



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

7 July 2016
EMA/270645/2015
Procedure Management and Committees Support

List of nationally authorised medicinal products

Active substance: mycophenolic acid (apart from mycophenolate mofetil)

Procedure no.: PSUSA/00010243/201510



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	2004030120	NOVARTIS PHARMA N.V. (ART57)	LU
Myfortic 360 mg magensaftresistente Tabletten	FR/H/0239/002	2004030119	NOVARTIS PHARMA N.V. (ART57)	LU
MYFORTIC 180 MG ΓΑΣΤΡΟΑΝΘΕΚΤΙΚΑ ΔΙΣΚΙΑ	FR/H/0239/001	262810101	NOVARTIS (HELLAS) S.A.C.I. (ART57)	GR
MYFORTIC 360 MG ΓΑΣΤΡΟΑΝΘΕΚΤΙΚΑ ΔΙΣΚΙΑ	FR/H/0239/001	262810102	NOVARTIS (HELLAS) S.A.C.I. (ART57)	GR
MYFORTIC 180 mg compreste gastroresistenti	FR/H/0239/001	036511018	NOVARTIS FARMA S.P.A. (ART57)	IT
MYFORTIC 180 mg compreste gastroresistenti	FR/H/0239/001	036511020	NOVARTIS FARMA S.P.A. (ART57)	IT
MYFORTIC 180 mg compreste gastroresistenti	FR/H/0239/001	036511032	NOVARTIS FARMA S.P.A. (ART57)	IT
MYFORTIC 180 mg compreste gastroresistenti	FR/H/0239/001	036511044	NOVARTIS FARMA S.P.A. (ART57)	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 comprimido gastroresistente	FR/H/0239/001	036511057	NOVARTIS FARMA S.P.A. (ART57)	IT
Myfortic 180 mg Comprimidos gastroresistentes	FR/H/0239/001	5051883	NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A. ART57	PT
Myfortic 180 mg Comprimidos gastroresistentes	FR/H/0239/001	5051982	NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A. ART57	PT
Myfortic 180 mg Comprimidos gastroresistentes	FR/H/0239/001	5052089	NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A. ART57	PT
MYFORTIC 360 mg comprimido gastroresistente	FR/H/0239/002	036511069	NOVARTIS FARMA S.P.A. (ART57)	IT
MYFORTIC 360 mg comprimido gastroresistente	FR/H/0239/002	036511071	NOVARTIS FARMA S.P.A. (ART57)	IT
MYFORTIC 360 mg comprimido gastroresistente	FR/H/0239/002	036511083	NOVARTIS FARMA S.P.A. (ART57)	IT
MYFORTIC 360 mg comprimido gastroresistente	FR/H/0239/002	036511095	NOVARTIS FARMA S.P.A. (ART57)	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 360 mg Comprimidos gastrorresistentes	FR/H/0239/002	5052188	NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A. ART57	PT
Myfortic 360 mg Comprimidos gastrorresistentes	FR/H/0239/002	5052287	NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A. ART57	PT
MYFORTIC 180 mg comprimidos gastrorresistentes	FR/H/0239/001	66140	NOVARTIS FARMACÉUTICA S.A. (ART57)	ES
Myfortic 180 mg enterotabletti	FR/H/0239/001	18944	NOVARTIS FINLAND OY (ART57)	FI
MYFORTIC, 180 MG GASTRORESISTENTSED TABLETID	FR/H/0239/001	469105	NOVARTIS FINLAND OY (ART57)	EE
Myfortic 180 mg skrandyje neirios tabletės	FR/H/0239/001	LT/1/05/0288/001	NOVARTIS FINLAND OY (ART57)	LT
Myfortic 180 mg skrandyje neirios tabletės	FR/H/0239/001	LT/1/05/0288/002	NOVARTIS FINLAND OY (ART57)	LT
Myfortic 180 mg skrandyje neirios tabletės	FR/H/0239/001	LT/1/05/0288/003	NOVARTIS FINLAND OY (ART57)	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
Myfortic 180 mg skrandyje neirios tabletės	FR/H/0239/001	LT/1/05/0288/004	NOVARTIS FINLAND OY (ART57)	LT
Myfortic 180 mg skrandyje neirios tabletės	FR/H/0239/001	LT/1/05/0288/005	NOVARTIS FINLAND OY (ART57)	LT
Myfortic 180 mg zarnās šķīstošās tabletes	FR/H/0239/001	05-0269	NOVARTIS FINLAND OY (ART57)	LV
MYFORTIC 360 mg comprimidos gastrorresistentes	FR/H/0239/002	66141	NOVARTIS FARMACÉUTICA S.A. (ART57)	ES
Myfortic 360 mg enterotabletti	FR/H/0239/002	18945	NOVARTIS FINLAND OY (ART57)	FI
MYFORTIC, 360 MG GASTRORESISTENTSED TABLETID	FR/H/0239/002	469205	NOVARTIS FINLAND OY (ART57)	EE
MYFORTIC® 360 MG ZARNĀS ŠĶĪSTOŠĀS TABLETES	FR/H/0239/002	05-0270	NOVARTIS FINLAND OY (ART57)	LV
Myfortic	FR/H/0239/001	35821	NOVARTIS HEALTHCARE A/S (ART57)	DK

