



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

3 December 2015
EMA/829840/2015
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/00010298/201504



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	BE285284	Bio Csl Gmbh	Belgium
Afluria	DE/H/1938/001/MRP	59/241/14-C	Bio Csl Gmbh	Czech Republic
Afluria	DE/H/1938/001	37439	Bio Csl Gmbh	Denmark
Afluria	DE/H/1938/001	20234	Bio Csl Gmbh	Finland
Afluria	DE/H/1938/001	34009 279 598 9 9 \$ 34009 279 599 5 0 \$ 34009 279 600 3 1 \$ 34009 279 602 6 0	Bio Csl Gmbh	France
Afluria	DE/H/1938/001	PEI.H.03523.01.1	Bio Csl Gmbh	Germany
Afluria	DE/H/1938/001/MRP	210561/31-3-2015	Bio Csl Gmbh	Greece
Afluria	DE/H/1938/001	043216011 \$ 043216023 \$ 043216035 \$ 043216047	Bio Csl Gmbh	Italy
Afluria	DE/H/1938/001	1716/06040039	Bio Csl Gmbh	Luxembourg
Afluria	DE/H/1938/001	RVG 31924	Bio Csl Gmbh	Netherlands
Afluria	DE/H/1938/001	04-3084	Bio Csl Gmbh	Norway
Afluria	DE/H/1938/001/MRP	5643325,5643317, 5643309, 5643333	Bio Csl Gmbh	Portugal
Afluria	DE/H/1938/001	7123/2014/01-04	Bio Csl Gmbh	Romania
Afluria	DE/H/1938/001	78806 702570 – 2 \$ 78806 702573 – 3 \$ 78806 705470 – 2 \$ 78806 705471 – 9	Bio Csl Gmbh	Spain
Afluria	DE/H/1938/001	20546	Bio Csl Gmbh	Sweden
Enzira	DE/H/1938/001	PA 1373/1/1	Bio Csl Gmbh	Ireland
Enzira	DE/H/1938/001	PL 22236/0001	Bio Csl Gmbh	United Kingdom
Fluarix	DE/H/124/01	2-00382	Glaxosmithkline Pharma Gmbh.	Austria
Fluarix	DE/H/0124/001	HR-H-996462312	Glaxosmithkline D.O.O.	Croatia
Fluarix	DE/H/0124/001	20302	Glaxosmithkline (Cyprus) Limited	Cyprus
Fluarix	DE/H/124/01	59/1184/93-C	Glaxosmithkline Biologicals S.A.	Czech Republic

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Fluarix	DE/H/124/01	15746	Glaxosmithkline Pharma A/S	Denmark
Fluarix	DE/H/0124/001	160597	Glaxosmithkline Biologicals S.A.	Estonia
Fluarix	DE/H/0124/001	13153	Glaxosmithkline Biologicals S.A.	Finland
Fluarix	DE/H/124/01	NL10811	Laboratoire Glaxosmithkline S.A.S.	France
Fluarix	DE/H/124/01	PEI.H.11676.01.1	Glaxosmithkline Biologicals S.A.	Germany
Fluarix	DE/H/0124/001	38003/4-9-2014	Glaxosmithkline Aebe	Greece
Fluarix	DE/H/124/01	OGYI-T-8421/01 \$ OGYI-T-8421/02	Glaxosmithkline Kft.	Hungary
Fluarix	DE/H/124/01	930249	Glaxosmithkline Ehf.	Iceland
Fluarix	DE/H/0124/001	PA 1077/025/001	Glaxosmithkline (Ireland) Limited	Ireland
Fluarix	DE/H/0124/001	029245178 \$ 029245192 \$ 029245204 \$ 029245216 \$ 029245228	Glaxosmithkline S.P.A.	Italy
Fluarix	DE/H/0124/001	029245180	Glaxosmithkline S.P.A.	Italy
Fluarix	DE/H/124/01	029245230 \$ 029245242 \$ 029245255 \$ 029245267	Glaxosmithkline S.P.A.	Italy
Fluarix	DE/H/124/01	05-0197	Glaxosmithkline Biologicals S.A.	Latvia
Fluarix	DE/H/0124/001	LT/1/05/0274/002 \$ LT/1/05/0274/003	Glaxosmithkline Lietuva Uab	Lithuania
Fluarix	DE/H/124/01	LT/1/5/0274/001 \$ LT/1/5/0274/004 \$ LT/1/5/0274/005 \$ LT/1/5/0274/006 \$ LT/1/5/0274/007 \$ LT/1/5/0274/008 \$ LT/1/5/0274/009 \$ LT/1/5/0274/010	Glaxosmithkline Lietuva Uab	Lithuania

