



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

12 April 2018  
EMA/231137/2018  
Human Medicines Evaluation Division

## List of nationally authorised medicinal products

Active substance: fluvoxamine

Procedure no.: PSUSA/00001458/201707

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An agency of the European Union



<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	BGP PRODUCTS S.R.L.	IT
DUMIROX 100 mg compresse rivestite con film	not available	026104048	BGP PRODUCTS S.R.L.	IT
Dumirox 100 mg comprimidos recubiertos con película	DE/H/5314/002	58212	BGP PRODUCTS OPERATIONS SL	ES
DUMIROX 50 mg compresse rivestite con film	not available	026104036	BGP PRODUCTS S.R.L.	IT
DUMIROX 50 mg compresse rivestite con film	not available	026104036	BGP PRODUCTS S.R.L.	IT
Dumirox 50 mg comprimidos recubiertos con película	DE/H/5314/001	57233	BGP PRODUCTS OPERATIONS SL	ES
Dumyrox 100 mg comprimidos revestidos por película	DE/H/5314/002	4506986	BGP PRODUCTS UNIPessoal, LDA.	PT
Dumyrox 100 mg comprimidos revestidos por película	DE/H/5314/002	8610915	BGP PRODUCTS UNIPessoal, LDA.	PT
Dumyrox 50 mg comprimidos revestidos por película	DE/H/5314/001	5897681	BGP PRODUCTS UNIPessoal, LDA.	PT
Dumyrox 50 mg comprimidos revestidos por película	DE/H/5314/001	4506887	BGP PRODUCTS UNIPessoal, LDA.	PT

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Dumyrox 50 mg comprimidos revestidos por película	DE/H/5314/001	8610949	BGP PRODUCTS UNIPESSOAL, LDA.	PT
Dumyrox 50 mg comprimidos revestidos por película	DE/H/5314/001	4506788	BGP PRODUCTS UNIPESSOAL, LDA.	PT
DUMYROX® Επικαλυμμένα με λεπτό υμένιο δισκία 100mg	DE/H/5314/002	10260	BGP PRODUCTS LTD (GREECE)	GR
DUMYROX® Επικαλυμμένα με λεπτό υμένιο δισκία 50mg	DE/H/5314/001	10258	BGP PRODUCTS LTD (GREECE)	GR
Faverin 100 mg film-coated tablets	DE/H/5314/002	PA 2136/3/2	MYLAN PRODUCTS LIMITED	IE
Faverin 100 mg film-coated tablets	DE/H/5314/002	PL 46302/0033	MYLAN PRODUCTS LIMITED	UK
Faverin 100mg film-coated tablets	not available	11913	VARNAVAS HADJIPANAYIS LTD. (LATSIA)	CY
Faverin 100mg film-coated tablets	not available	11913	VARNAVAS HADJIPANAYIS LTD. (LATSIA)	CY
Faverin 50 mg film-coated tablets	DE/H/5314/001	PA 2136/3/1	MYLAN PRODUCTS LIMITED	IE

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Faverin 50 mg film-coated tablets	DE/H/5314/001	PL 46302/0034	MYLAN PRODUCTS LIMITED	UK
Faverin 50mg film-coated tablets	not available	11914	VARNAVAS HADJIPANAYIS LTD. (LATSIA)	CY
Faverin 50mg film-coated tablets	not available	11914	VARNAVAS HADJIPANAYIS LTD. (LATSIA)	CY
fevarin 100 filmom obalené tablety	not available	30/0055/97-S	BGP PRODUCTS B.V.	SK
fevarin 100 filmom obalené tablety	not available	30/0055/97-S	BGP PRODUCTS B.V.	SK
Fevarin 100 mg apvalkotās tabletes	not available	99-0055	BGP PRODUCTS B.V.	LV
Fevarin 100 mg apvalkotās tabletes	not available	99-0055	BGP PRODUCTS B.V.	LV
FEVARIN 100 mg compresse rivestite con film	DE/H/5314/002	027045044	BGP PRODUCTS B.V.	IT
FEVARIN 100 mg compresse rivestite con film	DE/H/5314/002	027045057	BGP PRODUCTS B.V.	IT

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Fevarin 100 mg comprimatate filmate	not available	8835/2016/01	BGP PRODUCTS B.V.	RO
Fevarin 100 mg comprimatate filmate	not available	8835/2016/01	BGP PRODUCTS B.V.	RO
Fevarin 100 mg filmdragerad tablett	DE/H/5314/002	11183	BGP PRODUCTS B.V.	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	BGP PRODUCTS B.V.	HU
Fevarin 100 mg filmtabletta	not available	OGYI-T-1422/01	BGP PRODUCTS B.V.	HU
Fevarin 100 mg plévele dengtos tabletés	not available	LT/1/97/1993/003	BGP PRODUCTS B.V.	LT
Fevarin 100 mg plévele dengtos tabletés	not available	LT/1/97/1993/003	BGP PRODUCTS B.V.	LT

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Fevarin 100 mg potahované tablety	not available	30/070/89-B/C	BGP PRODUCTS B.V.	CZ
Fevarin 100 mg potahované tablety	not available	30/070/89-B/C	BGP PRODUCTS B.V.	CZ
Fevarin 100 mg tableter, filmdrasjerte	DE/H/5314/002	00-7553	BGP PRODUCTS B.V.	NO
Fevarin 100, filmomhulde tabletten	DE/H/5314/002	RVG 11619	BGP PRODUCTS B.V.	NL
fevarin 50 filmom obalené tablety	not available	30/0055/97-S	BGP PRODUCTS B.V.	SK
fevarin 50 filmom obalené tablety	not available	30/0055/97-S	BGP PRODUCTS B.V.	SK
Fevarin 50 mg apvalkotās tabletes	not available	99-0054	BGP PRODUCTS B.V.	LV
Fevarin 50 mg apvalkotās tabletes	not available	99-0054	BGP PRODUCTS B.V.	LV
FEVARIN 50 mg compresse rivestite con film	DE/H/5314/001	027045032	BGP PRODUCTS B.V.	IT

