Influenza Vaccine Quadrivalent Inactivated

BIOLOGICAL PAGE

Alberta Health Services
Communicable Disease Control

Section 7	Biological Product Information	**Standard # 07.265**	
Created and approved by	Provincial Immunization Program Standards and Quality		
Approval date	September 4, 2015	**Revised**	September 25, 2024

	FLUCELVAX QUAD	**FluLaval Tetra**	**Fluzone Quadrivalent**
Manufacturer	Seqirus Canada Inc.	GlaxoSmithKline Inc.	Sanofi Pasteur Inc.
Classification	Quadrivalent, inactivated subunit	Quadrivalent, inactivated split virion vaccine	
Indications for Provincially Funded Vaccine	**For persons 6 months of age and older.** If available, high-dose quadrivalent inactivated influenza vaccine is recommended for adults 65 years of age and older and adults 18 years of age and older who are: • Hematopoietic stem cell transplant (HSCT) recipients; • CAR T-cell therapy recipients; or • Solid organ transplant (SOT) candidates or recipients **Note:** • ONLY persons who live, work, go to school or are visiting in Alberta are eligible to receive provincially funded influenza vaccine.		
Influenza Strains for 2024-2025 Season	Cell-Cultured A/Wisconsin/67/2022 (H1N1)pdm09-like virus A/Massachusetts/18/2022(H3N2)-like virus B/Austria/1359417/2021(B/Victoria lineage)-like virus B/Phuket/3073/2013(B/Yamagata lineage)-like virus	Egg-Based A/Victoria/4897/2022 (H1N1)pdm09-like virus A/Thailand/8/2022(H3N2)-like virus B/Austria/1359417/2021(B/Victoria lineage)-like virus B/Phuket/3073/2013(B/Yamagata lineage)-like virus	
Dose	0.5 mL		
Route	I.M.		
Schedule	**6 months up to and including 8 years of age who have not received influenza vaccine in a previous season:** • 2 doses with a minimum interval of 4 weeks between doses **6 months up to and including 8 years of age who have received influenza vaccine in a previous season:** • 1 dose **9 years of age and older:** • 1 dose		

© 2024 Alberta Health Services

	FLUCELVAX QUAD	FluLaval Tetra	Fluzone Quadrivalent
	Note: ○ 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: ○ Principles of Immunization in Hematopoietic Stem Cell Transplant Recipients and Solid Organ Transplant Recipients ○ Immunization for Adult HSCT Recipients ○ Immunization for Child HSCT Recipients		
Contraindications/ Precautions	**Contraindications:** • 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 ○ Recommendations should be provided for these individuals to be immunized when their symptoms have resolved. ○ Individuals with non-serious febrile illness may be immunized. **Precautions:** • 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 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	**Common:** • 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) **Uncommon:** • Pruritus, bruising, haemorrhage, warmth and induration at injection site • Lymphadenopathy • Dizziness • Rash • Nasopharyngitis • Otitis media • Cough, runny nose, sneezing, sore throat		

© 2024 Alberta Health Services

	FLUCELVAX QUAD	FluLaval Tetra	Fluzone Quadrivalent

	Rare:
	• Anaphylaxis, allergic reaction
	• Guillain-Barré Syndrome (GBS)
	• ORS is defined by the following symptoms occurring within 24 hours of immunization:
	  ○ 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.
	Note: People who have an occurrence or recurrence of ORS upon immunization do not necessarily experience further episodes with future immunizations.
	• 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	Each 0.5 mL dose contains:
	• 15 mcg influenza virus haemagglutinin from each of the four virus strains
	• Disodium phosphate dihydrate
	• Magnesium chloride hexahydrate
	• Potassium chloride
	• Potassium dihydrogen phosphate
	• Sodium chloride
	• Water for injection
	• Trace residual amounts of:
	  ○ beta-propiolactone
	  ○ cetyltrimethylammonium bromide
	  ○ polysorbate 80
	*Thimerosal is present in the multi-dose product only (25 mcg/0.5 mL dose)
	Propagated in Madin Darby Canine Kidney (MDCK) cells
		Each 0.5 mL dose contains:
		• 15 mcg influenza virus haemagglutinin surface antigen from each of the four virus strains
		• phosphate buffered saline composed of:
		  ○ sodium chloride
		  ○ potassium chloride
		  ○ disodium hydrogen phosphate heptahydrate
		  ○ potassium dihydrogen phosphate
		  ○ water for injection
		• α-tocopheryl hydrogen succinate
		• polysorbate 80
		• trace residual amounts of:
		  ○ egg proteins
		  ○ formaldehyde
		  ○ sodium deoxycholate
			Each 0.5 mL dose contains:
			• 15 mcg influenza virus haemagglutinin from each of the four virus strains
			• Formaldehyde
			• Sodium phosphate-buffered, isotonic sodium chloride solution
			• Triton X-100
			*Thimerosal is present in the multidose product only (25 mcg/0.5 mL dose)
			Propagated in embryonated chicken eggs

