2 September 2016
EMA/607581/2016
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: valaciclovir

Procedure no.: PSUSA/00003086/201512

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5525
Send a question via our website www.ema.europa.eu/contact

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
TALAVIR 1000 mg compresse rivestite con film	not available	029498021	SIGMA-TAU INDUSTRIE FARMACEUTICHE RIUNITE S.P.A.	IT
TALAVIR 250 mg compresse rivestite con film	not available	029498045	SIGMA-TAU INDUSTRIE FARMACEUTICHE RIUNITE S.P.A.	IT
TALAVIR 500 mg compresse rivestite con film	not available	029498019	SIGMA-TAU INDUSTRIE FARMACEUTICHE RIUNITE S.P.A.	IT
TALAVIR 500 mg compresse rivestite con film	not available	029498033	SIGMA-TAU INDUSTRIE FARMACEUTICHE RIUNITE S.P.A.	IT
TALAVIR 500 mg compresse rivestite con film	not available	029498058	SIGMA-TAU INDUSTRIE FARMACEUTICHE RIUNITE S.P.A.	IT
Valaciclovir "Orion"	UK/H/2940/01/DC	44083	ORION OYJ	DK
Valaciclovir "Orion"	UK/H/2940/01/DC	10/09/2020	ORION OYJ	DK
VALACICLOVIR ACTAVIS 1000 mg apvalkotās tabletes	AT/H/0179/003	08-0350	ACTAVIS GROUP PTC EHF.	LV
VALACICLOVIR ACTAVIS 1000 mg apvalkotās tabletes	AT/H/0179/003	08-0350	ACTAVIS GROUP PTC EHF.	LV
Valaciclovir Actavis 1000 mg filmom obalené tablety	AT/H/0179/003	42/0626/08-S	ACTAVIS GROUP PTC EHF.	SK
Valaciclovir Actavis 1000 mg filmom obalené tablety	AT/H/0179/003	42/0626/08-S	ACTAVIS GROUP PTC EHF.	SK
Valaciclovir Actavis 1000 mg plėvele dengtos tabletės	AT/H/0179/003	LT/1/09/1488/033-048	ACTAVIS GROUP PTC EHF.	LT
Valaciclovir Actavis 1000 mg plėvele dengtos tabletės	AT/H/0179/003	LT/1/09/1488/033-048	ACTAVIS GROUP PTC EHF.	LT
Valaciclovir Actavis 250 mg filmom obalené tablety	AT/H/0179/001	42/0624/08-S	ACTAVIS GROUP PTC EHF.	SK
Valaciclovir Actavis 250 mg	AT/H/0179/001	42/0624/08-S	ACTAVIS GROUP PTC EHF.	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
filmom obalené tablety				
Valaciclovir Actavis 250 mg plévele dengtos tabletés	AT/H/0179/001	LT/1/09/1488/001-016	ACTAVIS GROUP PTC EHF.	LT
Valaciclovir Actavis 250 mg plévele dengtos tabletés	AT/H/0179/001	LT/1/09/1488/001-016	ACTAVIS GROUP PTC EHF.	LT
Valaciclovir Actavis, 1000 mg õhukese polümeerikattega tabletid	AT/H/0179/003	609808	ACTAVIS GROUP PTC EHF.	EE
Valaciclovir Apotex 1000 mg	AT/H/0178/001-003	BE 329226 , 329235	Apotex NV/SA	BE
Valaciclovir Apotex 250 mg	AT/H/0178/001-003	BE 329183, 329192	Apotex NV/SA	BE
Valaciclovir Orion 1000 mg filmdragerade tabletter	UK/H/2940/01/DC	13/02/1970	ORION OYJ	FI
Valaciclovir Orion 500 mg tabletti, kalvopäällysteinen	UK/H/2940/01/DC	25611	ORION OYJ	FI
