

## Influenza Vaccine: Quadrivalent Inactivated (2018–2019)

**Revision Date: June 13, 2018**

Please consult the Product Monographs<sup>1,2</sup> for further information about the vaccine.

	Fluzone® Quadrivalent	Flulaval® Tetra
<b>Manufacturer</b>	Sanofi Pasteur Inc.	GlaxoSmithKline Inc
<b>Off-license use</b>	None	
<b>Influenza strains for 2018-2019 season</b>	A/Michigan/45/2015 (H1N1)pdm09-like virus <sup>1,2,3</sup> A/Singapore/INFIMH-16-0019/2016 (H3N2)-like virus <sup>1,2,3</sup> B/Phuket/3073/2013-like virus <sup>1,2,3</sup> B/Colorado/6/2017-like virus <sup>1,2,3</sup>	
<b>Indications for use of provincially funded vaccine</b>	<b>Albertans:</b> <ul style="list-style-type: none"> <li><b>Six months of age and older</b></li> </ul>	
<b>Dose</b>	0.5 mL <sup>1,2,4</sup>	
<b>Route</b>	Intramuscular injection	
<b>Schedule</b>	<b>6 months to 8 years of age:</b> <ul style="list-style-type: none"> <li>❖ 1 or 2 doses</li> </ul> <b>Note:</b> Children younger than nine years of age, who have never received a dose of seasonal influenza vaccine, require two doses with a minimum interval of four weeks between doses. <sup>1,2,4</sup> Children younger than nine years of age, who have received one or more doses of seasonal influenza vaccine in the past, should receive one dose. <sup>1,2,4</sup> <b>9 years of age and older:</b> <ul style="list-style-type: none"> <li>❖ 1 dose</li> </ul>	
<b>Contraindications</b>	<ul style="list-style-type: none"> <li>Known severe hypersensitivity to any component of the vaccine with the exception of egg<sup>4</sup> (see Precautions below).</li> <li>Anaphylactic or other allergic reaction to a previous dose of influenza vaccine.<sup>1,2</sup></li> <li>Avoiding subsequent immunization of individuals known to have had Guillain-Barré Syndrome (GBS) within six weeks of a previous influenza immunization appears prudent at this time.<sup>1,2,4</sup> However, the potential risk of GBS recurrence associated with influenza vaccine must be balanced against the risk of GBS associated with influenza infection itself and the other benefits of influenza immunization.<sup>1,2,4</sup> The relative and attributable risks of GBS after seasonal influenza immunization are lower than those after influenza illness.<sup>5</sup></li> </ul>	
<b>Precautions</b>	<ul style="list-style-type: none"> <li>Egg-allergic individuals may be immunized against influenza using inactivated vaccine without a prior influenza vaccine skin test and with the full dose of vaccine, irrespective of a past severe reaction to egg.<sup>4</sup> Egg-allergic vaccine recipients should be kept under observation for 30 minutes following the administration of inactivated influenza vaccine.</li> <li>Expert review of the risks and benefits of influenza immunization should be sought for individuals who previously experienced severe lower-respiratory symptoms (wheeze, chest tightness, difficulty breathing) within 24 hours of influenza immunization, an apparent significant allergic reaction to the vaccine or any other symptoms (e.g., throat constriction or difficulty swallowing) that raise concern regarding the safety of re-immunization.<sup>4</sup> This advice may be obtained from the local Medical Officer of Health or other experts in infectious disease, allergy, immunology and/or public health or any combination of these specialties.<sup>4</sup></li> </ul>	

