EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

11 July 2019
EMA/408177/2019
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: valaciclovir

Procedure no.: PSUSA/00003086/201812

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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	ALFASIGMA S.P.A.	IT
TALAVIR 250 mg compresse rivestite con film	not available	029498045	ALFASIGMA S.P.A.	IT
TALAVIR 500 mg compresse rivestite con film	not available	029498033	ALFASIGMA S.P.A.	IT
TALAVIR 500 mg compresse rivestite con film	not available	029498058	ALFASIGMA S.P.A.	IT
TALAVIR 500 mg compresse rivestite con film	not available	029498019	ALFASIGMA S.P.A.	IT
VALACICLOVIR ACTAVIS 1000 mg apvalkotās tabletes	AT/H/0179/003	08-0350	ACTAVIS GROUP PTC EHF.	LV
Valaciclovir Actavis 1000 mg plévele dengtos tabletés	AT/H/0179/003	LT/1/09/1488/033-050	ACTAVIS GROUP PTC EHF.	LT
Valaciclovir Actavis, 1000 mg õhukese polümeerikattega tabletid	AT/H/0179/003	609808	ACTAVIS GROUP PTC EHF.	EE
VALACICLOVIR BIOGARAN 500 mg, comprime pellicule	not available	NL35715	LABORATOIRE GLAXOSMITHKLINE	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
Valaciclovir Sandoz 1000 mg - Filmtabletten	not available	1-21107	SANDOZ GMBH	AT
Valaciclovir Sandoz 250 mg – Filmtabletten	not available	1-22633	SANDOZ GMBH	AT
Valaciclovir Sandoz 500 mg - Filmtabletten	not available	1-21105	SANDOZ GMBH	AT
VALACICLOVIR ZENTIVA 500 mg, comprime pellicule	not available	NL35716	LABORATOIRE GLAXOSMITHKLINE	FR
Valavir 500 mg kalvopäällysteiset tabletit	not available	12585	ORION OYJ	FI
Valavir 500 mg kalvopäällysteiset tabletit	not available	12585	ORION OYJ	FI
Valtrex 1000 mg - Filmtabletten	SE/H/1041/03	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 con película	SE/H/1041/03	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
Valtrex 1000 mg comprimidos revestidos por película	SE/H/1041/003	2965986	LABORATORIOS WELLCOME DE PORTUGAL LDA	PT
Valtrex 1000 mg filmdragerade tabletter	SE/H/1041/03	12213	GLAXOSMITHKLINE AB	SE
Valtrex 1000 mg filmdrasjerte tabletter	SE/H/1041/03	94-1772	GLAXOSMITHKLINE AS	NO
Valtrex 1000 mg επικαλυμμένα με λεπτό υμένιο δισκία	SE/H/1041/003	2244402	GLAXOSMITHKLINE AEBE	GR
Valtrex 250 mg comprimidos revestidos por película	SE/H/1041/001	2966083	LABORATORIOS WELLCOME DE PORTUGAL LDA	PT
Valtrex 250 mg comprimidos revestidos por película	SE/H/1041/01	3131786	LABORATORIOS WELLCOME DE PORTUGAL LDA	PT
Valtrex 250 mg film-coated tablets	SE/H/1041/001	PL 00003/0371	THE WELLCOME FOUNDATION LTD	UK
Valtrex 250 mg filmdragerade tabletter	SE/H/1041/001	12935	GLAXOSMITHKLINE OY	FI
Valtrex 250 mg filmdragerade tabletter	SE/H/1041/01	13714	GLAXOSMITHKLINE AB	SE