Valaciclovir Sandoz 1000 mg - Filmtabletten	936.023	1-21107	SANDOZ GMBH	AT
Valaciclovir Sandoz 250 mg - Filmtabletten	942.392	1-22633	SANDOZ GMBH	AT
Valaciclovir Sandoz 500 mg - Filmtabletten	936.022	1-21105	SANDOZ GMBH	AT
VALACICLOVIR ZENTIVA 500 mg, comprimé pelliculé	not available	NL35716	LABORATOIRE GLAXOSMITHKLINE S.A.S.	FR
Valdacir 1000 mg filmsko obložene tablete	AT/H/0179/003	5363-I-1649/13	ACTAVIS GROUP PTC EHF.	SI
Valdacir 250 mg filmsko obložene tablete	AT/H/0179/001	5363-I-1647/13	ACTAVIS GROUP PTC EHF.	SI
Valtrex 1000 mg - Filmtabletten	SE/H/1041/003	1-21103	GLAXOSMITHKLINE PHARMA GMBH.	AT
Valtrex 500 mg - Filmtabletten	SE/H/1041/002	1-21007	GLAXOSMITHKLINE PHARMA GMBH.	AT
Valtrex 1.000 mg comprimidos recubiertos	SE/H/1041/003	61.241	GLAXOSMITHKLINE, 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
con película				
Valtrex 1000 mg comprimidos revestidos por película	SE/H/1041/003	2965986	LABORATORIOS WELLCOME DE PORTUGAL LIMITADA	PT
Valtrex 1000 mg filmdragerade tabletter	SE/H/1041/003	12213	GLAXOSMITHKLINE AB	SE
Valtrex 1000 mg filmdrasjerte tabletter	SE/H/1041/003	94-1772	GLAXOSMITHKLINE AS	NO
Valtrex 1000 mg επικαλυμμένα με λεπτό υμένιο δισκία	SE/H/1041/003	8916/04-02-13	THE WELLCOME FOUNDATION LTD	GR
Valtrex 250 mg comprimidos revestidos por película	SE/H/1041/001	2966083	LABORATORIOS WELLCOME DE PORTUGAL LIMITADA	PT
Valtrex 250 mg comprimidos revestidos por película	SE/H/1041/001	3131786	LABORATORIOS WELLCOME DE PORTUGAL LIMITADA	PT
Valtrex 250 mg filmdragerade tabletter	SE/H/1041/001	13714	GLAXOSMITHKLINE AB	SE
Valtrex 250 mg filmdrasjerte tabletter	SE/H/1041/001	97-2744	GLAXOSMITHKLINE AS	NO
Valtrex 250 mg filmuhúðaðar töflur	SE/H/1041/01	990226(IS)	GLAXOSMITHKLINE PHARMA A/S	IS
Valtrex 250 mg kalvopäällysteiset tabletit	SE/H/1041/001	12935	GLAXOSMITHKLINE OY	FI
Valtrex 250 mg kalvopäällysteiset tabletit	SE/H/1041/001	12935	GLAXOSMITHKLINE OY	FI
Valtrex 250 mg επικαλυμμένα με λεπτό υμένιο δισκία	SE/H/1041/001	8915/04-02-13	THE WELLCOME FOUNDATION LTD	GR
Valtrex 500 mg	SE/H/1041/002	42/0222/99-S	GLAXOSMITHKLINE SLOVAKIA S.R.O.	SK
Valtrex 500 mg apvalkotas tabletes	SE/H/1041/002	99-0877	GLAXOSMITHKLINE LATVIA SIA	LV
Valtrex 500 mg	SE/H/1041/02	4643/2012/01	THE WELLCOME FOUNDATION	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
comprimate filmate			LTD	
Valtrex 500 mg comprimate filmate	SE/H/1041/02	4643/2012/02	THE WELLCOME FOUNDATION LTD	RO
Valtrex 500 mg comprimate filmate	SE/H/1041/02	4643/2012/03	THE WELLCOME FOUNDATION LTD	RO
