



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

31 October 2019
EMA/600346/2019
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: influenza vaccine (surface antigen, inactivated)

Procedure no.: PSUSA/00001744/201903

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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
Xanaflu, suspensie voor injectie 0,5 ml (influenza vaccin, oppervlakte antigeen, geïnactiveerd)	NL/H/2374/001	RVG 109736	MYLAN HEALTHCARE B.V.	NL
Batrevac, suspensie voor injectie 0,5 ml (influenza vaccin, oppervlakte antigeen, geïnactiveerd)	NL/H/0169/001	RVG 24037	MYLAN HEALTHCARE B.V.	NL
Vacciflu, suspensie voor injectie 0,5 ml (influenza vaccin, oppervlakte antigeen, geïnactiveerd)	NL/H/0581/001	RVG 31136	MYLAN HEALTHCARE B.V.	NL
Influpozzi Subunità, Sospensione iniettabile in siringa pre-riempita Vaccino influenzale inattivato, antigene di superficie (STAGIONE 2016/2017)	not available	025984271	SEQIRUS S.R.L.	IT
Influpozzi Subunità, Sospensione iniettabile in siringa pre-riempita Vaccino influenzale inattivato, antigene di superficie (STAGIONE 2016/2017)	not available	025984283	SEQIRUS S.R.L.	IT
Influpozzi Subunità, Sospensione iniettabile in siringa pre-riempita Vaccino influenzale inattivato, antigene di superficie (STAGIONE 2016/2017)	not available	025984384	SEQIRUS S.R.L.	IT
Influpozzi Subunità, Sospensione iniettabile in siringa pre-riempita	not available	025984269	SEQIRUS S.R.L.	IT

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
Vaccino influenzale inattivato, antigene di superficie (STAGIONE 2016/2017)				
Influpozzi Subunità, Sospensione iniettabile in siringa pre-riempita Vaccino influenzale inattivato, antigene di superficie (STAGIONE 2016/2017)	not available	025984283	SEQIRUS S.R.L.	IT
Influpozzi Subunità, Sospensione iniettabile in siringa pre-riempita Vaccino influenzale inattivato, antigene di superficie (STAGIONE 2016/2017)	not available	025984321	SEQIRUS S.R.L.	IT
Influpozzi Subunità, Sospensione iniettabile in siringa pre-riempita Vaccino influenzale inattivato, antigene di superficie (STAGIONE 2016/2017)	not available	025984384	SEQIRUS S.R.L.	IT
Influpozzi Subunità, Sospensione iniettabile in siringa pre-riempita Vaccino influenzale inattivato, antigene di superficie (STAGIONE 2016/2017)	not available	025984257	SEQIRUS S.R.L.	IT
Batrevac Tetra, suspensie voor injectie in voorgevulde spuit 0,5 ml (influenza vaccin, oppervlakte antigeen,	NL/H/3845/001	RVG 119824	MYLAN HEALTHCARE B.V.	NL

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geïnactiveerd)				
Influvac suspensija za injekciju u napunjenoj štrcaljki, cjepivo protiv influence (površinski antigeni), inaktivirano	not available	HR-H-531363777	MYLAN HRVATSKA D.O.O.	HR
Influvac Tetra, suspensie voor injectie in voorgevulde spuit 0,5 ml (influenza vaccin, oppervlakte antigeen, geïnactiveerd)	NL/H/3844/001	RVG 119816.	ABBOTT BIOLOGICALS B.V. (WEESP)	NL
Influvac, suspensie voor injectie 0,5 ml (influenza vaccin, oppervlakte antigeen, geïnactiveerd)	NL/H/0137/001	RVG 22289	ABBOTT BIOLOGICALS B.V. (WEESP)	NL
Influvac Junior, suspensie voor injectie 0,25 ml Influenza vaccin (oppervlakte antigeen, geïnactiveerd)	NL/H/0137/003	RVG 109238	ABBOTT BIOLOGICALS B.V. (WEESP)	NL
Serinflu, suspensie voor injectie 0,5 ml (influenza vaccin, oppervlakte antigeen, geïnactiveerd).	not available	RVG 115203	ABBOTT BIOLOGICALS B.V. (WEESP)	NL
AGRIPPAL®, Injektionssuspension in Fertigspritze Influenza-Impfstoff - Oberflächenantigene, inaktiviert (Saison 2016/2017)	IT/H/0102/001	BE 211617	SEQIRUS S.R.L.	BE
Agrippal, suspension injectable en seringue pré-remplie Vaccin antigrippal, antigènes de surface, inactivé (Saison	IT/H/0102/001	BE211617	SEQIRUS S.R.L.	BE

