# Yukon Immunization Program Manual

## Section 8 - Biological Products

## Influenza

# SECTION 8 – BIOLOGICAL PRODUCTS

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July 2023

## Seasonal Quadrivalent Influenza Vaccine (Inactivated Split Virion or Subunit)

****Recommended and provided free to all Yukon residents****

**2023-2024 Seasonal Influenza Vaccine: Quadrivalent Inactivated Influenza Vaccines (QIIV) Contains:**

- 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 (B/Yamagata lineage)-like virus**Special attention should be given to encourage immunization in these high risk groups:**

**(1) People at high risk of influenza-related complications or hospitalization**

- All children 6–59 months of age
- Adults and children with the following chronic health conditions:
  - cardiac or pulmonary disorders (includes bronchopulmonary dysplasia, cystic fibrosis, and asthma)
  - diabetes mellitus and other metabolic diseases;
  - cancer, immune compromising conditions (due to underlying disease, therapy, or both, such as solid organ transplant or hematopoietic stem cell transplant recipients);
  - renal disease;
  - anemia or hemoglobinopathy;
  - neurologic or neurodevelopment conditions (includes neuromuscular, neurovascular, neurodegenerative, neurodevelopmental conditions, and seizure disorders [and, for children, includes febrile seizures and isolated developmental delay], but excludes migraines and psychiatric conditions without neurological conditions);
  - morbid obesity (BMI of 40 and over); and
  - children 6 months to 18 years of age undergoing treatment for long periods with acetylsalicylic acid, because of the potential increase of Reye's syndrome associated with influenza.
- All pregnant individuals
- People of any age who are residents of nursing homes and other chronic care facilities;
- Adults 65 years of age and older; and
- Indigenous peoples.

**(2) People capable of transmitting influenza to those at high risk**

- Health care and other care providers in facilities and community settings who, through their activities, are capable of transmitting influenza to those at high risk;
- Household contacts, both adults and children, of individuals at high risk, whether or not the individual at high risk has been vaccinated:
- Household contacts of individuals at high risk;
- Household contacts of infants less than 6 months of age, as these infants are at high risk but cannot receive influenza vaccine;
- Members of a household expecting a newborn during the influenza season;
- Those providing regular child care to children 0–59 months of age, whether in or out of the home; and
- Those who provide services within closed or relatively closed settings to people at high risk (e.g., crew on a ship).

**(3) Others**

- People who provide essential community services; and
- People who are in direct contact with poultry infected with avian influenza during culling operations.

| (FLUMIST® QUADRIVALENT) Influenza Virus Vaccine Trivalent Types A and B (Live Split Virion) (LAIV4) |
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| ****Recommended and provided free to all Yukon residents****<br>**2023-2024 Seasonal Influenza Vaccine:**<br>• A/Victoria/4897/2022 (H1N1)pdm09-like virus<br>• A/Darwin/9/2021 (H3N2)-like virus<br>• B/Austria/1359417/2021-like virus<br>• B/Phuket/3073/2013-like virus (in quadrivalent vaccines only)<br><br>**The A/Victoria strain was not contained in the 2022/23 season vaccines** |

## Safety Issues Applicable to Influenza Vaccines

2023 July

### 1. Egg Allergic Individuals

After careful review of clinical and post-licensure safety data, NACI has concluded that egg allergic individuals may be vaccinated against influenza using any influenza vaccine, including egg-based vaccines and LAIV, without prior influenza vaccine skin test and with the full dose, irrespective of a past severe reaction to egg and without any particular consideration, including vaccination setting. The amount of trace ovalbumin allowed in influenza vaccines that are authorized for use in Canada is associated with a low risk of adverse events (AE).