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
Valtrex 250 mg filmdrasjerte tabletter	SE/H/1041/001	97-2744	GLAXOSMITHKLINE AS	NO
Valtrex 250 mg filmuhúðaðar töflur	SE/H/1041/001	990226(IS)	GLAXOSMITHKLINE PHARMA A/S	IS
Valtrex 250 mg kalvopäällysteiset tabletit	SE/H/1041/001	12935	GLAXOSMITHKLINE OY	FI
Valtrex 500 mg apvalkotas tabletes	SE/H/1041/02	99-0877	GLAXOSMITHKLINE LATVIA SIA	LV
Valtrex 500 mg comprimate filmate	SE/H/1041/002	4643/2012/01	GLAXOSMITHKLINE (IRELAND) LIMITED	RO
Valtrex 500 mg comprimate filmate	SE/H/1041/002	4643/2012/02	GLAXOSMITHKLINE (IRELAND) LIMITED	RO
Valtrex 500 mg comprimate filmate	SE/H/1041/02	4643/2012/03	GLAXOSMITHKLINE (IRELAND) LIMITED	RO
Valtrex 500 mg comprimate filmate	SE/H/1041/02	4643/2012/04	GLAXOSMITHKLINE (IRELAND) LIMITED	RO
Valtrex 500 mg comprimate filmate	SE/H/1041/02	4643/2012/05	GLAXOSMITHKLINE (IRELAND) LIMITED	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
Valtrex 500 mg comprimate filmate	SE/H/1041/02	4643/2012/06	GLAXOSMITHKLINE (IRELAND) LIMITED	RO
Valtrex 500 mg comprimidos recubiertos con película	SE/H/1041/02	61.240	GLAXOSMITHKLINE, S.A.	ES
Valtrex 500 mg comprimidos revestidos por película	SE/H/1041/002	2965788	LABORATORIOS WELLCOME DE PORTUGAL LDA	PT
Valtrex 500 mg comprimidos revestidos por película	SE/H/1041/002	2965887	LABORATORIOS WELLCOME DE PORTUGAL LDA	PT
Valtrex 500 mg comprimidos revestidos por película	SE/H/1041/02	3131885	LABORATORIOS WELLCOME DE PORTUGAL LDA	PT
Valtrex 500 mg comprimidos revestidos por película	SE/H/1041/02	3872280	LABORATORIOS WELLCOME DE PORTUGAL LDA	PT
Valtrex 500 mg film-coated tablets	SE/H/1041/02	PL 00003/0352	THE WELLCOME FOUNDATION LTD	UK
Valtrex 500 mg filmdragerade tabletter	SE/H/1041/002	11839	GLAXOSMITHKLINE (IRELAND) LIMITED	FI
Valtrex 500 mg filmdragerade tabletter	SE/H/1041/02	12212	GLAXOSMITHKLINE AB	SE

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
Valtrex 500 mg filmdrasjerte tabletter	SE/H/1041/002	94-1771	GLAXOSMITHKLINE AS	NO
Valtrex 500 mg filmom obalene tablety	SE/H/1041/002	42/0222/99-S	GLAXOSMITHKLINE SLOVAKIA S.R.O.	SK
VALTREX 500 mg filmsko obložene tablete	SE/H/1041/02	H/99/01609/001	GLAXOSMITHKLINE D.O.O.	SI
VALTREX 500 mg filmsko obložene tablete	SE/H/1041/02	H/99/01609/002	GLAXOSMITHKLINE D.O.O.	SI
VALTREX 500 mg filmsko obložene tablete	SE/H/1041/02	H/99/01609/003	GLAXOSMITHKLINE D.O.O.	SI
VALTREX 500 mg filmsko obložene tablete	SE/H/1041/02	H/99/01609/004	GLAXOSMITHKLINE D.O.O.	SI
VALTREX 500 mg filmsko obložene tablete	SE/H/1041/02	H/99/01609/005	GLAXOSMITHKLINE D.O.O.	SI
VALTREX 500 mg filmsko obložene tablete	SE/H/1041/02	H/99/01609/006	GLAXOSMITHKLINE D.O.O.	SI
Valtrex 500 mg filmuhúðaðar töflur	SE/H/1041/002	940254	GLAXOSMITHKLINE PHARMA 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
Valtrex 500 mg kalvopäällysteiset tabletit	SE/H/1041/02	11839	GLAXOSMITHKLINE (IRELAND) LIMITED	FI
Valtrex 500 mg plevele dengtos tabletes	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/1041/002	16180	GLAXOSMITHKLINE (IRELAND) LIMITED	CY
Valtrex 500 mg επικαλυμμένα με λεπτό υμένιο δισκία	SE/H/1041/002	2244401	GLAXOSMITHKLINE AEBE	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
Valtrex 500 mg, potahované tablety	SE/H/1041/002	42/384/96-C	GLAXOSMITHKLINE (IRELAND) LIMITED	CZ
Valtrex, 500 mg õhukese polümeerikattega tabletid	SE/H/1041/002	141696	GLAXOSMITHKLINE (IRELAND) LIMITED	EE
Valtrex, 500 mg, tabletki powlekane	SE/H/1041/002	7665	GLAXOSMITHKLINE (IRELAND) LIMITED	PL
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/1041/001	RVG 21719	GLAXOSMITHKLINE B.V.	NL

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 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/1041/02	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

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
Валтрекс 500 mg филмирани таблетки	SE/H/1041/002	9700507	GLAXOSMITHKLINE (IRELAND) LIMITED	BG