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Fluarix	DE/H/0124/001	MA 172/01001	Smithkline Beecham Plc	Malta
Fluarix	DE/H/0124/001	RVG 22307	Glaxosmithkline B.V.	Netherlands
Fluarix	DE/H/0124/001	02-1030	Glaxosmithkline As	Norway
Fluarix	DE/H/0124/001	12831	Glaxosmithkline Biologicals S.A.	Poland
Fluarix	DE/H/0124/001	2454684 \$ 2943587 \$ 5304670	Smith Kline & French Portuguesa-Produtos Farmaceuticos, Lda	Portugal
Fluarix	DE/H/0124/001	2704880	Smith Kline & French Portuguesa-Produtos Farmaceuticos, Lda	Portugal
Fluarix	DE/H/0124/001	3088/2010/01 \$ 3088/2010/02 \$ 3088/2010/03 \$ 3088/2010/04 \$ 3088/2010/05 \$ 3088/2010/06	Glaxosmithkline Biologicals S.A.	Romania
Fluarix	DE/H/124/01	59/0270/06-S	Glaxosmithkline Slovakia S.R.O.	Slovakia
Fluarix	DE/H/124/01	H/04/00626/001	Glaxosmithkline D.O.O.	Slovenia
Fluarix	DE/H/124/01	H/04/00626/002	Glaxosmithkline D.O.O.	Slovenia
Fluarix	DE/H/0124/001	60.772	Glaxosmithkline S.A.	Spain
Fluarix	DE/H/124/01	14056	Glaxosmithkline Ab	Sweden
Fluarix	DE/H/0124/001	PL 10592/0118	Smithkline Beecham Ltd	United Kingdom
Fluarix Tetra	DE/H/1939/001	59/145/14-C	Glaxosmithkline Biologicals S.A.	Czech Republic
Fluarix Tetra	DE/H/1939/001	NL42097	Laboratoire Glaxosmithkline S.A.S.	France
Fluarix Tetra	DE/H/1939/001	21057/31-3-2015	Laboratoire Glaxosmithkline A.E.B.E	Greece
Fluarix Tetra	DE/H/1939/001	043132012	Glaxosmithkline Biologicals S.A.	Italy
Fluarix Tetra	DE/H/1939/001/DC	043132024 \$ 043132036	Glaxosmithkline	Italy

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		\$ 043132048	Biologicals S.A.	
Fluarix Tetra	DE/H/1939/001	59/0114/14-S	Glaxosmithkline Biologicals S.A.	Slovakia
Fluarix Tetra	DE/H/1939/001	78.568	Glaxosmithkline Biologicals S.A.	Spain
Fluarix Tetra	DE/H/1939/001/DC	PL 10592/0302	Smithkline Beecham Ltd	United Kingdom
Fluarix® Tetra	DE/H/1939/001/DC	235552	Glaxosmithkline Pharma Gmbh.	Austria
Inactivated Influenza Vaccine (Split Virion) Bp Sanofi Pasteur	FR/H/0121/001	PA544/34/1	Sanofi Pasteur Msd Limited	Ireland
Inactivated Influenza Vaccine (Split Virion) Bp Sanofi Pasteur Msd	FR/H/0121/001	PL 06745/0095	Sanofi Pasteur Msd Limited (Uk)	United Kingdom
Influsplit Ssw 2014/2015	DE/H/124/01	PEI.H.00084.01.1	Glaxosmithkline Gmbh & Co. Kg	Germany
Influsplit Tetra	DE/H/1939/001	PEI.H.11629.01.1	Glaxosmithkline Gmbh & Co. Kg	Germany
Istivac	FR/H/0122/001	2638286 \$ 2638385 \$ 2638484 \$ 4316980 \$ 4317087 \$ 4317186 \$ 4317285 \$ 8650309	Sanofi Pasteur Msd, S.A. (Portugal)	Portugal
Mutagrip	FR/H/0122/001	BE119971	Sanofi Pasteur Msd	Belgium
Mutagrip	FR/H/0122/001	19303	Sanofi Pasteur Msd	Denmark
Mutagrip	FR/H/0122/001	13129	Sanofi Pasteur Msd	Finland
Mutagrip	FR/H/0122/001	NL 10161-1	Sanofi Pasteur Msd Snc	France
Mutagrip	FR/H/122/01	58703/22-09-2006	Sanofi Pasteur Msd Snc	Greece
Mutagrip	FR/H/0122/001	2009010130	Sanofi Pasteur Msd	Luxembourg
Mutagrip	FR/H/0122/001	51.577	Sanofi Pasteur Msd S.A. (Spain)	Spain
Vaxigrip	FR/H/0121/001	2-00215	Sanofi Pasteur Msd Snc	Austria
Vaxigrip	FR/H/0121/001	BE108184	Sanofi Pasteur Msd	Belgium

