



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

6 September 2018
EMA/PRAC/583558/2018
Human Medicines Evaluation Division

List of nationally authorised medicinal products for maintenance

Active substance(s): Famciclovir

Procedure No.: PSUSA/00001349/201712



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
AFAMCIVIR 500 MG, FILMOMHULDE TABLETTEN	UK/H/5067/001/DC	RVG 110214	GLAXOSMITHKLINE CONSUMER HEALTHCARE B.V	NL
Afamcivir 500 mg tabletti, kalvopäällysteinen	UK/H/4775/001/DC	30048	GLAXOSMITHKLINE CONSUMER HEALTHCARE A/S	FI
Afamcivir 500 mg filmuhúðaðar töflur	UK/H/4775/001/DC	IS/1/14/001/01	GLAXOSMITHKLINE CONSUMER HEALTHCARE A/S	IS
FENICURE 500 mg compresse rivestite con film	UK/H/5067/001/DC	041775014	GLAXOSMITHKLINE CONSUMER HEALTHCARE S.P.A.	IT
FAMVIR 125 MG ΕΠΙΚΑΛΥΜΜΕΝΑ ΜΕ ΛΕΠΤΟ ΥΜΕΝΙΟ ΔΙΣΚΙΑ	DE/H/5447/001	222260301	NOVARTIS (HELLAS) S.A.C.I.	GR
FAMVIR 250 MG ΕΠΙΚΑΛΥΜΜΕΝΑ ΜΕ ΛΕΠΤΟ ΥΜΕΝΙΟ ΔΙΣΚΙΑ	DE/H/5447/002	222260101	NOVARTIS (HELLAS) S.A.C.I.	GR
FAMVIR 250 MG ΕΠΙΚΑΛΥΜΜΕΝΑ ΜΕ ΛΕΠΤΟ ΥΜΕΝΙΟ ΔΙΣΚΙΑ	DE/H/5447/002	222260102	NOVARTIS (HELLAS) S.A.C.I.	GR
FAMVIR 250 MG ΕΠΙΚΑΛΥΜΜΕΝΑ ΜΕ ΛΕΠΤΟ ΥΜΕΝΙΟ ΔΙΣΚΙΑ	DE/H/5447/002	222260103	NOVARTIS (HELLAS) S.A.C.I.	GR
FAMVIR 125 mg compresse rivestite con film	DE/H/5447/001	029172044	NOVARTIS FARMA S.P.A.	IT
FAMVIR 250 mg compresse rivestite con film	DE/H/5447/002	029172018	NOVARTIS FARMA S.P.A.	IT
FAMVIR 250 mg compresse rivestite con film	DE/H/5447/002	029172032	NOVARTIS FARMA S.P.A.	IT
FAMVIR 500 mg compresse rivestite con film	DE/H/5447/003	029172057	NOVARTIS FARMA S.P.A.	IT
FAMVIR 500 mg	DE/H/5447/003	029172069	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
compresse rivestite con film				
FAMVIR 125 MG COMPRIMIDOS RECUBIERTOS CON PELÍCULA	DE/H/5447/001	61.597	NOVARTIS FARMACÉUTICA S.A.	ES
Famvir 125 mg filmdragerade tabletter	DE/H/5447/001	12160	NOVARTIS FINLAND OY	FI
Famvir 125 mg tabletti, kalvopäällysteinen	DE/H/5447/001	12160	NOVARTIS FINLAND OY	FI
FAMVIR 250 MG COMPRIMIDOS RECUBIERTOS CON PELÍCULA	DE/H/5447/002	60.609	NOVARTIS FARMACÉUTICA S.A.	ES
Famvir 250 mg filmdragerade tabletter	DE/H/5447/002	11680	NOVARTIS FINLAND OY	FI
Famvir 250 mg tabletti, kalvopäällysteinen	DE/H/5447/002	11680	NOVARTIS FINLAND OY	FI
FAMVIR 500 MG COMPRIMIDOS RECUBIERTOS CON PELÍCULA	DE/H/5447/003	65.027	NOVARTIS FARMACÉUTICA S.A.	ES
Famvir 500 mg filmdragerade tabletter	DE/H/5447/003	12161	NOVARTIS FINLAND OY	FI
Famvir 500 mg tabletti, kalvopäällysteinen	DE/H/5447/003	12161	NOVARTIS FINLAND OY	FI
Famvir	DE/H/5447/003	18930	NOVARTIS HEALTHCARE A/S	DK
Famvir	DE/H/5447/001	16988	NOVARTIS HEALTHCARE A/S	DK
Famvir 125 mg filmtablett	DE/H/5447/001	OGYI-T-5174/01	NOVARTIS HUNGÁRIA KFT. PHARMA	HU
Famvir® 125 mg Filmtabletten	DE/H/5447/001	34198.00.00	NOVARTIS PHARMA GMBH	DE
Famvir 250 mg filmtablett	DE/H/5447/002	OGYI-T-5174/02	NOVARTIS HUNGÁRIA KFT. PHARMA	HU
Famvir® 250 mg	DE/H/5447/002	34198.01.00	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
Filmtabletten				
Famvir® 500 mg Filmtabletten	DE/H/5447/003	39463.02.00	NOVARTIS PHARMA GMBH	DE
Famvir 250 mg film-coated tablets	DE/H/5447/002	MA088/01002	NOVARTIS PHARMACEUTICALS UK LIMITED	MT
