



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

13 June 2019
EMA/369093/2019
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: didanosine

Procedure no.: PSUSA/00001054/201810

Official address Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us

Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

An agency of the European Union



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
Videx 250 mg gastro-resistant hard capsules	FR/H/0034/014	PA 0002/057/018	BRISTOL-MYERS SQUIBB PHARMACEUTICALS UNLIMITED COMPANY	IE
Videx 400 mg gastro-resistant hard capsules	FR/H/0034/015	PA 0002/057/019	BRISTOL-MYERS SQUIBB PHARMACEUTICALS UNLIMITED COMPANY	IE
Videx 200 mg gastro-resistant hard capsules	FR/H/0034/013	PA 0002/057/017	BRISTOL-MYERS SQUIBB PHARMACEUTICALS UNLIMITED COMPANY	IE
Videx 125 mg gastro-resistant hard capsules	FR/H/0034/012	PA 0002/057/016	BRISTOL-MYERS SQUIBB PHARMACEUTICALS UNLIMITED COMPANY	IE
Videx 250 mg gastro-resistant hard capsules	FR/H/0034/014	PL 11184/0085	BRISTOL-MYERS SQUIBB PHARMACEUTICALS LIMITED	UK
Videx 200 mg gastro-resistant hard capsules	FR/H/0034/013	PL 11184/0084	BRISTOL-MYERS SQUIBB PHARMACEUTICALS LIMITED	UK
Videx 400 mg gastro-resistant hard capsules	FR/H/0034/015	PL 11184/0086	BRISTOL-MYERS SQUIBB PHARMACEUTICALS LIMITED	UK
Videx 125 mg gastro-resistant hard capsules	FR/H/0034/012	PL 11184/0083	BRISTOL-MYERS SQUIBB PHARMACEUTICALS LIMITED	UK
Videx 250 mg - magensaftresistente Hartkapseln	FR/H/0034/014	1-23 828	BRISTOL-MYERS SQUIBB GESMBH	AT

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
Videx 400 mg - magensaftresistente Hartkapseln	FR/H/0034/015	1-23 829	BRISTOL-MYERS SQUIBB GESMBH	AT
VIDEX 400 mg cápsulas duras gastrorresistentes	FR/H/0034/015	63.303	BRISTOL-MYERS SQUIBB SA	ES
VIDEX 250 mg cápsulas duras gastrorresistentes	FR/H/0034/014	63.305	BRISTOL-MYERS SQUIBB SA	ES
VIDEX 200 mg cápsulas duras gastrorresistentes	FR/H/0034/013	63.304	BRISTOL-MYERS SQUIBB SA	ES
VIDEX 125 mg cápsulas duras gastrorresistentes	FR/H/0034/012	63.302	BRISTOL-MYERS SQUIBB SA	ES
Videx d.d.l 2g poudre pour solution buvable	FR/H/0034/009	2006028437-0178141	BRISTOL-MYERS SQUIBB BELGIUM S.A.	LU
Videx 2 g, poeder voor drank	FR/H/0034/009	RVG 30023	BRISTOL-MYERS SQUIBB B.V.	NL
VIDEX® 400 mg magensaftresistente Hartkapseln	FR/H/0034/015	49487.03.00	BRISTOL-MYERS SQUIBB GMBH & CO. KGAA	DE
VIDEX Pulver-2g Pulver zur Herstellung einer Lösung zum Einnehmen	FR/H/0034/009	27082.00.00	BRISTOL-MYERS SQUIBB GMBH & CO. KGAA	DE

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
VIDEX® 125 mg magensaftresistente Hartkapseln	FR/H/0034/012	49487.00.00	BRISTOL-MYERS SQUIBB GMBH & CO. KGAA	DE
VIDEX® 200 mg magensaftresistente Hartkapseln	FR/H/0034/013	49487.01.00	BRISTOL-MYERS SQUIBB GMBH & CO. KGAA	DE
VIDEX® 250 mg magensaftresistente Hartkapseln	FR/H/0034/014	49487.02.00	BRISTOL-MYERS SQUIBB GMBH & CO. KGAA	DE
Videx 200 mg capsule rigide gastroresistenti	FR/H/0034/014	028341170	BRISTOL-MYERS SQUIBB S.R.L.	IT
Videx 400 mg capsule rigide gastroresistenti	FR/H/0034/015	028341194	BRISTOL-MYERS SQUIBB S.R.L.	IT
Videx 250 mg capsule rigide gastroresistenti	FR/H/0034/014	028341182	BRISTOL-MYERS SQUIBB S.R.L.	IT
Videx 125 mg capsule rigide gastroresistenti	FR/H/0034/012	028341168	BRISTOL-MYERS SQUIBB S.R.L.	IT
Videx 2 g polvere per soluzione orale	FR/H/0034/009	028341131	BRISTOL-MYERS SQUIBB S.R.L.	IT
VIDEX ® EC 250 mg γαστροανθεκτικά καψάκια, σκληρά	FR/H/0034/014	66966/17-10-2008	BRISTOL-MYERS SQUIBB A.E.	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
VIDEX® EC 400 mg γαστροανθεκτικά καψάκια, σκληρά	FR/H/0034/015	66967/17-10-2008	BRISTOL-MYERS SQUIBB A.E.	GR
Videx d.d.I 2g poudre pour solution buvable	FR/H/0034/009	BE162373	BRISTOL-MYERS SQUIBB BELGIUM S.A.	BE
Videx EC, 125 mg, cápsulas gastroresistentes	FR/H/0034/012	3332681	BRISTOL-MYERS SQUIBB FARMACÉUTICA PORTUGUESA, SA	PT
Videx EC 250 mg cápsulas gastroresistentes	FR/H/0034/014	3332889	BRISTOL-MYERS SQUIBB FARMACÉUTICA PORTUGUESA, SA	PT
Videx EC 400 mg cápsulas gastroresistentes	FR/H/0034/015	3332988	BRISTOL-MYERS SQUIBB FARMACÉUTICA PORTUGUESA, SA	PT
VIDEX 125 mg, gélules gastro-résistantes	FR/H/0034/012	34009 353 742 7 1	BRISTOL-MYERS SQUIBB	FR
VIDEX 200 mg, gélules gastro-résistantes	FR/H/0034/013	34009 353 743 3 2	BRISTOL-MYERS SQUIBB	FR
VIDEX 250 mg, gélules gastro-résistantes	FR/H/0034/014	34009 353 745 6 1	BRISTOL-MYERS SQUIBB	FR
VIDEX 400 mg, gélules gastro-résistantes	FR/H/0034/015	34009 353 727 8 9	BRISTOL-MYERS SQUIBB	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
VIDEX 100 mg, comprimés à croquer ou dispersibles	FR/H/0034/003	34009 343 735 8 9	BRISTOL-MYERS SQUIBB	FR
VIDEX 150 mg, comprimés à croquer ou dispersibles	FR/H/0034/004	34009 343 736 4 0	BRISTOL-MYERS SQUIBB	FR
VIDEX 25 mg, comprimés à croquer ou dispersibles	FR/H/0034/001	34009 343 708 0 9	BRISTOL-MYERS SQUIBB	FR
VIDEX 50 mg, comprimés à croquer ou dispersibles	FR/H/0034/002	34009 343 709 7 7	BRISTOL-MYERS SQUIBB	FR
VIDEX 2 g, poudre pour solution buvable en flacon	FR/H/0034/009	34009 367 415 3 9	BRISTOL-MYERS SQUIBB	FR