### 2. Oculo-Respiratory Syndrome (ORS)

Oculorespiratory syndrome (ORS), which is defined as the presence of bilateral red eyes and one or more associated respiratory symptoms (cough, wheeze, chest tightness, difficulty breathing, difficulty swallowing, hoarseness, or sore throat) that starts within 24 hours of vaccination, with or without facial edema, was identified during the 2000–2001 influenza season(20). Since then, there have been far fewer cases per year reported to the Canadian Adverse Event Following Immunization Surveillance System (CAEFISS). ORS is not considered to be an allergic response. People who have an occurrence or recurrence of ORS upon vaccination do not necessarily experience further episodes with future vaccinations.

Individuals who have experienced ORS without lower respiratory tract symptoms may be safely revaccinated with influenza vaccine. Individuals who experienced ORS with lower respiratory tract symptoms should have an expert review. Health care providers who are unsure whether an individual previously experienced ORS versus an immunoglobulin E (IgE) mediated hypersensitivity immune response should seek advice. Data on clinically significant AEs do not support the preference of one vaccine product over another when revaccinating those who have previously experienced ORS.

For further details on ORS, consult the Canadian Immunization Guide and CCDR volume 31 at http://www.phac-aspc.gc.ca/publicat/ccdr-rmtc/05vol31/dr3121a-eng.php

### 3. Guillain-Barré syndrome (GBS)

Studies estimate the excess risk of GBS following influenza vaccination is negligible (about 1 per million doses). The risk of GBS after influenza illness is higher than with influenza vaccination (estimated at 17 occurrences per million influenza infections). Although the evidence considering influenza vaccination and GBS is inadequate to accept or reject a causal relation between GBS in adults and seasonal influenza vaccination, avoiding subsequent influenza vaccination of individuals known to have had GBS without other known etiology within 6 weeks of a previous influenza vaccination appears prudent at this time. However, the potential risk of GBS recurrence associated with influenza vaccination must be balanced against the risk of GBS associated with influenza infection itself and the benefits of influenza vaccination.

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| | | | **September 2023** |
| **FLUZONE® QUADRIVALENT Quadrivalent Inactivated Influenza Vaccine** | | | |
| **Panorama Alternate ID:** | Fluzone<br>Influenza QIV FLUZONE 10 dose vial per box | **Panorama Catalogue Number** (level 5) | 186 |
| **Manufacturer** | Sanofi Pasteur Limited | **Biological Classification** | Quadrivalent, inactivated split virion vaccine |
| **Indications** | **Recommended and provided free** to all Yukon residents 6 months of age and older.<br>See Seasonal Quadrivalent Influenza Vaccine | | |
| **DOSES AND SCHEDULE** | **Age Group** | **Dosage** | **Number of Doses** |
| | **6 months** up to and including **8 years** of age **who have not** received influenza vaccine in a previous season | **0.5 mL IM** | **2 doses given 4 weeks apart.** |
| | **6 months** up to and including **8 years** of age **who have** received influenza vaccine in a previous season | **0.5 mL IM** | **1 dose** |
| | **≥ 9 years** | **0.5 mL IM** | **1 dose** |
| | • **65 years of age and older – refer to FluzoneHD product information.** | | |
| **Booster Doses** | • Yearly | | |
| **Administration** | • No reconstitution is required.<br>• Shake product well before administration.<br>• The vial contains 10 doses of 0.5mL.<br>• Inspect for extraneous particulate matter and/or discoloration before use. If these conditions exist, the product should not be administered.<br>• Administer IM only. The deltoid muscle is the preferred site for anyone 1 year of age and older. The anterolateral aspect of the mid-thigh (vastus lateralis muscle) is the preferred site for anyone under one year of age. Do not administer into the gluteal muscle. | | |
| **Contraindications** | 1. History of anaphylactic reaction to a previous dose of any type of influenza vaccine or to any component of FLUZONE® QUADRIVALENT, with the exception of egg<br>2. History of Guillain-Barré syndrome (GBS) within 6 weeks of receipt of a previous dose of influenza vaccine<br>3. Receipt of a CTLA-4 inhibitor (e.g., ipilimumab) alone or in combination with other checkpoint inhibitors for the treatment of cancer. Inactivated influenza vaccine should be given 4-6 weeks before starting treatment or 4-6 weeks after last dose. | | |

