

# Influenza Vaccine High-Dose Quadrivalent Inactivated

## BIOLOGICAL PAGE

<b>Section 7</b>	Biological Product Information	<b>Standard # 07.266</b>
<b>Created and approved by</b>	Provincial Immunization Program Standards and Quality	
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	FLUZONE High-Dose
<b>Manufacturer</b>	Sanofi Pasteur
<b>Classification</b>	Quadrivalent, split virus inactivated influenza vaccine
<b>Indications for Provincially Funded Vaccine</b>	<p><b>For persons 65 years of age and older</b></p> <p><b>Adults 18 to 64 years of age, including pregnant individuals, who are:</b></p> <ul style="list-style-type: none"> <li>Hematopoietic stem cell transplant (HSCT) recipients;</li> <li>CAR-T-cell therapy recipients; or</li> <li>Solid organ transplant (SOT) candidates or recipients</li> </ul> <p><b>Note:</b></p> <ul style="list-style-type: none"> <li><b>ONLY</b> persons who live, work, go to school or are visiting in Alberta are eligible to receive provincially funded influenza vaccine.</li> </ul>
<b>Influenza Strains for the 2024-25 Season</b>	<p>A/Victoria/4897/2022 (H1N1)pdm09-like virus</p> <p>A/Thailand/8/2022(H3N2) like virus</p> <p>B/Austria/13594/2021(B/Victoria lineage)-like virus</p> <p>B/Phuket/3073/2013 (B/Yamagata lineage)-like virus</p>
<b>Dose</b>	0.7 mL
<b>Route</b>	I.M.
<b>Schedule</b>	<p><b>65 years of age and older:</b></p> <ul style="list-style-type: none"> <li>1 dose</li> </ul> <p><b>Adults 18 to 64 years of age, including pregnant individuals, who are an HSCT recipient, a CAR T-cell therapy recipient or a SOT candidate or recipient:</b></p> <ul style="list-style-type: none"> <li>1 dose</li> </ul> <p><b>Note:</b></p> <ul style="list-style-type: none"> <li>CAR T-cell therapy recipients without a prior history of HSCT who received influenza vaccine pre-CAR T-cell therapy are eligible to restart their influenza vaccine series, beginning at least 3 months post-CAR T-cell therapy. Consultation with their physician is not necessary if a clearance letter has been received to proceed with inactivated vaccines.</li> <li>For HSCT recipients who had their post-HSCT vaccine series interrupted by CAR T-cell therapy, see the following HSCT guidance: <ul style="list-style-type: none"> <li>Principles of Immunization in Hematopoietic Stem Cell Transplant Recipients and Solid Organ Transplant Recipients.</li> <li>Immunization for Adult HSCT Recipients.</li> </ul> </li> </ul>
<b>Contraindications/Precautions</b>	<p><b>Contraindications:</b></p> <ul style="list-style-type: none"> <li>Known hypersensitivity to any component of the vaccine excluding eggs.</li> <li>Anaphylactic or other allergic reactions to a previous dose of influenza vaccine.</li> </ul>

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	<ul style="list-style-type: none"> <li>• Known history of Guillain Barré Syndrome (GBS) within 6 weeks of a <b>previous dose of influenza vaccine</b>.</li> <li>• Individuals presenting with a serious acute febrile illness. <ul style="list-style-type: none"> <li>◦ Recommendations should be provided for these individuals to be immunized when their symptoms have resolved.</li> <li>◦ Individuals with non-serious febrile illness may be immunized.</li> </ul> </li> </ul> <p><b>Precautions:</b></p> <ul style="list-style-type: none"> <li>• Egg allergy is not considered a contraindication for inactivated influenza vaccine. <ul style="list-style-type: none"> <li>◦ Egg-allergic individuals may be safely immunized using inactivated influenza vaccine without a prior influenza vaccine skin test and with the full dose of vaccine, irrespective of a past severe reaction to egg. They can be immunized in any setting and should be kept under observation for 30 minutes following administration of inactivated influenza vaccine.</li> <li>◦ Known history of oculorespiratory syndrome (ORS) symptoms that included lower respiratory symptoms within 24 hours of receiving influenza vaccine pending consultation with the Medical Officer of Health to review the risks and benefits of further influenza immunization.</li> </ul> </li> </ul>
Possible Reactions	<p><b>Common:</b></p> <ul style="list-style-type: none"> <li>• Pain, redness, swelling, induration, bruising at the injection site</li> <li>• Shivering</li> <li>• Malaise</li> <li>• Headache, myalgia</li> </ul> <p><b>Uncommon:</b></p> <ul style="list-style-type: none"> <li>• Pruritus at the injection site</li> <li>• Fever</li> <li>• Vertigo</li> <li>• Nausea, diarrhea</li> <li>• Cough</li> </ul> <p><b>Rare:</b></p> <ul style="list-style-type: none"> <li>• Anaphylaxis, allergic reaction</li> <li>• Urticaria</li> <li>• Arthralgia</li> <li>• Fatigue</li> <li>• Dizziness</li> <li>• Vomiting</li> <li>• Flushing</li> <li>• Pruritus</li> <li>• Pain in extremity</li> <li>• Guillain-Barré Syndrome (GBS)</li> <li>• ORS is defined by the following symptoms occurring within 24 hours of immunization: <ul style="list-style-type: none"> <li>◦ bilateral red eyes <b>and</b></li> <li>◦ one or more of the following respiratory symptoms (cough, wheeze, chest tightness, difficulty breathing, difficulty swallowing, hoarseness, sore throat) <b>with or without facial swelling</b>.</li> </ul> </li> </ul> <p><b>Note:</b> People who have an occurrence or recurrence of ORS upon immunization do not necessarily experience further episodes with future immunizations.</p> <ul style="list-style-type: none"> <li>• As with any immunization, unexpected or unusual side effects can occur. Refer to product monograph for more detailed information.</li> </ul>

