17 May 2018
EMA/303471/2018
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: vigabatrin

Procedure no.: PSUSA/00003112/201709

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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
Sabril	not available	16875	SANOFI-AVENTIS CYPRUS LTD	CY
Sabril	not available	16875	SANOFI-AVENTIS CYPRUS LTD	CY
SABRIL	not available	21/566/94-C	SANOFI-AVENTIS SRO	CZ
SABRIL	not available	21/566/94-C	SANOFI-AVENTIS SRO	CZ
SABRIL	not available	R/3128	SANOFI-AVENTIS FRANCE	PL
SABRIL	not available	8327	AVENTIS PHARMA LTD	PL
SABRIL	not available	R/3128	SANOFI-AVENTIS FRANCE	PL
SABRIL	not available	8327	AVENTIS PHARMA LTD	PL
SABRIL 500 MG COMPRESSE RIVESTITE CON FILM	FI/H/0139/001	027443011	SANOFI SPA	IT
SABRIL 500 MG COMPRESSE RIVESTITE CON FILM	FI/H/0139/001	027443011	SANOFI SPA	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
SABRIL 500 mg comprimés pelliculés	FI/H/0139/001	BE155337	SANOFI BELGIUM	BE
SABRIL 500 mg comprimés pelliculés	FI/H/0139/001	BE155337	SANOFI BELGIUM	BE
SABRIL 500 mg comprimés pelliculés	FI/H/0139/001	BE155337	SANOFI BELGIUM	BE
SABRIL 500 mg comprimés pelliculés	FI/H/0139/001	BE155337	SANOFI BELGIUM	BE
SABRIL 500 mg comprimés pelliculés	FI/H/0139/001	BE155337	SANOFI BELGIUM	BE
SABRIL 500 mg comprimés pelliculés	FI/H/0139/001	BE155337	SANOFI BELGIUM	BE
SABRIL 500 mg comprimés pelliculés	FI/H/0139/001	BE155337	SANOFI BELGIUM	BE
SABRIL 500 mg comprimés pelliculés	FI/H/0139/001	BE155337	SANOFI BELGIUM	BE
SABRIL 500 mg comprimés pelliculés	FI/H/0139/001	BE155337	SANOFI BELGIUM	BE

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
SABRIL 500 mg comprimés pelliculés	FI/H/0139/001	BE155337	SANOFI BELGIUM	BE
Sabril 500 mg comprimidos revestidos por película.	FI/H/0139/001	8768812	SANOFI - PRODUTOS FARMACEUTICOS LDA	PT
Sabril 500 mg comprimidos revestidos por película.	FI/H/0139/001	8768804	SANOFI - PRODUTOS FARMACEUTICOS LDA	PT
Sabril 500 mg comprimidos revestidos por película.	FI/H/0139/001	8768812	SANOFI - PRODUTOS FARMACEUTICOS LDA	PT
Sabril 500 mg comprimidos revestidos por película.	FI/H/0139/001	8768804	SANOFI - PRODUTOS FARMACEUTICOS LDA	PT
Sabril 500 mg film-coated tablets.	FI/H/0139/001	PL 04425/0171	AVENTIS PHARMA LTD	UK
Sabril 500 mg film-coated tablets.	FI/H/0139/001	PL 04425/0171	AVENTIS PHARMA LTD	UK
Sabril 500 mg film-coated tablets.	FI/H/0139/001	PL 04425/0171	AVENTIS PHARMA LTD	UK
Sabril 500 mg film-coated tablets.	FI/H/0139/001	PL 04425/0171	AVENTIS PHARMA LTD	UK

