



Quadrivalent Inactivated Influenza Vaccine (QIV) Biological Page

Section 7:	Biological Product Information	Standard #: 07.265
Created by:	Provincial Immunization Program Standards and Quality	
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	Fluzone® Quadrivalent	FluLaval Tetra®
Manufacturer	Sanofi Pasteur Inc.	GlaxoSmithKline Inc.
Biological Classification	Quadrivalent, inactivated split virion vaccine	
Indications for Provincially Funded Vaccine	<p>For persons 6 months of age and older.</p> <p>Notes:</p> <ul style="list-style-type: none"> • ONLY persons who live, work, go to school or are visiting in Alberta are eligible to receive provincially funded influenza vaccine. • Individuals 65 years of age and older should be offered Fluzone® High Dose influenza vaccine as first option. 	
Influenza Strains for 2023-2024 Season	A/Victoria/4897/2022 (H1N1)pdm09-like virus A/Darwin/9/2021(H3N2)-like virus B/Austria/1359417/2021(B/Victoria lineage)-like virus B/Phuket/3073/2013-like virus (B/Yamagata lineage)-like virus	
Dose	0.5 mL	
Route	I.M.	
Schedule	<p>6 months up to and including 8 years of age who have not received influenza vaccine in a previous season:</p> <ul style="list-style-type: none"> • 2 doses with a minimum interval of 4 weeks between doses <p>6 months up to and including 8 years of age who have received influenza vaccine in a previous season:</p> <ul style="list-style-type: none"> • 1 dose <p>9 years of age and older:</p> <ul style="list-style-type: none"> • 1 dose <p>Note:</p> <ul style="list-style-type: none"> ○ 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 as long as a clearance letter has been received to proceed with inactivated vaccines. • 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"> ○ Principles of Immunization in Hematopoietic Stem Cell Transplant Recipients and Solid Organ Transplant Recipients ○ Immunization for Adult HSCT Recipients ○ Immunization for Child HSCT Recipients 	

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Contraindications/ Precautions	<p>Contraindications:</p> <ul style="list-style-type: none"> • Infants less than 6 months of age. • Known hypersensitivity to any component of the vaccine excluding eggs. • Anaphylactic or other allergic reactions to a previous dose of influenza vaccine. • Known history of Guillain Barré Syndrome (GBS) within 6 weeks of a previous dose of influenza vaccine. • Individuals presenting with a serious acute febrile illness <ul style="list-style-type: none"> ○ Recommendations should be provided for these individuals to be immunized when their symptoms have resolved. ○ Individuals with non-serious febrile illness may be immunized. <p>Precautions:</p> <ul style="list-style-type: none"> • Egg allergy is not considered a contraindication for inactivated influenza vaccine. • 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 the administration of inactivated influenza vaccine. • Known history of severe 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. 	
Possible Reactions	<p>Common:</p> <ul style="list-style-type: none"> • Pain, tenderness, redness, and swelling at the injection site • Fever, shivering • Fatigue, drowsiness, malaise • Irritability, abnormal crying, • Headache, arthralgia, myalgia • Loss of appetite • Gastrointestinal symptoms (nausea, vomiting, diarrhea, abdominal pain) <p>Uncommon:</p> <ul style="list-style-type: none"> • Pruritus, bruising, haemorrhage, warmth and induration at injection site • Lymphadenopathy • Dizziness • Rash, pruritus • Otitis media • Cough, runny nose, sneezing, sore throat <p>Rare:</p> <ul style="list-style-type: none"> • Anaphylaxis, allergic reaction • Guillain-Barré Syndrome (GBS) • ORS is defined by the following symptoms occurring within 24 hours of immunization: 	

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	<ul style="list-style-type: none"> ○ bilateral red eyes and ○ one or more of the following respiratory symptoms (cough, wheeze, chest tightness, difficulty breathing, difficulty swallowing, hoarseness, sore throat) with or without facial swelling. <p>Note: 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"> ● As with any immunization, unexpected or unusual side effects can occur. Refer to product monograph for more detailed information. 	
Pregnancy	No contraindication. Inactivated influenza immunization is recommended for all pregnant women, at any stage of pregnancy, due to the risk of influenza morbidity. The safety of inactivated influenza vaccine during pregnancy has been reviewed and has not shown evidence of harm to the mother or fetus.	
Lactation	No contraindication	
Composition	<p>Each 0.5 mL dose contains:</p> <ul style="list-style-type: none"> ● 15 mcg influenza virus hemagglutinin from each of the four virus strains ● Formaldehyde ● Sodium phosphate-buffered, isotonic sodium chloride solution ● Triton® X-100 <p>*Thimerosal is present in the multi-dose product only (25 µg/0.5 mL dose) Propagated in embryonated chicken eggs</p>	<p>Each 0.5 mL dose contains:</p> <ul style="list-style-type: none"> ● 15 mcg influenza virus hemagglutinin surface antigen from each of the four virus strains ● phosphate buffered saline composed of: <ul style="list-style-type: none"> ○ sodium chloride ○ potassium chloride ○ disodium hydrogen phosphate heptahydrate ○ potassium dihydrogen phosphate ○ water for injection ● α-tocopheryl hydrogen succinate ● polysorbate 80 ● trace residual amounts of: <ul style="list-style-type: none"> ○ egg proteins ○ formaldehyde ○ sodium deoxycholate ○ ethanol ○ sucrose <p>*Thimerosal is present in the multi-dose product only (50 mcg/0.5 mL dose) Propagated in the allantoic cavity of embryonated hens' eggs.</p>
Blood/Blood Products	Does not contain human blood/blood products.	
Bovine/Porcine Products	Does not contain bovine or porcine products.	
Latex	Does not contain latex.	
Interchangeability	For children requiring a second dose of influenza vaccine, either quadrivalent inactivated influenza vaccine or quadrivalent live attenuated influenza vaccine can be used as long as there is a minimum interval of 4 weeks between doses. If a child receives a dose of trivalent inactivated influenza vaccine as their first dose, quadrivalent inactivated influenza vaccine can be administered as the second dose.	

