05-2011	UCB A.E. (ATHENS GR)	GR
ΝΟΟΤΡΟΠ®	not available	42560/10/31-05-2011	UCB A.E. (ATHENS GR)	GR
ΝΟΟΤΡΟΠ®	not available	42561/10/31-05-2011	UCB A.E. (ATHENS GR)	GR
ΝΟΟΤΡΟΠ®	not available	42563/10/31-05-2011	UCB A.E. (ATHENS GR)	GR
ΝΟΟΤΡΟΠ®	not available	42567/10/31-05-2011	UCB A.E. (ATHENS GR)	GR
Nootropil 1200 mg plėvele dengtos tabletės	not available	LT/1/97/2411/004	UCB PHARMA OY (ESPOO FI)	LT
Nootropil 800 mg plevele dengtos tabletes	not available	LT/1/97/2411/003	UCB PHARMA OY (ESPOO FI)	LT
Nootropil 800, 800 mg filmomhulde tabletten	not available	RVG 07353	UCB PHARMA B.V. (BREDA NL)	NL

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Nootropil 1200, 1200 mg filmomhulde tabletten	not available	RVG 11783	UCB PHARMA B.V. (BREDA NL)	NL
Nootropil 33% Oral Solution	not available	PL 00039/0534	UCB PHARMA LTD (SLOUGH GB)	UK
Nootropil 800 mg film-coated tablets	not available	PL 00039/0535	UCB PHARMA LTD (SLOUGH GB)	UK
Nootropil 1200 mg film-coated tablets	not available	PL 00039/0536	UCB PHARMA LTD (SLOUGH GB)	UK
Nootropil 1200 mg filmdragerad tablett	FI/H/0103/001	13370	UCB NORDIC A/S (COPENHAGEN DK)	SE
Nootropil 1200 mg kalvopäällysteiset tabletit	FI/H/0103/001	12411	UCB PHARMA OY FINLAND (ESPOO FI)	FI
Piracetam-ELBE-MED® 1 g/5 ml Lösung zur Infusion und Injektion	not available	8481.00.00	HOFMANN & SOMMER GMBH U. CO. KG, CHEMISCH-PHARMAZEUTISCHE FABRIK	DE
Piracetam-ELBE-MED® 1200 mg Tabletten	not available	14819.00.00	HOFMANN & SOMMER GMBH U. CO. KG, CHEMISCH-PHARMAZEUTISCHE FABRIK	DE
Piracetam-ELBE-MED® 800 mg Tabletten	not available	6437.00.01	HOFMANN & SOMMER GMBH U. CO. KG, CHEMISCH-PHARMAZEUTISCHE FABRIK	DE

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Piracetam-ELBE-MED® 333,3 mg/ml Lösung zum Einnehmen	not available	6437.00.00	HOFMANN & SOMMER GMBH U. CO. KG, CHEMISCH- PHARMAZEUTISCHE FABRIK	DE
Piracetam-ELBE-MED® 1200 mg Tabletten	not available	14819.00.00	HOFMANN & SOMMER GMBH U. CO. KG, CHEMISCH- PHARMAZEUTISCHE FABRIK	DE
Nootrop 1200 mg Filmtabletten	not available	31546.00.00	UCB PHARMA GMBH (MONHEIM DE)	DE
Nootrop 800 800 mg Filmtabletten	not available	6084043.00.00	UCB PHARMA GMBH (MONHEIM DE)	DE
Nootrop to Nootrop 12 g/60 ml Infusionslösung	not available	6449819.00.00	UCB PHARMA GMBH (MONHEIM DE)	DE
Nootrop 3 g Injektionslösung	not available	6084014.00.00	UCB PHARMA GMBH (MONHEIM DE)	DE
Nootropil (piracetam) 800 mg film-coated tablets	not available	MA030/00503	UCB PHARMA S.A. (ANDERL BE)	MT
Nootropil 1200 mg tabletter, filmdrasjerte	not available	96-2709	UCB NORDIC A/S (COPENHAGEN DK)	NO
Nootropil 1200 mg filmsko obložene tablete	not available	5363-I-1095/14	UCB PHARMA S.A. (ANDERL BE)	SI

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Nootropil 1200 mg filmsko obložene tablete	not available	5363-I-1096/14	UCB PHARMA S.A. (ANDERL BE)	SI
Nootropil 1200 mg filmsko obložene tablete	not available	5363-I-1097/14	UCB PHARMA S.A. (ANDERL BE)	SI
Nootropil (piracetam) 200 mg/ml oral solution	not available	7087	UCB PHARMA S.A. (ANDERL BE)	CY
Nootropil (piracetam) 1 g/5 ml solution for injection	not available	4139	UCB PHARMA S.A. (ANDERL BE)	CY
Nootropil (piracetam) 3 g/15 ml solution for injection	not available	13874	UCB PHARMA S.A. (ANDERL BE)	CY
NOOTROPIL (piracetam) 1200 mg film-coated tablet	not available	17692	UCB PHARMA S.A. (ANDERL BE)	CY
NOOTROPIL (piracetam) 800 mg film-coated tablet	not available	7086	UCB PHARMA S.A. (ANDERL BE)	CY
OXYNIUM® Κοκκία μιας δόσης για πόσιμο υγρό 1250 mg/sachet	not available	13061	UNI-PHARMA KLEON TSETIS PHARMACEUTICAL LABORATORIES S.A.	GR
CICLOFALINA® 800 Sobres	not available	53.167	KERN PHARMA, S.L.	ES

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CICLOFALINA® 800 Comprimidos	not available	53.130	KERN PHARMA, S.L.	ES
CICLOFALINA® 800 Sobres	not available	53.167	KERN PHARMA, S.L.	ES
Nootropil 200 mg/ml solución oral	not available	54.713	UCB PHARMA S.A. (MADRID ES)	ES
Nootropil 200 mg/ml solución inyectable	not available	55.917	UCB PHARMA S.A. (MADRID ES)	ES
NOOTROPIL 1200 mg filmom obalené tablety	not available	06/0868/92 - S	UCB PHARMA S.R.O. (PRAGUE CZ)	SK
NOOSTAN 12 g/60 ml solução para perfusão	not available	8359554	UCB PHARMA (PRODUTOS FARMACÊUTICOS), LDA. (PACO PT)	PT
NOOSTAN 1200 mg comprimidos revestidos por película	not available	4337184	UCB PHARMA (PRODUTOS FARMACÊUTICOS), LDA. (PACO PT)	PT
NOOSTAN 1200 mg comprimidos revestidos por película	not available	8421636	UCB PHARMA (PRODUTOS FARMACÊUTICOS), LDA. (PACO PT)	PT
NOOSTAN 1200 mg comprimidos revestidos por película	not available	8421644	UCB PHARMA (PRODUTOS FARMACÊUTICOS), LDA. (PACO PT)	PT

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Ноотропил 2400 mg гранули за перорален разтвор	not available	20060072	UCB PHARMA S.A. (ANDERL BE)	BG
Ноотропил 12 g/60 ml инфузионен разтвор	not available	20000130	UCB PHARMA S.A. (ANDERL BE)	BG
Ноотропил 3 g/15 ml инжекционен разтвор	not available	20060071	UCB PHARMA S.A. (ANDERL BE)	BG
Ноотропил 1200 mg филмирани таблетки	not available	20000128	UCB PHARMA S.A. (ANDERL BE)	BG
Ноотропил 800 mg филмирани таблетки	not available	20000132	UCB PHARMA S.A. (ANDERL BE)	BG