



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

1 December 2016
EMA/750653/2016
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: valganciclovir

Procedure no.: PSUSA/00003089/201603



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
RoValcyte 450 mg, comprimé pelliculé	NL/H/323/001	34009 360 136 1 2	ROCHE	FR
RoValcyte 50 mg/ml pó para solução oral	NL/H/0323/002	5105713	ROCHE FARMACÊUTICA QUÍMICA, LDA.	PT
RoValcyte 50 mg/ml, poudre pour solution buvable	NL/H/0323/001	34009 386 733 7 1	ROCHE	FR
RoValcyte, 450 mg, comprimidos revestidos por película	NL/H/323/001	3958287	ROCHE FARMACÊUTICA QUÍMICA, LDA.	PT
Valcyte ® 450 mg επικαλυμμένα με λεπτό υμένιο δισκία	NL/H/0323/001	20089	G.A. STAMATIS & CO LTD	CY
Valcyte ® 450 mg επικαλυμμένα με λεπτό υμένιο δισκία	NL/H/0323/001	73713 /04.09.2014	ROCHE (HELLAS) SA	GR
VALCYTE ® 50 mg/ml κόνις για πόσιμο διάλυμα	NL/H/0323/002	20549	G.A. STAMATIS & CO LTD	CY
VALCYTE ® 50 mg/ml κόνις για πόσιμο διάλυμα	NL/H/0323/002	73714 /04.09.2014	ROCHE (HELLAS) SA	GR
Valcyte 450 mg - Filmtabletten	NL/H/0323/001	1-24510	ROCHE AUSTRIA GMBH	AT
Valcyte 450 mg - Filmtabletten	NL/H/0323/001	1-24510	ROCHE AUSTRIA GMBH	LI
Valcyte 450 mg apvalkotās tabletes	NL/H/0323/001	05-0128	ROCHE LATVIJA SIA	LV
Valcyte 450 mg compresse rivestite con film	NL/H/0323/001	035739010	ROCHE S.P.A.	IT
Valcyte 450 mg comprimate filmate	NL/H/0323/001	6279/2014/01	ROCHE ROMANIA SRL	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
Valcyte 450 mg comprimés pelliculés	NL/H/0323/001	BE236941	N.V. ROCHE S.A.	BE
Valcyte 450 mg comprimés pelliculés	NL/H/0323/001	2009070439	N.V. ROCHE S.A.	LU
Valcyte 450 mg comprimidos recubiertos con película	NL/H/0323/001	64.829	ROCHE FARMA, S.A.	ES
Valcyte 450 mg Film-coated Tablets	NL/H/323/001	PA 50/150/1	ROCHE PRODUCTS LTD	IE
Valcyte 450 mg Film-coated Tablets	NL/H/0323/001	MA060/01501	ROCHE PRODUCTS LTD	MT
Valcyte 450 mg film-coated tablets	NL/H/0323/001	PL00031/0599	ROCHE PRODUCTS LTD	UK
Valcyte 450 mg filmdragerade tabletter	NL/H/323/01	17019	ROCHE OY	FI
Valcyte 450 mg filmdragerade tabletter	NL/H/0323/001	18053	ROCHE AB	SE
Valcyte 450 mg filmom obalené tablety	NL/H/0323/001	42/0131/05-S	ROCHE SLOVENSKO S.R.O.	SK
Valcyte 450 mg filmom obložene tablete	NL/H/0323/001	UP/I-530-09/13-01/49	ROCHE D.O.O.	HR
Valcyte 450 mg filmomhulde tabletten	NL/H/0323/001	BE236941	N.V. ROCHE S.A.	BE
Valcyte 450 mg filmomhulde tabletten	NL/H/0323/001	RVG25992	ROCHE NEDERLAND B.V.	NL
Valcyte 450 mg filmsko obložene tablete	NL/H/0323/001	H/14/01593/001	ROCHE FARMACEVTSKA DRUŽBA D.O.O.	SI
Valcyte 450 mg filmtablettá	NL/H/0323/001	OGYI-T-9016/01	ROCHE (MAGYARORSZÁG) KFT	HU

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
Valcyte 450 mg Filmtabletten	NL/H/323/01	BE236941	N.V. ROCHE S.A.	BE
Valcyte 450 mg Filmtabletten	NL/H/0323/001	2009070439	N.V. ROCHE S.A.	LU
Valcyte 450 mg filmuhúðaðar töflur	NL/H/0323/001	IS/1/02/007/01	ROCHE A/S	IS
Valcyte 450 mg plėvele dengtos tabletės	NL/H/0323/001	LT/1/05/0386/001	UAB "ROCHE LIETUVA"	LT
Valcyte 450 mg potahované tablety	NL/H/0323/001	42/122/03-C	ROCHE S.R.O.	CZ
Valcyte 450 mg tabletter, filmdrasjerte	NL/H/0323/001	01-11894	ROCHE NORGE AS, NORWAY	NO
Valcyte 450 mg tabletti, kalvopäällysteinen	NL/H/0323/001	17019	ROCHE OY	FI
Valcyte 50 mg/ml - Pulver zur Herstellung einer Lösung zum Einnehmen	NL/H/0323/002	1-27549	ROCHE AUSTRIA GMBH	AT
Valcyte 50 mg/ml - Pulver zur Herstellung einer Lösung zum Einnehmen	NL/H/0323/002	1-27549	ROCHE AUSTRIA GMBH	LI
Valcyte 50 mg/ml jauhe oraalliuosta varten	NL/H/0323/002	22935	ROCHE OY	FI
Valcyte 50 mg/ml milteliai geriamajam tirpalui	NL/H/0323/002	LT/1/08/1131/001	UAB "ROCHE LIETUVA"	LT
Valcyte 50 mg/ml mixtúrduft, lausn	NL/H/0323/002	IS/1/07/009/01	ROCHE A/S	IS
Valcyte 50 mg/ml poeder voor drank	NL/H/0323/002	BE314912	N.V. ROCHE S.A.	BE

