14 April 2016
EMA/284169/2016
Procedure Management and Committees Support

List of nationally authorised medicinal products

Active substance: influenza vaccine (split virion, inactivated) (non centrally authorised products)

Procedure no.: PSUSA/00010298/201508

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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
Afluria	DE/H/1938/001	59/241/14-C	bioCSL GmbH	CZ
Afluria Injeksjonsvæske, suspensjon, i ferdigfylt sprøyte Vaksine mot influensa (inaktivert, splittvirus)	DE/H/1938/001	04-3084	BIO CSL GMBH	NO
Afluria injektionsvätska, suspension i förfylld spruta Vaccin mot influensa (spjälkat virus inaktiverat)	DE/H/1938/001	20546	BIO CSL GMBH	SE
Afluria Suspensão injetável, em seringa pré-cheia Vacina contra a gripe (vírião fragmentado, inativado)	DE/H/1938/001	5643309	BIO CSL GMBH	PT
Afluria Suspensão injetável, em seringa pré-cheia Vacina contra a gripe (vírião fragmentado, inativado)	DE/H/1938/001	5643317	BIO CSL GMBH	PT
Afluria Suspensão injetável, em seringa pré-cheia Vacina contra a gripe (vírião fragmentado, inativado)	DE/H/1938/001	5643325	BIO CSL GMBH	PT
Afluria Suspensão injetável, em seringa pré-cheia Vacina contra a gripe (vírião fragmentado, inativado)	DE/H/1938/001	5643333	BIO CSL GMBH	PT
Afluria suspensie voor injectie, in een voorgevulde spuit	DE/H/1938/001	RVG 31924	BIO CSL GMBH	NL

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Influenzavaccin (split virus, geïnactiveerd)				
Afluria Suspension injectable dans une seringue préremplie. Vaccin contre l'influenza (virion fragmenté, inactivé)	DE/H/1938/001	BE285284	BIO CSL GMBH	BE
Afluria Suspensión inyectable en jeringa precargada	DE/H/1938/001	705471 – 9	BIO CSL GMBH	ES
Afluria Suspensión inyectable en jeringa precargada	DE/H/1938/001	702570 – 2	BIO CSL GMBH	ES
Afluria, injektioneste, suspensio, esitäytetyssä ruiskussa. Influenssarokote (pilkottu, inaktivoitu)	DE/H/1938/001	20234	BIO CSL GMBH	FI
Afluria, injektionsvæske, suspension, fyldt injektionssprøjte	DE/H/1938/001	37439	BIO CSL GMBH	DK
Afluria, suspension injectable dans une seringue préremplie. Vaccin contre l'influenza (virion fragmenté, inactivé)	DE/H/1938/001	1716/06040039	BIO CSL GMBH	LU
Afluria®, Suspension zur Injektion in Fertigspritzen Influenza-Impfstoff (Spaltvirus, inaktiviert)	DE/H/1938/001	PEI.H.03523.01.1	BIO CSL GMBH	DE
a-RIX	DE/H/0124/001	BE147244	GlaxoSmithKline Biologicals S.A.	BE
a-RIX	DE/H/0124/001	2008089872	GlaxoSmithKline Biologicals S.A	LU

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a-RIX-Tetra	PEI/H/11629.01.1	BE456924	GlaxoSmithKline Biologicals S.A.	BE
a-RIX-Tetra	PEI/H/11629.01.1	2014090216	GlaxoSmithKline Biologicals S.A.,	LU
Enzira® Suspension for injection, pre-filled syringe Influenza vaccine (split virion, inactivated)	DE/H/1938/001	PA 1373/1/1	BIO CSL GMBH	IE
Enzira® Suspension for injection, pre-filled syringe Influenza vaccine (split virion, inactivated)	DE/H/1938/001	PL 22236/0001	BIO CSL GMBH	UK
Fluarix	DE/H/0124/001	2-00382	GlaxoSmithKline Pharma GmbH	AT
Fluarix	DE/H/0124/001	9700046	GlaxoSmithKline EOOD	BG
Fluarix	DE/H/0124/001	HR-H-996462312	GlaxoSmithKline d.o.o	CR
Fluarix	DE/H/0124/001	20302	GlaxoSmithKline (Cyprus) Limited	CY
Fluarix	DE/H/0124/001	59/1184/93-C	GlaxoSmithKline Biologicals S.A.,	CZ
Fluarix	DE/H/0124/001	PEI.H.11676.01.1	GlaxoSmithKline Biologicals S.A	DE
Fluarix	DE/H/0124/001	15746	GlaxoSmithKline Pharma A/S	DK
Fluarix	DE/H/0124/001	60.772	GlaxoSmithKline S.A.	ES
Fluarix	DE/H/0124/001	160597	GlaxoSmithKline Biologicals S.A.	ET
Fluarix	DE/H/0124/001	13153	GlaxoSmithKline Biologicals S.A.	FI
Fluarix	DE/H/0124/001	NL10811	Laboratoire GlaxoSmithKline	FR
Fluarix	DE/H/0124/001	38003/4-9-2014	GlaxoSmithKline	GR

