20 October 2022
EMA/622432/2022
Human Medicines Division

List of nationally authorised medicinal products

Active substance(s): valaciclovir

Procedure No. PSUSA/00003086/202112

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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
Valaciclovir Sandoz 1000 mg - Filmtabletten	not available	1-21107	SANDOZ GMBH	AT
Valaciclovir Sandoz 500 mg - Filmtabletten	not available	1-21105	SANDOZ GMBH	AT
Valtrex 500 mg - Filmtabletten	SE/H/1041/002	1-21007	GLAXOSMITHKLINE PHARMA GMBH.	AT
Zelitrex 500 mg comprimés pelliculés	SE/H/1041/002	BE 181036	GLAXOSMITHKLINE PHARMACEUTICALS SA	BE
Zelitrex 500 mg filmomhulde tabletten	SE/H/1041/002	BE 181036	GLAXOSMITHKLINE PHARMACEUTICALS SA	BE
Zelitrex 500 mg Filmtabletten	SE/H/1041/002	BE 181036	GLAXOSMITHKLINE PHARMACEUTICALS SA	BE
Валтрекс 500 mg филмирани таблетки	SE/H/1041/002	9700507	GLAXOSMITHKLINE (IRELAND) LIMITED	BG
Valtrex 500 mg επικαλυμμένα με λεπτό υμένιο δισκία	SE/H/1041/002	16180	GLAXOSMITHKLINE (IRELAND) LIMITED	CY
Valtrex 500 mg, potahované tablety	SE/H/1041/002	42/384/96-C	GLAXOSMITHKLINE (IRELAND) LIMITED	CZ
Valtrex 500 mg Filmtabletten	SE/H/1041/002	33325.00.00	GLAXOSMITHKLINE GMBH & CO. KG	DE
Valaciclovir Actavis, 1000 mg õhukese polümeerikattega tabletid	AT/H/0179/003	609808	ACTAVIS GROUP PTC EHF.	EE
Valtrex, 500 mg õhukese polümeerikattega tabletid	SE/H/1041/002	141696	GLAXOSMITHKLINE (IRELAND) LIMITED	EE
Valtrex 500 mg comprimidos recubiertos con película	SE/H/1041/002	61.240	GLAXOSMITHKLINE, S.A.	ES
Valtrex 1.000 mg comprimidos recubiertos con película	SE/H/1041/003	61.241	GLAXOSMITHKLINE, S.A.	ES
Valavir 500 mg	not available	12585	ORION OYJ	FI

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filmdragerade tabletter				
Valavir 500 mg kalvopäällysteiset tabletit	not available	12585	ORION OYJ	FI
VALACICLOVIR BIOGARAN 500 mg, comprime pellicule	not available	NL35715	LABORATOIRE GLAXOSMITHKLINE	FR
VALACICLOVIR ZENTIVA 500 mg, comprime pellicule	not available	NL35716	LABORATOIRE GLAXOSMITHKLINE	FR
ZELITREX 500 mg, comprimé pelliculé	SE/H/1041/002	NL20459	LABORATOIRE GLAXOSMITHKLINE	FR
Valtrex 500 mg επικαλυμμένα με λεπτό υμένιο δισκία	SE/H/1041/002	2244401	GLAXOSMITHKLINE SINGLE MEMBER A.E.B.E.	GR
Valtrex 1000 mg επικαλυμμένα με λεπτό υμένιο δισκία	SE/H/1041/003	2244402	GLAXOSMITHKLINE SINGLE MEMBER A.E.B.E.	GR
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
Valtrex 250 mg filmuhúðaðar töflur	SE/H/1041/001	990226(IS)	GLAXOSMITHKLINE PHARMA A/S	IS
Valtrex 500 mg filmuhúðaðar töflur	SE/H/1041/002	940254	GLAXOSMITHKLINE PHARMA A/S	IS
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 1000 mg compresse rivestite con film	not available	029498021	ALFASIGMA S.P.A.	IT
TALAVIR 500 mg compresse rivestite con film	not available	029498019	ALFASIGMA S.P.A.	IT

