14 April 2023
EMA/175273/2023
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: fluoxetine

Procedure no.: PSUSA/00001442/202209

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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
ADOFEN 20 mg cápsulas duras	not available	58049	FERRER INTERNACIONAL, S.A.	ES
ADOFEN 20 mg comprimidos dispersables	not available	61419	FERRER INTERNACIONAL, S.A.	ES
DIGASSIM 20 mg cápsulas	not available	4539490	LABORATÓRIOS VITÓRIA, SA	PT
DIGASSIM 20 mg cápsulas	not available	2219590	LABORATÓRIOS VITÓRIA, SA	PT
DIGASSIM 20 mg cápsulas	not available	2051191	LABORATÓRIOS VITÓRIA, SA	PT
Fluctine 20 mg - Kapseln	FR/H/0242/002	1-18570	ELI LILLY GES. M.B.H	AT
FLUOXEREN 20 mg capsule rigide.	not available	025959014	A. MENARINI - INDUSTRIE FARMACEUTICHE RIUNITE - S.R.L.	IT
FLUOXEREN 20 mg capsule rigide.	not available	025959040	A. MENARINI - INDUSTRIE FARMACEUTICHE RIUNITE - S.R.L.	IT
FLUOXEREN 20 mg compresse dispersibili.	not available	025959038	A. MENARINI - INDUSTRIE FARMACEUTICHE RIUNITE - S.R.L.	IT
FLUOXEREN 20 mg compresse dispersibili.	not available	025959053	A. MENARINI - INDUSTRIE FARMACEUTICHE RIUNITE - S.R.L.	IT
FLUOXEREN 20 mg/5 ml soluzione orale.	not available	025959026	A. MENARINI - INDUSTRIE FARMACEUTICHE RIUNITE - S.R.L.	IT
Fluoxetin Amdipharm 60 mg, Hartkapseln	NL/H/3535/005	2017070224	AMDIPHARM LIMITED	LU
Fluoxetin HEXAL, dispergible tabletter	SE/H/0525/002	38720	HEXAL A/S	DK
Fluoxetine 10 mg Film-coated Tablets	not available	PL 43808/0010	ENDO VENTURES LIMITED	XI
Fluoxetine 10mg hard capsules	not available	PL 20117/0152	MORNINGSIDE HEALTHCARE LTD	XI
Fluoxetine 20 mg Capsules	not available	PL 17907/0374	BRISTOL LABORATORIES LIMITED	XI
Fluoxétine Amdipharm 60 mg gélules	NL/H/3535/005	34009 300 811 8 1	AMDIPHARM LIMITED	FR

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Fluoxétine Amdipharm 60 mg gélules	NL/H/3535/005	34009 300 811 9 8	AMDIPHARM LIMITED	FR
Fluoxétine Amdipharm 60 mg gélules	NL/H/3535/005	34009 300 811 7 4	AMDIPHARM LIMITED	FR
Fluoxétine Amdipharm 60 mg gélules	NL/H/3535/005	2017070224	AMDIPHARM LIMITED	LU
Fluoxetine Amdipharm 60 mg, harde capsules	NL/H/3535/001	RVG 118221	AMDIPHARM LIMITED	NL
FLUOXETINE MICROLABS 10 mg, gélule	DE/H/7071/001	34009 302 516 2 1	MICRO LABS GMBH	FR
FLUOXETINE MICROLABS 10 mg, gélule	DE/H/7071/001	34009 302 516 3 8	MICRO LABS GMBH	FR
FLUOXETINE MICROLABS 10 mg, gélule	DE/H/7071/001	34009 302 516 4 5	MICRO LABS GMBH	FR
FLUOXETINE MICROLABS 10 mg, gélule	DE/H/7071/001	34009 302 516 5 2	MICRO LABS GMBH	FR
FLUOXETINE MICROLABS 10 mg, gélule	DE/H/7071/001	34009 302 516 6 9	MICRO LABS GMBH	FR
FLUOXETINE MICROLABS 10 mg, gélule	DE/H/7071/001	34009 302 516 7 6	MICRO LABS GMBH	FR
FLUOXETINE MICROLABS 10 mg, gélule	DE/H/7071/001	34009 302 516 8 3	MICRO LABS GMBH	FR
FLUOXETINE MICROLABS 10 mg, gélule	DE/H/7071/001	34009 302 516 9 0	MICRO LABS GMBH	FR