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			A.E.B.E.	
Fluarix	DE/H/0124/001	OGYI-T-8421/01 OGYI-T-8421/02	GlaxoSmithKline Kft.	HU
Fluarix	DE/H/0124/001	PA 1077/25/1	GlaxoSmithKline (Ireland) Limited	IE
Fluarix	DE/H/0124/001	930249	GlaxoSmithKline ehf	IS
Fluarix	DE/H/0124/001	029245178 029245180 029245192 029245204 029245216 029245228 029245230 029245242 029245255 029245267	GlaxoSmithKline S.p.A	IT
Fluarix	DE/H/0124/001	LT/1/5/0274/001 - 010	GlaxoSmithKline Lietuva UAB,	LT
Fluarix	DE/H/0124/001	05-0197	GlaxoSmithKline Biologicals S.A	LV
Fluarix	DE/H/0124/001	MA 172/01001	SmithKline Beecham PLC	MT
Fluarix	DE/H/0124/001	RVG 22307	GlaxoSmithKline B.V.,	NL
Fluarix	DE/H/0124/001	02-1030	GlaxoSmithKline AS	NO
Fluarix	DE/H/0124/001	12831	GlaxoSmithKline Biologicals S.A.	PL
Fluarix	DE/H/0124/001	2454684	SmithKline & French Portuguesa-Produtos Farmaceuticos LDA	PT
Fluarix	DE/H/0124/001	3088/2010/01 - 06	GlaxoSmithKline Biologicals S.A.	RO
Fluarix	DE/H/0124/001	14056	GlaxoSmithKline AB	SE
Fluarix	DE/H/0124/001	H/04/00626/001 - 002	GSK d.o.o	SI

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Fluarix	DE/H/0124/001	59/0270/06-S	GlaxoSmithKline Slovakia s.r.o	SK
Fluarix	DE/H/0124/001	PL 10592/0118	SmithKline Beecham PLC,	UK
Fluarix Tetra	PEI/H/11629.01.1	235552	GlaxoSmithKline Pharma GmbH	AT
Fluarix Tetra	PEI/H/11629.01.1	59/145/14-C	GlaxoSmithKline Biologicals S.A.	CZ
Fluarix Tetra	PEI/H/11629.01.1	PEI.H.11629.01.1	GlaxoSmithKline GmbH & Co. KG	DE
Fluarix Tetra	PEI/H/11629.01.1	78568	GlaxoSmithKline Biologicals S.A.,	ES
Fluarix Tetra	PEI/H/11629.01.1	NL42097	Laboratoire GlaxoSmithKline,	FR
Fluarix Tetra	PEI/H/11629.01.1	21057/31-3-2015	GlaxoSmithKline A.E.B.E.	GR
Fluarix Tetra	PEI/H/11629.01.1	043132012 043132024 043132036 043132048	GlaxoSmithKline Biologicals S.A.,	IT
Fluarix Tetra	PEI/H/11629.01.1	59/0114/14-S	GlaxoSmithKline Biologicals S.A.,	SK
Fluarix Tetra	PEI/H/11629.01.1	PL 10592/0302	SmithKline Beecham Limited	UK
Influsplit SSW	DE/H/0124/001	PEI.H.00084.01.1	GlaxoSmithKline GmbH & Co. KG	DE
Istivac	FR/H/122/01	8650309; 2638385; 2638286; 2638484; 4316980; 4317087; 4317186; 4317285	Sanofi Pasteur MSD s.a.	PT
Istivac Infantil	FR/H/139/01	2906188; 2906386; 2906287; 4317384; 4317483; 43175	Sanofi Pasteur MSD SA, Belgium	PT
Mutagrip	FR/H/122/01	19303	Sanofi Pasteur MSD SA, Belgium	DK
Mutagrip	FR/H/122/01	51.577	Sanofi Pasteur MSD s.a.	ES

