



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

12 April 2018
EMA/243033/2018
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: fenofibrate

Procedure no.: PSUSA/00001362/201707



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
FÉNOFIBRATE BIOGARAN® 300 mg, gélule	not available	3400936089204	BIOGARAN	FR
FENOFIBRATE TEVA SANTE 160 mg, comprimé pelliculé	not available	NL31090	TEVA SANTÉ	FR
Lipofen 100 mg cápsula	not available	9483834	LABORATÓRIOS VITÓRIA, SA	PT
Lipofen 100 mg cápsula	not available	9483826	LABORATÓRIOS VITÓRIA, SA	PT
Elipsia® 145 mg Filmtablette	not available	59178.00.00	ABBOTT LABORATORIES GMBH	DE
Fenofibrat Abbott 160mg Filmtabletten	not available	98905.00.00	ABBOTT LABORATORIES LIMITED	DE
Lipanthyl 200 mg, kapsel, hård	IE/H/0120/002	15661	MYLAN MEDICAL SAS	SE
Lipantil Micro 200 mg capsule, hard	IE/H/0120/002	PA 2010/15/2	MYLAN IRE HEALTHCARE LIMITED	IE
Apteor® 160 mg Filmtablette	DE/H/0236/001	45089.00.00	MYLAN HEALTHCARE GMBH	DE
Fulcrosupra 160 mg compresse rivestite con film	DE/H/0236/001	035928023	BGP PRODUCTS S.R.L.	IT
Fulcrosupra 160 mg compresse rivestite con film	DE/H/0236/001	035928047	BGP PRODUCTS S.R.L.	IT
Fulcrosupra 160 mg compresse rivestite con film	DE/H/0236/001	035928035	BGP PRODUCTS S.R.L.	IT
Fulcrosupra 160 mg compresse rivestite con film	DE/H/0236/001	035928050	BGP PRODUCTS S.R.L.	IT
Fulcrosupra 160 mg compresse rivestite con film	DE/H/0236/001	035928062	BGP PRODUCTS S.R.L.	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
Fulcrosupra 160 mg compresse rivestite con film	DE/H/0236/001	035928074	BGP PRODUCTS S.R.L.	IT
Fulcrosupra 160 mg compresse rivestite con film	DE/H/0236/001	035928086	BGP PRODUCTS S.R.L.	IT
Fulcrosupra 160 mg compresse rivestite con film	DE/H/0236/001	035928098	BGP PRODUCTS S.R.L.	IT
Fulcrosupra 160 mg compresse rivestite con film	DE/H/0236/001	035928100	BGP PRODUCTS S.R.L.	IT
Fulcrosupra 160 mg compresse rivestite con film	DE/H/0236/001	035928112	BGP PRODUCTS S.R.L.	IT
Fulcrosupra 160 mg compresse rivestite con film	DE/H/0236/001	035928011	BGP PRODUCTS S.R.L.	IT
Lipanthyl S 215 mg, potahovaná tableta	IE/H/0157/001	31/288/05-C	MYLAN IRE HEALTHCARE LIMITED	CZ
Lipanthyl Supra 215 mg, 215 mg, tabletki powlekane	IE/H/0157/001	12005	BGP PRODUCTS POLAND SP. Z.O.O.	PL
LIPANTHYL SUPRA 215 mg filmom obalené tablety	IE/H/0157/001	31/0390/05-S	MYLAN IRE HEALTHCARE LIMITED	SK
Lipantil Supra 215 mg, film-coated tablet	IE/H/0157/001	PA 2010/15/4	MYLAN IRE HEALTHCARE LIMITED	IE
Secalip 250 mg cápsulas duras de liberación prolongada	not available	56.864	LACER S.A.	ES
Secalip 200 mg cápsulas duras	not available	60.176	LACER S.A.	ES
Secalip supra 160 mg comprimidos recubiertos con película	DE/H/0235/001	63533	LACER S.A.	ES

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
Secalip 145 mg comprimidos recubiertos con película	DE/H/0497/001	66.861	LACER S.A.	ES