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Zelitrex 250 mg compresse rivestite con film	SE/H/1041/001	029503048	GLAXOSMITHKLINE S.P.A.	IT
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 1000 mg compresse rivestite con film	SE/H/1041/003	029503024	GLAXOSMITHKLINE S.P.A.	IT
Valaciclovir Actavis 1000 mg plévele dengtos tabletés	AT/H/0179/003	LT/1/09/1488/034	ACTAVIS GROUP PTC EHF.	LT
Valaciclovir Actavis 1000 mg plévele dengtos tabletés	AT/H/0179/003	LT/1/09/1488/035	ACTAVIS GROUP PTC EHF.	LT
Valaciclovir Actavis 1000 mg plévele dengtos tabletés	AT/H/0179/003	LT/1/09/1488/037	ACTAVIS GROUP PTC EHF.	LT
Valaciclovir Actavis 1000 mg plévele dengtos tabletés	AT/H/0179/003	LT/1/09/1488/039	ACTAVIS GROUP PTC EHF.	LT
Valaciclovir Actavis 1000 mg plévele dengtos tabletés	AT/H/0179/003	LT/1/09/1488/036	ACTAVIS GROUP PTC EHF.	LT
Valaciclovir Actavis 1000 mg plévele dengtos tabletés	AT/H/0179/003	LT/1/09/1488/038	ACTAVIS GROUP PTC EHF.	LT
Valaciclovir Actavis 1000 mg plévele dengtos tabletés	AT/H/0179/003	LT/1/09/1488/040	ACTAVIS GROUP PTC EHF.	LT
Valaciclovir Actavis 1000 mg plévele dengtos tabletés	AT/H/0179/003	LT/1/09/1488/042	ACTAVIS GROUP PTC EHF.	LT
Valaciclovir Actavis 1000 mg plévele dengtos	AT/H/0179/003	LT/1/09/1488/041	ACTAVIS GROUP PTC EHF.	LT

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tabletés				
Valaciclovir Actavis 1000 mg plėvele dengtos tabletės	AT/H/0179/003	LT/1/09/1488/043	ACTAVIS GROUP PTC EHF.	LT
Valaciclovir Actavis 1000 mg plėvele dengtos tabletės	AT/H/0179/003	LT/1/09/1488/044	ACTAVIS GROUP PTC EHF.	LT
Valaciclovir Actavis 1000 mg plėvele dengtos tabletės	AT/H/0179/003	LT/1/09/1488/045	ACTAVIS GROUP PTC EHF.	LT
Valaciclovir Actavis 1000 mg plėvele dengtos tabletės	AT/H/0179/003	LT/1/09/1488/046	ACTAVIS GROUP PTC EHF.	LT
Valaciclovir Actavis 1000 mg plėvele dengtos tabletės	AT/H/0179/003	LT/1/09/1488/047	ACTAVIS GROUP PTC EHF.	LT
Valaciclovir Actavis 1000 mg plėvele dengtos tabletės	AT/H/0179/003	LT/1/09/1488/048	ACTAVIS GROUP PTC EHF.	LT
Valaciclovir Actavis 1000 mg plėvele dengtos tabletės	AT/H/0179/003	LT/1/09/1488/050	ACTAVIS GROUP PTC EHF.	LT
Valaciclovir Actavis 1000 mg plėvele dengtos tabletės	AT/H/0179/003	LT/1/09/1488/049	ACTAVIS GROUP PTC EHF.	LT
Valaciclovir Actavis 1000 mg plėvele dengtos tabletės	AT/H/0179/003	LT/1/09/1488/033	ACTAVIS GROUP PTC EHF.	LT
Valtrex 500 mg plevele dengtos tabletes	SE/H/1041/002	LT/1/96/2894/001	GLAXOSMITHKLINE TRADING SERVICES LIMITED	LT
Valtrex 500 mg plevele dengtos tabletes	SE/H/1041/002	LT/1/96/2894/002	GLAXOSMITHKLINE TRADING SERVICES LIMITED	LT
Valtrex 500 mg plevele dengtos tabletes	SE/H/1041/002	LT/1/96/2894/003	GLAXOSMITHKLINE TRADING SERVICES LIMITED	LT
Valtrex 500 mg plevele	SE/H/1041/002	LT/1/96/2894/004	GLAXOSMITHKLINE	LT