FLUOXETINE MICROLABS 10 mg, gélule	DE/H/7071/001	34009 302 517 0 6	MICRO LABS GMBH	FR
FLUOXETINE MICROLABS 10 mg, gélule	DE/H/7071/001	34009 302 517 1 3	MICRO LABS GMBH	FR
FLUOXETINE MICROLABS 10 mg, gélule	DE/H/7071/001	34009 302 517 2 0	MICRO LABS GMBH	FR
FLUOXETINE MICROLABS 10 mg, gélule	DE/H/7071/001	34009 302 517 3 7	MICRO LABS GMBH	FR
FLUOXETINE MICROLABS 10 mg, gélule	DE/H/7071/001	34009 302 517 4 4	MICRO LABS GMBH	FR
FLUOXETINE MICROLABS	DE/H/7071/001	34009 302 517 5 1	MICRO LABS GMBH	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
10 mg, gélule				
FLUOXETINE MICROLABS 10 mg, gélule	DE/H/7071/001	34009 302 517 7 5	MICRO LABS GMBH	FR
FLUOXETINE MICROLABS 10 mg, gélule	DE/H/7071/001	34009 302 517 8 2	MICRO LABS GMBH	FR
FLUOXETINE MICROLABS 10 mg, gélule	DE/H/7071/001	34009 302 517 9 9	MICRO LABS GMBH	FR
FLUOXETINE MICROLABS 30 mg, gélule	DE/H/7071/003	34009 302 520 1 7	MICRO LABS GMBH	FR
FLUOXETINE MICROLABS 30 mg, gélule	DE/H/7071/003	34009 302 520 2 4	MICRO LABS GMBH	FR
FLUOXETINE MICROLABS 30 mg, gélule	DE/H/7071/003	34009 302 520 4 8	MICRO LABS GMBH	FR
FLUOXETINE MICROLABS 30 mg, gélule	DE/H/7071/003	34009 302 520 5 5	MICRO LABS GMBH	FR
FLUOXETINE MICROLABS 30 mg, gélule	DE/H/7071/003	34009 302 520 8 6	MICRO LABS GMBH	FR
FLUOXETINE MICROLABS 30 mg, gélule	DE/H/7071/003	34009 302 520 9 3	MICRO LABS GMBH	FR
FLUOXETINE MICROLABS 30 mg, gélule	DE/H/7071/003	34009 302 521 0 9	MICRO LABS GMBH	FR
FLUOXETINE MICROLABS 30 mg, gélule	DE/H/7071/003	34009 302 521 1 6	MICRO LABS GMBH	FR
FLUOXETINE MICROLABS 30 mg, gélule	DE/H/7071/003	34009 302 521 2 3	MICRO LABS GMBH	FR
FLUOXETINE MICROLABS 30 mg, gélule	DE/H/7071/003	34009 302 521 4 7	MICRO LABS GMBH	FR
FLUOXETINE MICROLABS 30 mg, gélule	DE/H/7071/003	34009 302 521 5 4	MICRO LABS GMBH	FR
FLUOXETINE MICROLABS 30 mg, gélule	DE/H/7071/003	34009 302 521 6 1	MICRO LABS GMBH	FR
FLUOXETINE MICROLABS 30 mg, gélule	DE/H/7071/003	34009 302 521 7 8	MICRO LABS GMBH	FR
FLUOXETINE MICROLABS 30 mg, gélule	DE/H/7071/003	34009 302 521 8 5	MICRO LABS GMBH	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
FLUOXETINE MICROLABS 30 mg, gélule	DE/H/7071/003	34009 550 892 2 3	MICRO LABS GMBH	FR
FLUOXETINE MICROLABS 30 mg, gélule	DE/H/7071/003	34009 550 892 3 0	MICRO LABS GMBH	FR
FLUOXETINE MICROLABS 30 mg, gélule	DE/H/7071/003	34009 550 892 4 7	MICRO LABS GMBH	FR
FLUOXETINE MICROLABS 40 mg, gélule	DE/H/7071/004	34009 302 521 9 2	MICRO LABS GMBH	FR
FLUOXETINE MICROLABS 40 mg, gélule	DE/H/7071/004	34009 302 522 0 8	MICRO LABS GMBH	FR
FLUOXETINE MICROLABS 40 mg, gélule	DE/H/7071/004	34009 302 522 1 5	MICRO LABS GMBH	FR
FLUOXETINE MICROLABS 40 mg, gélule	DE/H/7071/004	34009 302 522 2 2	MICRO LABS GMBH	FR
FLUOXETINE MICROLABS 40 mg, gélule	DE/H/7071/004	34009 302 522 3 9	MICRO LABS GMBH	FR
FLUOXETINE MICROLABS 40 mg, gélule	DE/H/7071/004	34009 302 522 4 6	MICRO LABS GMBH	FR
FLUOXETINE MICROLABS 40 mg, gélule	DE/H/7071/004	34009 302 522 5 3	MICRO LABS GMBH	FR