Lipcor 200 mg-Kapseln	not available	1-20108	BGP PRODUCTS GES. M. B. H.	AT
Secalip 250 mg cápsulas duras de liberación prolongada	not available	56.864	LACER S.A.	ES
Secalip 200 mg cápsulas duras	not available	60.176	LACER S.A.	ES
CATALIP 200 mg cápsulas	not available	2496784	LABORATÓRIO MEDINFAR - PRODUTOS FARMACÊUTICOS, S.A.	PT
CATALIP 200 mg cápsulas	not available	2459980	LABORATÓRIO MEDINFAR - PRODUTOS FARMACÊUTICOS, S.A.	PT
CATALIP 267 MICRONIZADO 267 mg cápsulas	not available	3268182	LABORATÓRIO MEDINFAR - PRODUTOS FARMACÊUTICOS, S.A.	PT
Catalip 267 Micronizado 267 mg cápsulas	not available	5120985	LABORATÓRIO MEDINFAR - PRODUTOS FARMACÊUTICOS, S.A.	PT
Lipanthyl 200 Micronised, 200 mg Hartkapseln	not available	BE157972	MYLAN EPD SPRL	BE
Lipanthyl 267 Micronised, 267 mg Hartkapseln	not available	BE198274	MYLAN EPD SPRL	BE
LIPANTHYL 267 Micronised, 267 mg, capsules, hard	not available	BE198274	MYLAN EPD SPRL	BE
Lipanthyl 67 Micronised, 67 mg Hartkapseln	not available	BE198256	MYLAN EPD SPRL	BE
LIPANTHYL 267 Micronised gélules	not available	BE198274	MYLAN EPD SPRL	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
LIPANTHYL 267 Micronised gélules	not available	2011010946	MYLAN EPD SPRL	LU
LIPANTHYL 200 Micronised gélules	not available	BE157972	MYLAN EPD SPRL	BE
LIPANTHYL 67 Micronised, 67 mg gélules	not available	BE198256	MYLAN EPD SPRL	BE
LIPANTHYL-200 MICRONISED	not available	2011010945	MYLAN EPD SPRL	LU
LIPANTHYL 67 Micronised, 67 mg gélules	not available	2011010944	MYLAN EPD SPRL	LU
LIPANTHYL 200 Micronised, capsules, hard	not available	BE157972	MYLAN EPD SPRL	BE
LIPANTHYL 67 Micronised, capsules, hard	not available	BE198256	MYLAN EPD SPRL	BE
Липантил Супра 160 mg филмирани таблетки	not available	20050342	MYLAN MEDICAL SAS	BG
Липантил 200M 200 mg капсули, твърди	not available	9700549	MYLAN MEDICAL SAS	BG
Lipidil® NT 145 mg, film- coated tablet	not available	21153	VARNAVAS HADJIPANAYIS LTD. (LATSIA)	CY
LIPANTHYL SUPRA 160 mg Potahovaná tableta	not available	31/463/00-C	MYLAN IRE HEALTHCARE LIMITED	CZ
LIPANTHYL 267 M tvrdá tobolka	not available	31/105/00-C	MYLAN IRE HEALTHCARE LIMITED	CZ
Lipidil® 200 mg Hartkapseln	not available	13762.00.00	MYLAN HEALTHCARE 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
Lipanthyl, 200 mg kővakapszid	not available	210298	BGP PRODUCTS SIA	EE
LIPANTHYL 200 micronisé, gélule	not available	34009 332 635 7 7	MYLAN MEDICAL SAS	FR
LIPANTHYL 200 micronisé, gélule	not available	34009 371 785 6 3	MYLAN MEDICAL SAS	FR
LIPANTHYL 200 micronisé, gélule	not available	34009 332 636 3 8	MYLAN MEDICAL SAS	FR
LIPANTHYL 67 Micronisé, gélule	not available	34009 334 303 1 3	MYLAN MEDICAL SAS	FR
LIPIDIL 145 mg filmom obložene tablete	not available	UP/I-530-09/12-02/101	MYLAN HRVATSKA D.O.O.	HR
TRICOR 145 mg filmom obložene tablete	not available	UP/I-530-09/12-02/102	MYLAN HRVATSKA D.O.O.	HR
LIPIDIL 160 mg filmom obložene tablete	not available	UP/I-530-09/12-02/99	MYLAN HRVATSKA D.O.O.	HR
