



New, high dose influenza vaccine available to over 65's this influenza season

Fluzone® High-Dose, specifically designed for adults over 65 years of age, will be made available on the National Immunisation Program (NIP) ahead of 2018 influenza season

Sydney, Australia, 18th February, 2018 – Today Sanofi Pasteur, the vaccines business unit of Sanofi, welcomed the news that Fluzone High-Dose will be made available on the NIP for adults aged 65 years of age or older.

Influenza is a contagious disease caused the influenza virus, and can spread rapidly, especially in nursing homes or other institutions.¹ Influenza is much more severe in certain populations, particularly in older adults.¹

Fluzone High-Dose, a new influenza vaccine for adults aged ≥ 65 years, was registered by the Therapeutic Goods Administration (TGA) in December 2017. It is designed to protect against three influenza strains (i.e. trivalent) that are likely to circulate in the coming influenza season.

The vaccine contains four times the amount of antigen, or active ingredient, for each of the three strains in the vaccine, compared with regular influenza vaccines. The clinical value of vaccinating older adults with high dose influenza vaccine has been proven in clinical trials.^{2,3}

The 2017 influenza season in Australia saw the highest level of influenza activities on record, with almost 250,000 laboratory-confirmed influenza cases - three times the number of 2016.⁴

Older adults were most affected by the 2017 influenza season. In NSW alone, 784 aged care residents were hospitalised as a result of multiple influenza outbreaks. Furthermore, 304 residents died due to confirmed cases of influenza or its complications.⁵

"Influenza is a significant cause of illness and regular influenza vaccines have been less effective in older adults, compared with younger adults and children, due to the gradual deterioration of the immune system brought on by natural age advancement," said infectious disease expert, Professor Raina MacIntyre.

"Any vaccine that can help older people mount a better immune response is a welcome addition ahead of the 2018 influenza season, particularly for older adults, as we look to reduce GP visits and hospitalisations and avoid serious health complications. The high dose vaccine is one of these," said Professor MacIntyre.

Fluzone High-Dose has been used in the USA since 2009 and was registered in Canada in 2016. Australia is the first country outside the Northern American continent in which Sanofi Pasteur has introduced its high dose influenza vaccine.



In addition to Fluzone High-Dose, Sanofi Pasteur will also supply the Australian Government with FluQuadri, available to eligible people aged three years and older, and FluQuadri Junior, for eligible children aged six months to less than three years.

“Sanofi Pasteur is pleased to supply the Australian Government with Fluzone High-Dose, FluQuadri and FluQuadri Junior, ahead of the 2018 influenza season,” said Russell Jacobson, General Manager, Sanofi Pasteur Australia and New Zealand.

“As always, our local priority is to meet the public health needs of all Australians. We are committed to assisting both the Health Department and the Australian community to reduce the impact of influenza now and in the future,” he added.

Fluzone High-Dose, FluQuadri and FluQuadri Junior will be made available for eligible individuals on the NIP in 2018 season.

For further information regarding influenza disease and vaccination, please speak with a health care professional or visit www.vaccinehub.com.au

For a copy of the Consumer Medicine Information (CMI) for Fluzone High-Dose, FluQuadri or FluQuadri Junior, please ask your health care professional. Otherwise, it can be obtained online by accessing these links:

- **Fluzone High-Dose CMI**
<http://www.medicines.org.au/files/swcfluhd.pdf>
- **FluQuadri and FluQuadri Junior CMI**
<http://www.medicines.org.au/files/swcfluqu.pdf?CFID=1560124&CFTOKEN=62801370&jsessionid=e63085109f551f7e9270113b78133774063eTR>

Sanofi Pasteur
Building D, 12-24 Talavera Road, Macquarie Park, NSW 2113
+61 (0)2 8666 2000
ABN 31 008 558 807
SPANZ.IFLU.18.02.0043
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Media Contacts:

Kate Fouracre
Senior Account Director
Weber Shandwick
P +61 2 9994 4492
M +61 (0) 425 329 921
E hrayment@webershandwick.com

Peter Bayliss
Communications Manager
Sanofi Australia & New Zealand
P +61 2 8666 2489
M +61 (0) 417 861 984
E Peter.Bayliss@sanofi.com



About influenza⁶⁻⁸

Influenza (flu) is transmitted from person to person during coughing or sneezing, or by direct contact with respiratory secretions. Flu virus infection causes a wide range of disease, from no or minimal symptoms, to respiratory illness, and can lead to complications including viral or secondary bacterial pneumonia. In the worst case scenario this can lead to death.

Severe disease is more likely in the elderly, those with chronic (long-term) conditions, those that are pregnant and smokers. During an outbreak of a new influenza virus or 'pandemic', severe flu can affect otherwise healthy young adults.

In adults, the onset of illness due to flu is often quick, usually after a development period of 1 to 3 days. Symptoms include malaise, fever, chills, headache, loss of appetite and muscle pain. These symptoms may be accompanied by a cough, runny nose and sneezing.