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Administration with Other Products	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. For co-administration with COVID-19 vaccines, refer to the “Administration with Other Products” section in the relevant COVID-19 vaccine biological page.	
Appearance	<ul style="list-style-type: none"> • Clear to slightly opalescent suspension. • Shake product well before administration. 	<ul style="list-style-type: none"> • Opalescent translucent to off-white suspension • Shake product well before administration.
Storage	<ul style="list-style-type: none"> • Store at +2°C to +8°C • Do not freeze. • Store in original packaging when possible to protect from light. • Discard 28 days after first puncture into the vial for the multi-dose product. • Do not use beyond the labeled expiry date. 	
Vaccine Code	FLU	
Antigen Code	FLU	
Licensed for	Individuals 6 months of age and older.	
Program Notes:		
<ul style="list-style-type: none"> • 1992 (approx.): Influenza vaccine split virus Influenza split virus vaccine first used in Canada in approximately 1992. (Fluviral® & Vaxigrip®) • 2009 October: Influenza vaccine for H1N1 Pandemic universal program for everyone six months of age and older. • 2009-October: Influenza seasonal vaccine universal program to include all Albertans six months of age and older. • 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). • 2016 August 29: Influenza vaccines 2016-2017 season: Fluzone®, Fludac®, Flumist® • 2017 July: Influenza Vaccines 2017-2018 season: Fluzone®, Fludac®. • 2018 August: Influenza Vaccines 2018-2019 season: Fluzone®, FluLaval® Tetra. • 2019: Influenza Vaccine 2019-2020 season: Fluzone®, FluLaval® Tetra. • 2020: Influenza Vaccines 2020-2021 season: Fluzone®, FluLaval® Tetra, Alfuria® Tetra, Trivalent Fluzone HD (65 years of age and older who reside in long term care beds). • 2021: Influenza Vaccine 2021-2022 season: Fluzone®, FluLaval® Tetra, Alfuria® Tetra, Fluzone® HD (65 years of age and older). • 2022: Influenza Vaccine 2022-2023 season: Fluzone®, FluLaval® Tetra, Alfuria® Tetra, Fluzone® HD (65 years of age and older). • 2023 Influenza Vaccines 2023-2024 season: Fluzone®, FluLaval® Tetra, Fluzone® HD (65 years of age and older). 		
Related Resources		
<ul style="list-style-type: none"> • Alberta Health Services Website (2023). Influenza Immunization Influenza (flu) (alberta.ca) Alberta Health Services Website (2023). Influenza Immunization: Information for Health Professionals Influenza Immunization Health Professionals Alberta Health Services 		
References		
<ol style="list-style-type: none"> 1. Alberta Immunization Policy, Biological Products, Government of Alberta (2023, August). <i>Influenza Vaccine Quadrivalent Inactivated</i>. 2. GlaxoSmithKline Inc. (April 12, 2023). FLULAVAL TETRA (2023-2024) Quadrivalent Influenza Vaccine (Split Virion, Inactivated). <i>Product monograph</i>. 		

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3.	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 . <i>Lancet Infectious Disease</i> , 13, 769-76.	
4.	National Advisory Committee on Immunization. <i>Canadian immunization guide (Evergreen Edition)</i> . Ottawa, ON: Public Health Agency of Canada. http://www.phac-aspc.gc.ca/publicat/cig-gci/index-eng.php	
5.	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. http://www.phac-aspc.gc.ca/publicat/ccdr-rmtc/05vol31/dr3121a-eng.php	
6.	National Advisory Committee on Immunization (2023). Statement on seasonal influenza vaccine for 2023-2024. https://www.canada.ca/en/public-health/services/publications/vaccines-immunization/national-advisory-committee-immunization-statement-seasonal-influenza-vaccine-2023-2024.html	
7.	Sanofi Pasteur Inc. (April 20, 2023). FLUZONE® Quadrivalent (2023-2024) Influenza Virus Vaccine Quadrivalent Types A and B (Split Virion). <i>Product Monograph</i>	