Help Prevent Influenza in Canada

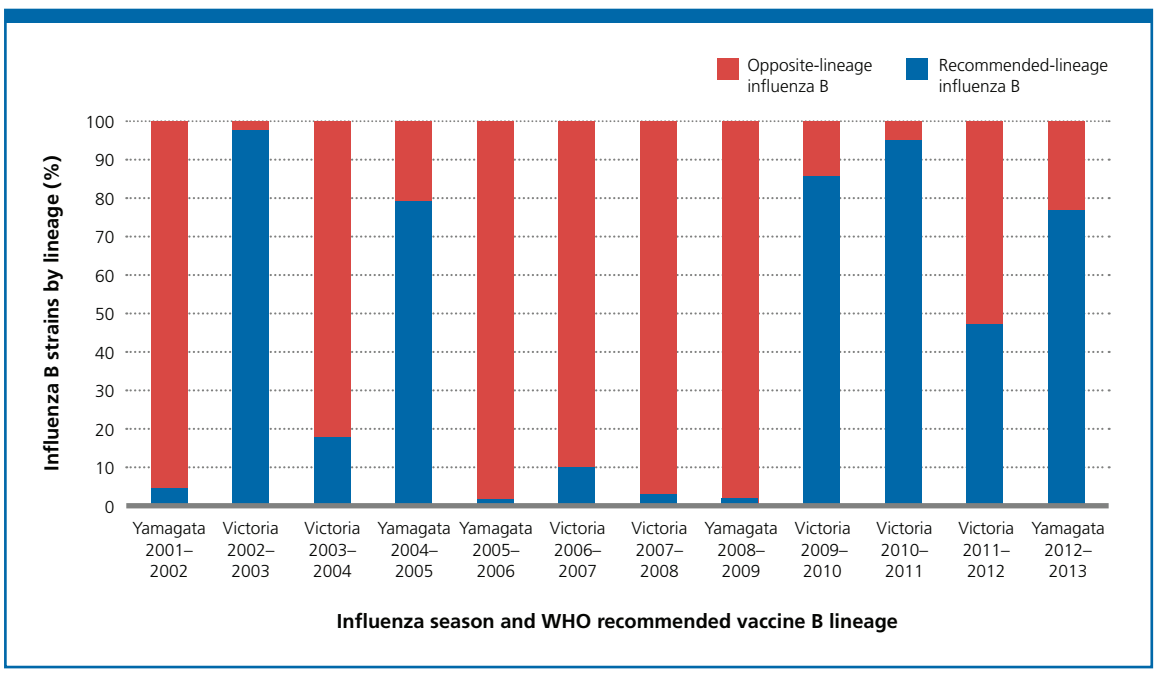
Did you know that up to 1 in 5 Canadians becomes infected by seasonal influenza annually?[1]

Two virus types, **influenza A** and **influenza B** contribute to seasonal influenza across all age groups each year.[2]

FluLaval® Tetra
Quadrivalent Influenza Vaccine (Split Virion, Inactivated)

The only 4-strain influenza vaccine manufactured in Canada*

B-strain mismatch



A mismatch between the predicted and actual circulating B strain has occurred in **more than half** of Canadian influenza seasons since 2000.[3]

Learn about the FLULAVAL® TETRA 4-strain influenza vaccine from our self-directed learning module

Indication and Clinical Use:

- FLULAVAL® TETRA is a quadrivalent vaccine indicated for active immunization of adults and children from 6 months of age for the prevention of influenza disease caused by influenza virus types A and B contained in the vaccine.†
- A decrease in influenza disease following vaccination with FLULAVAL® TETRA has been demonstrated in a controlled clinical trial in children 3–8 years of age. The indication in children aged 6–35 months is based on immune response elicited following vaccination; efficacy of the vaccine in this age group has not been established.

Contraindications:

- FLULAVAL® TETRA should not be administered to subjects with known hypersensitivity to egg proteins or after previous administration of any influenza vaccine produced in eggs or to any component of the vaccine.

Most Serious Warnings and Precautions:

- **Anaphylaxis**: As with all injectable vaccines, appropriate medical treatment and supervision should always be readily available in case of an anaphylactic event following the administration of the vaccine.