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2016/2017))				
Agrippal® Suspensie voor injectie in voorgevulde spuit Influenza vaccin, oppervlakteantigeen, geïnactiveerd (Seizoen 2016/2017)	IT/H/0102/001	BE 211617	SEQIRUS S.R.L.	BE
Begripal, Injektionssuspension in Fertigspritze Influenza-Impfstoff, Oberflächenantigen, inaktiviert (Saison 2016/2017)	IT/H/0102/001	PEI.H.00968.01.1	SEQIRUS S.R.L.	DE
Agrippal, injektionsvæske, suspension i fyldt injektionsprøjte	IT/H/0102/001	30283	SEQIRUS S.R.L.	DK
Chiroflu, suspensión inyectable en jeringa precargada Vacuna antigripal de antígeno de superficie, inactivado (CAMPAÑA 2016/2017)	IT/H/0102/001	62.792	SEQIRUS S.R.L.	ES
Chiroflu, suspensión inyectable en jeringa precargada Vacuna antigripal de antígeno de superficie, inactivado (CAMPAÑA 2016/2017)	IT/H/0102/001	62.792	SEQIRUS S.R.L.	ES
Chiroflu, suspensión inyectable en jeringa precargada Vacuna antigripal de antígeno de superficie, inactivado (CAMPAÑA 2016/2017)	IT/H/0102/001	62.792	SEQIRUS S.R.L.	ES
Chiroflu, suspensión inyectable en jeringa	IT/H/0102/001	62.792	SEQIRUS S.R.L.	ES

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precargada Vacuna antigripal de antígeno de superficie, inactivado (CAMPAÑA 2016/2017)				
Chiroflu, suspensión inyectable en jeringa precargada Vacuna antigripal de antígeno de superficie, inactivado (CAMPAÑA 2016/2017)	IT/H/0102/001	62.792	SEQIRUS S.R.L.	ES
Chiroflu, suspensión inyectable en jeringa precargada Vacuna antigripal de antígeno de superficie, inactivado (CAMPAÑA 2016/2017)	IT/H/0102/001	62.792	SEQIRUS S.R.L.	ES
Chiroflu, suspensión inyectable en jeringa precargada Vacuna antigripal de antígeno de superficie, inactivado (CAMPAÑA 2016/2017)	IT/H/0102/001	62.792	SEQIRUS S.R.L.	ES
Chiroflu, suspensión inyectable en jeringa precargada Vacuna antigripal de antígeno de superficie, inactivado (CAMPAÑA 2016/2017)	IT/H/0102/001	62.792	SEQIRUS S.R.L.	ES
Chiroflu, suspensión inyectable en jeringa precargada Vacuna antigripal de antígeno de superficie, inactivado (CAMPAÑA 2016/2017)	IT/H/0102/001	62.792	SEQIRUS S.R.L.	ES
Agrippal injektioneste, suspensio, esitäytetyssä ruiskussa Influenssarokote, pinta-antigeeni, inaktivoitu (KAUSI 2016/2017)	IT/H/0102/001	13749	SEQIRUS S.R.L.	FI
Agrippal injektioneste, suspensio, esitäytetty ruisku Influenssarokote,	IT/H/0102/001	13749	SEQIRUS S.R.L.	FI

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pinta-antigeeni, inaktivoitu (KAUSI 2016/2017)				
AGRIPPAL, suspension injectable en seringue préremplie Vaccin grippal inactivé à antigènes de surface Saison 2016/2017	IT/H/0102/001	3400935231291	SEQIRUS S.R.L.	FR
AGRIPPAL, suspension injectable en seringue préremplie Vaccin grippal inactivé à antigènes de surface Saison 2016/2017	IT/H/0102/001	3400935947673	SEQIRUS S.R.L.	FR
AGRIPPAL, suspension injectable en seringue préremplie Vaccin grippal inactivé à antigènes de surface Saison 2016/2017	IT/H/0102/001	3400935947505	SEQIRUS S.R.L.	FR
AGRIPPAL, suspension injectable en seringue préremplie Vaccin grippal inactivé à antigènes de surface Saison 2016/2017	IT/H/0102/001	3400935231062	SEQIRUS S.R.L.	FR
AGRIPPAL, suspension injectable en seringue préremplie Vaccin grippal inactivé à antigènes de surface Saison 2016/2017	IT/H/0102/001	3400935080066	SEQIRUS S.R.L.	FR
AGRIPPAL, suspension injectable en seringue préremplie Vaccin grippal inactivé à antigènes de surface Saison 2016/2017	IT/H/0102/001	3400935947444	SEQIRUS S.R.L.	FR
AGRIPPAL, suspension injectable en seringue préremplie Vaccin grippal inactivé à antigènes de surface Saison 2016/2017	IT/H/0102/001	3400935947383	SEQIRUS S.R.L.	FR