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Mutagrip	FR/H/122/01	13129	Sanofi Pasteur MSD SA, Belgium	FI
Mutagrip	FR/H/122/01	NL 10161-1	Sanofi Pasteur MSD S.N.C., France	FR
Mutagrip	FR/H/122/01	58703/22-09-2006	Sanofi Pasteur MSD SNC, France	GR
Mutagrip	FR/H/122/01	2009010130	Sanofi Pasteur MSD SA, Belgium	LU
Vaxigrip	FR/H/121/01	2-00215	Sanofi Pasteur MSD S.N.C., France	AT
Vaxigrip	FR/H/121/01	BE108184	Sanofi Pasteur MSD SA, Belgium	BE
Vaxigrip	FR/H/121/01	II-1582/14.02.2008	Sanofi Pasteur SA, France	BG
Vaxigrip		UP/I-530-09/12-02/145	Sanofi Pasteur SA, France	CR
Vaxigrip	FR/H/121/01	20507	Sanofi Pasteur SA, France	CY
Vaxigrip	FR/H/121/01	59/1035/94-C	Sanofi Pasteur SA, France	CZ
Vaxigrip	FR/H/121/01	PEI.H.00189.01.01	Sanofi Pasteur MSD GMBH, Germany	DE
Vaxigrip	FR/H/121/01	11708	Sanofi Pasteur MSD SA, Belgium	DK
Vaxigrip	FR/H/121/01	61.108	Sanofi Pasteur MSD s.a.	ES
Vaxigrip	FR/H/121/01	186597	Sanofi Pasteur SA, France	ET
Vaxigrip	FR/H/121/01	13130	Sanofi Pasteur SA, France	FI
Vaxigrip	FR/H/121/01	NL 11155-1	Sanofi Pasteur SA, France	FR
Vaxigrip	FR/H/121/01	NL 11 155-2	Sanofi Pasteur SA, France	FR
Vaxigrip	FR/H/121/01	31555/1-9-2015	Sanofi Pasteur MSD SNC, France	GR
Vaxigrip	FR/H/121/01	OGYI-T-8606/01-16	Sanofi Pasteur SA,	HU

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			France	
Vaxigrip	FR/H/121/01	PA 544/34/1	Sanofi Pasteur MSD; Ireland	IE
Vaxigrip	FR/H/121/01	IS/1/07/042/01	Sanofi Pasteur MSD SA, Belgium	IS
Vaxigrip	FR/H/121/01	026032 209-375-274-387-286-399-298-401-300-312-324-336	Sanofi Pasteur MSD SNC, France	IT
Vaxigrip	FR/H/121/01	LT/1/07/0789/001-002-003-004-005-006-007-008	Sanofi Pasteur SA, France	LT
Vaxigrip	FR/H/121/01	2009010131	Sanofi Pasteur MSD SA, Belgium	LU
Vaxigrip	FR/H/121/01	07-0162	Sanofi Pasteur SA, France	LV
Vaxigrip		MA573/00101	Sanofi Pasteur SA, France	MT
Vaxigrip	FR/H/121/01	RVG 22306	Sanofi Pasteur MSD SA, Belgium	NL
Vaxigrip	FR/H/121/01	1107233	Sanofi Pasteur MSD SA, Belgium	NO
Vaxigrip		R/0498	Sanofi Pasteur SA, France	PL
Vaxigrip	FR/H/121/01	2637882; 2638088; 2638187; 4317681; 4317780; 4317889; 4317988	Sanofi Pasteur MSD s.a.	PT
Vaxigrip		1289/2008/01-02-03-04-05-06-07-08-09-10	Sanofi Pasteur SA, France	RO
Vaxigrip	FR/H/121/01	14029	Sanofi Pasteur MSD SA, Belgium	SE
Vaxigrip		5363-I-1718/11	Sanofi Pasteur SA, France	SI
Vaxigrip	FR/H/121/01	59/0228/07-S	Sanofi Pasteur SA, France	SK
Vaxigrip	FR/H/121/01	PL 6745/0095	Sanofi Pasteur MSD Ltd,	UK

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			UK	
Vaxigrip Enfants	FR/H/139/01	NL 22390	Sanofi Pasteur SA, France	FR
Vaxigrip Junior	FR/H/139/01	II-0008/11.06.2007	Sanofi Pasteur SA, France	BG