



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

16 March 2023  
EMA/105810/2023  
Human Medicines Evaluation Division

## List of nationally authorised medicinal products

Active substance: fluvoxamine

Procedure no.: PSUSA/00001458/202207

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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>
DUMIROX 100 mg compresse rivestite con film	not available	026104048	MYLAN ITALIA S.R.L.	IT
Dumirox 100 mg comprimidos recubiertos con película	DE/H/5314/002	58.212	MYLAN IRE HEALTHCARE LIMITED	ES
DUMIROX 50 mg compresse rivestite con film	not available	026104036	MYLAN ITALIA S.R.L.	IT
Dumirox 50 mg comprimidos recubiertos con película	DE/H/5314/001	57.233	MYLAN IRE HEALTHCARE LIMITED	ES
Dumyrox 100 mg comprimidos revestidos por película	DE/H/5314/002	4506986	BGP PRODUCTS UNIPESOAL, LDA.	PT
Dumyrox 100 mg comprimidos revestidos por película	DE/H/5314/002	8610915	BGP PRODUCTS UNIPESOAL, LDA.	PT
Dumyrox 50 mg comprimidos revestidos por película	DE/H/5314/001	5897681	BGP PRODUCTS UNIPESOAL, LDA.	PT
Dumyrox 50 mg comprimidos revestidos por película	DE/H/5314/001	4506887	BGP PRODUCTS UNIPESOAL, LDA.	PT
Dumyrox 50 mg comprimidos revestidos por película	DE/H/5314/001	8610949	BGP PRODUCTS UNIPESOAL, LDA.	PT
Dumyrox 50 mg comprimidos revestidos por película	DE/H/5314/001	4506788	BGP PRODUCTS UNIPESOAL, LDA.	PT
Dumyrox® 100 mg επικαλυμμένα με λεπτό υμένιο δισκία	DE/H/5314/002	10260/09-02-2011	BGP PRODUCTS S.LTD	GR
Faverin 100 mg film-coated tablets	DE/H/5314/002	PA 2010/31/2	MYLAN IRE HEALTHCARE LIMITED	IE
Faverin 100 mg film-	not available	MA 1187/00502	MYLAN IRE HEALTHCARE	MT

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coated tablets			LIMITED	
Faverin 100 mg film-coated tablets	DE/H/5314/002	PL 46302/0033	MYLAN PRODUCTS LIMITED	XI
Faverin 100mg film-coated tablets	not available	11913	MYLAN IRE HEALTHCARE LIMITED	CY
Faverin 50 mg film-coated tablets	DE/H/5314/001	PA 2010/31/1	MYLAN IRE HEALTHCARE LIMITED	IE
Faverin 50 mg film-coated tablets	not available	MA 1187/00501	MYLAN IRE HEALTHCARE LIMITED	MT
Faverin 50 mg film-coated tablets	DE/H/5314/001	PL 46302/0034	MYLAN PRODUCTS LIMITED	XI
Faverin 50mg film-coated tablets	not available	11914	MYLAN IRE HEALTHCARE LIMITED	CY
fevarin 100 filmom obalené tablety	not available	30/0098/18-S	VIATRIS HEALTHCARE LTD	SK
Fevarin 100 mg apvalkotās tabletes	not available	99-0055	MYLAN HEALTHCARE SIA	LV
FEVARIN 100 mg compresse rivestite con film	DE/H/5314/002	027045044	MYLAN IRE HEALTHCARE LIMITED	IT
FEVARIN 100 mg compresse rivestite con film	DE/H/5314/002	027045057	MYLAN IRE HEALTHCARE LIMITED	IT
Fevarin 100 mg comprimato filmate	not available	8835/2016/01	VIATRIS HEALTHCARE LTD	RO
Fevarin 100 mg filmdragerad tablett	DE/H/5314/002	11183	VIATRIS AB	SE
Fevarin 100 mg filmom obložene tablete	not available	HR-H-748870845	MYLAN HRVATSKA D.O.O.	HR
Fevarin 100 mg filmom obložene tablete	not available	HR-H-748870845	MYLAN HRVATSKA D.O.O.	HR
Fevarin 100 mg filmtabletta	not available	OGYI-T-1422/01	MYLAN EPD KFT.	HU
Fevarin 100 mg plėvele dengtos tabletės	not available	LT/1/97/1993/003	MYLAN HEALTHCARE SIA	LT
Fevarin 100 mg	not available	30/070/89-B/C	VIATRIS HEALTHCARE LTD	CZ