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<b>Pregnancy</b>	<ul style="list-style-type: none"> <li>Animal reproductive studies have not been conducted with Fluzone High-Dose Quadrivalent. It is also not known whether Fluzone High-Dose Quadrivalent can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity.</li> <li>Despite a lack of available evidence for use in pregnant individuals, Alberta transplant experts recommend that high-dose influenza vaccine be offered to pregnant women who are: <ul style="list-style-type: none"> <li>Hematopoietic stem cell transplant (HSCT) recipients;</li> <li>CAR T-cell therapy recipients; or</li> <li>Solid organ transplant (SOT) candidates or recipients.</li> </ul> </li> <li>Pregnant SOT, HSCT and/or CAR T-cell candidates or recipients may wish to discuss the risks and benefits with their specialist.</li> </ul>
<b>Lactation</b>	It is not known whether FLUZONE High-Dose Quadrivalent is excreted in human milk.
<b>Composition</b>	<p>Each 0.7 mL dose contains:</p> <ul style="list-style-type: none"> <li>60 mcg influenza virus hemagglutinin from each of the four virus strains</li> <li>Formaldehyde</li> <li>Sodium phosphate-buffered isotonic sodium chloride solution</li> <li>Octylphenol ethoxylate (Triton X-100)</li> <li>Egg ovalbumin (egg protein) (propagated in embryonated chicken eggs).</li> </ul>
<b>Blood/Blood Products</b>	Does not contain human blood/blood products.
<b>Bovine/Porcine Products</b>	Does not contain bovine or porcine products.
<b>Latex</b>	Does not contain latex.
<b>Interchangeability</b>	Any other inactivated influenza vaccine may be interchanged for persons 65 years of age and older.
<b>Administration with Other Products</b>	<ul style="list-style-type: none"> <li>May be given at the same time as most other inactivated and live vaccines using a separate needle and syringe for each vaccine. The same limb may be used, if necessary, but different sites on the limb must be chosen.</li> <li>Space RSV vaccine by 2 weeks before or after seasonal influenza and/or seasonal COVID-19 vaccines. <ul style="list-style-type: none"> <li>Limited efficacy and safety studies have been conducted on giving RSV vaccine at the same time as other vaccines.</li> <li>Some studies suggest that giving RSV vaccine and other vaccines at the same time may not produce as strong of an immune response. The clinical significance of this is unknown and more evidence is required to understand if this is a risk.</li> </ul> </li> <li>Prioritize giving seasonal influenza and seasonal COVID-19 vaccines first during respiratory season.</li> <li>Consider the dose valid if RSV vaccine is inadvertently administered without the recommended 2- or 6-week spacing interval.</li> <li>For co-administration with COVID-19 vaccines, refer to the “Administration with Other Products” section in the relevant COVID-19 vaccine biological page.</li> </ul>
<b>Appearance</b>	<ul style="list-style-type: none"> <li>Clear to slightly opalescent in colour.</li> <li>Shake product well before administration.</li> </ul>
<b>Storage</b>	<ul style="list-style-type: none"> <li>Store at +2°C to +8°C.</li> <li>Do not freeze.</li> <li>Store in original packaging, when possible, to protect from light.</li> </ul>
<b>Vaccine Code</b>	FLU-HD
<b>Antigen Code</b>	FLU
<b>Licensed for</b>	Individuals 65 years of age and older.