TRICOR 160 mg filmom obložene tablete	not available	UP/I-530-09/12-02/100	MYLAN HRVATSKA D.O.O.	HR
TRICOR 215 mg filmom obložene tablete	not available	UP/I-530-09/12-02/104	MYLAN HRVATSKA D.O.O.	HR
Lipidil Supra 160 mg filmtabletta	not available	OGYI-T-7695/01	MYLAN PRODUCTS LIMITED	HU
Lipidil 267 mg kemény kapszula	not available	OGYI-T-8697/01	MYLAN EPD KFT.	HU
FULCRO 200 mg capsule rigide	not available	028590014	BGP PRODUCTS S.R.L.	IT
LIPANTHYL 200 mg kietosios kapsulės	not available	LT/1/96/2568/001	MYLAN MEDICAL SAS	LT

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
LIPANTHYL 67 Micronisé, gélule	not available	34009 335 269 1 7	MYLAN MEDICAL SAS	FR
LIPANTHYL 67 Micronisé, gélule	not available	34009 336 438 1 2	MYLAN MEDICAL SAS	FR
LIPANTHYL 67 Micronisé, gélule	not available	34009 335 271 6 7	MYLAN MEDICAL SAS	FR
LIPANTHYL 67 Micronisé, gélule	not available	34009 335 272 2 8	MYLAN MEDICAL SAS	FR
LIPANTHYL 67 Micronisé, gélule	not available	34009 336 437 5 1	MYLAN MEDICAL SAS	FR
Lipanthyl 200 mg cietās kapsulas	not available	97-0309	BGP PRODUCTS SIA	LV
Lipanthyl Supra 160, 160 mg, tabletki powlekane	not available	9039	BGP PRODUCTS POLAND SP. Z.O.O.	PL
Lipanthyl 200M, 200 mg, kapsułki	not available	R/2587	BGP PRODUCTS POLAND SP. Z.O.O.	PL
Lipanthyl 267M, 267 mg, kapsułki	not available	4928	BGP PRODUCTS POLAND SP. Z.O.O.	PL
LIPANTIL NANO 145 mg comprimate filmate	not available	9126/2016/01	MYLAN MEDICAL SAS	RO
Lipanthyl Supra 160 mg comprimate cu eliberare modificată	not available	1075/2008/02	MYLAN MEDICAL SAS	RO
Lipanthyl Supra 160 mg comprimate cu eliberare modificată	not available	1075/2008/01	MYLAN MEDICAL SAS	RO
LIPANTHYL SUPRA 160 mg filmom obalené tablety	not available	31/0394/00-S	MYLAN IRE HEALTHCARE LIMITED	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
Lipantil® Micro 200 mg, capsules	not available	PL 46302/0042	MYLAN PRODUCTS LIMITED	UK
Lipantil® Micro 267 mg, capsules	not available	PL 46302/0043	MYLAN PRODUCTS LIMITED	UK
Lipantil® Micro 67 mg, capsules	not available	PL 46302/0044	MYLAN PRODUCTS LIMITED	UK
FENOFIBRATE EG 160 mg, comprimé pelliculé	not available	NL31362	EG LABO LABORATOIRES EUROGENERICS	FR
LIPSIN 200 mg capsule rigide	not available	029257019	I.B.N. SAVIO S.R.L.	IT
Lipofene 100 mg capsule	not available	024157036	TEOFARMA S.R.L.	IT
FENOFIBRATE TEVA 300 mg, gélule	not available	NL21839	TEVA SANTÉ	FR
FENOFIBRATE TEVA 100 mg, gélule	not available	NL21838	TEVA SANTÉ	FR
Lipantil Micro 67 mg capsule, hard	IE/H/0120/001	PA 2010/15/1	MYLAN IRE HEALTHCARE LIMITED	IE
Secalip 145 mg comprimidos recubiertos con película	DE/H/0497/001	66.861	LACER S.A.	ES
Lipanthyl Nanopartikel 145 mg - Filmtabletten	DE/H/0497/001	1-26345	BGP PRODUCTS GES. M. B. H.	AT
LipanthylNano 145 mg Filmtabletten	DE/H/0497/001	BE280716	MYLAN EPD SPRL	BE