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potahované tablety				
Fevarin 100 mg tableter, filmdrasjerte	DE/H/5314/002	00-7553	VIATRIS AS	NO
Fevarin 100, filmomhulde tabletten	DE/H/5314/002	RVG 11619	MYLAN HEALTHCARE B.V.	NL
fevarin 50 filmom obalené tablety	not available	30/0055/97-S	VIATRIS HEALTHCARE LTD	SK
Fevarin 50 mg apvalkotās tabletes	not available	99-0054	MYLAN HEALTHCARE SIA	LV
FEVARIN 50 mg compresse rivestite con film	DE/H/5314/001	027045032	MYLAN IRE HEALTHCARE LIMITED	IT
Fevarin 50 mg comprimate filmate	not available	8834/2016/01	VIATRIS HEALTHCARE LTD	RO
Fevarin 50 mg filmdragerad tablett	DE/H/5314/001	11182	VIATRIS AB	SE
Fevarin 50 mg filmtabletta	not available	OGYI-T-1422/02	MYLAN EPD KFT.	HU
Fevarin 50 mg plėvele dengtos tabletės	not available	LT/1/97/1993/002	MYLAN HEALTHCARE SIA	LT
Fevarin 50 mg plėvele dengtos tabletės	not available	LT/1/97/1993/001	MYLAN HEALTHCARE SIA	LT
Fevarin 50 mg potahované tablety	not available	30/070/89-A/C	VIATRIS HEALTHCARE LTD	CZ
Fevarin 50 mg tableter, filmdrasjerte	DE/H/5314/001	00-7544	VIATRIS AS	NO
Fevarin 50, filmomhulde tabletten	DE/H/5314/001	RVG 10245	MYLAN HEALTHCARE B.V.	NL
Fevarin, 100 mg õhukese polümeerikattega tabletid	not available	241998	MYLAN HEALTHCARE SIA	EE
Fevarin, 100 mg, tabletki powlekane	not available	R/3478	MYLAN HEALTHCARE SP. Z.O.O.	PL
Fevarin, 50 mg õhukese polümeerikattega tabletid	not available	242098	MYLAN HEALTHCARE SIA	EE
Fevarin, 50 mg, tabletki powlekane	not available	R/3477	MYLAN HEALTHCARE SP. Z.O.O.	PL
Fevarin® 100 mg	DE/H/5314/002	35047.01.00	VIATRIS HEALTHCARE GMBH	DE

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Filmtabletten				
Fevarin® 50 mg Filmtabletten	DE/H/5314/001	35047.00.00	VIATRIS HEALTHCARE GMBH	DE
Floxyfral 100 mg – Filmtabletten	DE/H/5314/002	1-21364	MYLAN ÖSTERREICH GMBH	AT
FLOXYFRAL 100 mg comprimés pelliculés	DE/H/5314/002	BE135746	MYLAN EPD BVBA/SPRL	BE
FLOXYFRAL 100 mg comprimés pelliculés	DE/H/5314/002	2011071227	MYLAN EPD BVBA/SPRL	LU
FLOXYFRAL 100 mg filmomhulde tabletten	DE/H/5314/002	BE135746	MYLAN EPD BVBA/SPRL	BE
Floxyfral 100 mg Filmtabletten	DE/H/5314/002	BE135746	MYLAN EPD BVBA/SPRL	BE
Floxyfral 100 mg Filmtabletten	DE/H/5314/002	2011071227	MYLAN EPD BVBA/SPRL	LU
FLOXYFRAL 100 mg, comprimé pelliculé sécable	DE/H/5314/002	34009 331 984 8 0	MYLAN MEDICAL SAS	FR
FLOXYFRAL 100 mg, comprimé pelliculé sécable	DE/H/5314/002	34009 331 985 4 1	MYLAN MEDICAL SAS	FR
FLOXYFRAL 100 mg, comprimé pelliculé sécable	DE/H/5314/002	34009 558 548 8 3	MYLAN MEDICAL SAS	FR
FLOXYFRAL 100 mg, comprimé pelliculé sécable	DE/H/5314/002	34009 558 549 4 4	MYLAN MEDICAL SAS	FR
FLOXYFRAL 100 mg, comprimé pelliculé sécable	DE/H/5314/002	34009 331 983 1 2	MYLAN MEDICAL SAS	FR
Floxyfral 50 mg – Filmtabletten	DE/H/5314/001	1-21368	MYLAN ÖSTERREICH GMBH	AT
FLOXYFRAL 50 mg, comprimé pelliculé sécable	DE/H/5314/001	34009 327 293 4 0	MYLAN MEDICAL SAS	FR
FLOXYFRAL 50 mg, comprimé pelliculé sécable	DE/H/5314/001	34009 327 291 1 1	MYLAN MEDICAL SAS	FR
FLOXYFRAL 50 mg, comprimé pelliculé sécable	DE/H/5314/001	34009 327 292 8 9	MYLAN MEDICAL SAS	FR
FLOXYFRAL 50 mg, comprimé pelliculé sécable	DE/H/5314/001	34009 327 290 5 0	MYLAN MEDICAL SAS	FR
Fluvoxamine 100 mg film-	not available	PL 11311/0489	TILLOMED LABORATORIES	XI

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coated tablets			LTD	
Fluvoxamine 100 mg film-coated tablets	not available	PL 11311/0489	TILLOMED LABORATORIES LTD	XI
Fluvoxamine 50 mg film-coated tablets	not available	PL 11311/0488	TILLOMED LABORATORIES LTD	XI
Fluvoxamine 50 mg film-coated tablets	not available	PL 11311/0488	TILLOMED LABORATORIES LTD	XI
FLUVOXAMINE ABBOTT 100 mg, comprimé pelliculé sécable	FR/H/0730/002	NL47712	ABBOTT HEALTHCARE PRODUCTS B.V. (WEESP)	FR
FLUVOXAMINE ABBOTT 50 mg, comprimé pelliculé sécable	FR/H/0730/001	NL47711	ABBOTT HEALTHCARE PRODUCTS B.V. (WEESP)	FR
MAVERAL 100 mg compresse rivestite con film	not available	026102044	MYLAN ITALIA S.R.L.	IT
MAVERAL 50 mg compresse rivestite con film	not available	026102032	MYLAN ITALIA S.R.L.	IT
Феварин 100 мг филмирани таблетки	not available	20010889	MYLAN EOOD	BG
Феварин 50 мг филмирани таблетки	not available	20010888	MYLAN EOOD	BG