Valtrex 500 mg comprimate filmate	SE/H/1041/02	4643/2012/04	THE WELLCOME FOUNDATION LTD	RO
Valtrex 500 mg comprimate filmate	SE/H/1041/02	4643/2012/05	THE WELLCOME FOUNDATION LTD	RO
Valtrex 500 mg comprimate filmate	SE/H/1041/02	4643/2012/06	THE WELLCOME FOUNDATION LTD	RO
Valtrex 500 mg comprimidos recubiertos con película	SE/H/1041/002	61.240	GLAXOSMITHKLINE, S.A.	ES
Valtrex 500 mg comprimidos revestidos por película	SE/H/1041/002	2965788	LABORATORIOS WELLCOME DE PORTUGAL LIMITADA	PT
Valtrex 500 mg comprimidos revestidos por película	SE/H/1041/002	2965887	LABORATORIOS WELLCOME DE PORTUGAL LIMITADA	PT
Valtrex 500 mg comprimidos revestidos por película	SE/H/1041/002	3131885	LABORATORIOS WELLCOME DE PORTUGAL LIMITADA	PT
Valtrex 500 mg comprimidos revestidos por película	SE/H/1041/002	3872280	LABORATORIOS WELLCOME DE PORTUGAL LIMITADA	PT
Valtrex 500 mg film-coated tablets	SE/H/1041/002	MA 168/01201	THE WELLCOME FOUNDATION LTD	MT
Valtrex 500 mg film-coated tablets	SE/H/1041/002	PL 00003/0352	THE WELLCOME FOUNDATION LTD	UK
Valtrex 500 mg filmdragerade tabletter	SE/H/1041/002	12212	GLAXOSMITHKLINE AB	SE
Valtrex 500 mg filmdrasjerte tabletter	SE/H/1041/002	94-1771	GLAXOSMITHKLINE AS	NO
VALTREX 500 mg filmsko	SE/H/1041/002	H/99/01609/001	GLAXOSMITHKLINE 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
obložene tablete				
VALTREX 500 mg filmsko obložene tablete	SE/H/1041/002	H/99/01609/002	GLAXOSMITHKLINE D.O.O.	SI
VALTREX 500 mg filmsko obložene tablete	SE/H/1041/002	H/99/01609/003	GLAXOSMITHKLINE D.O.O.	SI
VALTREX 500 mg filmsko obložene tablete	SE/H/1041/002	H/99/01609/004	GLAXOSMITHKLINE D.O.O.	SI
VALTREX 500 mg filmsko obložene tablete	SE/H/1041/002	H/99/01609/005	GLAXOSMITHKLINE D.O.O.	SI
VALTREX 500 mg filmsko obložene tablete	SE/H/1041/002	H/99/01609/006	GLAXOSMITHKLINE D.O.O.	SI
Valtrex 500 mg filmuhúðaðar töflur	SE/H/1041/02	940254	GLAXOSMITHKLINE PHARMA A/S	IS
Valtrex 500 mg kalvopäällysteiset tabletit	SE/H/1041/002	11839	THE WELLCOME FOUNDATION LTD	FI
Valtrex 500 mg kalvopäällysteiset tabletit	SE/H/1041/002	11839	THE WELLCOME FOUNDATION LTD	FI
Valtrex 500 mg plėvele dengtos tabletės	SE/H/1041/002	LT/1/96/2894/001	GLAXOSMITHKLINE LIETUVA UAB	LT
Valtrex 500 mg plėvele dengtos tabletės	SE/H/1041/002	LT/1/96/2894/002	GLAXOSMITHKLINE LIETUVA UAB	LT
Valtrex 500 mg plėvele dengtos tabletės	SE/H/1041/002	LT/1/96/2894/003	GLAXOSMITHKLINE LIETUVA UAB	LT
Valtrex 500 mg plėvele dengtos tabletės	SE/H/1041/002	LT/1/96/2894/004	GLAXOSMITHKLINE LIETUVA UAB	LT
Valtrex 500 mg plėvele dengtos tabletės	SE/H/1041/002	LT/1/96/2894/005	GLAXOSMITHKLINE LIETUVA UAB	LT
