



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

14 April 2016  
EMA/346549/2016  
Procedure Management and Committees Support

## List of nationally authorised medicinal products

Active substance: influenza vaccine (surface antigen, inactivated)

Procedure no.: PSUSA/00001744/201508



<b>Product Name (in authorisation country)</b>	<b>MRP/DCP Authorisation number</b>	<b>National Authorisation Number</b>	<b>MAH of product in the member state</b>	<b>Member State where product is authorised</b>
AGRIPPAL	IT/H/0102/001	13749	NOVARTIS VACCINES INFLUENZA S.R.L.	Finland
AGRIPPAL	IT/H/0102/001	14757	NOVARTIS VACCINES INFLUENZA S.R.L.	Sweden
AGRIPPAL	IT/H/0102/001	30283	NOVARTIS VACCINES INFLUENZA S.R.L.	Denmark
AGRIPPAL	IT/H/0102/001	1999040005	NOVARTIS VACCINES INFLUENZA S.R.L.	Luxembourg
AGRIPPAL	IT/H/0102/001	BE 211617	NOVARTIS VACCINES INFLUENZA S.R.L.	Belgium
AGRIPPAL	IT/H/0102/001	PA 2032/001/001	NOVARTIS VACCINES INFLUENZA S.R.L.	Ireland
AGRIPPAL	IT/H/0102/001	PL 44368/0001	NOVARTIS VACCINES INFLUENZA S.R.L.	United Kingdom
AGRIPPAL	IT/H/0102/001	RVG 23265	NOVARTIS VACCINES INFLUENZA S.R.L.	Netherlands
AGRIPPAL S1	IT/H/0102/001	026405264	NOVARTIS VACCINES INFLUENZA S.R.L.	Italy
AGRIPPAL S1	IT/H/0102/001	026405276	NOVARTIS VACCINES INFLUENZA S.R.L.	Italy

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AGRIPPAL S1	IT/H/0102/001	026405288	NOVARTIS VACCINES INFLUENZA S.R.L.	Italy
AGRIPPAL S1	IT/H/0102/001	026405290	NOVARTIS VACCINES INFLUENZA S.R.L.	Italy
AGRIPPAL S1	IT/H/0102/001	026405326	NOVARTIS VACCINES INFLUENZA S.R.L.	Italy
AGRIPPAL S1	IT/H/0102/001	026405338	NOVARTIS VACCINES INFLUENZA S.R.L.	Italy
AGRIPPAL S1	IT/H/0102/001	026405340	NOVARTIS VACCINES INFLUENZA S.R.L.	Italy
AGRIPPAL S1	IT/H/0102/001	026405353	NOVARTIS VACCINES INFLUENZA S.R.L.	Italy
BATREVAC	NL/H/0169/001	035619016	BGP PRODUCTS S.R.L.	Italy
BATREVAC	NL/H/0169/001	035619028	BGP PRODUCTS S.R.L.	Italy
BATREVAC	NL/H/0169/001	RVG 24037	BGP PRODUCTS B.V.	Netherlands

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AGRIPPAL	IT/H/0102/001	PEI.H.00968.01.1	NOVARTIS VACCINES INFLUENZA S.R.L.	Germany
CHIROFLU	IT/H/0102/001	2898781	NOVARTIS VACCINES INFLUENZA S.R.L.	Portugal
CHIROFLU	IT/H/0102/001	3179983	NOVARTIS VACCINES INFLUENZA S.R.L.	Portugal
CHIROFLU	IT/H/0102/001	3180080	NOVARTIS VACCINES INFLUENZA S.R.L.	Portugal
CHIROFLU	IT/H/0102/001	3180189	NOVARTIS VACCINES INFLUENZA S.R.L.	Portugal
CHIROFLU	IT/H/0102/001	3983780	NOVARTIS VACCINES INFLUENZA S.R.L.	Portugal
CHIROFLU	IT/H/0102/001	3983889	NOVARTIS VACCINES INFLUENZA S.R.L.	Portugal
CHIROFLU	IT/H/0102/001	3983988	NOVARTIS VACCINES INFLUENZA S.R.L.	Portugal
CHIROFLU	IT/H/0102/001	3984085	NOVARTIS VACCINES INFLUENZA S.R.L.	Portugal

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CHIROFLU	IT/H/0102/001	62.792	NOVARTIS VACCINES INFLUENZA S.R.L.	Spain
FLUVACCINOL	NL/H/0581/001	2-00310	BGP PRODUCTS GES. M. B. H.	Austria
GRIPPE-IMPfstoff STADA N	NL/H/0581/001	PEI.H.03210.01.1	MYLAN HEALTHCARE GMBH	Germany
IMUVAC JUNIOR	NL/H/0137/003	PL 43900/0041	BGP PRODUCTS LIMITED	United Kingdom
INFLUVAC		R/6473	BGP PRODUCTS B.V.	Poland
INFLUVAC		UP/I-530-09/10-02/302	ABBOTT LABORATORIES D.O.O. (KORANSKA)	Croatia
INFLUVAC	NL/H/0137/001	01-667	BGP PRODUCTS B.V.	Norway
INFLUVAC	NL/H/0137/001	05-0097	BGP PRODUCTS B.V.	Latvia
INFLUVAC	NL/H/0137/001	09191	BGP PRODUCTS B.V.	Denmark