LipanthylNano 145 mg comprimés pelliculés	DE/H/0497/001	BE280716	MYLAN EPD SPRL	BE
LipanthylNano 145 mg comprimés pelliculés	DE/H/0497/001	2006040005	MYLAN EPD SPRL	LU

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
LipanthylNano 145 mg filmomhulde tabletten	DE/H/0497/001	BE280716	MYLAN EPD SPRL	BE
Lipanthyl NT 145 mg, potahované tablety	DE/H/0497/001	31/214/05-C	MYLAN IRE HEALTHCARE LIMITED	CZ
Lipanthyl Penta 145 mg, kalvopäällysteinen tabletti	DE/H/0497/001	20343	MYLAN MEDICAL SAS	FI
LIPANTHYL 145 mg, comprimé pelliculé	DE/H/0497/001	34009 369 642 7 3	MYLAN MEDICAL SAS	FR
LIPANTHYL 145 mg, comprimé pelliculé	DE/H/0497/001	34009 567 146 6 7	MYLAN MEDICAL SAS	FR
LIPANTHYL 145 mg, comprimé pelliculé	DE/H/0497/001	34009 369 641 0 5	MYLAN MEDICAL SAS	FR
LIPIDIL® NT 145mg επικαλυμμένο με λεπτό υμένιο δισκίο	DE/H/0497/001	71610/30-09-2016	BGP PRODUCTS LTD (GREECE)	GR
Lipidil 145 mg filmtabletta	DE/H/0497/001	OGYI-T-8967/02	MYLAN EPD KFT.	HU
Fulcrosupra 145 mg compresse rivestite con film	DE/H/0497/001	035928136/M	BGP PRODUCTS S.R.L.	IT
Fulcrosupra 145 mg compresse rivestite con film	DE/H/0497/001	035928148/M	BGP PRODUCTS S.R.L.	IT
Fulcrosupra 145 mg compresse rivestite con film	DE/H/0497/001	035928151/M	BGP PRODUCTS S.R.L.	IT
Fulcrosupra 145 mg compresse rivestite con film	DE/H/0497/001	035928163/M	BGP PRODUCTS S.R.L.	IT
Fulcrosupra 145 mg compresse rivestite con film	DE/H/0497/001	035928175/M	BGP PRODUCTS S.R.L.	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
Fulcrosupra 145 mg compresse rivestite con film	DE/H/0497/001	035928187/M	BGP PRODUCTS S.R.L.	IT
Fulcrosupra 145 mg compresse rivestite con film	DE/H/0497/001	035928199/M	BGP PRODUCTS S.R.L.	IT
Fulcrosupra 145 mg compresse rivestite con film	DE/H/0497/001	035928201/M	BGP PRODUCTS S.R.L.	IT
Fulcrosupra 145 mg compresse rivestite con film	DE/H/0497/001	035928213/M	BGP PRODUCTS S.R.L.	IT
Fulcrosupra 145 mg compresse rivestite con film	DE/H/0497/001	035928225/M	BGP PRODUCTS S.R.L.	IT
Fulcrosupra 145 mg compresse rivestite con film	DE/H/0497/001	035928124/M	BGP PRODUCTS S.R.L.	IT
Lipanthyl NT 145, 145 mg, tabletki powlekane	DE/H/0497/001	11728	BGP PRODUCTS POLAND SP. Z.O.O.	PL
LIPANTHYL NT 145 mg filmom obalené tablety	DE/H/0497/001	31/0396/05-S	MYLAN IRE HEALTHCARE LIMITED	SK
LIPIDIL 145 ONE® 145 mg Filmtabletten	DE/H/0497/001	59176.00.00	MYLAN HEALTHCARE GMBH	DE
Lipantil Supra 145 mg film-coated tablet	DE/H/0497/001	PA 2010/15/3	MYLAN IRE HEALTHCARE LIMITED	IE
Lipanthyl Penta 145 mg, filmdragerad tablett	DE/H/0497/001	20343	MYLAN MEDICAL SAS	FI
Liperial 145 mg compresse rivestite con film	DE/H/0500/001	037160025/M	BGP PRODUCTS S.R.L.	IT
Liperial 145 mg compresse rivestite con film	DE/H/0500/001	037160037/M	BGP PRODUCTS S.R.L.	IT
Liperial 145 mg compresse rivestite con film	DE/H/0500/001	037160049/M	BGP PRODUCTS S.R.L.	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
Liperial 145 mg compresse rivestite con film	DE/H/0500/001	037160052/M	BGP PRODUCTS S.R.L.	IT
