



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

1 December 2016
EMA/848467/2016
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: mycophenolic acid (apart from mycophenolate mofetil)

Procedure no.: PSUSA/00010243/201605



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
Myfortic 180 mg comprimés gastro-résistants	FR/H/0239/001	2004030120	NOVARTIS PHARMA N.V.	LU
Myfortic 360 mg comprimés gastro-résistants	FR/H/0239/002	2004030119	NOVARTIS PHARMA N.V.	LU
Myfortic 180 mg magensaftresistente Tabletten	FR/H/0239/001	2004030120	NOVARTIS PHARMA N.V.	LU
Myfortic 360 mg magensaftresistente Tabletten	FR/H/0239/002	2004030119	NOVARTIS PHARMA N.V.	LU
Myfortic 180 mg magensaftresistente Tabletten	FR/H/0239/001	BE272054	NOVARTIS PHARMA N.V.	BE
Myfortic 360 mg magensaftresistente Tabletten	FR/H/0239/002	BE272063	NOVARTIS PHARMA N.V.	BE
Myfortic 180 mg gastrorezistentne tablete	FR/H/0239/001	H/05/01070/001	NOVARTIS PHARMA GMBH	SI
Myfortic 180 mg gastrorezistentne tablete	FR/H/0239/001	H/05/01070/002	NOVARTIS PHARMA GMBH	SI
Myfortic 180 mg gastrorezistentne tablete	FR/H/0239/001	H/05/01070/003	NOVARTIS PHARMA GMBH	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
Myfortic 180 mg gastrorezistentne tablete	FR/H/0239/001	H/05/01070/004	NOVARTIS PHARMA GMBH	SI
Myfortic 180 mg gastrorezistentne tablete	FR/H/0239/001	H/05/01070/005	NOVARTIS PHARMA GMBH	SI
Myfortic 360 mg gastrorezistentne tablete	FR/H/0239/002	H/05/01070/006	NOVARTIS PHARMA GMBH	SI
Myfortic 360 mg gastrorezistentne tablete	FR/H/0239/002	H/05/01070/007	NOVARTIS PHARMA GMBH	SI
Myfortic 360 mg gastrorezistentne tablete	FR/H/0239/002	H/05/01070/008	NOVARTIS PHARMA GMBH	SI
Myfortic 360 mg gastrorezistentne tablete	FR/H/0239/002	H/05/01070/009	NOVARTIS PHARMA GMBH	SI
Myfortic 180 mg želučanooporne tablete	not available	HR-H-505070647	NOVARTIS HRVATSKA D.O.O.	HR
Myfortic 360 mg želučanooporne tablete	not available	HR-H-950094160	NOVARTIS HRVATSKA D.O.O.	HR
MYFORTIC 180 mg comprimate gastrorezistente	not available	8649/2016/01	NOVARTIS PHARMA GMBH	RO
MYFORTIC 180 mg comprimate gastrorezistente	not available	8649/2016/02	NOVARTIS PHARMA GMBH	RO

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
MYFORTIC 180 mg comprimate gastrorezistente	not available	8649/2016/03	NOVARTIS PHARMA GMBH	RO
MYFORTIC 180 mg comprimate gastrorezistente	not available	8649/2016/04	NOVARTIS PHARMA GMBH	RO
MYFORTIC 360 mg comprimate gastrorezistente	not available	8650/2016/01	NOVARTIS PHARMA GMBH	RO
MYFORTIC 360 mg comprimate gastrorezistente	not available	8650/2016/02	NOVARTIS PHARMA GMBH	RO
MYFORTIC 360 mg comprimate gastrorezistente	not available	8650/2016/03	NOVARTIS PHARMA GMBH	RO
MYFORTIC 360 mg comprimate gastrorezistente	not available	8650/2016/04	NOVARTIS PHARMA GMBH	RO
Myfortic 180 mg γαστροανθεκτικά δισκία	FR/H/0239/001	262810101	NOVARTIS (HELLAS) S.A.C.I.	GR
Myfortic 180 mg γαστροανθεκτικά δισκία	FR/H/0239/001	262810102	NOVARTIS (HELLAS) S.A.C.I.	GR