FLUOXETINE MICROLABS 40 mg, gélule	DE/H/7071/004	34009 302 522 6 0	MICRO LABS GMBH	FR
FLUOXETINE MICROLABS 40 mg, gélule	DE/H/7071/004	34009 302 522 7 7	MICRO LABS GMBH	FR
FLUOXETINE MICROLABS 40 mg, gélule	DE/H/7071/004	34009 550 892 5 4	MICRO LABS GMBH	FR
FLUOXETINE MICROLABS 40 mg, gélule	DE/H/7071/004	34009 550 892 6 1	MICRO LABS GMBH	FR
FLUOXETINE MICROLABS 40 mg, gélule	DE/H/7071/004	34009 550 892 7 8	MICRO LABS GMBH	FR
FLUOXETINE MICROLABS 40 mg, gélule	DE/H/7071/004	34009 550 892 8 5	MICRO LABS GMBH	FR
FLUOXETINE MICROLABS 40 mg, gélule	DE/H/7071/004	34009 550 892 9 2	MICRO LABS GMBH	FR
FLUOXETINE MICROLABS	DE/H/7071/004	34009 550 893 0 8	MICRO LABS GMBH	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
40 mg, gélule				
FLUOXETINE MICROLABS 40 mg, gélule	DE/H/7071/004	34009 550 893 1 5	MICRO LABS GMBH	FR
FLUOXETINE MICROLABS 40 mg, gélule	DE/H/7071/004	34009 550 893 2 2	MICRO LABS GMBH	FR
FLUOXETINE MICROLABS 60 mg, gélule	DE/H/7071/005	34009 302 522 8 4	MICRO LABS GMBH	FR
FLUOXETINE MICROLABS 60 mg, gélule	DE/H/7071/005	34009 302 522 9 1	MICRO LABS GMBH	FR
FLUOXETINE MICROLABS 60 mg, gélule	DE/H/7071/005	34009 302 523 0 7	MICRO LABS GMBH	FR
FLUOXETINE MICROLABS 60 mg, gélule	DE/H/7071/005	34009 302 523 1 4	MICRO LABS GMBH	FR
FLUOXETINE MICROLABS 60 mg, gélule	DE/H/7071/005	34009 302 523 2 1	MICRO LABS GMBH	FR
FLUOXETINE MICROLABS 60 mg, gélule	DE/H/7071/005	34009 302 523 3 8	MICRO LABS GMBH	FR
FLUOXETINE MICROLABS 60 mg, gélule	DE/H/7071/005	34009 302 523 4 5	MICRO LABS GMBH	FR
FLUOXETINE MICROLABS 60 mg, gélule	DE/H/7071/005	34009 302 523 5 2	MICRO LABS GMBH	FR
FLUOXETINE MICROLABS 60 mg, gélule	DE/H/7071/005	34009 302 523 7 6	MICRO LABS GMBH	FR
FLUOXETINE MICROLABS 60 mg, gélule	DE/H/7071/005	34009 550 893 3 9	MICRO LABS GMBH	FR
FLUOXETINE MICROLABS 60 mg, gélule	DE/H/7071/005	34009 550 893 4 6	MICRO LABS GMBH	FR
FLUOXETINE MICROLABS 60 mg, gélule	DE/H/7071/005	34009 550 893 5 3	MICRO LABS GMBH	FR
FLUOXETINE MICROLABS 60 mg, gélule	DE/H/7071/005	34009 550 893 6 0	MICRO LABS GMBH	FR
FLUOXETINE MICROLABS 60 mg, gélule	DE/H/7071/005	34009 550 893 7 7	MICRO LABS GMBH	FR
FLUOXETINE MICROLABS 60 mg, gélule	DE/H/7071/005	34009 550 893 9 1	MICRO LABS GMBH	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
FLUOXETINE MICROLABS 60 mg, gélule	DE/H/7071/005	34009 550 894 0 7	MICRO LABS GMBH	FR
FLUOXETINE MICROLABS 60 mg, gélule	DE/H/7071/005	34009 550 894 1 4	MICRO LABS GMBH	FR
Fluoxetin-neuraxpharm 10 mg (Tabletten)	not available	62145.00.00	NEURAXPHARM ARZNEIMITTEL GMBH	DE
Fluoxetin-neuraxpharm 40 mg Filmtabletten	not available	61327.00.00	NEURAXPHARM ARZNEIMITTEL GMBH	DE
Fontex 20 mg dispergerbar tablett	FR/H/0242/001	95-3722	ELI LILLY NORGE A.S.	NO
Fontex 20 mg dispergerbar tablett	FR/H/0242/001	12892	ELI LILLY SWEDEN AB	SE
Fontex 20 mg dreifitafla.	FR/H/0242/001	960037	ELI LILLY DANMARK A/S	IS
Fontex 20 mg gélules	FR/H/0242/002	BE201442	S.A. ELI LILLY BENELUX N.V.	BE