	<ul style="list-style-type: none"> <li>Individuals who have experienced oculorespiratory syndrome (ORS) including those with a severe presentation (bilateral red eyes, cough, sore throat, hoarseness, facial swelling) but without lower respiratory tract symptoms, may be safely re-immunized.<sup>4</sup> Advice of an expert should be sought before immunizing individuals who experienced ORS with lower respiratory tract symptoms.<sup>4</sup></li> <li>Although influenza vaccine can inhibit the clearance of warfarin and theophylline, clinical studies have not shown any adverse effects attributable to these drugs in people receiving influenza vaccine.<sup>4</sup></li> </ul>
<p><b>Possible reactions</b></p>	<p>The vaccine contains only non-infectious viruses therefore cannot cause influenza disease.<sup>1,2</sup></p> <p>Adverse events following immunization are generally mild and of limited duration.<sup>1,2</sup></p> <p><b>Common:</b></p> <ul style="list-style-type: none"> <li>Injection site pain, tenderness, erythema and swelling.<sup>1,2</sup></li> <li>Headache, irritability, myalgia, fever, malaise, fatigue, loss of appetite, vomiting, nausea, diarrhea, arthralgia.<sup>1,2</sup></li> </ul> <p><b>Uncommon:</b></p> <ul style="list-style-type: none"> <li>Lymphadenopathy, dizziness, cough, rash, upper respiratory tract infection, injection site pruritis.<sup>1</sup></li> </ul> <p><b>Rare:</b></p> <ul style="list-style-type: none"> <li>Allergic reactions, anaphylaxis<sup>4</sup></li> <li>Guillain-Barré Syndrome<sup>4</sup></li> <li>Oculorespiratory syndrome<sup>4</sup></li> </ul> <p><u>For Fluzone<sup>®</sup> only:</u></p> <ul style="list-style-type: none"> <li>Currently there are no post-marketing data available for Fluzone<sup>®</sup> Quadrivalent.</li> <li>The following additional adverse events have been reported through post-marketing surveillance of trivalent Fluzone<sup>®</sup>: anaphylaxis, other allergic/hypersensitivity reactions including (urticaria and angioedema), GBS, lymphadenopathy, facial palsy, optic neuritis/neuropathy, brachial neuritis, dizziness, paresthesia, vasculitis, dyspnea, pharyngitis, rhinitis, Steven-Johnson syndrome, rash, cough, throat tightness, asthenia, fatigue, chest pain, pain in extremity, vomiting, ocular hyperemia, thrombocytopenia, and febrile convulsions.<sup>1</sup></li> </ul> <p><u>For Flulaval<sup>®</sup> Tetra only:</u></p> <ul style="list-style-type: none"> <li>Currently there are no post-marketing data available for Flulaval<sup>®</sup> Tetra.</li> <li>The following additional adverse events have been reported through post-marketing surveillance for Fluviral<sup>®</sup> and may occur in Flulaval<sup>®</sup> Tetra: anaphylactic and anaphylactoid reactions, GBS, urticaria, angioedema.<sup>2</sup></li> </ul> <p>Refer to: <i>Adverse Events Following Immunization (AEFI), Policy for Alberta Immunization Providers.</i><sup>6</sup></p>
<p><b>Pregnancy</b></p>	<p>Inactivated influenza immunization is recommended for all pregnant women, at any stage of pregnancy, due to the risk of influenza related morbidity.<sup>4</sup> The safety of inactivated influenza vaccine during pregnancy has been reviewed and has not shown evidence of harm to the mother or fetus.<sup>4</sup></p>
<p><b>Lactation</b></p>	<p>Breastfeeding women should be immunized.</p>

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### References

- <sup>1</sup> Sanofi Pasteur Inc. (2018, May). Fluzone® Quadrivalent. Influenza virus vaccine quadrivalent types A and B (Split Virion). *Product Monograph*.
- <sup>2</sup> GlaxoSmithKline Inc. (2018, April) Flulaval® Tetra. Quadrivalent Influenza Vaccine (Split Virion, Inactivated). *Product Monograph*.
- <sup>3</sup> World Health Organization. (2018). Recommended composition of influenza virus vaccines for use in the 2018-2019 northern hemisphere influenza season. Retrieved from:  
[http://www.who.int/influenza/vaccines/virus/recommendations/2018\\_19\\_north/en/](http://www.who.int/influenza/vaccines/virus/recommendations/2018_19_north/en/)
- <sup>4</sup> National Advisory Committee on Immunization. (2018). Statement on seasonal influenza vaccine for 2018-2019. <https://www.canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-guide-statement-seasonal-influenza-vaccine-2018-2019.html>.
- <sup>5</sup> Kwong, J. C., Vasa, P. P., Campitelli, S. H., et al. (2013). Risk of Guillain-Barré syndrome after seasonal influenza vaccination and influenza health-care encounter: a self-controlled study. *Lancet Infectious Disease*, 13, 769-76.
- <sup>6</sup> Alberta Health. (2016, December). *Adverse Events Following Immunization (AEFI), Policy for Alberta Immunization Providers*. Retrieved: <https://open.alberta.ca/dataset/d86b52a9-45f4-4948-8a06-53b2c045135e/resource/7598f59a-3dfc-4c70-9065-c3bf5b4ee363/download/AIP-AEFI-Policy.pdf>.