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
Sabril 500 mg film-coated tablets.	FI/H/0139/001	PL 04425/0171	AVENTIS PHARMA LTD	UK
Sabril 500 mg film-coated tablets.	FI/H/0139/001	PL 04425/0171	AVENTIS PHARMA LTD	UK
Sabril 500 mg film-coated tablets.	FI/H/0139/001	PL 04425/0171	AVENTIS PHARMA LTD	UK
Sabril 500 mg film-coated tablets.	FI/H/0139/001	PL 04425/0171	AVENTIS PHARMA LTD	UK
Sabril 500 mg film-coated tablets.	FI/H/0139/001	PL 04425/0171	AVENTIS PHARMA LTD	UK
Sabril 500 mg film-coated tablets.	FI/H/0139/001	PL 04425/0171	AVENTIS PHARMA LTD	UK
Sabril 500 mg filmomhulde tablet, filmomhulde tabletten	FI/H/0139/001	RVG 13707	SANOFI-AVENTIS NETHERLANDS B.V.	NL
Sabril 500 mg filmomhulde tablet, filmomhulde tabletten	FI/H/0139/001	RVG 13707	SANOFI-AVENTIS NETHERLANDS B.V.	NL
Sabril 500 mg filmomhulde tablet, filmomhulde tabletten	FI/H/0139/001	RVG 13707	SANOFI-AVENTIS NETHERLANDS B.V.	NL

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**
Sabril 500 mg filmomhulde tablet, filmomhulde tabletten	FI/H/0139/001	RVG 13707	SANOFI-AVENTIS NETHERLANDS B.V.	NL
Sabril 500 mg filmomhulde tablet, filmomhulde tabletten	FI/H/0139/001	RVG 13707	SANOFI-AVENTIS NETHERLANDS B.V.	NL
Sabril 500 mg filmomhulde tablet, filmomhulde tabletten	FI/H/0139/001	RVG 13707	SANOFI-AVENTIS NETHERLANDS B.V.	NL
Sabril 500 mg filmomhulde tablet, filmomhulde tabletten	FI/H/0139/001	RVG 13707	SANOFI-AVENTIS NETHERLANDS B.V.	NL
Sabril 500 mg filmomhulde tablet, filmomhulde tabletten	FI/H/0139/001	RVG 13707	SANOFI-AVENTIS NETHERLANDS B.V.	NL
Sabril 500 mg filmomhulde tablet, filmomhulde tabletten	FI/H/0139/001	RVG 13707	SANOFI-AVENTIS NETHERLANDS B.V.	NL
Sabril 500 mg filmomhulde tablet, filmomhulde tabletten	FI/H/0139/001	RVG 13707	SANOFI-AVENTIS NETHERLANDS B.V.	NL
SABRIL 500 mg filmomhulde tabletten	FI/H/0139/001	BE155337	SANOFI BELGIUM	BE
SABRIL 500 mg filmomhulde tabletten	FI/H/0139/001	BE155337	SANOFI BELGIUM	BE

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
SABRIL 500 mg filmomhulde tabletten	FI/H/0139/001	BE155337	SANOFI BELGIUM	BE
SABRIL 500 mg filmomhulde tabletten	FI/H/0139/001	BE155337	SANOFI BELGIUM	BE
SABRIL 500 mg filmomhulde tabletten	FI/H/0139/001	BE155337	SANOFI BELGIUM	BE
SABRIL 500 mg filmomhulde tabletten	FI/H/0139/001	BE155337	SANOFI BELGIUM	BE
SABRIL 500 mg filmomhulde tabletten	FI/H/0139/001	BE155337	SANOFI BELGIUM	BE
SABRIL 500 mg filmomhulde tabletten	FI/H/0139/001	BE155337	SANOFI BELGIUM	BE
SABRIL 500 mg filmomhulde tabletten	FI/H/0139/001	BE155337	SANOFI BELGIUM	BE
SABRIL 500 mg filmomhulde tabletten	FI/H/0139/001	BE155337	SANOFI BELGIUM	BE
SABRIL 500 mg filmsko obložene tablete	not available	H/95/01388/001	SANOFI-AVENTIS D.O.O.	SI