Fontex 20 mg gélules	FR/H/0242/002	2009060416	S.A. ELI LILLY BENELUX N.V.	LU
Fontex 20 mg harde capsules	FR/H/0242/002	BE201442	S.A. ELI LILLY BENELUX N.V.	BE
FONTEX 20 mg Hartkapseln	FR/H/0242/002	BE201442	S.A. ELI LILLY BENELUX N.V.	BE
Fontex 4 mg/ml oral lösning	FR/H/0242/003	12136	ELI LILLY SWEDEN AB	SE
Fontex, dispergible tabletter	FR/H/0242/001	17965	ELI LILLY DANMARK A/S	DK
Ladose 20 mg διασπειρόμενα δισκία	FR/H/0242/001	49665/02-09-2015	PHARMASERVE-LILLY SACI	GR
Ladose 20 mg σκληρά καψάκια	FR/H/0242/002	49663/02-09-2015	PHARMASERVE-LILLY SACI	GR
Ladose 20 mg/ 5 ml πόσιμο διάλυμα	FR/H/0242/003	49664/02-09-2015	PHARMASERVE-LILLY SACI	GR
Mutan 60 mg-Filmtabletten	not available	1-30873	G.L. PHARMA GMBH	AT
Prozac 20 mg cápsulas	FR/H/0242/002	8716811	LILLY PORTUGAL - PRODUTOS FARMACÊUTICOS, LDA	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
Prozac 20 mg cápsulas	FR/H/0242/002	4581088	LILLY PORTUGAL - PRODUTOS FARMACÊUTICOS, LDA	PT
PROZAC 20 mg cápsulas duras.	FR/H/0242/002	57.954	LILLY, S.A. (SPAIN)	ES
PROZAC 20 mg capsule rigide	FR/H/0242/002	025970043	ELI LILLY ITALIA S.P.A.	IT
Prozac 20 mg compresse dispersibili.	FR/H/0242/001	025970056	ELI LILLY ITALIA S.P.A.	IT
Prozac 20 mg comprimate dispersabile	not available	11794/2019/01	LILLY, S.A. (SPAIN)	RO
Prozac 20 mg comprimate dispersabile	not available	11794/2019/02	LILLY, S.A. (SPAIN)	RO
Prozac 20 mg comprimés dispersibles	FR/H/0242/001	BE198186	S.A. ELI LILLY BENELUX N.V.	BE
Prozac 20 mg comprimés dispersibles	FR/H/0242/001	2009060414	S.A. ELI LILLY BENELUX N.V.	LU
Prozac 20 mg dispergeerbare tabletten	FR/H/0242/001	BE198186	S.A. ELI LILLY BENELUX N.V.	BE
Prozac 20 mg dispergeerbare tabletten	FR/H/0242/001	RVG 19429	ELI LILLY NEDERLAND B.V.	NL
Prozac 20 mg gélules	FR/H/0242/002	BE135362	S.A. ELI LILLY BENELUX N.V.	BE
Prozac 20 mg gélules	FR/H/0242/002	2009060415	S.A. ELI LILLY BENELUX N.V.	LU
Prozac 20 mg harde capsules	FR/H/0242/002	BE135362	S.A. ELI LILLY BENELUX N.V.	BE
Prozac 20 mg Hartkapseln	FR/H/0242/002	BE135362	S.A. ELI LILLY BENELUX N.V.	BE
Prozac 20 mg per 5 mL oral solution	FR/H/0242/002	PA 2276/004/001	ELI LILLY NEDERLAND B.V.	IE
PROZAC 20 mg Tabletten zur Herstellung einer Suspension zum Einnehmen	FR/H/0242/001	BE198186	S.A. ELI LILLY BENELUX N.V.	BE
PROZAC 20 mg, comprimé dispersible sécable	FR/H/0242/001	34009 345 052 5 6	LILLY FRANCE	FR
PROZAC 20 mg, comprimé	FR/H/0242/001	34009 563 114 2 2	LILLY 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
dispersible sécable				
PROZAC 20 mg, comprimé dispersible sécable	FR/H/0242/001	34009 345 053 1 7	LILLY FRANCE	FR
PROZAC 20 mg, gélule	FR/H/0242/002	34009 331 008 9 6	LILLY FRANCE	FR
PROZAC 20 mg, gélule	FR/H/0242/002	34009 556 284 3 9	LILLY FRANCE	FR
PROZAC 20 mg, gélule	FR/H/0242/002	34009 331 009 5 7	LILLY FRANCE	FR
Prozac 20 mg/5ml solução oral	FR/H/0242/003	2685188	LILLY PORTUGAL - PRODUTOS FARMACÊUTICOS, LDA	PT