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| | **September 2023** |
| **FLUZONE® QUADRIVALENT Quadrivalent Inactivated Influenza Vaccine** | |
| **Precautions** | • **Severe oculo-respiratory syndrome (ORS) after a previous dose of influenza vaccine** (see safety issues applicable to influenza vaccines on page 3 for further information).<br>• Influenza vaccination should usually be postponed in people with serious acute illnesses until their symptoms have abated |
| **Special Considerations** | • Egg allergic individuals (including those who have experienced anaphylaxis following egg ingestion) can be immunized with inactivated or live attenuated influenza vaccine in any setting attended by immunization service providers who are following standard vaccine administration practice (see safety issues applicable to influenza vaccines on page 3 for further information). |
| **Interchangeability** | • For children requiring a second dose of influenza vaccine, QIIV may be given interchangeably with LAIV4 for the 1st or 2nd dose if LAIV-Q is not available and provided there is a minimum of 4 weeks between doses. |
| **Concurrent Administration with Other Vaccines** | • May be given at the same time as other inactivated and live vaccines using a separate needle and syringe for each vaccine.<br>• The same limb may be used if necessary, but different sites on the limb must be chosen. |
| **Serological Testing** | • Serological testing is not recommended before or after immunization. |
| **Vaccine Components** | • **Potential allergens**: egg protein, thimerosal (50 µg per 0.5mL dose; 0.01% w/v) (see SPECIAL CONSIDERATIONS)<br>• **Other components**: formaldehyde, sodium phosphate-buffered, isotonic sodium chloride solution, Triton® X-100. |
| **Appearance** | • Opalescent translucent to off-white suspension |
| **Pregnancy and Lactation** | • No contraindication. Inactivated influenza immunization is recommended for all pregnant and breastfeeding individuals, and 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 |
| **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. |

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| | **September 2023** |
| **FLUZONE® QUADRIVALENT Quadrivalent Inactivated Influenza Vaccine** | |
| **Expected Reactions** | • Local: pain, tenderness, swelling, redness, induration, ecchymosis.<br>• Systemic: myalgia, headache, fever, malaise. Infants and toddlers may also experience irritability, abnormal crying, drowsiness, loss of appetite and vomiting.<br>• Rare: Anaphylaxis, allergic reaction, Guillain-Barré Syndrome (GBS), oculo-respiratory syndrome (ORS). |
| **Storage and Handling** | • Store at +2°C to +8°C until labeled expiry date.<br>• Do not freeze.<br>• Store in original packaging to protect from light.<br>• Product can be used up to expiry date post-puncture |

**PROGRAM NOTES**

- Updated September 2023

**RELATED RESOURCES**

- https://www.canada.ca/en/public-health/services/publications/vaccines-immunization/canadian-immunization-guide-statement-seasonal-influenza-vaccine-2022-2023.html
- http://www.phac-aspc.gc.ca/naci-ccni/index-eng.php
- https://www.canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-guide-part-4-active-vaccines/page-10-influenza-vaccine.html

**REFERENCES**

- Canadian Immunization Guide
- National Advisory Committee on Immunization
- Product Monograph

