28 September 2017
EMA/639167/2017
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: zanamivir

Procedure no.: PSUSA/00003141/201701

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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
Relenza	SE/H/0180/001	30685	GLAXOSMITHKLINE PHARMA A/S	DK
Relenza 5 mg pulbere unidoză de inhalat	not available	537/2008/01	GLAXO GROUP LIMITED	RO
Relenza 5 mg pulbere unidoză de inhalat	not available	537/2008/02	GLAXO GROUP LIMITED	RO
Relenza 5 mg pulbere unidoză de inhalat	not available	537/2008/01	GLAXO GROUP LIMITED	RO
Relenza 5 mg pulbere unidoză de inhalat	not available	537/2008/02	GLAXO GROUP LIMITED	RO
Relenza 5 mg/ deva, dozets inhalacijas pulveris	SE/H/0180/001	07-0088	GLAXOSMITHKLINE LATVIA SIA	LV
Relenza 5 mg/adag, adagolt inhalációs por	SE/H/0180/001	OGYI-T-20325/01	GLAXOSMITHKLINE KFT.	HU
Relenza 5 mg/annos inhalaatiojauhe, annosteltu	SE/H/0180/001	13990	GLAXOSMITHKLINE OY	FI
Relenza 5 mg/davka upraveny inhalacny prasok	SE/H/0180/001	42/0084/07-S	GLAXOSMITHKLINE SLOVAKIA S.R.O.	SK
Relenza 5 mg/dos, inhalationspulver, avdelad dos	SE/H/0180/001	13990	GLAXOSMITHKLINE OY	FI

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
Relenza 5 mg/dos, inhalationspulver, avdelad dos	SE/H/0180/001	14997	GLAXOSMITHKLINE AB	SE
Relenza 5 mg/dose inhalasjonspulver, dosedispensert	SE/H/0180/001	06-4537	GLAXOSMITHKLINE AS	NO
RELENZA 5 mg/dose polvere per inalazione in contenitore monodose	SE/H/0180/001	034497026	GLAXOSMITHKLINE S.P.A.	IT
RELENZA 5 mg/dose polvere per inalazione in contenitore monodose.	SE/H/0180/001	034497014	GLAXOSMITHKLINE S.P.A.	IT
Relenza 5 mg/dose, pó para inalação, em recipiente unidose.	SE/H/0180/001	2944387	GLAXO WELLCOME FARMACÊUTICA, LDA	PT
Relenza 5 mg/dose, pó para inalação, em recipiente unidose.	SE/H/0180/001	2944486	GLAXO WELLCOME FARMACÊUTICA, LDA	PT
RELENZA 5 mg/dose, poudre pour inhalation en récipient unidose	SE/H/0180/001	BE 205231	GLAXOSMITHKLINE PHARMACEUTICALS SA	BE
RELENZA 5 mg/dose, poudre pour inhalation en récipient unidose	SE/H/180/001	NL24551	LABORATOIRE GLAXOSMITHKLINE S.A.S.	FR
RELENZA 5 mg/dose, poudre pour inhalation en récipient unidose	SE/H/0180/001	0260/09/10/0597	GLAXOSMITHKLINE PHARMACEUTICALS SA	LU

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
RELENZA 5 mg/Dosis, einzeldosiertes Pulver zur Inhalation	SE/H/0180/001	BE205231	GLAXOSMITHKLINE PHARMACEUTICALS SA	BE
RELENZA 5 mg/Dosis, einzeldosiertes Pulver zur Inhalation	SE/H/0180/001	0260/09/10/0597	GLAXOSMITHKLINE PHARMACEUTICALS SA	LU
RELENZA 5 mg/dosis, inhalatiepoeder, voorverdeeld	SE/H/0180/001	BE 205231	GLAXOSMITHKLINE PHARMACEUTICALS SA	BE
RELENZA 5 mg/dosis, inhalatiepoeder, voorverdeeld	SE/H/0180/001	0260/09/10/0597	GLAXOSMITHKLINE PHARMACEUTICALS SA	LU
Relenza 5 mg/dosis, inhalatiepoeder, voorverdeeld.	SE/H/0180/001	RVG 24094	GLAXOSMITHKLINE B.V.	NL
Relenza 5 mg/dosis, polvo para inhalación, pre-dispensado	SE/H/0180/001	62.712	GLAXOSMITHKLINE S.A.	ES
Relenza 5 mg/dozėje dozuoti įkvepiamieji milteliai	SE/H/0180/001	LT/1/07/0769/001	GLAXOSMITHKLINE LIETUVA UAB	LT
Relenza 5 mg/dozėje dozuoti įkvepiamieji milteliai	SE/H/0180/001	LT/1/07/0769/002	GLAXOSMITHKLINE LIETUVA UAB	LT
Relenza 5 mg/dozi, prašak inhalata, dozirani	not available	UP/I-530-09/12-02/64	GLAXOSMITHKLINE D.O.O.	HR

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
Relenza 5 mg/odmerek, odmerjeni prašek za inhaliranje	SE/H/0180/001	H/00/01329/002	GLAXOSMITHKLINE D.O.O.	SI
Relenza 5 mg/odmerek, odmerjeni prašek za inhaliranje	SE/H/0180/001	H/00/01329/001	GLAXOSMITHKLINE D.O.O.	SI
Relenza 5 mg/skammt innöndunarduft, afmældir skammtar	SE/H/0180/001	990042	GLAXOSMITHKLINE PHARMA A/S	IS
Relenza 5 mg/δόση, κόνις για εισπνοή, σε δόσεις	SE/H/0180/001	2452701	GLAXO GROUP LIMITED	GR
Relenza 5mg/dose, inhalation powder, pre-dispensed	SE/H/0180/001	PA 1077/11/1	GLAXOSMITHKLINE (IRELAND) LIMITED	IE
Relenza 5mg/dose, inhalation powder, pre-dispensed	SE/H/0180/001	MA 167/01601	GLAXO WELLCOME UK LTD TRADING AS GLAXOSMITHKLINE UK	MT
Relenza 5mg/dose, inhalation powder, pre-dispensed	SE/H/0180/001	PL 10949/0327	GLAXO WELLCOME UK LTD TRADING AS GLAXOSMITHKLINE UK	UK
Relenza Rotadisks 5 mg/Dosis – einzeldosiertes Pulver zur Inhalation	SE/H/0180/001	1-23120	GLAXOSMITHKLINE PHARMA GMBH.	AT
Relenza, 5 mg/annuses, annustatud inhaleeritav pulber	SE/H/0180/001	280499	GLAXOSMITHKLINE EESTI OÜ	EE

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
Relenza, 5 mg/dávka, dávkovaný prášek k inhalaci	SE/H/0180/001	42/445/00-C	GLAXO GROUP LIMITED	CZ
Relenza, 5 mg/dawke proszek do inhalacji, podzielony	SE/H/0180/001	14008	GLAXOSMITHKLINE EXPORT LTD	PL
RelenzaTM 5 mg/Dosis, einzeldosiertes Pulver zur Inhalation	SE/H/0180/001	45815.00.00	GLAXOSMITHKLINE GMBH & CO. KG	DE
Реленца 5 mg/доза, прах за инхалация, предварително дозиран	not available	20010521	GLAXO GROUP LIMITED	BG