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
Myfortic 180 mg γαστροανθεκτικά δισκία	FR/H/0239/001	262810103	NOVARTIS (HELLAS) S.A.C.I.	GR
Myfortic 180 mg γαστροανθεκτικά δισκία	FR/H/0239/001	262810104	NOVARTIS (HELLAS) S.A.C.I.	GR
Myfortic 180 mg γαστροανθεκτικά δισκία	FR/H/0239/001	262810105	NOVARTIS (HELLAS) S.A.C.I.	GR
Myfortic 180 mg γαστροανθεκτικά δισκία	FR/H/0239/001	262810106	NOVARTIS (HELLAS) S.A.C.I.	GR
Myfortic 360 mg γαστροανθεκτικά δισκία	FR/H/0239/002	262810201	NOVARTIS (HELLAS) S.A.C.I.	GR
Myfortic 360 mg γαστροανθεκτικά δισκία	FR/H/0239/002	262810202	NOVARTIS (HELLAS) S.A.C.I.	GR
Myfortic 360 mg γαστροανθεκτικά δισκία	FR/H/0239/002	262810203	NOVARTIS (HELLAS) S.A.C.I.	GR
Myfortic 360 mg γαστροανθεκτικά δισκία	FR/H/0239/002	262810204	NOVARTIS (HELLAS) S.A.C.I.	GR
Myfortic 360 mg γαστροανθεκτικά δισκία	FR/H/0239/002	262810205	NOVARTIS (HELLAS) S.A.C.I.	GR
MYFORTIC 180 mg comprese gastroresistenti	FR/H/0239/001	036511018	NOVARTIS FARMA S.P.A.	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
MYFORTIC 180 mg comprese gastroresistenti	FR/H/0239/001	036511020	NOVARTIS FARMA S.P.A.	IT
MYFORTIC 180 mg comprese gastroresistenti	FR/H/0239/001	036511032	NOVARTIS FARMA S.P.A.	IT
MYFORTIC 180 mg comprese gastroresistenti	FR/H/0239/001	036511044	NOVARTIS FARMA S.P.A.	IT
MYFORTIC 180 mg comprese gastroresistenti	FR/H/0239/001	036511057	NOVARTIS FARMA S.P.A.	IT
Myfortic 180 mg Comprimidos gastroresistentes	FR/H/0239/001	5051883	NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A.	PT
Myfortic 180 mg Comprimidos gastroresistentes	FR/H/0239/001	5051982	NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A.	PT
Myfortic 180 mg Comprimidos gastroresistentes	FR/H/0239/001	5052089	NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A.	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
MYFORTIC 360 mg comprese gastroresistenti	FR/H/0239/002	036511069	NOVARTIS FARMA S.P.A.	IT
MYFORTIC 360 mg comprese gastroresistenti	FR/H/0239/002	036511071	NOVARTIS FARMA S.P.A.	IT
MYFORTIC 360 mg comprese gastroresistenti	FR/H/0239/002	036511083	NOVARTIS FARMA S.P.A.	IT
MYFORTIC 360 mg comprese gastroresistenti	FR/H/0239/002	036511095	NOVARTIS FARMA S.P.A.	IT
Myfortic 360 mg Comprimidos gastroresistentes	FR/H/0239/002	5052188	NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A.	PT
Myfortic 360 mg Comprimidos gastroresistentes	FR/H/0239/002	5052287	NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A.	PT
MYFORTIC 180 mg comprimidos gastroresistentes	FR/H/0239/001	66140	NOVARTIS FARMACÊUTICA S.A.	ES
Myfortic 180 mg enterotabletti	FR/H/0239/001	18944	NOVARTIS FINLAND 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
Myfortic, 180 mg gastroresistentsed tabletid	FR/H/0239/001	469105	NOVARTIS FINLAND OY	EE
Myfortic 180 mg skrandyje neirios tabletės	FR/H/0239/001	LT/1/05/0288/001	NOVARTIS FINLAND OY	LT
Myfortic 180 mg skrandyje neirios tabletės	FR/H/0239/001	LT/1/05/0288/002	NOVARTIS FINLAND OY	LT
Myfortic 180 mg skrandyje neirios tabletės	FR/H/0239/001	LT/1/05/0288/003	NOVARTIS FINLAND OY	LT
Myfortic 180 mg skrandyje neirios tabletės	FR/H/0239/001	LT/1/05/0288/004	NOVARTIS FINLAND OY	LT
Myfortic 180 mg skrandyje neirios tabletės	FR/H/0239/001	LT/1/05/0288/005	NOVARTIS FINLAND OY	LT
Myfortic 180 mg enterotabletter	FR/H/0239/001	18944	NOVARTIS FINLAND OY	FI
MYFORTIC 360 mg comprimidos gastrorresistentes	FR/H/0239/002	66141	NOVARTIS FARMACÉUTICA 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
Myfortic 360 mg enterotabletti	FR/H/0239/002	18945	NOVARTIS FINLAND OY	FI
Myfortic, 360 mg gastroresistentsed tabletid	FR/H/0239/002	469205	NOVARTIS FINLAND OY	EE
Myfortic 360 mg zarnās šķīstošās tabletes	FR/H/0239/002	05-0270	NOVARTIS FINLAND OY	LV
Myfortic 360 mg enterotabletter	FR/H/0239/002	18945	NOVARTIS FINLAND OY	FI
Myfortic	FR/H/0239/001	35821	NOVARTIS HEALTHCARE A/S	DK
Myfortic	FR/H/0239/002	35822	NOVARTIS HEALTHCARE A/S	DK
Myfortic 180 mg, maagsapresistente tablet	FR/H/0239/001	RVG 30202	NOVARTIS PHARMA B.V.	NL
МИФОРТИК 180 МГ СТОМАШНО-УСТОЙЧИВИ ТАБЛЕТКИ	not available	20050056	NOVARTIS PHARMA GMBH	BG
Myfortic 180 mg gyomornedv-ellenálló tableta	FR/H/0239/001	OGYI-T-10075/02	NOVARTIS HUNGÁRIA KFT. PHARMA	HU
Myfortic® 180 mg magensaftresistente Tabletten	FR/H/0239/001	58399.00.00	NOVARTIS PHARMA 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
Myfortic 180 mg tabletki dojelitowe	FR/H/0239/001	11469	NOVARTIS POLAND SP. Z O. O.	PL
Myfortic 360 mg, maagsapresistente tablet	FR/H/0239/002	RVG 30203	NOVARTIS PHARMA B.V.	NL
МИФОРТИК 360 МГ СТОМАШНО-УСТОЙЧИВИ ТАБЛЕТКИ	not available	20050057	NOVARTIS PHARMA GMBH	BG
Myfortic 360 mg gyomornedv-ellenálló tablettá	FR/H/0239/002	OGYI-T-10075/01	NOVARTIS HUNGÁRIA KFT. PHARMA	HU
Myfortic® 360 mg magensaftresistente Tabletten	FR/H/0239/002	58399.01.00	NOVARTIS PHARMA GMBH	DE
Myfortic 360 mg tabletki dojelitowe	FR/H/0239/002	11452	NOVARTIS POLAND SP. Z O. O.	PL
MYFORTIC 180 MG GASTRO-RESISTANT TABLETS	FR/H/0239/001	PL 00101/0664	NOVARTIS PHARMACEUTICALS UK LIMITED	UK
MYFORTIC 360 MG GASTRO-RESISTANT TABLETS	FR/H/0239/002	PL 00101/0665	NOVARTIS PHARMACEUTICALS UK LIMITED	UK
Myfortic 180 mg enterosolventní tablety	FR/H/0239/001	59/111/05-C	NOVARTIS, S.R.O.	CZ

