



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

9 February 2017
EMA/112843/2017
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: ganciclovir

Procedure no.: PSUSA/00001516/201606



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
Cymevene 500 mg poudre pour solution à diluer pour perfusion	NL/H/3775/001	BE143157	N.V. ROCHE S.A.	BE
Cymevene 500 mg poeder voor concentraat voor oplossing voor infusie	NL/H/3775/001	BE143157	N.V. ROCHE S.A.	BE
Cymevene Pulver für ein Konzentrat zur Herstellung einer Infusionslösung	NL/H/3775/001	BE143157	N.V. ROCHE S.A.	BE
Cymevene 500 mg pulver till infusionsvätska, lösning	NL/H/3775/001	10049	ROCHE OY	FI
Симевен 500 mg прах за инфузионен разтвор	not available	20010180	ROCHE BULGARIA EOOD	BG
Citovirax 500 mg polvere per concentrato per soluzione per infusione	NL/H/3775/001	032837015	ROCHE S.P.A.	IT
Cymevene Pulver für ein Konzentrat zur Herstellung einer Infusionslösung	NL/H/3775/001	0178/04048212	N.V. ROCHE S.A.	LU
VIRGAN 1,5 mg/g gel oftálmico	FR/H/0264/001	67075	LABORATOIRES THEA	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
VIRGAN 1,5 mg/g, gel ophtalmique	not available	339512-8	LABORATOIRES THEA	FR
VIRGAN eye gel	not available	PL 20162/0006	LABORATOIRES THEA	UK
Virgan Gele Oftálmico 1,5 mg/g	not available	3549680	LABORATOIRES THEA	PT
VIRGAN 1,5 mg/g oční gel	FR/H/0264/001	64/365/05-C	LABORATOIRES THEA	CZ
Cymevene 500 mg/vial κόινις για διάλυμα προς έγχυση	NL/H/3775/001	74045/13.10.2014	ROCHE (HELLAS) SA	GR
VIRGAN 1,5 mg/g Augengel	FR/H/0264/001	61789.00.00	LABORATOIRES THEA	DE
VIRGAN, 1,5 mg/g, žel do oczu	FR/H/0264/001	11808	LABORATOIRES THEA	PL
Cymevene 500 mg polvo para solución para perfusion	NL/H/3775/001	58.266	ROCHE FARMA, S.A.	ES
Cymevene 500 mg milteliai infuzinio tirpalo koncentratui	NL/H/3775/001	LT/1/96/2511/001	UAB "ROCHE LIETUVA"	LT

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Cymevene® 500 mg infuusiokuiva-aine, liuosta varten	NL/H/3775/001	10049	ROCHE OY	FI
Cymevene infusioonilahuse kontsentraadi pulber	NL/H/3775/001	142696	ROCHE EESTI OÜ	EE
Cymevan 500 mg poudre pour solution à diluer pour perfusion	NL/H/3775/001	34009 347 804 4 8	ROCHE	FR
Cymevene 500 mg powder for concentrate for solution for infusion	NL/H/3775/001	PA 50/125/2	ROCHE PRODUCTS LTD	IE
Cymevene® 500 mg powder for concentrate for solution for infusion	NL/H/3775/001	PL 0031/0465	ROCHE PRODUCTS LTD	UK
Cymeven® i.v. 500 mg Pulver für ein Konzentrat zur Herstellung einer Infusionslösung	NL/H/003775	14837.00.00	ROCHE PHARMA AG	DE
Cymevene, 500 mg, pulver till infusionsvätska, lösning	NL/H/3775/001	10934	ROCHE AB	SE
Cymevene 500 mg por oldatos infúzióhoz való koncentrátumhoz	NL/H/3775/001	OGYI-T-1491/01	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
Cymevene 500 mg prášek pro koncentrát pro infuzní roztok	NL/H/3775/001	42/138/91-C	ROCHE S.R.O.	CZ
Cymevene 500 mg	NL/H/3775/001	42/0138/91-C/S	ROCHE SLOVENSKO S.R.O.	SK
Cymevene 500 mg poeder voor concentraat voor oplossing voor infusie	NL/H/3775/001	RVG 13007	ROCHE NEDERLAND B.V.	NL
Cymevene 500 mg poudre pour solution à diluer pour perfusion	NL/H/3775/001	0178/04048212	N.V. ROCHE S.A.	LU
VIRGAN 1,5 mg/g gel oftalmic	not available	7775/2006/01	LABORATOIRES THEA	RO
Cymevene "Roche" 500 mg - Trockensubstanz zur Infusionsbereitung	NL/H/3775/001	1-19235	ROCHE AUSTRIA GMBH	AT
VIRGAN 1.5 mg/g gel oftalmico	FR/H/0264/001	037145012/M	LABORATOIRES THEA	IT
Cymevene 500 mg pulver til infusjonsvæske, oppløsning	NL/H/3775/001	7417	F. HOFFMANN-LA ROCHE AG	NO
Cymevene, pulver til infusionsvæske, opløsning	NL/H/3775/001	13137	ROCHE A/S	DK