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dengtos tabletes			TRADING SERVICES LIMITED	
Valtrex 500 mg plevele dengtos tabletes	SE/H/1041/002	LT/1/96/2894/005	GLAXOSMITHKLINE TRADING SERVICES LIMITED	LT
Valtrex 500 mg plevele dengtos tabletes	SE/H/1041/002	LT/1/96/2894/006	GLAXOSMITHKLINE TRADING SERVICES LIMITED	LT
Zelitrex 500 mg comprimés pelliculés	SE/H/1041/002	2003 07 7472	GLAXOSMITHKLINE PHARMACEUTICALS SA	LU
Zelitrex 500 mg Filmtabletten	SE/H/1041/002	2003 07 7472	GLAXOSMITHKLINE PHARMACEUTICALS SA	LU
VALACICLOVIR ACTAVIS 1000 mg apvalkotās tabletes	AT/H/0179/003	08-0350	ACTAVIS GROUP PTC EHF.	LV
Valtrex 500 mg apvalkotās tabletes	SE/H/1041/002	99-0877	GLAXOSMITHKLINE TRADING SERVICES LIMITED	LV
Zelitrex 250 mg filmomhulde tabletten	SE/H/1041/001	RVG 21719	GLAXOSMITHKLINE B.V.	NL
Zelitrex 500 mg filmomhulde tabletten	SE/H/1041/002	RVG 18065	GLAXOSMITHKLINE B.V.	NL
Valtrex 250 mg filmdrasjerte tabletter	SE/H/1041/001	97-2744	GLAXOSMITHKLINE AS	NO
Valtrex 500 mg filmdrasjerte tabletter	SE/H/1041/002	94-1771	GLAXOSMITHKLINE AS	NO
Valtrex 1000 mg filmdrasjerte tabletter	SE/H/1041/03	94-1772	GLAXOSMITHKLINE AS	NO
Valtrex, 500 mg, tabletki powlekane	SE/H/1041/002	7665	GLAXOSMITHKLINE (IRELAND) LIMITED	PL
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	SE/H/1041/02	3131885	LABORATORIOS WELLCOME DE PORTUGAL LDA	PT

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por película				
Valtrex 500 mg comprimidos revestidos por película	SE/H/1041/02	3872280	LABORATORIOS WELLCOME DE PORTUGAL LDA	PT
Valtrex 1000 mg comprimidos revestidos por película	SE/H/1041/003	2965986	LABORATORIOS WELLCOME DE PORTUGAL LDA	PT
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 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
Valtrex 500 mg comprimate filmate	SE/H/1041/02	4643/2012/06	GLAXOSMITHKLINE (IRELAND) LIMITED	RO
Valtrex 250 mg filmdragerade tabletter	SE/H/1041/001	13714	GLAXOSMITHKLINE AB	SE
Valtrex 500 mg filmdragerade tabletter	SE/H/1041/002	12212	GLAXOSMITHKLINE AB	SE
Valtrex 1000 mg filmdragerade tabletter	SE/H/1041/003	12213	GLAXOSMITHKLINE AB	SE
VALTREX 500 mg filmsko obložene tablete	SE/H/1041/02	H/99/01609/001	GLAXOSMITHKLINE TRADING SERVICES LIMITED	SI
VALTREX 500 mg filmsko obložene tablete	SE/H/1041/02	H/99/01609/002	GLAXOSMITHKLINE TRADING SERVICES LIMITED	SI
VALTREX 500 mg filmsko	SE/H/1041/02	H/99/01609/003	GLAXOSMITHKLINE	SI

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obložene tablete			TRADING SERVICES LIMITED	
VALTREX 500 mg filmsko obložene tablete	SE/H/1041/02	H/99/01609/004	GLAXOSMITHKLINE TRADING SERVICES LIMITED	SI
VALTREX 500 mg filmsko obložene tablete	SE/H/1041/02	H/99/01609/005	GLAXOSMITHKLINE TRADING SERVICES LIMITED	SI
VALTREX 500 mg filmsko obložene tablete	SE/H/1041/02	H/99/01609/006	GLAXOSMITHKLINE TRADING SERVICES LIMITED	SI
Valtrex 500 mg filmom obalene tablety	SE/H/1041/002	42/0222/99-S	GLAXOSMITHKLINE TRADING SERVICES LIMITED	SK
Valtrex 250 mg film-coated tablets	SE/H/1041/001	PL 00003/0371	THE WELLCOME FOUNDATION LTD	XI
Valtrex 500 mg film-coated tablets	SE/H/1041/002	PL 00003/0352	THE WELLCOME FOUNDATION LTD	XI