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
MYFORTIC 180 MG – MAGENSAFTRESISTENTE TABLETTEN	FR/H/0239/001	1-25367	NOVARTIS PHARMA GMBH	AT
MYFORTIC 180 mg comprimé gastro-résistant	FR/H/0239/001	3400936308428	NOVARTIS PHARMA S.A.S.	FR
MYFORTIC 180 mg comprimé gastro-résistant	FR/H/0239/001	3400936308596	NOVARTIS PHARMA S.A.S.	FR
MYFORTIC 180 mg comprimé gastro-résistant	FR/H/0239/001	3400936308657	NOVARTIS PHARMA S.A.S.	FR
MYFORTIC 180 mg comprimé gastro-résistant	FR/H/0239/001	3400936308718	NOVARTIS PHARMA S.A.S.	FR
MYFORTIC 180 mg comprimé gastro-résistant	FR/H/0239/001	3400936308886	NOVARTIS PHARMA S.A.S.	FR
Myfortic 180 mg enterotablett	FR/H/0239/001	20225	NOVARTIS SVERIGE AB	SE
Myfortic 180 mg gastro-resistant tablets	FR/H/0239/001	PA 13/115/1	NOVARTIS PHARMACEUTICALS UK LIMITED	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
Myfortic 180 mg gastrorezistentné tablety	FR/H/0239/001	59/0073/05-S	NOVARTIS, S.R.O.	SK
Myfortic 180 mg gastro-resistant tablets	FR/H/0239/001	088/04901	NOVARTIS PHARMACEUTICALS UK LIMITED	MT
Myfortic 360 mg enterosolventní tablety	FR/H/0239/002	59/112/05-C	NOVARTIS, S.R.O.	CZ
MYFORTIC 360 MG – MAGENSAFTRESISTENTE TABLETTEN	FR/H/0239/002	1-25368	NOVARTIS PHARMA GMBH	AT
MYFORTIC 360 mg comprimé gastro-résistant	FR/H/0239/002	3400936308947	NOVARTIS PHARMA S.A.S.	FR
MYFORTIC 360 mg comprimé gastro-résistant	FR/H/0239/002	3400936309029	NOVARTIS PHARMA S.A.S.	FR
MYFORTIC 360 mg comprimé gastro-résistant	FR/H/0239/002	3400936309197	NOVARTIS PHARMA S.A.S.	FR
MYFORTIC 360 mg comprimé gastro-résistant	FR/H/0239/002	3400936309258	NOVARTIS PHARMA S.A.S.	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
Myfortic 360 mg comprimés gastro-résistants	FR/H/0239/002	BE272063	NOVARTIS PHARMA N.V.	BE
Myfortic 360 mg enterotablett	FR/H/0239/002	20226	NOVARTIS SVERIGE AB	SE
Myfortic 360 mg gastro-resistant tablets	FR/H/0239/002	PA 13/115/2	NOVARTIS PHARMACEUTICALS UK LIMITED	IE
Myfortic 360 mg gastrorezistentné tablety	FR/H/0239/002	59/0074/05-S	NOVARTIS, S.R.O.	SK
Myfortic 360 mg gastro-resistant tablets	FR/H/0239/002	088/04902	NOVARTIS PHARMACEUTICALS UK LIMITED	MT
Myfortic 360 mg maagsapresistente tabletten	FR/H/0239/002	BE272063	NOVARTIS PHARMA N.V.	BE
Myfortic® 180 mg γαστροανθεκτικό δισκίο	FR/H/0239/001	19691	NOVARTIS PHARMACEUTICALS UK LIMITED	CY
Myfortic 360mg γαστροανθεκτικό δισκίο	FR/H/0239/002	19692	NOVARTIS PHARMACEUTICALS UK LIMITED	CY