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Cymevene 500 mg pó para concentrado para solução para perfusão	NL/H/3775/001	8766709	ROCHE FARMACÊUTICA QUÍMICA, LDA.	PT
Cymevene 500 mg pó para concentrado para solução para perfusão	NL/H/3775/001	8766717	ROCHE FARMACÊUTICA QUÍMICA, LDA.	PT
Cymevene 500 mg pulbere pentru concentrat pentru soluție perfuzabilă	NL/H/3775/001	7024/2014/01	ROCHE ROMANIA SRL	RO
Cymevene, 500 mg, proszek do sporządzania koncentratu roztworu do infuzji	NL/H/3775/001	R/1898	ROCHE POLSKA SP.O.O.	PL
Cymevene	NL/H/3775/001	PL 70204 (IS)	ROCHE A/S	IS
Virgan 1,50 mg/g gel ophtalmique	not available	BE204145	THEA PHARMA	BE
VIRGAN 1,50 mg/g oogel	not available	BE204145	THEA PHARMA	BE
VIRGAN 1,5 mg/g οφθαλμική γέλη	FR/H/0264/001	1596/11-1-2006	LABORATOIRES THEA	GR
Cymevene 500 mg prašak za koncentrat za otopinu za infuziju	NL/H/3775/001	HR-H-230718931	ROCHE D.O.O.	HR

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VIRGAN 1,5 mg/g, gel ophtalmique	FR/H/0264/001	1536/06060036	LABORATOIRES THEA	LU
Virgan 1,5 mg/g szemgél	FR/H/0264/001	OGYI-T 20035/01	LABORATOIRES THEA	HU
VIRGAN 1,5 mg/g gel oftálmico	FR/H/0264/001	67075	LABORATOIRES THEA	ES
VIRGAN 1,5 mg/g, gel ophtalmique	not available	339512-8	LABORATOIRES THEA	FR
VIRGAN eye gel	not available	PL 20162/0006	LABORATOIRES THEA	UK
Virgan Gele Oftálmico 1,5 mg/g	not available	3549680	LABORATOIRES THEA	PT
VIRGAN 1,5 mg/g oční gel	FR/H/0264/001	64/365/05-C	LABORATOIRES THEA	CZ
VIRGAN 1,5 mg/g Augengel	FR/H/0264/001	61789.00.00	LABORATOIRES THEA	DE
VIRGAN, 1,5 mg/g, żel do oczu	FR/H/0264/001	11808	LABORATOIRES THEA	PL

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
VIRGAN 1,5 mg/g gel oftalmic	not available	7775/2006/01	LABORATOIRES THEA	RO
VIRGAN 1.5 mg/g gel oftalmico	FR/H/0264/001	037145012/M	LABORATOIRES THEA	IT
Virgan 1,50 mg/g gel ophtalmique	not available	BE204145	THEA PHARMA	BE
VIRGAN 1,50 mg/g ooggel	not available	BE204145	THEA PHARMA	BE
VIRGAN 1,5 mg/g οφθαλμική γέλη	FR/H/0264/001	1596/11-1-2006	LABORATOIRES THEA	GR
VIRGAN 1,5 mg/g, gel ophtalmique	FR/H/0264/001	1536/06060036	LABORATOIRES THEA	LU
Virgan 1,5 mg/g szemgél	FR/H/0264/001	OGYI-T 20035/01	LABORATOIRES THEA	HU