Valtrex 500 mg plėvele dengtos tabletės	SE/H/1041/002	LT/1/96/2894/006	GLAXOSMITHKLINE LIETUVA UAB	LT
Valtrex 500 mg επικαλυμμένα με λεπτό υμένιο δισκία	SE/H/1041/02	16180	GLAXO GROUP LIMITED	CY
Valtrex 500 mg επικαλυμμένα με λεπτό	SE/H/1041/002	8914/04-02-13	THE WELLCOME FOUNDATION LTD	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
υμένιο δισκία				
Valtrex 500 mg, potahované tablety	SE/H/1041/002	42/384/96-C	THE WELLCOME FOUNDATION LTD	CZ
Valtrex, 500 mg õhukese polümeerikattega tabletid	SE/H/1041/002	141696	GLAXO WELLCOME LTD	EE
Valtrex, 500 mg, tabletki powlekane	SE/H/1041/02	7665	GLAXOSMITHKLINE EXPORT LTD	PL
Valtrex® 250 mg film-coated tablets	SE/H/1041/001	PL 00003/0371	THE WELLCOME FOUNDATION LTD	UK
Valtrex® 500 mg Filmtabletten	SE/H/1041/002	33325.00.00	GLAXOSMITHKLINE GMBH & CO. KG	DE
Valtrex™ 250 mg film-coated tablets	SE/H/1041/001	PA 1077/082/001	GLAXOSMITHKLINE (IRELAND) LIMITED	IE
Valtrex™ 500 mg film-coated tablets	SE/H/1041/002	PA 1077/082/002	GLAXOSMITHKLINE (IRELAND) LIMITED	IE
Zelitrex 1000 mg compresse rivestite con film	SE/H/1041/003	029503024	GLAXOSMITHKLINE S.P.A.	IT
Zelitrex 250 mg compresse rivestite con film	SE/H/1041/001	029503048	GLAXOSMITHKLINE S.P.A.	IT
Zelitrex 250 mg filmomhulde tabletten	SE/H/1041/01	RVG 21719	GLAXOSMITHKLINE B.V.	NL
Zelitrex 500 mg compresse rivestite con film	SE/H/1041/002	029503012	GLAXOSMITHKLINE S.P.A.	IT
Zelitrex 500 mg compresse rivestite con film	SE/H/1041/002	029503036	GLAXOSMITHKLINE S.P.A.	IT
Zelitrex 500 mg comprimés pelliculés	SE/H/1041/002	BE 181036	GLAXOSMITHKLINE PHARMACEUTICALS SA	BE
Zelitrex 500 mg comprimés pelliculés	SE/H/1041/002	2003 07 7472	GLAXOSMITHKLINE PHARMACEUTICALS SA	LU
Zelitrex 500 mg filmomhulde tabletten	SE/H/1041/002	BE 181036	GLAXOSMITHKLINE PHARMACEUTICALS SA	BE
Zelitrex 500 mg filmomhulde tabletten	SE/H/1041/002	2003 07 7472	GLAXOSMITHKLINE PHARMACEUTICALS SA	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
Zelitrex 500 mg filmomhulde tabletten	SE/H/1041/02	RVG 18065	GLAXOSMITHKLINE B.V.	NL
Zelitrex 500 mg Filmtabletten	SE/H/1041/002	BE 181036	GLAXOSMITHKLINE PHARMACEUTICALS SA	BE
Zelitrex 500 mg Filmtabletten	SE/H/1041/002	2003 07 7472	GLAXOSMITHKLINE PHARMACEUTICALS SA	LU
ZELITREX 500 mg, comprimé pelliculé	SE/H/1041/002	NL20459	LABORATOIRE GLAXOSMITHKLINE	FR
Zelitrex, filmovertrukne tabletter	SE/H/1041/001	19065	GLAXOSMITHKLINE PHARMA A/S	DK
Zelitrex, filmovertrukne tabletter	SE/H/1041/002	16801	GLAXOSMITHKLINE PHARMA A/S	DK
Валтрекс 500 mg филмирани таблетки	SE/H/1041/002	9700507	GLAXO GROUP LIMITED	BG