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| | | | **September 2023** |
| **FLUZONE® HIGH DOSE Quadrivalent Inactivated Influenza Vaccine** | | | |
| **Panorama Alternate ID** | Fluzone HD<br>Influenza QIV FLUZONE HIGH-DOSE QUADRIVALENT 0.7mL prefilled syringe (5/box) | **Panorama Catalogue Number** (level 5) | 449 |
| **Manufacturer** | Sanofi Pasteur Limited | **Biological Classification** | Quadrivalent, inactivated split virion vaccine |
| **Indications** | • Individuals 65 years of age and older<br><br>This is the preferred product for those 65 years of age and older.<br>**See** Seasonal Quadrivalent Influenza Vaccine | | |
| **Primary Series** | • 1 dose given as 0.7 mL IM | | |
| **Booster Doses** | • Annually | | |
| **Administration** | • No reconstitution is required.<br>• Shake product well before administration.<br>• Each syringe is prefilled with one 0.7mL dose.<br>• Inspect for extraneous particulate matter and/or discoloration before use. If these conditions exist, the product should not be administered.<br>• Administer IM only. The deltoid muscle is the preferred site for anyone 1 year of age and older. Do not administer into the gluteal muscle, or any area with major nerve trunks. | | |
| **Contraindications** | 1. History of anaphylactic reaction to a previous dose of any type of influenza vaccine or any component of FLUZONE® HIGH-DOSE , with the exception of egg<br>2. History of Guillain-Barre syndrome (GBS) within 6 weeks of receipt of a previous dose of influenza vaccine without another cause being identified.<br>3. Receipt of a CTLA-4 inhibitor (e.g., ipilimumab) alone or in combination with other checkpoint inhibitors for the treatment of cancer. Inactivated influenza vaccine should be given 4-6 weeks before starting treatment or 4-6 weeks after the last dose. | | |
| **Precautions** | • Severe oculo-respiratory syndrome (ORS) after a previous dose of influenza vaccine (see safety issues applicable to influenza vaccines on page 3 for further information).<br>• Influenza vaccination should usually be postponed in people with serious acute illnesses until their symptoms have abated | | |
| **Special Considerations** | • Egg allergic individuals (including those who have experienced anaphylaxis following egg ingestion) can be immunized with inactivated or live attenuated influenza vaccine in any setting attended by immunization service providers who are following standard vaccine administration practice (see safety issues applicable to influenza vaccines on page 3 for further information). | | |

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| | **September 2023** |
| **FLUZONE® HIGH DOSE Quadrivalent Inactivated Influenza Vaccine** | |
| **Interchangeability** | • Any other inactivated influenza vaccine may be interchanged for persons 65 years of age and older. |
| **Concurrent Administration with Other Vaccines** | • May be given at the same time as other inactivated and live vaccines using a separate needle and syringe for each vaccine.<br>• The same limb may be used if necessary, but different sites on the limb must be chosen. |
| **Serological Testing** | • Serological testing is not recommended before or after immunization. |
| **Vaccine Components** | • **Potential allergens**: may contain traces of ovalbumin (egg protein) (see SPECIAL CONSIDERATIONS)<br>• **Other components**: formaldehyde, sodium phosphate-buffered isotonic sodium chloride solution, octylphenol ethoxylate (Triton® X-100). |
| **Appearance** | • Clear to slightly opalescent in colour.<br>• Shake product well before administration |
| **Pregnancy and Lactation** | • Not applicable |
| **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. |
| **Expected Reactions** | • Local: pain, swelling, redness, induration, ecchymosis.<br>• Systemic: malaise, shivering, fever.<br>• Rare: Anaphylaxis, allergic reaction, Guillain-Barré Syndrome (GBS), oculo-respiratory syndrome (ORS). |
| **Storage and Handling** | • Store at +2°C to +8°C until labeled expiry date.<br>• Do not freeze.<br>• Store in original packaging to protect from light.<br>• Product can be used up to expiry date post-puncture. |
| **PROGRAM NOTES** | |
| • Updated September 2023 | |

September 2023

## FLUZONE® HIGH DOSE Quadrivalent Inactivated Influenza Vaccine

### RELATED RESOURCES

- https://www.canada.ca/en/public-health/services/publications/vaccines-immunization/canadian-immunization-guide-statement-seasonal-influenza-vaccine-2022-2023.html
- http://www.phac-aspc.gc.ca/naci-ccni/index-eng.php

### REFERENCES

- Canadian Immunization Guide
- National Advisory Committee on Immunization
- Product Monograph