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INFLUVAC	NL/H/0137/001	13141	BGP PRODUCTS B.V.	Finland
INFLUVAC	NL/H/0137/001	14026	BGP PRODUCTS B.V.	Sweden
INFLUVAC	NL/H/0137/001	2-00216	BGP PRODUCTS GES. M. B. H.	Austria
INFLUVAC	NL/H/0137/001	224698	BGP PRODUCTS B.V.	Estonia
INFLUVAC	NL/H/0137/001	34009 336 521 6 6	MYLAN MEDICAL SAS	France
INFLUVAC	NL/H/0137/001	34009 395 232 7 9	MYLAN MEDICAL SAS	France
INFLUVAC	NL/H/0137/001	34009 558 968 7 6	MYLAN MEDICAL SAS	France
INFLUVAC	NL/H/0137/001	34009 575 419 8 9	MYLAN MEDICAL SAS	France
INFLUVAC	NL/H/0137/001	4331484	BGP PRODUCTS UNIPessoal, LDA.	Portugal

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INFLUVAC	NL/H/0137/001	57523	BGP PRODUCTS OPERATIONS SL	Spain
INFLUVAC	NL/H/0137/001	59/1004/97-C	BGP PRODUCTS B.V.	Czech Republic
INFLUVAC	NL/H/0137/001	6963/2014/01	BGP PRODUCTS B.V.	Romania
INFLUVAC	NL/H/0137/001	6963/2014/02	BGP PRODUCTS B.V.	Romania
INFLUVAC	NL/H/0137/001	6963/2014/03	BGP PRODUCTS B.V.	Romania
INFLUVAC	NL/H/0137/001	6963/2014/04	BGP PRODUCTS B.V.	Romania
INFLUVAC	NL/H/0137/001	8567404	BGP PRODUCTS UNIPessoal, LDA.	Portugal
INFLUVAC	NL/H/0137/001	LT/1/05/0178/001	BGP PRODUCTS B.V.	Lithuania
INFLUVAC	NL/H/0137/001	LT/1/05/0178/002	BGP PRODUCTS B.V.	Lithuania

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INFLUVAC	NL/H/0137/001	MA968/00101	ABBOTT BIOLOGICALS B.V. (WEESP)	Malta
INFLUVAC	NL/H/0137/001	PEI.H.00191.01.1	MYLAN HEALTHCARE GMBH	Germany
INFLUVAC	NL/H/0137/001	RVG 22289	ABBOTT BIOLOGICALS B.V. (WEESP)	Netherlands
INFLUVAC DESU	NL/H/0169/001	PL 43900/0043	BGP PRODUCTS LIMITED	United Kingdom
INFLUVAC ENFANT	NL/H/0137/003	34009 275 618 5 6	MYLAN MEDICAL SAS	France
INFLUVAC ENFANT	NL/H/0137/003	34009 275 619 1 7	MYLAN MEDICAL SAS	France
INFLUVAC ENFANT	NL/H/0137/003	34009 275 621 6 7	MYLAN MEDICAL SAS	France
INFLUVAC ENFANT	NL/H/0137/003	34009 275 622 2 8	MYLAN MEDICAL SAS	France
INFLUVAC JUNIOR	NL/H/0137/003	30767	BGP PRODUCTS B.V.	Finland



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INFLUVAC JUNIOR	NL/H/0137/003	5571211	BGP PRODUCTS UNIPESOAL, LDA.	Portugal
INFLUVAC JUNIOR	NL/H/0137/003	PEI.H.11640.01.1	MYLAN HEALTHCARE GMBH	Germany
INFLUVAC JUNIOR	NL/H/0137/003	RVG 109238	ABBOTT BIOLOGICALS B.V. (WEESP)	Netherlands
INFLUVAC S	NL/H/0137/001	028851133	BGP PRODUCTS S.R.L.	Italy
INFLUVAC S	NL/H/0137/001	028851145	BGP PRODUCTS S.R.L.	Italy
INFLUVAC S	NL/H/0137/001	2008099952	MYLAN EPD SPRL	Luxembourg
INFLUVAC S	NL/H/0137/001	BE199026	MYLAN EPD SPRL	Belgium
INFLUVAC S JUNIOR	NL/H/0137/003	2013060179	MYLAN EPD SPRL	Luxembourg
INFLUVAC S JUNIOR	NL/H/0137/003	BE434314	MYLAN EPD SPRL	Belgium

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INFLUVAC SUB-UNIT		19476	VARNAVAS HADJIPANAYIS LTD. (LATSIA)	Cyprus
INFLUVAC SUB-UNIT	NL/H/0137/001	PA 2007/10/1	BGP PRODUCTS LIMITED	Ireland
INFLUVAC SUB-UNIT	NL/H/0137/001	PL 43900/0044	BGP PRODUCTS LIMITED	United Kingdom
SANDOVAC	IT/H/0102/001	2-00235	NOVARTIS PHARMA GMBH (ART57)	Austria
VACCIFLU	NL/H/0581/001	RVG 31136	BGP PRODUCTS B.V.	Netherlands
XANAFLU	NL/H/2374/001	PEI.H.11534.01.1	MYLAN HEALTHCARE GMBH	Germany
XANAFLU	NL/H/2374/001	RVG 109736	BGP PRODUCTS B.V.	Netherlands
ИНФЛУВАК	NL/H/0137/001	20000716	BGP PRODUCTS B.V.	Bulgaria
INFLUVAC SUB-UNIT	NL/H/0137/001	2263201 b02	BGP PRODUCTS LTD	Greece

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INFLUVAC	NL/H/0137/001	5363-I-620/07	BGP Products B.V.	Slovenia
INFLUVAC	NL/H/0137/001	61553069	BGP PRODUCTS B.V.	Slovakia
GRIPPEIMPfstoff-RATIOPHARM	NL/H/0581/001	PEI.H.00900.01.1	BIOKANOL PHARMA GmbH	Germany
AGRIPPAL	IT/H/0102/001	1320701	NOVARTIS VACCINES INFLUENZA S.R.L.	Greece
AGRIPPAL	IT/H/0102/001	NL24054	NOVARTIS VACCINES INFLUENZA S.R.L.	France