Liperial 145 mg compresse rivestite con film	DE/H/0500/001	037160076/M	BGP PRODUCTS S.R.L.	IT
Liperial 145 mg compresse rivestite con film	DE/H/0500/001	037160064/M	BGP PRODUCTS S.R.L.	IT
Liperial 145 mg compresse rivestite con film	DE/H/0500/001	037160088/M	BGP PRODUCTS S.R.L.	IT
Liperial 145 mg compresse rivestite con film	DE/H/0500/001	037160090/M	BGP PRODUCTS S.R.L.	IT
Liperial 145 mg compresse rivestite con film	DE/H/0500/001	037160102/M	BGP PRODUCTS S.R.L.	IT
Liperial 145 mg compresse rivestite con film	DE/H/0500/001	037160013/M	BGP PRODUCTS S.R.L.	IT
Liperial 145 mg compresse rivestite con film	DE/H/0500/001	037160114/M	BGP PRODUCTS S.R.L.	IT
Liperial® 145 mg Filmlablette	DE/H/0500/001	59179.00.00	MYLAN HEALTHCARE GMBH	DE
Secalip supra 160 mg comprimidos recubiertos con película	DE/H/0235/001	63533	LACER S.A.	ES
LIPANTHYL 160 mg, comprimé pelliculé	DE/H/0235/001	34009 371 780 4 4	MYLAN MEDICAL SAS	FR
LIPANTHYL 160 mg, comprimé pelliculé	DE/H/0235/001	34009 562 936 9 8	MYLAN MEDICAL SAS	FR
LIPANTHYL 160 mg, comprimé pelliculé	DE/H/0235/001	34009 355 373 9 3	MYLAN MEDICAL SAS	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
Supralip® 160 mg, film-coated tablet	DE/H/0235/001	PL 46302/0024	MYLAN PRODUCTS LIMITED	UK
Lipidil-Ter® 160 mg Filmtablette	DE/H/0235/001	45088.00.00	MYLAN HEALTHCARE GMBH	DE
CATALIP 200 mg cápsulas	not available	2496784	LABORATÓRIO MEDINFAR - PRODUTOS FARMACÊUTICOS, S.A.	PT
CATALIP 200 mg cápsulas	not available	2459980	LABORATÓRIO MEDINFAR - PRODUTOS FARMACÊUTICOS, S.A.	PT
CATALIP 267 MICRONIZADO 267 mg cápsulas	not available	3268182	LABORATÓRIO MEDINFAR - PRODUTOS FARMACÊUTICOS, S.A.	PT
Catalip 267 Micronizado 267 mg cápsulas	not available	5120985	LABORATÓRIO MEDINFAR - PRODUTOS FARMACÊUTICOS, S.A.	PT
Xafenor® 145 mg Filmtablette	DE/H/0498/001	59177.00.00	MYLAN HEALTHCARE GMBH	DE
Supralip 145 mg comprimidos revestidos por película	DE/H/0498/001	5412887	BGP PRODUCTS UNIPESOAAL, LDA.	PT
Supralip 145 mg comprimidos revestidos por película	DE/H/0498/001	5412986	BGP PRODUCTS UNIPESOAAL, LDA.	PT
Supralip 145 mg comprimidos revestidos por película	DE/H/0498/001	5412788	BGP PRODUCTS UNIPESOAAL, LDA.	PT
Fenogal Lidose 200 mg géluless	not available	BE195386	LABORATOIRES SMB S.A.	BE
Fenogal Lidose 200 mg capsules, hard	not available	BE195386	LABORATOIRES SMB S.A.	BE
Fenogal Lidose 200 mg Hartkapseln	not available	BE195386	LABORATOIRES SMB S.A.	BE

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Fenogal Lidose 200 mg gélules	not available	2005128327	LABORATOIRES SMB S.A.	LU
Fenogal Lidose 200 mg Hartkapseln	not available	2005128327	LABORATOIRES SMB S.A.	LU
FENOFIBRATE BIOGARAN 100 mg, gélule	not available	3400935652638	BIOGARAN	FR
FENOFIBRATE BIOGARAN 100 mg, gélule	not available	3400932344024	BIOGARAN	FR
FENOFIBRATE BIOGARAN 100 mg, gélule	not available	3400932732760	BIOGARAN	FR