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| | | | **September 2023** |
| **(FLUMIST® QUADRIVALENT) Live Attenuated influenza vaccine, quadrivalent Types A and B** | | | |
| **Panorama Alternate ID** | Flumist<br>Influenza LAIV-Q FluMist 0.2 mL single dose (10/box) | **Panorama Catalogue Number** (level 5) | 171 |
| **Manufacturer** | AstraZeneca Canada | **Biological Classification** | Live Attenuated (LAIV4) |
| **Indications** | **See Seasonal Quadrivalent Influenza Vaccine**<br>**Intended for use in eligible individuals 2 – 17 years of age (inclusive).**<br>FLUMIST may be offered to those 18-59 years of age who have needle phobia and are unwilling to get another influenza vaccine, provided informed consent includes that QIIV provides better protection against influenza for this age group. | | |
| **Primary Series** | Children 2-8 years of age (inclusive): 1 or 2 doses given as 0.2 mL (0.1 mL in each nostril) **Intranasal spray**.<br>• Children under 9 years of age who have not previously received any seasonal influenza vaccine require 2 doses given 4 weeks apart. If the child has received 1 or more doses in any previous season, only a single dose is required.<br>• For children requiring 2 doses within the season, QIIV may be given interchangeably with LAIV-Q with either product used for the 1st or 2nd dose if LAIV-Q is not available.<br>Children and adolescents 9-17 years of age (inclusive) and adults 18-59 years: 1 dose given as 0.2 mL (0.1 mL in each nostril) **intranasal spray**. | | |
| **Booster Doses** | Annually | | |

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| | **September 2023** |
| **(FLUMIST® QUADRIVALENT) Live Attenuated influenza vaccine, quadrivalent Types A and B** | |
| **Contraindications** | 1. FLUMIST is not authorized for use in individuals younger than 2 years of age or older than 59 years of age.<br>2. History of anaphylactic reaction to a previous dose of any type of influenza vaccine or any component of LAIV4 or its container, including gentamicin, gelatin, or arginine.<br>3. Severe asthma or active wheezing (on high dose inhaled or oral steroids or medically attended wheezing in the 7 days prior to vaccination).<br>4. Adults and children with immunocompromising conditions.<br>5. HCWs working with immunocompromised individuals (See PRECAUTIONS).<br>6. Pregnancy.<br>7. Individuals 2-17 years of age receiving aspirin-containing therapy because of the association of Reye syndrome with aspirin and wild-type influenza infection. It is recommended that aspirin-containing products in children under 18 years of age be delayed for four weeks after receipt of LAIV-4.<br>8. History of Guillain-Barre syndrome (GBS) within 6 weeks of receipt of a previous dose of influenza vaccine without another cause being identified. |
| **Contraindications (continued)** | 9. Receipt of a CTLA-4 inhibitor (e.g., ipilimumab) alone or in combination with other checkpoint inhibitors for the treatment of cancer. Inactivated influenza vaccine should be given 4-6 weeks before starting treatment or 4-6 weeks after the last dose. |
| **Precautions** | • Vaccine recipients should be informed that LAIV4 is a vaccine that contains a weakened strain of influenza virus and could possibly be transmitted to another person through contact with respiratory secretions. An infection with this weakened virus could cause a serious infection in a small category of patients who are severely immunocompromised and receiving care in hospital in a protected environment (e.g., post bone marrow transplant). Both health care workers and close contacts of such patients should avoid contact with these patients for two weeks after getting LAIV-Q. If such contact cannot be avoided offer an inactivated influenza vaccine instead of LAIV4.<br>• Antiviral agents interfere with the immune response to LAIV4. LAIV4 should not be administered to individuals while taking antiviral agents active against influenza (oseltamivir and zanamivir). Such individuals should receive inactivated influenza vaccine. If antiviral agents are administered from 48 hours before to 2 weeks after receipt of LAIV4, revaccinate when antiviral agents have been discontinued for at least 48 hours. |