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Vaxigrip		UP/I-530-09/12-02/145	Sanofi Pasteur Sa	Croatia
Vaxigrip	FR/H/0121/001	20507	Sanofi Pasteur Sa	Cyprus
Vaxigrip	FR/H/121/01	59/1035/94-C	Sanofi Pasteur Sa	Czech Republic
Vaxigrip	FR/H/0121/001	11708	Sanofi Pasteur Msd	Denmark
Vaxigrip	FR/H/0121/001	186597	Sanofi Pasteur Sa	Estonia
Vaxigrip	FR/H/0121/001	13130	Sanofi Pasteur Msd	Finland
Vaxigrip	FR/H/0121/002	NL 11 155-2	Sanofi Pasteur Sa	France
Vaxigrip	FR/H/0121/003	NL 22 930	Sanofi Pasteur Sa	France
Vaxigrip	FR/H/121/01	NL 11 155-1	Sanofi Pasteur Sa	France
Vaxigrip	FR/H/0121/001	PEI.H.00189.01.1	Sanofi Pasteur Msd Gmbh	Germany
Vaxigrip	FR/H/0121/001	<u>43522/27-09-2012</u>	Sanofi Pasteur Msd Snc	Greece
Vaxigrip	FR/H/121/01	OGYI-T-8606/01 <u>16</u>	Sanofi Pasteur Sa	Hungary
Vaxigrip	FR/H/121/01/E/01	IS/1/07/042/01	Sanofi Pasteur Msd	Iceland
Vaxigrip	FR/H/0121/001	026032209 \$ 026032274 \$ 026032286 \$ 026032298 \$ 026032300 \$ 026032312 \$ 026032324 \$ 026032336 \$ 026032375 \$ 026032387 \$ 026032399 \$ 026032401	Sanofi Pasteur Msd Snc	Italy
Vaxigrip	FR/H/121/01	07-0162	Sanofi Pasteur Sa	Latvia
Vaxigrip	FR/H/121/01	LT/1/07/0789/001-008	Sanofi Pasteur Sa	Lithuania
Vaxigrip	FR/H/0121/001	2009010131	Sanofi Pasteur Msd	Luxembourg
Vaxigrip		MA573/00101	Sanofi Pasteur Sa	Malta
Vaxigrip	FR/H/0121/001	RVG 22306	Sanofi Pasteur Msd	Netherlands
Vaxigrip	FR/H/121/01/E/01	07-4931	Sanofi Pasteur Msd	Norway
Vaxigrip		R/0498	Sanofi Pasteur Sa	Poland

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Vaxigrip	FR/H/0121/001	2637882 \$ 2637981 \$ 2638088 \$ 4317681 \$ 4317780 \$ 4317889 \$ 4317988	Sanofi Pasteur Msd, S.A. (Portugal)	Portugal
Vaxigrip	FR/H/0121/001	2638187	Sanofi Pasteur Msd, S.A. (Portugal)	Portugal
Vaxigrip		1289/2008/01-10	Sanofi Pasteur Sa	Romania
Vaxigrip	FR/H/0121/001	59/0228/07-S	Sanofi Pasteur Sa	Slovakia
Vaxigrip		5363-I-1444/13	Sanofi Pasteur Sa	Slovenia
Vaxigrip	FR/H/0121/001	61.108	Sanofi Pasteur Msd S.A. (Spain)	Spain
Vaxigrip	FR/H/0121/001	14029	Sanofi Pasteur Msd	Sweden
Vaxigrip Enfants	FR/H/139/01	NL 22 390	Sanofi Pasteur Sa	France
Vaxigrip Junior		4956	Sanofi Pasteur Sa	Poland
Vaxigrip Junior	FR/H/0139/001	2906188 \$ 2906287 \$ 2906386 \$ 4317384 \$ 4317483 \$ 4317582	Sanofi Pasteur Msd, S.A. (Portugal)	Portugal
Vaxigrip για παιδιά	FR/H/0139/001	<u>38324/4-9-2014</u>	Sanofi Pasteur Msd Snc	Greece
α-Rix	DE/H/0124/001	BE147244	Glaxosmithkline Biologicals S.A.	Belgium
α-Rix	DE/H/0124/001	2008089872	Glaxosmithkline Biologicals S.A.	Luxembourg
α-Rix-Tetra	DE/H/1939/001	BE456924	Glaxosmithkline Biologicals S.A.	Belgium
α-Rix-Tetra	DE/H/1939/001/DC	2014090216	Glaxosmithkline Biologicals S.A.	Luxembourg
ваксигрип	FR/H/121/01	<u>II-007/11.06.2007</u>	Sanofi Pasteur Sa	Bulgaria
ваксигрип за деца	FR/H/139/01	<u>II-08/11.06.2007</u>	Sanofi Pasteur Sa	Bulgaria
флуарикс	DE/H/0124/001	9700046	Glaxosmithkline Eood	Bulgaria