	FLUZONE High-Dose
<b>Off-License Use</b>	<p>Adults 18 to 64 years of age, including pregnant individuals, who are:</p> <ul style="list-style-type: none"> <li>• Hematopoietic stem cell transplant (HSCT) recipients;</li> <li>• CAR T-cell therapy recipients; or</li> <li>• Solid organ transplant (SOT) candidates or recipients.</li> </ul>
<b>Notes</b>	<ul style="list-style-type: none"> <li>• 1992 (approx.): Influenza vaccine split virus Influenza split virus vaccine first used in Canada in approximately 1992 (Fluviral &amp; Vaxigrip).</li> <li>• 2009 October: Influenza vaccine for H1N1 Pandemic universal program for everyone six months of age and older.</li> <li>• 2009 October: Influenza seasonal vaccine universal program to include all Albertans six months of age and older.</li> <li>• 2015 August 12: Influenza Vaccines 2015-2016 season: Fludac (all Albertans aged 65 years and older.), Flumist Quadrivalent, Fluviral, Influvac (This is the vaccine of choice for adults 18 to 64 years of age).</li> <li>• 2016 August 29: Influenza vaccines 2016-2017 season: Fluzone, Fludac, Flumist.</li> <li>• 2017 July: Influenza Vaccines 2017-2018 season: Fluzone, Fludac.</li> <li>• 2018 August: Influenza Vaccines 2018-2019 season: Fluzone, FluLaval Tetra.</li> <li>• 2019: Influenza Vaccines 2019-2020 season: Fluzone, FluLaval Tetra.</li> <li>• 2020: Influenza Vaccines 2020-2021 season: Fluzone, FluLaval Tetra, Alfurina Tetra, Fluzone HD (65 years of age and older who reside in long term care beds).</li> <li>• 2021: Influenza Vaccine 2021-2022 season: Fluzone, FluLaval Tetra, Alfurina Tetra, Fluzone HD (65 years of age and older).</li> <li>• 2022: Influenza Vaccine 2022-2023 season: Fluzone, FluLaval Tetra, Alfurina Tetra, Fluzone HD (65 years of age and older).</li> <li>• 2023 Influenza Vaccines 2023-2024 season: Fluzone, FluLaval Tetra, Fluzone HD (65 years of age and older).</li> <li>• 2024 Influenza Vaccines 2024-2025 season: Flucelvax Quad, Fluzone, FluLaval Tetra, Fluzone HD (65 years of age and older). Added off-license use for high dose vaccine for adults 18 years of age and older, including pregnant individuals, who are hematopoietic stem cell transplant (HSCT) recipients, CAR T-cell therapy recipients or solid organ transplant (SOT) candidates or recipients.</li> </ul>
<b>Related Resources</b>	<p>Alberta Health Services Website (2024). <a href="#">Influenza Immunization Professionals   Alberta Health Services</a></p>
<b>References</b> <p>Alberta Health. (2024, September) Influenza Vaccine High Dose Quadrivalent Inactivated. In <i>Alberta immunization Policy: Biological Products</i>. (2024). Government of Alberta.</p> <p>Expert opinion of Alberta SOT and HSCT Program physicians. (November 2023 and September 2024).</p> <p>Kwong, J. C., Vasa, P. P., Campitelli, S. H., et al. (2013). <i>Risk of Guillain-Barré syndrome after seasonal influenza vaccination and influenza health-care encounter: a self-controlled study</i>. <i>Lancet Infectious Disease</i>, 13, 769-76. 3.</p> <p>National Advisory Committee on Immunization (2006, January03). <i>Oculo-respiratory syndrome following influenza vaccination: Review of post-marketing surveillance through four influenza seasons in Canada</i>. Public Health Agency of Canada.</p> <p>National Advisory Committee on Immunization (2024, July 25)4). <i>Statement on seasonal influenza vaccine for 2024-2025</i>. Public Health Agency of Canada.</p> <p>Public Health Agency of Canada. (2019, December) Influenza. In <i>Canadian Immunization Guide: Part 4. Immunizing Agents</i>. Government of Canada.</p> <p>Sanofi Pasteur Inc. (April 23, 2024). FLUZONE High-Dose Quadrivalent (2024-2025). High-Dose Quadrivalent Influenza Virus Vaccine -Types A and B (Split Virion). Health Canada drug product database. <a href="https://pdf.hres.ca/dpd_pm/00076979.PDF">https://pdf.hres.ca/dpd_pm/00076979.PDF</a></p>	