

<b>Section 7:</b>	<b>Biological Product Information</b>	<b>Standard #: 07.266</b>
<b>Created by:</b>	Province-wide Immunization Program Standards and Quality	
<b>Approved by:</b>	Province-wide Immunization Program Standards and Quality	
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FLUZONE® High-Dose	
<b>Manufacturer</b>	Sanofi Pasteur
<b>Biological 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>Notes:</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 2020-2021 Season</b>	A/Victoria/2570/2019 (H1N1)pdm09-like virus A/Cambodia/e826360/202 (H3N2)-like virus B/Washington/02/2019 (B/Victoria lineage)-like virus B/Phuket/3073/2013 (B/Yamagata lineage)-like virus
<b>Dose</b>	<b>0.7 mL</b>
<b>Route</b>	I.M.
<b>Schedule</b>	65 years of age and older: <ul style="list-style-type: none"> <li>• 1 dose</li> </ul>
<b>Contraindications/Precautions</b>	<p><b>Contraindications:</b></p> <ul style="list-style-type: none"> <li>• Persons under 65 years of age.</li> <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> <li>• Known history of <b>severe</b> 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> <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.</li> <li>• Egg-allergic individuals may be immunized using trivalent influenza vaccine (TIV) without a prior influenza vaccine skin test and with the full dose of vaccine. They can be immunized in any setting and should be kept under observation for 30 minutes following administration of inactivated influenza vaccine.</li> </ul>
<b>Possible Reactions</b>	<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> </ul>

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	<ul style="list-style-type: none"> <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>• 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</b> facial swelling.</li> </ul> </li> </ul> <p><b>Note:</b> Approximately 5 to 34% of individuals who experienced ORS with a previous dose of influenza vaccine may have a recurrence, but usually in a milder form.</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>
<b>Pregnancy</b>	Not applicable
<b>Lactation</b>	Not applicable
<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>• Triton® X-100</li> </ul> <p>Egg protein; propagated in embryonated chicken eggs</p>
<b>Blood/Blood Products</b>	Contains no human blood/blood products.
<b>Bovine/Porcine Products</b>	Contains no 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>	May be given at the same time as 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.
<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>

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<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.
<b>Program 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, Alfuria® Tetra, Fluzone HD (65 years of age and older who reside in long term care beds).</li> </ul>	
<b>Related Resources</b>	
<ul style="list-style-type: none"> <li>• Alberta Health Services Website (2021). Influenza Immunization <a href="#">Influenza Immunization Health Professionals   Alberta Health Services</a></li> </ul>	
<b>References</b>	
<ol style="list-style-type: none"> <li>1. Alberta Health. (2021, September). Alberta Influenza Immunization Policy. Health and Wellness Promotion Branch, Public Health and Compliance Division, Alberta Health.</li> <li>2. Alberta Immunization Policy, Biological Products, Government of Alberta (2021, September). <i>Influenza Vaccine High-Dose Quadrivalent Inactivated</i></li> <li>3. National Advisory Committee on Immunization. <i>Canadian immunization guide (Evergreen Edition)</i>. Ottawa, ON: Public Health Agency of Canada. <a href="http://www.phac-aspc.gc.ca/publicat/cig-gci/index-eng.php">http://www.phac-aspc.gc.ca/publicat/cig-gci/index-eng.php</a></li> <li>4. National Advisory Committee on Immunization (2006-01-03). Oculo-respiratory syndrome following influenza vaccination: Review of post-marketing surveillance through four influenza seasons in Canada. Ottawa, ON: Public Health Agency of Canada. <a href="http://www.phac-aspc.gc.ca/publicat/ccdr-rmtc/05vol31/dr3121a-eng.php">http://www.phac-aspc.gc.ca/publicat/ccdr-rmtc/05vol31/dr3121a-eng.php</a></li> <li>5. National Advisory Committee on Immunization (2021). Canadian Immunization Guide Chapter on Influenza and Statement on Seasonal Influenza Vaccine for 2021-2022. Ottawa, ON: Public Health Agency of Canada.</li> <li>6. Sanofi Pasteur Inc. (April 14, 2021). FLUZONE® High-Dose Quadrivalent (2021-2022). High-Dose Quadrivalent Influenza Virus Vaccine - Types A and B (Split Virion). <i>Product Monograph</i></li> </ol>	