© 2024 Alberta Health Services

	FLUCELVAX QUAD	FluLaval Tetra	Fluzone Quadrivalent
		○ ethanol ○ sucrose *Thimerosal is present in the multi-dose product only (50 mcg/0.5 mL dose) Propagated in the allantoic cavity of embryonated hens' eggs.	
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.		
Administration with Other Products	• 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. • Space RSV vaccine by 2 weeks before or after seasonal influenza and/or seasonal COVID-19 vaccines. ○ Limited efficacy and safety studies have been conducted on giving RSV vaccine at the same time as other vaccines. ○ 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. • Prioritize giving seasonal influenza and seasonal COVID-19 vaccines first during respiratory season. • Consider the dose valid if RSV vaccine is inadvertently administered without the recommended 2-or 6-week spacing interval. • For co-administration with COVID-19 vaccines, refer to the "Administration with Other Products" section in the relevant COVID-19 vaccine biological page.		
Appearance	• Clear to slightly opalescent suspension. • Shake product well before administration.	• Opalescent translucent to off-white suspension • Shake product well before administration.	• Clear to slightly opalescent suspension. • Shake product well before administration
Storage	• 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		

© 2024 Alberta Health Services

	FLUCELVAX QUAD	FluLaval Tetra	Fluzone Quadrivalent
Antigen Code	FLU		
Licensed for	Individuals 6 months of age and older.		
Notes	• 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: Fluad (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, Fluad, Flumist • 2017 July: Influenza Vaccines 2017-2018 season: Fluzone, Fluad. • 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). • 2024 Influenza Vaccines 2024-2025 season: Flucelvax, Fluzone, FluLaval Tetra, Fluzone HD (65 years of age and older).		
Related Resources	• Alberta Health Services Website (2024). Influenza Immunization Influenza (flu) (alberta.ca) • Alberta Health Services Website (2024). Influenza Immunization: Information for Health Professionals Influenza Immunization Health Professionals | Alberta Health Services		

References

Alberta Health. (2024, September) Influenza Vaccine Quadrivalent Inactivated. In *Alberta immunization Policy: Biological Products.* (2024). Government of Alberta

GlaxoSmithKline Inc. (April 26, 2024). FLULAVAL TETRA (2024-2025) Quadrivalent Influenza Vaccine (Split Virion, Inactivated). Health Canada drug product database. https://pdf.hres.ca/dpd_pm/00075393.PDF.

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.

National Advisory Committee on Immunization. (2006, January03). *Oculo-respiratory syndrome following influenza vaccination: Review of post-marketing surveillance through four influenza seasons in Canada.* Public Health Agency of Canada.

National Advisory Committee on Immunization (2024, July 25)4). *Statement on seasonal influenza vaccine for 2024-2025*. Public Health Agency of Canada. **Error! Hyperlink reference not valid.**

Public Health Agency of Canada. (2024, September 3). Influenza. In *Canadian Immunization Guide: Part 4: Immunizing Agents.* Government of Alberta

Sanofi Pasteur Inc. (April 23, 2024). FLUZONE® Quadrivalent (2024-2025) Influenza Virus Vaccine Quadrivalent Types A and B (Split Virion). Health Canada drug product database. https://pdf.hres.ca/dpd_pm/00075545.PDF

Seqirus Canada Inc. (April 16, 2024) FLUCELVAX® QUAD (2024-2025) Influenza Vaccine (surface antigen, inactivated, prepared in cell cultures). Health Canada drug product database. https://pdf.hres.ca/dpd_pm/00076974.PDF

© 2024 Alberta Health Services