



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

26 October 2017
EMA/715528/2017
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: influenza vaccine (split virion, inactivated, prepared in cell cultures)

Procedure no.: PSUSA/00010299/201703



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
Preflucel 2012/2013, suspensie voor injectie 0,5 ml Griepvaccin (gesplitst virion, geïnactiveerd, bereid in celculturen)	not available	RVG 108793	NANOTHERAPEUTICS UK LIMITED	NL
Preflucel 2012/2013, suspensie voor injectie 0,5 ml. Griepvaccin (gesplitst virion, geïnactiveerd, bereid in celculturen)	not available	BE393556	NANOTHERAPEUTICS BOHUMIL, S.R.O.	BE
PREFLUCEL Injekční suspenze v předplněné injekční stříkačce Vakcína proti chřipce (štěpený virion, inaktivovaná, připravovaná na buněčných kulturách)	not available	59/772/10-C	NANOTHERAPEUTICS BOHUMIL, S.R.O.	CZ
Preflucel injeksjonsvæske, suspensjon i ferdigfylt sprøyte Vaksine mot influensa (inaktivert, splittvirus, fremstilt i cellekulturer)	not available	10-8003	NANOTHERAPEUTICS UK LIMITED	NO
Preflucel injektioneste, suspensio, esitäytetyssä ruiskussa Influenssarokote	not available	29303	NANOTHERAPEUTICS BOHUMIL, S.R.O.	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
(soluissa tuotettu inaktivoitu osavirusrokote)				
PREFLUCEL Injektionssuspension in einer Fertigspritze Influenza-Impfstoff (Spaltimpfstoff, inaktiviert, in Zellkulturen hergestellt)	not available	2-00373	NANOTHERAPEUTICS BOHUMIL, S.R.O.	AT
PREFLUCEL Injektionssuspension in einer Fertigspritze. Influenza-Impfstoff (Spaltimpfstoff, inaktiviert, in Zellkulturen hergestellt)	not available	BE393556	NANOTHERAPEUTICS BOHUMIL, S.R.O.	BE
Preflucel injektionsvätska, suspension i förfylld spruta Vaccin mot influensa (spjälkat virus, inaktiverat, tillverkat i cellkultur)	not available	45349	NANOTHERAPEUTICS UK LIMITED	SE
PREFLUCEL Suspensão injectável em seringa pré-cheia Vacina contra a gripe (vírião fragmentado, inactivo,	not available	5380407	NANOTHERAPEUTICS BOHUMIL, S.R.O.	PT

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
preparado em culturas de células)				
PREFLUCEL Suspensão injectável em seringa pré-cheia Vacina contra a gripe (virião fragmentado, inactivo, preparado em culturas de células)	not available	5380415	NANOTHERAPEUTICS BOHUMIL, S.R.O.	PT
PREFLUCEL suspension injectable en seringue préremplie Vaccin grippal (virus fragmenté inactivé, préparé à partir de cultures cellulaires)	not available	BE393556	NANOTHERAPEUTICS BOHUMIL, S.R.O.	BE
Preflucel, injektionsvæske, suspension, fyldt injektionssprøjte	not available	47867	NANOTHERAPEUTICS BOHUMIL, S.R.O.	DK
PREFLUCEL, zawiesina do wstrzykiwań w ampułko-strzykawce Szczepionka przeciw grypie (rozszczepiony wirion), inaktywowana, przygotowana w hodowlach komórek	not available	18259	NANOTHERAPEUTICS BOHUMIL, S.R.O.	PL