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AGRIPPAL, suspension injectable en seringue préremplie Vaccin grippal inactivé à antigènes de surface Saison 2016/2017	IT/H/0102/001	3400934975448	SEQIRUS S.R.L.	FR
Agrippal, Suspension for injection in pre-filled syringe Influenza Vaccine Surface Antigen, Inactivated (2016/2017 SEASON)	IT/H/0102/001	PA 2032/001/001	SEQIRUS S.R.L.	IE
Agrippal® S1, Sospensione iniettabile in siringa pre-riempita Vaccino influenzale inattivato, antigene di superficie (STAGIONE 2016/2017)	IT/H/0102/001	026405288	SEQIRUS S.R.L.	IT
Agrippal® S1, Sospensione iniettabile in siringa pre-riempita Vaccino influenzale inattivato, antigene di superficie (STAGIONE 2016/2017)	IT/H/0102/001	026405326	SEQIRUS S.R.L.	IT
Agrippal® S1, Sospensione iniettabile in siringa pre-riempita Vaccino influenzale inattivato, antigene di superficie (STAGIONE 2016/2017)	IT/H/0102/001	026405338	SEQIRUS S.R.L.	IT
Agrippal® S1, Sospensione iniettabile in siringa pre-riempita Vaccino influenzale inattivato, antigene di	IT/H/0102/001	026405290	SEQIRUS S.R.L.	IT

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superficie (STAGIONE 2016/2017)				
Agrippal® S1, Sospensione iniettabile in siringa pre-riempita Vaccino influenzale inattivato, antigene di superficie (STAGIONE 2016/2017)	IT/H/0102/001	026405264	SEQIRUS S.R.L.	IT
Agrippal® S1, Sospensione iniettabile in siringa pre-riempita Vaccino influenzale inattivato, antigene di superficie (STAGIONE 2016/2017)	IT/H/0102/001	026405340	SEQIRUS S.R.L.	IT
Agrippal® S1, Sospensione iniettabile in siringa pre-riempita Vaccino influenzale inattivato, antigene di superficie (STAGIONE 2016/2017)	IT/H/0102/001	026405353	SEQIRUS S.R.L.	IT
Agrippal® S1, Sospensione iniettabile in siringa pre-riempita Vaccino influenzale inattivato, antigene di superficie (STAGIONE 2016/2017)	IT/H/0102/001	026405276	SEQIRUS S.R.L.	IT
Agrippal, suspension injectable en seringue pré-remplie Vaccin antigrippal, antigènes de surface, inactivé (Saison 2016/2017)	IT/H/0102/001	AUTHORIZATION NUMBER: AMM 1999040005. NATIONAL CODE: 0298105	SEQIRUS S.R.L.	LU
Agrippal, suspension	IT/H/0102/001	AUTHORIZATION NUMBER: AMM	SEQIRUS S.R.L.	LU

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injectable en seringue pré-remplie Vaccin antigrippal, antigènes de surface, inactivé (Saison 2016/2017)		1999040005. NATIONAL CODE: 0334491		
Agrippal, suspension injectable en seringue pré-remplie Vaccin antigrippal, antigènes de surface, inactivé (Saison 2016/2017)	IT/H/0102/001	AUTHORIZATION NUMBER: AMM 1999040005. NATIONAL CODE: 0334523	SEQIRUS S.R.L.	LU
Agrippal, suspension injectable en seringue pré-remplie Vaccin antigrippal, antigènes de surface, inactivé (Saison 2016/2017)	IT/H/0102/001	AUTHORIZATION NUMBER: AMM 1999040005. NATIONAL CODE: 0298069	SEQIRUS S.R.L.	LU
Agrippal, suspension injectable en seringue pré-remplie Vaccin antigrippal, antigènes de surface, inactivé (Saison 2016/2017)	IT/H/0102/001	AUTHORIZATION NUMBER: AMM 1999040005. NATIONAL CODE: 0298086	SEQIRUS S.R.L.	LU
Agrippal, suspension injectable en seringue pré-remplie Vaccin antigrippal, antigènes de surface, inactivé (Saison 2016/2017)	IT/H/0102/001	AUTHORIZATION NUMBER: AMM 1999040005. NATIONAL CODE: 0334487	SEQIRUS S.R.L.	LU
Agrippal, suspension injectable en seringue pré-remplie Vaccin antigrippal, antigènes de surface, inactivé (Saison 2016/2017)	IT/H/0102/001	AUTHORIZATION NUMBER: AMM 1999040005. NATIONAL CODE: 0334506	SEQIRUS S.R.L.	LU
Agrippal, suspension injectable en seringue pré-	IT/H/0102/001	AUTHORIZATION NUMBER: AMM 1999040005. NATIONAL CODE:	SEQIRUS S.R.L.	LU