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	FR/H/0239/002	35822	NOVARTIS HEALTHCARE A/S (ART57)	DK
Myfortic 180 mg comprimate filmate gastrorezistente	not available	5599/2005/04	NOVARTIS PHARMA GMBH (ART57)	RO
Myfortic 180 mg filmomhulde maagsapresistente tablet	FR/H/0239/001	RVG 30202	NOVARTIS PHARMA B.V. (ART57)	NL
МИФОРТИК 180 МГ СТОМАШНО-УСТОЙЧИВИ ТАБЛЕТКИ	not available	20050056	NOVARTIS PHARMA GMBH (ART57)	BG
Myfortic 180 mg gastrorezistentne tablete	FR/H/0239/001	H/05/01070/001	NOVARTIS PHARMA GMBH (ART57)	SI
Myfortic 180 mg gyomornedv-ellenálló tabletta	FR/H/0239/001	OGYI-T-10075/02	NOVARTIS HUNGÁRIA KFT. PHARMA (ART57)	HU
MYFORTIC® 180 MG MAGENSAFTRESISTENTE TABLETTEN	FR/H/0239/001	58399.00.00	NOVARTIS PHARMA GMBH (ART57)	DE
Myfortic 180 mg tabletki dojelitowe	FR/H/0239/001	11469	NOVARTIS POLAND SP. Z O. O. (ART57)	PL