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Valcyte 50 mg/ml polvere per soluzione orale	NL/H/0323/002	035739022	ROCHE S.P.A.	IT
Valcyte 50 mg/ml polvo para solución oral	NL/H/0323/002	69.760	ROCHE FARMA, S.A.	ES
Valcyte 50 mg/ml por belsőleges oldathoz	NL/H/0323/002	OGYI-T-9016/02	ROCHE (MAGYARORSZÁG) KFT	HU
Valcyte 50 mg/ml poudre pour solution buvable	NL/H/0323/002	BE314912	N.V. ROCHE S.A.	BE
Valcyte 50 mg/ml poudre pour solution buvable	NL/H/0323/002	2008060003	N.V. ROCHE S.A.	LU
Valcyte 50 mg/ml Powder for Oral Solution	NL/H/0323/002	PA 50/150/2	ROCHE PRODUCTS LTD	IE
Valcyte 50 mg/ml powder for oral solution	NL/H/0323/002	MA060/01502	ROCHE PRODUCTS LTD	MT
Valcyte 50 mg/ml Powder for oral solution	NL/H/0323/002	PL00031/0829	ROCHE PRODUCTS LTD	UK
Valcyte 50 mg/ml prašak za oralnu otopinu	NL/H/0323/002	UP/I-530-09/13-01/48	ROCHE D.O.O.	HR
Valcyte 50 mg/ml prašek za peroralno raztopino	NL/H/0323/002	H/14/01593/002	ROCHE FARMACEVTSKA DRUŽBA D.O.O.	SI
Valcyte 50 mg/ml prášok na perorálny roztok	NL/H/0323/002	42/0177/08-S	ROCHE SLOVENSKO S.R.O.	SK
Valcyte 50 mg/ml pulbere pentru soluție orală	NL/H/0323/002	6586/2014/01	ROCHE ROMANIA SRL	RO
Valcyte 50 mg/ml pulver til mikstur, oppløsning	NL/H/0323/002	13-9715	ROCHE NORGE AS, NORWAY	NO
Valcyte 50 mg/ml pulver till oral lösning	NL/H/323/02	22935	ROCHE OY	FI

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Valcyte 50 mg/ml pulver till oral lösning	NL/H/0323/002	24802	ROCHE AB	SE
Valcyte 50 mg/ml Pulver zur Herstellung einer Lösung zum Einnehmen	NL/H/323/02	BE314912	N.V. ROCHE S.A.	BE
VALCYTE 50 mg/ml Pulver zur Herstellung einer Lösung zum Einnehmen	NL/H/0323/002	2008060003	N.V. ROCHE S.A.	LU
Valcyte 50 mg/ml pulveris iekšķīgi lietojama šķīduma pagatavošanai	NL/H/0323/002	08-0052	ROCHE LATVIJA SIA	LV
Valcyte 50 mg/ml, poeder voor drank	NL/H/0323/002	RVG 34730	ROCHE NEDERLAND B.V.	NL
Valcyte 50 mg/ml, prášek pro perorální roztok	NL/H/0323/002	42/302/08-C	ROCHE S.R.O.	CZ
Valcyte, 450 mg õhukese polümeerikattega tabletid	NL/H/0323/001	408303	ROCHE EESTI OÜ	EE
Valcyte, 450 mg, tabletki powlekane	NL/H/0323/001	15878	ROCHE POLSKA SP.O.O.	PL
VALCYTE, 50 mg/ml suukaudse lahuse pulber	NL/H/0323/002	588708	ROCHE EESTI OÜ	EE
Valcyte, 50 mg/ml, proszek do sporządzania roztworu doustnego	NL/H/0323/002	22066	ROCHE POLSKA SP.O.O.	PL
Valcyte, filmovertukne tabletter	NL/H/0323/001	33226	ROCHE A/S	DK
Valcyte, pulver til oral opløsning	NL/H/0323/002	40361	ROCHE A/S	DK
Valcyte® 450 mg Filmtabletten	NL/H/0323/001	53452.00.00	ROCHE PHARMA AG	DE

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Valcyte® 50 mg/ml Pulver zur Herstellung einer Lösung zum Einnehmen	NL/H/0323/002	68145.00.00	ROCHE PHARMA AG	DE
Валцит 450 mg филмирани таблетки	NL/H/0323/001	20040580	ROCHE BULGARIA EOOD	BG
ВАЛЦИТ 50 mg/ml прах за перорален разтвор	NL/H/0323/002	20140198	ROCHE BULGARIA EOOD	BG