Other Relevant Warnings and Precautions:

- **FLULAVAL® TETRA must not be administered intravenously.** Vaccination should be carried out by intramuscular injection preferably into the deltoid muscle or anterolateral thigh (depending on the muscle mass).
- Syncope (fainting) can occur following, or even before, any vaccination as a psychogenic response to the needle injection. It is important that procedures are in place to avoid injury from faints.
- As with any vaccine, a protective immune response may not be elicited in all vaccinees.
- FLULAVAL® TETRA is not effective against all possible strains of influenza virus. FLULAVAL® TETRA is intended to provide protection against those strains of virus from which the vaccine is prepared and to closely related strains.
- As with other vaccines, vaccination with FLULAVAL® TETRA should be postponed in subjects suffering from an acute severe febrile illness. The presence of a minor infection, such as a cold, should not result in the deferral of vaccination.
- As with other vaccines administered intramuscularly, FLULAVAL® TETRA should be given with caution to individuals with thrombocytopenia or any coagulation disorder since bleeding may occur following an intramuscular administration to these subjects.
- An adequate immune response may not be elicited in patients receiving immunosuppressive treatment or patients with immunodeficiency.
- Soreness and redness at the injection site may occur and may last for up to two days. Prophylactic acetaminophen may decrease the frequency of pain at the injection site.
- If Guillain-Barré syndrome has occurred within 6 weeks of receipt of prior influenza vaccine, the decision to give FLULAVAL® TETRA should be based on the careful consideration of the potential benefits and risks.
- Immunization should be delayed in a patient with an active neurologic disorder, but should be considered when the disease process has been stabilized.
- FLULAVAL® TETRA should be used during pregnancy only when clearly needed, and the possible advantages outweigh the potential risks for the fetus.
- FLULAVAL® TETRA should only be used during breast-feeding when the possible advantages outweigh the potential risks for the fetus.

Adverse Events:

- In adults, the most common (≥10%) solicited local reaction was pain (60%); the most common solicited systemic adverse events were myalgia (26%), headache (22%), fatigue (22%), and arthralgia (15%).
- In children 3–17 years of age, the most common (≥10%) solicited local reaction was pain (65%). In children 3–4 years of age, the most common (≥10%) solicited systemic adverse events were irritability (26%), drowsiness (21%) and loss of appetite (17%). In children 5–17 years of age, the most common (≥10%) systemic adverse events were muscle aches (29%), fatigue (22%), headache (22%), arthralgia (13%) and gastrointestinal symptoms (10%).
- In children 6–35 months of age, injection site pain was the most frequently reported solicited local reaction (23.0%). Irritability (29.1%) was the most frequently solicited general reaction followed by loss of appetite (22.5%) and drowsiness (21.6%).

Dosage and Method of Administration:

- FLULAVAL® TETRA should be administered as a single 0.5 mL intramuscular injection. It is recommended to use a 1 mL syringe equipped with a needle gauge not larger than 23-G.
- Children 6 months to less than 9 years of age who have not previously been vaccinated against influenza should receive a second dose of 0.5 mL after an interval of at least 4 weeks.

For More Information:

Please consult the Product Monograph at http://ca.gsk.com/media/590283/flulaval-tetra.pdf for important information relating to adverse reactions, drug interactions, and dosing information, which have not been discussed in this piece. The Product Monograph is also available by calling 1-800-387-7374.

To report an adverse event, please call 1-800-387-7374.

Sign up for access at health.gsk.ca

* Comparative clinical significance unknown.

† The 2016–2017 Northern Hemisphere influenza virus strains are: A/California/7/2009 (H1N1)pdm09-like virus; A/Hong Kong/4801/2014 (H3N2)-like virus; B/Phuket/3073/2013-like virus; B/Brisbane/60/2008-like virus.

References: 1. Advisory Committee Statement (ACS), National Advisory Committee on Immunization (NACI), Canada Communicable Disease Report. Statement on Seasonal Influenza Vaccine for 2013–2014. October 2013; Volume 39; ACS-4 ISSN 1481–8531. http://www.phac-aspc.gc.ca/publicat/ccdr-rmtc/13vol39/acs-dcc-4/assets/pdf/13vol39-acs-dcc4-eng.pdf. Accessed April 2016. **2.** World Health Organization (WHO). Influenza (Seasonal). Fact Sheet No. 211, March 2014. http://www.who.int/mediacentre/factsheets/fs211/en/. Accessed April 2016. **3.** Advisory Committee Statement (ACS), National Advisory Committee on Immunization (NACI), Statement on Seasonal Influenza Vaccine for 2014–2015.

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