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Fevarin 50 mg comprimé filmaté	not available	8834/2016/01	BGP PRODUCTS B.V.	RO
Fevarin 50 mg comprimé filmaté	not available	8834/2016/01	BGP PRODUCTS B.V.	RO
Fevarin 50 mg filmdragérad tablett	DE/H/5314/001	11182	BGP PRODUCTS B.V.	SE
Fevarin 50 mg filmtablettá	not available	OGYI-T-1422/02	BGP PRODUCTS B.V.	HU
Fevarin 50 mg filmtablettá	not available	OGYI-T-1422/02	BGP PRODUCTS B.V.	HU
Fevarin 50 mg plévele dengtos tablettés	not available	LT/1/97/1993/002	BGP PRODUCTS B.V.	LT
Fevarin 50 mg plévele dengtos tablettés	not available	LT/1/97/1993/001	BGP PRODUCTS B.V.	LT
Fevarin 50 mg plévele dengtos tablettés	not available	LT/1/97/1993/002	BGP PRODUCTS B.V.	LT
Fevarin 50 mg plévele dengtos tablettés	not available	LT/1/97/1993/001	BGP PRODUCTS B.V.	LT

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Fevarin 50 mg potahované tablety	not available	30/070/89-A/C	BGP PRODUCTS B.V.	CZ
Fevarin 50 mg potahované tablety	not available	30/070/89-A/C	BGP PRODUCTS B.V.	CZ
Fevarin 50 mg tabletter, filmdrasjerte	DE/H/5314/001	00-7544	BGP PRODUCTS B.V.	NO
Fevarin 50, filmomhulde tabletten	DE/H/5314/001	RVG 10245	BGP PRODUCTS B.V.	NL
Fevarin, 100 mg õhukese polümeerikattega tabletid	not available	241998	BGP PRODUCTS B.V.	EE
Fevarin, 100 mg õhukese polümeerikattega tabletid	not available	241998	BGP PRODUCTS B.V.	EE
Fevarin, 100 mg, tabletki powlekane	not available	R/3478	BGP PRODUCTS POLAND SP. Z.O.O.	PL
Fevarin, 100 mg, tabletki powlekane	not available	R/3478	BGP PRODUCTS POLAND SP. Z.O.O.	PL
Fevarin, 50 mg õhukese polümeerikattega tabletid	not available	242098	BGP PRODUCTS B.V.	EE



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Fevarin, 50 mg õhukese polümeerikattega tabletid	not available	242098	BGP PRODUCTS B.V.	EE
Fevarin, 50 mg, tabletki powlekane	not available	R/3477	BGP PRODUCTS POLAND SP. Z.O.O.	PL
Fevarin, 50 mg, tabletki powlekane	not available	R/3477	BGP PRODUCTS POLAND SP. Z.O.O.	PL
Fevarin® 100 mg Filmtabletten	DE/H/5314/002	35047.01.00	MYLAN HEALTHCARE GMBH	DE
Fevarin® 50 mg Filmtabletten	DE/H/5314/001	35047.00.00	MYLAN HEALTHCARE GMBH	DE
Floxyfral 100 mg – Filmtabletten	DE/H/5314/002	1-21364	BGP PRODUCTS GES. M. B. H.	AT
FLOXYFRAL 100 mg comprimés pelliculés	DE/H/5314/002	BE135746	MYLAN EPD SPRL	BE
FLOXYFRAL 100 mg comprimés pelliculés	DE/H/5314/002	2011071227	MYLAN EPD SPRL	LU
FLOXYFRAL 100 mg filmomhulde tabletten	DE/H/5314/002	BE135746	MYLAN EPD SPRL	BE

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Floxyfral 100 mg Filmtabletten	DE/H/5314/002	BE135746	MYLAN EPD SPRL	BE
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	BGP PRODUCTS GES. M. B. H.	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

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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-coated tablets	not available	PL 11311/0489	TILLOMED LABORATORIES LTD	UK
Fluvoxamine 50 mg film-coated tablets	not available	PL 11311/0488	TILLOMED LABORATORIES LTD	UK
Luvox 100 mg filmom obložene tablete	not available	HR-H-951309090	MYLAN HRVATSKA D.O.O.	HR
Luvox 100 mg filmom obložene tablete	not available	HR-H-951309090	MYLAN HRVATSKA D.O.O.	HR
MAVERAL 100 mg compresse rivestite con film	not available	026102044	BGP PRODUCTS S.R.L.	IT
MAVERAL 100 mg compresse rivestite con film	not available	026102044	BGP PRODUCTS S.R.L.	IT
MAVERAL 50 mg compresse rivestite con film	not available	026102032	BGP PRODUCTS S.R.L.	IT

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MAVERAL 50 mg compresse rivestite con film	not available	026102032	BGP PRODUCTS S.R.L.	IT
Феварин 100 мг филмирани таблетки	not available	20010889	BGP PRODUCTS B.V.	BG
Феварин 100 мг филмирани таблетки	not available	20010889	BGP PRODUCTS B.V.	BG
Феварин 50 мг филмирани таблетки	not available	20010888	BGP PRODUCTS B.V.	BG
Феварин 50 мг филмирани таблетки	not available	20010888	BGP PRODUCTS B.V.	BG