Quadrivalent Inactivated Influenza Vaccine (QIV) Biological Page

Section 7:	**Biological Product Information**		**Standard #: 07.265**
Created by:	Province-wide Immunization Program Standards and Quality		
Approved by:	Province-wide Immunization Programs 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	**For persons 6 months of age and older.** **Notes:** • 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 2021-2022 Season	A/Victoria/25702019 (H1N1)pdm09-like virus A/Cambodia/e0826360/2020 (H3N2)-like virus B/Washington/02/2019 (B/Victoria lineage)-like virus B/Phuket/3073/2013-like virus (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	
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 **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. • Known history of Guillain Barré Syndrome (GBS) within 6 weeks of a **previous dose of influenza vaccine.**	

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	• 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.	

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, pruritus
	• Otitis media
	• Cough, nasopharyngitis, upper respiratory tract infection, influenza-like illness
	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: 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.
	• 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.	

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Composition	Each 0.5 mL dose contains:
	• 15 mcg influenza virus hemagglutinin from each of the four virus strains
	• Formaldehyde
	• Sodium phosphate-buffered, isotonic sodium chloride solution
	• Triton® X-100
	*Thimerosal is present in the multi-dose product only (25 µg/0.5 mL dose)
	Propagated in embryonated chicken eggs
		Each 0.5 mL dose contains:
		• 15 mcg influenza virus hemagglutinin 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
		  ○ 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 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.	
Appearance	• Clear to slightly opalescent suspension. • Shake product well before administration.	• Opalescent translucent to off-white 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.	

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Vaccine Code	FLU	
Antigen Code	FLU	
Licensed for	Individuals 6 months of age and older.	

Program 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).

Related Resources

- Alberta Health Services Website (2021). Influenza Immunization http://www.albertahealthservices.ca/influenza.asp
- Alberta Health Services Website (2021). Influenza Immunization: Information for Health Professionals http://www.albertahealthservices.ca/2824.asp

References

1. Alberta Health. (2021, September). Alberta Influenza Immunization Policy. Health and Wellness Promotion Branch, Public Health and Compliance Division, Alberta Health.
2. Alberta Immunization Policy, Biological Products, Government of Alberta (2021, September). *Influenza Vaccine Quadrivalent Inactivated*.
3. GlaxoSmithKline Inc. (April 21, 2021). FLULAVAL TETRA (2021-2022) Quadrivalent Influenza Vaccine (Split Virion, Inactivated). *Product monograph.*
4. National Advisory Committee on Immunization. *Canadian immunization guide (Evergreen Edition*). 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 (2021). Canadian Immunization Guide Chapter on Influenza and Statement on Seasonal Influenza Vaccine for 2021-2022. Ottawa, ON: Public Health Agency of Canada.
7. National Advisory Committee on Immunization. (July 6, 2012). Statement on Seasonal Influenza Vaccine for 2012-2013: Appendix I: New Evidence Review for Children 24 to 59 Months of Age.
8. Sanofi Pasteur Inc. (April 14, 2021). FLUZONE® Quadrivalent (2021-2022) Influenza Virus Vaccine Quadrivalent Types A and B (Split Virion). *Product Monograph*