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
SABRIL 500 mg filmsko obložene tablete	not available	H/95/01388/001	SANOFI-AVENTIS D.O.O.	SI
Sabril 500 mg filmtabletta	not available	OGYI-T-2330/01	SANOFI-AVENTIS ZRT	HU
Sabril 500 mg filmtabletta	not available	OGYI-T-2330/01	SANOFI-AVENTIS ZRT	HU
SABRIL 500 MG FILMTABLETTEN	FI/H/0139/001	1-19486	SANOFI-AVENTIS GMBH OSTERREICH	AT
SABRIL 500 MG FILMTABLETTEN	FI/H/0139/001	1-19486	SANOFI-AVENTIS GMBH OSTERREICH	AT
SABRIL 500 MG FILMTABLETTEN	FI/H/0139/001	26034.00.00	SANOFI-AVENTIS DEUTSCHLAND GMBH	DE
SABRIL 500 MG FILMTABLETTEN	FI/H/0139/001	26034.00.00	SANOFI-AVENTIS DEUTSCHLAND GMBH	DE
SABRIL 500 MG FILMTABLETTEN	FI/H/0139/001	26034.00.00	SANOFI-AVENTIS DEUTSCHLAND GMBH	DE
SABRIL 500 MG FILMTABLETTEN	FI/H/0139/001	26034.00.00	SANOFI-AVENTIS DEUTSCHLAND GMBH	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
SABRIL 500 MG FILMTABLETTEN	FI/H/0139/001	26034.00.00	SANOFI-AVENTIS DEUTSCHLAND GMBH	DE
SABRIL 500 MG FILMTABLETTEN	FI/H/0139/001	26034.00.00	SANOFI-AVENTIS DEUTSCHLAND GMBH	DE
SABRIL 500 MG FILMTABLETTEN	FI/H/0139/001	26034.00.00	SANOFI-AVENTIS DEUTSCHLAND GMBH	DE
SABRIL 500 MG FILMTABLETTEN	FI/H/0139/001	26034.00.00	SANOFI-AVENTIS DEUTSCHLAND GMBH	DE
Sabril 500 mg granulaat voor drank, granulaat voor drank	FI/H/0139/002	RVG 15722	SANOFI-AVENTIS NETHERLANDS B.V.	NL
Sabril 500 mg granulaat voor drank, granulaat voor drank	FI/H/0139/002	RVG 15722	SANOFI-AVENTIS NETHERLANDS B.V.	NL
Sabril 500 mg granulaat voor drank, granulaat voor drank	FI/H/0139/002	RVG 15722	SANOFI-AVENTIS NETHERLANDS B.V.	NL
Sabril 500 mg granulaat voor drank, granulaat voor drank	FI/H/0139/002	RVG 15722	SANOFI-AVENTIS NETHERLANDS B.V.	NL
Sabril 500 mg granulaat voor drank, granulaat voor drank	FI/H/0139/002	RVG 15722	SANOFI-AVENTIS NETHERLANDS B.V.	NL

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
Sabril 500 mg granulaat voor drank, granulaat voor drank	FI/H/0139/002	RVG 15722	SANOFI-AVENTIS NETHERLANDS B.V.	NL
Sabril 500 mg granulado para solução oral	FI/H/0139/002	2552180	SANOFI - PRODUTOS FARMACEUTICOS LDA	PT
Sabril 500 mg granulado para solução oral	FI/H/0139/002	2842383	SANOFI - PRODUTOS FARMACEUTICOS LDA	PT
Sabril 500 mg granulado para solução oral	FI/H/0139/002	2552180	SANOFI - PRODUTOS FARMACEUTICOS LDA	PT
Sabril 500 mg granulado para solução oral	FI/H/0139/002	2842383	SANOFI - PRODUTOS FARMACEUTICOS LDA	PT
SABRIL 500 MG GRANULATO PER SOLUZIONE ORALE	FI/H/0139/002	027443047	SANOFI SPA	IT
SABRIL 500 MG GRANULATO PER SOLUZIONE ORALE	FI/H/0139/002	027443047	SANOFI SPA	IT
Sabril 500 mg granules for oral solution	FI/H/0139/002	PL 04425/0170	AVENTIS PHARMA LTD	UK
Sabril 500 mg granules for oral solution	FI/H/0139/002	PL 04425/0170	AVENTIS PHARMA LTD	UK