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| | **September 2023** |
| **(FLUMIST® QUADRIVALENT) Live Attenuated influenza vaccine, quadrivalent Types A and B** | |
| **Special Considerations** | • Egg allergic individuals (including those who have experienced anaphylaxis following egg ingestion) can be immunized with inactivated or live attenuated influenza vaccine in any setting attended by immunization service providers who are following standard vaccine administration practice.<br>• LAIV4 may be considered for children 2-17 years of age with HIV infection and pediatric oncology clients, including autologous HSCT, who are ≥12 months post-treatment. **Consult with Specialist for approval with each specific client before use.**<br>• LAIV-Q can be safely given to children and adolescents with cystic fibrosis unless they have contraindications (e.g., immunosuppressive therapy) for its use |
| **Pregnancy and Lactation** | • Contraindicated |
| **Interchangeability** | • For children requiring a second dose of influenza vaccine, QIIV may be given interchangeably with LAIV4 for the 1st or 2nd dose if LAIV-Q is not available and provided there is a minimum of 4 weeks between doses. |
| **Administration** | No reconstitution is required.<br>Each syringe is prefilled with one 0.2mL dose.<br>Inspect for extraneous particulate matter and/or discoloration before use. If these conditions exist, the product should not be administered.<br>1. **LAIV-Q is an intranasal spray and is not for injection. DO NOT INJECT.** Remove the rubber tip protector. Do not remove the dose-divider clip at the other end of the sprayer.<br>2. With the recipient sitting upright, place tip of the sprayer just inside a nostril to ensure vaccine is delivered into the nose.<br>3. In one motion depress the plunger **as rapidly as possible** until the dose-divider clip prevents you from going further.<br>4. Pinch and remove the dose divider clip from the plunger.<br>5. Place the tip of the sprayer just inside the **other nostril** and with a single motion depress the plunger **as rapidly as possible** to deliver the rest of the vaccine. |
| **Concurrent Administration with Other Vaccines** | • LAIV4 can be given concomitantly with, or any time before or after any other live vaccines.<br>• LAIV4 can be given concomitantly with, or any time before or after a TB skin test. |
| **Serological Testing** | Serological testing is not recommended before or after immunization. |
| **Vaccine Components** | **Potential allergens:** gelatin hydrolysate (porcine Type A), gentamicin, arginine hydrochloride and traces of egg protein (ovalbumin)<br>**Other components:** sucrose, dibasic potassium phosphate, monobasic potassium phosphate, monosodium glutamate. |

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| | **September 2023** |
| **(FLUMIST® QUADRIVALENT) Live Attenuated influenza vaccine, quadrivalent Types A and B** | |
| **Appearance** | The spray is a colourless to pale yellow, clear to opalescent liquid.<br>White small particles may be present. |
| **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. |
| **Expected Reactions** | Local: runny nose or nasal congestion.<br>Systemic: decreased appetite, weakness, headache, fever, sore throat, cough, malaise, muscle aches, cough, chills, abdominal pain, vomiting. |
| **Storage and Handling** | • The shelf-life of FLUMIST® is considerably shorter than that of inactivated influenza vaccines. Be sure to check the expiry date as they will differ from other influenza products.<br>• Product can be used up to expiry date post-puncture.<br>• Keep the nasal sprayer in the outer carton to protect from light.<br>• Use the product before the expiration date on the sprayer label.<br>• Store in a refrigerator (2°C – 8°C) upon receipt and until use.<br>• DO NOT FREEZE. |

- **PROGRAM NOTES**

- Updated September 2023

**RELATED RESOURCES**

- https://www.canada.ca/en/public-health/services/publications/vaccines-immunization/canadian-immunization-guide-statement-seasonal-influenza-vaccine-2022-2023.html
- http://www.phac-aspc.gc.ca/naci-ccni/index-eng.php

**REFERENCES**

- Canadian Immunization Guide
- National Advisory Committee on Immunization
- Product Monograph