FAMVIR 125 MG – FILMTABLETTEN	DE/H/5447/001	1-21508	NOVARTIS PHARMA GMBH	AT
Famvir 125 mg Film-Coated Tablets	DE/H/5447/001	PA0013/106/001	NOVARTIS PHARMACEUTICALS UK LIMITED	IE
Famvir 125 mg filmdragerade tabletter	DE/H/5447/001	12404	NOVARTIS SVERIGE AB	SE
Famvir® 125 mg film-coated tablets	DE/H/5447/001	PL 00101/0625	NOVARTIS PHARMACEUTICALS UK LIMITED	UK
FAMVIR 250 MG – FILMTABLETTEN	DE/H/5447/002	1-20836	NOVARTIS PHARMA GMBH	AT
Famvir® 250 mg film-coated tablets	DE/H/5447/002	PL 00101/0624	NOVARTIS PHARMACEUTICALS UK LIMITED	UK
Famvir 250 mg Film-Coated Tablets	DE/H/5447/002	PA0013/106/002	NOVARTIS PHARMACEUTICALS UK LIMITED	IE
Famvir 250 mg filmdragerade tabletter	DE/H/5447/002	12293	NOVARTIS SVERIGE AB	SE
Famvir 500 mg - Filmtabletten	DE/H/5447/003	1-21509	NOVARTIS PHARMA GMBH	AT
Famvir 500 mg filmdragerade tabletter	DE/H/5447/003	12603	NOVARTIS SVERIGE AB	SE
FAMVIR 125 MG ΕΠΙΚΑΛΥΜΜΕΝΑ ΜΕ ΛΕΠΤΟ ΥΜΕΝΙΟ ΔΙΣΚΙΑ	DE/H/5447/001	16371	NOVARTIS PHARMACEUTICALS UK LIMITED	CY
FAMVIR 250 MG ΕΠΙΚΑΛΥΜΜΕΝΑ ΜΕ	DE/H/5447/002	16080	NOVARTIS PHARMACEUTICALS UK	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
ΛΕΠΤΟ ΥΜΕΝΙΟ ΔΙΣΚΊΑ			LIMITED	
Famvir 125 mg film-coated tablets	DE/H/5447/001	MA088/01001	NOVARTIS PHARMACEUTICALS UK LIMITED	MT
Famvir® 500 mg film-coated tablets	DE/H/5447/003	PL 00101/0623	NOVARTIS PHARMACEUTICALS UK LIMITED	UK
FAMVIR 500 MG ΕΠΙΚΑΛΥΜΜΕΝΑ ΜΕ ΛΕΠΤΟ ΥΜΕΝΙΟ ΔΙΣΚΊΑ	DE/H/5447/003	222260201	NOVARTIS (HELLAS) S.A.C.I.	GR
FAMVIR 500 MG ΕΠΙΚΑΛΥΜΜΕΝΑ ΜΕ ΛΕΠΤΟ ΥΜΕΝΙΟ ΔΙΣΚΊΑ	DE/H/5447/003	222260202	NOVARTIS (HELLAS) S.A.C.I.	GR
FAMVIR 500 MG ΕΠΙΚΑΛΥΜΜΕΝΑ ΜΕ ΛΕΠΤΟ ΥΜΕΝΙΟ ΔΙΣΚΊΑ	DE/H/5447/003	222260203	NOVARTIS (HELLAS) S.A.C.I.	GR
FAMVIR 500 MG ΕΠΙΚΑΛΥΜΜΕΝΑ ΜΕ ΛΕΠΤΟ ΥΜΕΝΙΟ ΔΙΣΚΊΑ	DE/H/5447/003	222260204	NOVARTIS (HELLAS) S.A.C.I.	GR
ORAVIR 125 mg, comprimé pelliculé	DE/H/5447/001	3400935236906	NOVARTIS PHARMA S.A.S.	FR
ORAVIR 500mg, comprimé pelliculé	DE/H/5447/003	3400934138140	NOVARTIS PHARMA S.A.S.	FR
ORAVIR 500mg, comprimé pelliculé	DE/H/5447/003	3400934138201	NOVARTIS PHARMA S.A.S.	FR
ORAVIR 500mg, comprimé pelliculé	DE/H/5447/003	3400956046713	NOVARTIS PHARMA S.A.S.	FR
Famciclovir 125 mg film-coated tablets	not available	PL 40378/0150	APTIL PHARMA LIMITED	UK
Famciclovir 250 mg film-coated tablets	not available	PL 40378/0151	APTIL PHARMA LIMITED	UK
Famciclovir 500 mg film-coated tablets	not available	PL 40378/0152	APTIL PHARMA LIMITED	UK
Famvir 125 mg filmuhúðaðar töflur	DE/H/5447/001	950107	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
Famvir 500 mg filmuhúðaðar töflur	DE/H/5447/003	950106	NOVARTIS HEALTHCARE A/S	IS
Famvir 500mg Film-coated tablets	DE/H/5447/003	PA0013/106/006	NOVARTIS PHARMACEUTICALS UK LIMITED	IE
Famvir 500 mg film-coated tablets	DE/H/5447/003	MA088/01003	NOVARTIS PHARMACEUTICALS UK LIMITED	MT
Famciclovir 125 mg film-coated tablets	not available	PL 40378/0150	APTIL PHARMA LIMITED	UK
Famciclovir 250 mg film-coated tablets	not available	PL 40378/0151	APTIL PHARMA LIMITED	UK
Famciclovir 500 mg film-coated tablets	not available	PL 40378/0152	APTIL PHARMA LIMITED	UK