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
Myfortic 180 mg comprimés gastro-résistants	FR/H/0239/001	BE272054	NOVARTIS PHARMA N.V.	BE
Myfortic 180 mg, maagsapersistentente tabletten	FR/H/0239/001	BE272054	NOVARTIS PHARMA N.V.	BE
Myfortic 360 mg skrandyje neirios tabletės	FR/H/0239/002	LT/1/05/0288/007	NOVARTIS FINLAND OY	LT
Myfortic 360 mg skrandyje neirios tabletės	FR/H/0239/002	LT/1/05/0288/008	NOVARTIS FINLAND OY	LT
Myfortic 360 mg skrandyje neirios tabletės	FR/H/0239/002	LT/1/05/0288/009	NOVARTIS FINLAND OY	LT
Myfortic 360 mg skrandyje neirios tabletės	FR/H/0239/002	LT/1/05/0288/010	NOVARTIS FINLAND OY	LT
Myfortic 180 mg magasýrupolnar töflur	FR/H/0239/001	IS/1/04/003/01	NOVARTIS HEALTHCARE A/S	IS
Myfortic 360 mg magasýrupolnar töflur	FR/H/0239/002	IS/1/04/003/02	NOVARTIS HEALTHCARE A/S	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
MYFORTIC 180 mg enterotabletter	FR/H/0239/001	03-2258	NOVARTIS NORGE AS	NO
MYFORTIC 360 mg enterotabletter	FR/H/0239/002	03-2259	NOVARTIS NORGE AS	NO