Symptoms in infants and children are similar to those in adults. However, temperatures may be higher in children.

About Fluzone-High Dose²

Fluzone High-Dose is an inactivated flu virus vaccine. Antigens from the three strains included in the vaccine are produced separately to make the trivalent formulation. Fluzone High-Dose is recommended to help protect you against influenza. Fluzone High-Dose may be administered to persons aged 65 years and older.

Information regarding Fluzone High-Dose is contained within the Consumer Medicine Information (CMI), available at the following link: <http://www.medicines.org.au/files/swcfluhd.pdf>

A summary of this information is provided below, please review the CMI for further information.

Fluzone High-Dose should not be administered if you have ever had a severe allergic reaction to eggs or egg products, any of the other ingredients of Fluzone High-Dose, or a severe allergic reaction after getting any flu vaccine.

Tell your doctor if you have had Guillain-Barré syndrome (severe muscle weakness) after getting a flu vaccine, or have had an immune response problem because the immune response to the vaccine may be diminished. Tell your doctor if you have bleeding problems or bruise easily.

Some medicines may affect how Fluzone High-Dose works including corticosteroids (for example prednisone), medicines used to treat cancer (chemotherapy), radiotherapy or other medicines affecting the immune system. Tell your doctor if you have been treated with such medicines.

Your doctor will advise you if Fluzone High-Dose is to be given with another vaccine.

Like all medicines, Fluzone High-Dose can cause side effects, although not everybody gets them. The most common local side effects of Fluzone High-Dose include pain, redness and swelling at the injection site. Side effects affecting other parts of the body can include muscle aches, feeling unwell, headache and fever. These side effects usually clear up within a few days. If events continue or become severe, please tell your doctor or pharmacist.

About FluQuadri and FluQuadri Junior¹⁷

FluQuadri is an inactivated flu virus vaccine. Antigens from the four strains included in the vaccine are produced separately and then combined to make the quadrivalent formulation. FluQuadri Junior is may be administered to infants aged 6 months to 35 months. FluQuadri may be administered to individuals aged 3 years and older.¹⁸



Information regarding FluQuadri™ and FluQuadri™ Junior is contained within the Consumer Medicine Information (CMI), available at the following link:

<http://www.medicines.org.au/files/swcfluqu.pdf?CFID=1560124&CFTOKEN=62801370&jsessionid=e63085109f551f7e9270113b78133774063eTR>

A summary of this information is provided below, please review the CMI for further information.

FluQuadri or FluQuadri™ Junior should not be administered if you or your child ever had a severe allergic reaction to eggs or egg products, any of the other ingredients of FluQuadri™/FluQuadri™ Junior, or a severe allergic reaction after getting any flu vaccine.

Tell your doctor if you or your child has or has had Guillain-Barré syndrome (severe muscle weakness) after getting a flu vaccine, or has had an immune response problem because the immune response to the vaccine may be diminished.

Your doctor will discuss the benefits and possible risks and benefits of having FluQuadri™ during pregnancy or breastfeeding.

Some medicines may affect how FluQuadri™ and FluQuadri™ Junior work including corticosteroids (for example prednisone), medicines used to treat cancer (chemotherapy), radiotherapy or other medicines affecting the immune system. Tell your doctor if you have been treated with such medicines.

Your doctor will advise you if FluQuadri™/FluQuadri™ Junior is to be given with another vaccine.

Like all medicines, FluQuadri™/FluQuadri™ Junior can cause side effects, although not everybody gets them.

The most common local side effects of FluQuadri/FluQuadri Junior include pain, tenderness, redness, swelling, bruising and hardness at the site where the vaccine is injected. Side effects affecting other parts of the body can include feeling unwell, muscle ache, headache, shivering, fever, irritability, abnormal crying, drowsiness, appetite loss, vomiting (in children). These side effects usually clear up within a few days. If events continue or become severe, please tell your doctor or pharmacist.

About Sanofi:

Sanofi is dedicated to supporting people through their health challenges. We are a global biopharmaceutical company focused on human health. We prevent illness with vaccines, provide innovative treatments to fight pain and ease suffering. We stand by the few who suffer from rare diseases and the millions with long-term chronic conditions.

With more than 100,000 people in 100 countries, Sanofi is transforming scientific innovation into healthcare solutions around the globe.

Sanofi, Empowering Life

Additional Notes

The information contained within this media release does not contain all the available information. It does not take the place of talking to a healthcare professional. Please speak to your healthcare professional for further information about influenza or Fluzone High-Dose, FluQuadri or FluQuadri Junior.

Professor Raina MacIntyre received no honoraria for assisting with the preparation of this press release. The opinions expressed in the release are her own. Professor MacIntyre has been briefed by Sanofi on the approved use of this product. Professor Raina MacIntyre has served on Sanofi's



advisory boards and conducted research studies with funding provided by Sanofi, and has also done so with other vaccine manufacturers.

References

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