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 filmomhulde maagsapresistente tablet	FR/H/0239/002	RVG 30203	NOVARTIS PHARMA B.V. (ART57)	NL
МИФОРТИК 360 МГ СТОМАШНО-УСТОЙЧИВИ ТАБЛЕТКИ	not available	20050057	NOVARTIS PHARMA GMBH (ART57)	BG
Myfortic 360 mg gastrorezistentne tablete	FR/H/0239/002	H/05/01070/006	NOVARTIS PHARMA GMBH (ART57)	SI
Myfortic 360 mg gyomornedv-ellenálló tabletta	FR/H/0239/002	OGYI-T-10075/01	NOVARTIS HUNGÁRIA KFT. PHARMA (ART57)	HU
MYFORTIC® 360 MG MAGENSAFTRESISTENTE TABLETTEN	FR/H/0239/002	58399.01.00	NOVARTIS PHARMA GMBH (ART57)	DE
Myfortic 360 mg tabletki dojelitowe	FR/H/0239/002	11452	NOVARTIS POLAND SP. Z O. O. (ART57)	PL
Myfortic 360 mg, comprimate filmate gastrorezistente	not available	5600/2005/04	NOVARTIS PHARMA GMBH (ART57)	RO
MYFORTIC 180 MG GASTRO-RESISTANT TABLETS	FR/H/0239/001	PL 00101/0664	NOVARTIS PHARMACEUTICALS UK LIMITED	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
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. (ART57)	CZ
MYFORTIC 180 MG – MAGENSAFTRESISTENTE TABLETTEN	FR/H/0239/001	1-25367	NOVARTIS PHARMA GMBH (ART57)	AT
MYFORTIC 180 mg comprimé gastro-résistant	FR/H/0239/001	3400936308428	NOVARTIS PHARMA S.A.S. (ART57)	FR
MYFORTIC 180 mg comprimé gastro-résistant	FR/H/0239/001	3400936308596	NOVARTIS PHARMA S.A.S. (ART57)	FR
MYFORTIC 180 mg comprimé gastro-résistant	FR/H/0239/001	3400936308657	NOVARTIS PHARMA S.A.S. (ART57)	FR
MYFORTIC 180 mg comprimé gastro-résistant	FR/H/0239/001	3400936308718	NOVARTIS PHARMA S.A.S. (ART57)	FR
MYFORTIC 180 mg comprimé gastro-résistant	FR/H/0239/001	3400936308886	NOVARTIS PHARMA S.A.S. (ART57)	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 180 mg enterotablett	FR/H/0239/001	20225	NOVARTIS SVERIGE AB (ART57)	SE
MYFORTIC 180 MG GASTRO-RESISTANT TABLETS	FR/H/0239/001	PA 13/115/1	NOVARTIS PHARMACEUTICALS UK LIMITED	IE
Myfortic 180 mg filmom obalená gastrorezistentná tableta	FR/H/0239/001	59/0073/05-S	NOVARTIS, S.R.O. (ART57)	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. (ART57)	CZ
MYFORTIC 360 MG – MAGENSAFTRESISTENTE TABLETTEN	FR/H/0239/002	1-25368	NOVARTIS PHARMA GMBH (ART57)	AT
MYFORTIC 360 mg comprimé gastro-résistant	FR/H/0239/002	3400936308947	NOVARTIS PHARMA S.A.S. (ART57)	FR
MYFORTIC 360 mg comprimé gastro-résistant	FR/H/0239/002	3400936309029	NOVARTIS PHARMA S.A.S. (ART57)	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 comprimé gastro-résistant	FR/H/0239/002	3400936309197	NOVARTIS PHARMA S.A.S. (ART57)	FR
MYFORTIC 360 mg comprimé gastro-résistant	FR/H/0239/002	3400936309258	NOVARTIS PHARMA S.A.S. (ART57)	FR
Myfortic 360 mg enterotablett	FR/H/0239/002	20226	NOVARTIS SVERIGE AB (ART57)	SE
MYFORTIC 360 MG GASTRO-RESISTANT TABLETS	FR/H/0239/002	PA 13/115/2	NOVARTIS PHARMACEUTICALS UK LIMITED	IE
Myfortic 360 mg filmom obalená gastrorezistentná tableta	FR/H/0239/002	59/0074/05-S	NOVARTIS, S.R.O. (ART57)	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. (ART57)	BE
MYFORTIC® 180 MG ΕΠΙΚΑΛΥΜΜΕΝΟ ΜΕ ΛΕΠΤΟ ΥΜΕΝΙΟ ΓΑΣΤΡΟΑΝΘΕΚΤΙΚΟ	FR/H/0239/001	19691	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
ΔΙΣΚΊΟ				
MYFORTIC® 360MG ΕΠΙΚΑΛΥΜΜΈΝΟ ΜΕ ΛΕΠΤΌ ΥΜΈΝΙΟ ΓΑΣΤΡΟΑΝΘΕΚΤΙΚΌ ΔΙΣΚΊΟ	FR/H/0239/002	19692	NOVARTIS PHARMACEUTICALS UK LIMITED	CY
Myfortic 180 mg, maagsapresistente tabletten	FR/H/0239/001	BE272054	NOVARTIS PHARMA N.V. (ART57)	BE
Myfortic 360 mg skrandyje neirios tabletės	FR/H/0239/002	LT/1/05/0288/007	NOVARTIS FINLAND OY (ART57)	LT
Myfortic 360 mg skrandyje neirios tabletės	FR/H/0239/002	LT/1/05/0288/008	NOVARTIS FINLAND OY (ART57)	LT
Myfortic 360 mg skrandyje neirios tabletės	FR/H/0239/002	LT/1/05/0288/009	NOVARTIS FINLAND OY (ART57)	LT
Myfortic 360 mg skrandyje neirios tabletės	FR/H/0239/002	LT/1/05/0288/010	NOVARTIS FINLAND OY (ART57)	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
Myfortic 180 mg filmuhúðuð sýrupolin tafla	FR/H/0239/001	IS/1/04/003/01	NOVARTIS HEALTHCARE A/S (ART57)	IS
Myfortic 360 mg filmuhúðuð sýrupolin tafla	FR/H/0239/002	IS/1/04/003/02	NOVARTIS HEALTHCARE A/S (ART57)	IS
MYFORTIC 180 mg enterotabletter	FR/H/0239/001	03-2258	NOVARTIS NORGE AS (ART57)	NO
MYFORTIC 360 mg enterotabletter	FR/H/0239/002	03-2259	NOVARTIS NORGE AS (ART57)	NO
Myfortic 180 mg zelucanootporne tablete	not available	UP/I-530-09/10-01/618	NOVARTIS HRVATSKA D.O.O. (ART57)	HR
Myfortic 360 mg zelucanootporne tablete	not available	UP/I-530-09/10-02/89	NOVARTIS HRVATSKA D.O.O. (ART57)	HR