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
Sabril 500 mg granules for oral solution	FI/H/0139/002	PL 04425/0170	AVENTIS PHARMA LTD	UK
Sabril 500 mg granules for oral solution	FI/H/0139/002	PL 04425/0170	AVENTIS PHARMA LTD	UK
Sabril 500 mg granules for oral solution	FI/H/0139/002	PL 04425/0170	AVENTIS PHARMA LTD	UK
Sabril 500 mg granules for oral solution	FI/H/0139/002	PL 04425/0170	AVENTIS PHARMA LTD	UK
Sabril 500 mg lösliches Pulver	FI/H/0139/002	1-20114	SANOFI-AVENTIS GMBH OSTERREICH	AT
Sabril 500 mg lösliches Pulver	FI/H/0139/002	1-20114	SANOFI-AVENTIS GMBH OSTERREICH	AT
SABRIL 500 mg, comprimé pelliculé	FI/H/0139/001	337 804-1	SANOFI-AVENTIS FRANCE	FR
SABRIL 500 mg, comprimé pelliculé	FI/H/0139/001	337 804-1	SANOFI-AVENTIS FRANCE	FR
SABRIL 500 mg, filmom obalené tablety	not available	21/0339/94-S	SANOFI-AVENTIS SLOVAKIA SRO	SK

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
SABRIL 500 mg, filmom obalené tablety	not available	21/0339/94-S	SANOFI-AVENTIS SLOVAKIA SRO	SK
SABRIL 500 mg, granulés pour solution buvable en sachet-dose	FI/H/0139/002	337 806-4	SANOFI-AVENTIS FRANCE	FR
SABRIL 500 mg, granulés pour solution buvable en sachet-dose	FI/H/0139/002	337 806-4	SANOFI-AVENTIS FRANCE	FR
SABRIL 500 mg comprimés pelliculés	FI/H/0139/001	0171767	SANOFI BELGIUM	LU
SABRIL 500 mg comprimés pelliculés	FI/H/0139/001	0172778	SANOFI BELGIUM	LU
SABRIL 500 mg comprimés pelliculés	FI/H/0139/001	0171767	SANOFI BELGIUM	LU
SABRIL 500 mg comprimés pelliculés	FI/H/0139/001	0172778	SANOFI BELGIUM	LU
Sabril 500 mg film-coated tablets	FI/H/0139/001	PA 540/23/1	SANOFI-AVENTIS IRELAND LTD. T/A SANOFI	IE
Sabril 500 mg film-coated tablets	FI/H/0139/001	PA 540/23/1	SANOFI-AVENTIS IRELAND LTD. T/A SANOFI	IE

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
Sabril 500 mg granules for oral solution	FI/H/0139/002	PA 540/23/2	SANOFI-AVENTIS IRELAND LTD. T/A SANOFI	IE
Sabril 500 mg granules for oral solution	FI/H/0139/002	PA 540/23/2	SANOFI-AVENTIS IRELAND LTD. T/A SANOFI	IE
Sabril 500mg film-coated tablets	not available	MA082/02801	SANOFI MALTA LTD	MT
Sabril 500mg film-coated tablets	not available	MA082/02801	SANOFI MALTA LTD	MT
Sabril Beutel 500 mg Granulat zur Herstellung einer Lösung zum Einnehmen	FI/H/0139/002	18274.00.01	SANOFI-AVENTIS DEUTSCHLAND GMBH	DE
Sabril Beutel 500 mg Granulat zur Herstellung einer Lösung zum Einnehmen	FI/H/0139/002	18274.00.01	SANOFI-AVENTIS DEUTSCHLAND GMBH	DE
Sabril Beutel 500 mg Granulat zur Herstellung einer Lösung zum Einnehmen	FI/H/0139/002	18274.00.01	SANOFI-AVENTIS DEUTSCHLAND GMBH	DE
Sabril Beutel 500 mg Granulat zur Herstellung einer Lösung zum Einnehmen	FI/H/0139/002	18274.00.01	SANOFI-AVENTIS DEUTSCHLAND GMBH	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
Sabril® 500 mg επικαλυμμένα με λεπτό υμένιο δισκία	FI/H/0139/001	207290602	SANOFI-AVENTIS AEBE	GR
Sabril® 500 mg επικαλυμμένα με λεπτό υμένιο δισκία	FI/H/0139/001	207290602	SANOFI-AVENTIS AEBE	GR
SABRILEX	FI/H/0139/001	13704	SANOFI-AVENTIS DENMARK A/S	DK
SABRILEX	FI/H/0139/002	14732	SANOFI-AVENTIS DENMARK A/S	DK
SABRILEX	FI/H/0139/001	13704	SANOFI-AVENTIS DENMARK A/S	DK
SABRILEX	FI/H/0139/002	14732	SANOFI-AVENTIS DENMARK A/S	DK
SABRILEX	not available	920180	SANOFI-AVENTIS NORGE AS	IS
SABRILEX	not available	920180	SANOFI-AVENTIS NORGE AS	IS
SABRILEX	not available	920180	SANOFI-AVENTIS NORGE AS	IS