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remplie Vaccin antigrippal, antigènes de surface, inactivé (Saison 2016/2017)		0263113		
Agrippal, Suspensie voor injectie in voorgevulde spuit Influenza vaccin, oppervlakteantigeen, geïnactiveerd (Seizoen 2016/2017)	IT/H/0102/001	RVG 23265	SEQIRUS S.R.L.	NL
Chiroflu, Suspensão injetável em seringa pré-cheia Vacina contra a Gripe, Antígeno de Superfície, Inativado (Época de 2017/2018)	IT/H/0102/001	3180080	SEQIRUS S.R.L.	PT
Chiroflu, Suspensão injetável em seringa pré-cheia Vacina contra a Gripe, Antígeno de Superfície, Inativado (Época de 2017/2018)	IT/H/0102/001	3983988	SEQIRUS S.R.L.	PT
Chiroflu, Suspensão injetável em seringa pré-cheia Vacina contra a Gripe, Antígeno de Superfície, Inativado (Época de 2017/2018)	IT/H/0102/001	3984085	SEQIRUS S.R.L.	PT
Chiroflu, Suspensão injetável em seringa pré-cheia Vacina contra a Gripe, Antígeno de Superfície, Inativado (Época de 2017/2018)	IT/H/0102/001	3180189	SEQIRUS S.R.L.	PT
Chiroflu, Suspensão injetável em seringa pré-cheia Vacina contra a	IT/H/0102/001	2898781	SEQIRUS S.R.L.	PT

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Gripe, Antigénio de Superfície, Inativado (Época de 2017/2018)				
Chiroflu, Suspensão injetável em seringa pré-cheia Vacina contra a Gripe, Antigénio de Superfície, Inativado (Época de 2017/2018)	IT/H/0102/001	3983780	SEQIRUS S.R.L.	PT
Chiroflu, Suspensão injetável em seringa pré-cheia Vacina contra a Gripe, Antigénio de Superfície, Inativado (Época de 2017/2018)	IT/H/0102/001	3983889	SEQIRUS S.R.L.	PT
Chiroflu, Suspensão injetável em seringa pré-cheia Vacina contra a Gripe, Antigénio de Superfície, Inativado (Época de 2017/2018)	IT/H/0102/001	3179983	SEQIRUS S.R.L.	PT
Agrippal, Injektionsvätska, suspension i förfylld spruta Vaccin mot influensa (ytantigener, inaktiverade)	IT/H/0102/001	14757	SEQIRUS S.R.L.	SE
Agrippal, Suspension for injection in pre-filled syringe Influenza Vaccine Surface Antigen, Inactivated	IT/H/0102/001	PL 44368/0001	SEQIRUS S.R.L.	UK
AGRIPPAL, ???s?μ? e?a????μa se p???eμ?sm??? s?????a ?μβ???? ?at? t?? ???p?? (ep?fa?e?a?? a?t?????, ad?a??p???μ???) (ΠΕΡΙΟΔΟΣ 2016/2017)	IT/H/0102/001	60066/20-8-2009	SEQIRUS S.R.L.	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
Sandovac® Injektionssuspension in einer Fertigspritze Influenzaimpfstoff, Oberflächenantigene, inaktiviert (2016/2017)	IT/H/0102/001	2-00235	SEQIRUS S.R.L.	AT
Agrippal® S1, Sospensione iniettabile in siringa pre-riempita Vaccino influenzale inattivato, antigene di superficie (STAGIONE 2016/2017)	IT/H/0102/001	026405365	SEQIRUS S.R.L.	IT
Agrippal® S1, Sospensione iniettabile in siringa pre-riempita Vaccino influenzale inattivato, antigene di superficie (STAGIONE 2016/2017)	IT/H/0102/001	026405377	SEQIRUS S.R.L.	IT
Chiroflu, suspensión inyectable en jeringa precargada Vacuna antigripal de antígeno de superficie, inactivado (CAMPAÑA 2016/2017)	IT/H/0102/001	716130.1	SEQIRUS S.R.L.	ES
Chiroflu, suspensión inyectable en jeringa precargada Vacuna antigripal de antígeno de superficie, inactivado (CAMPAÑA 2016/2017)	IT/H/0102/001	716131.8	SEQIRUS S.R.L.	ES
Influvac sub-unit®, suspension for injection (influenza vaccine, surface antigen, inactivated)	not available	19476	MYLAN IRE HEALTHCARE LIMITED	CY
Influvac	not available	R/6473	MYLAN HEALTHCARE SP.	PL

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Zawiesina do wstrzykiwań Vaccinum influenzae inactivatum ex corticis antigeniis praeparatum Szczepionka przeciw grypie (antygen powierzchniowy), inaktywowana			Z.O.O.	