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
SABRILEX	not available	920180	SANOFI-AVENTIS NORGE AS	IS
SABRILEX	not available	920180	SANOFI-AVENTIS NORGE AS	IS
SABRILEX	not available	920180	SANOFI-AVENTIS NORGE AS	IS
SABRILEX	not available	920180	SANOFI-AVENTIS NORGE AS	IS
SABRILEX	not available	920180	SANOFI-AVENTIS NORGE AS	IS
SABRILEX	not available	920180	SANOFI-AVENTIS NORGE AS	IS
SABRILEX	not available	920180	SANOFI-AVENTIS NORGE AS	IS
SABRILEX	not available	7893	SANOFI-AVENTIS NORGE AS	NO
SABRILEX	not available	95-2201	SANOFI-AVENTIS NORGE AS	NO

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
SABRILEX	not available	7893	SANOFI-AVENTIS NORGE AS	NO
SABRILEX	not available	95-2201	SANOFI-AVENTIS NORGE AS	NO
Sabrilex 500 mg comprimidos recubiertos con película	FI/H/0139/001	59361	MARION MERRELL S.A.	ES
Sabrilex 500 mg comprimidos recubiertos con película	FI/H/0139/001	59361	MARION MERRELL S.A.	ES
Sabrilex 500 mg filmdragerade tabletter	FI/H/0139/001	11251	SANOFI AB	SE
Sabrilex 500 mg filmdragerade tabletter	FI/H/0139/001	11251	SANOFI AB	SE
Sabrilex 500 mg granulado para solución oral	FI/H/0139/002	59809	MARION MERRELL S.A.	ES
Sabrilex 500 mg granulado para solución oral	FI/H/0139/002	59809	MARION MERRELL S.A.	ES
Sabrilex 500 mg granulat till oral lösning	FI/H/0139/002	11690	SANOFI AB	SE

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
Sabrilex 500 mg granulat till oral lösning	FI/H/0139/002	11690	SANOFI AB	SE
Sabrilex 500 mg rakeet oraaliliuosta varten	FI/H/0139/002	11148	SANOFI OY	FI
Sabrilex 500 mg rakeet oraaliliuosta varten	FI/H/0139/002	11148	SANOFI OY	FI
Sabrilex 500 mg rakeet oraaliliuosta varten	FI/H/0139/002	11148	SANOFI OY	FI
Sabrilex 500 mg rakeet oraaliliuosta varten	FI/H/0139/002	11148	SANOFI OY	FI
Sabrilex 500 mg rakeet oraaliliuosta varten	FI/H/0139/002	11148	SANOFI OY	FI
Sabrilex 500 mg rakeet oraaliliuosta varten	FI/H/0139/002	11148	SANOFI OY	FI
Sabrilex 500 mg tabletti, kalvopäällysteinen	FI/H/0139/001	10620	SANOFI OY	FI
Sabrilex 500 mg tabletti, kalvopäällysteinen	FI/H/0139/001	10620	SANOFI OY	FI

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
Sabrilex 500 mg tabletti, kalvopäällysteinen	FI/H/0139/001	10620	SANOFI OY	FI
Sabrilex 500 mg tabletti, kalvopäällysteinen	FI/H/0139/001	10620	SANOFI OY	FI
Sabrilex 500 mg tabletti, kalvopäällysteinen	FI/H/0139/001	10620	SANOFI OY	FI
Sabrilex 500 mg tabletti, kalvopäällysteinen	FI/H/0139/001	10620	SANOFI OY	FI
Sabrilex 500 mg tabletti, kalvopäällysteinen	FI/H/0139/001	10620	SANOFI OY	FI
Sabrilex 500 mg tabletti, kalvopäällysteinen	FI/H/0139/001	10620	SANOFI OY	FI
Sabrilex 500 mg tabletti, kalvopäällysteinen	FI/H/0139/001	10620	SANOFI OY	FI
Sabrilex 500 mg tabletti, kalvopäällysteinen	FI/H/0139/001	10620	SANOFI OY	FI