Yukon Immunization Program Manual

Section 8 - Biological Products

Respiratory Syncytial Virus (RSV) Vaccine



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<tr><th colspan="4">Respiratory Syncytial Virus (RSV) Vaccine — ABRYSVO™</th></tr>
<tr><td>Manufacturer</td><td>Pfizer Canada Inc.</td><td>Biological Classification</td><td>Unadjuvanted Subunit Protein Vaccine, Bivalent</td></tr>
<tr><td>Current Formulation</td><td colspan="3">2025-2026: 60 mcg each of RSV A and RSV B proteins (prefusion F)</td></tr>
<tr><td rowspan="3">INDICATIONS</td><td colspan="3">SCHEDULE</td></tr>
<tr><td colspan="2">Adults 65 years and older:</td><td rowspan="2">1 Dose: 0.5 mL IM</td></tr>
<tr><td colspan="2">Adults 18 to 64 years at high risk of severe RSV disease (see Table 1)</td></tr>
<tr><td colspan="4">Table 1. Eligible Conditions for Adults 18 Years to 64 years of age at Increased Risk of Severe RSV Disease

Individuals who meet any of the following criteria are considered at increased risk:
• Residents of long-term care or chronic care facilities
• Recipients of a lung transplant
• Recipients of a hematopoietic stem cell transplant, either:
  ○ Within the past two years, or
  ○ Continuing immunosuppressive therapy
• Individuals requiring chronic oxygen therapy, including those:
  ○ On home oxygen, or
  ○ Receiving oxygen in any living setting
• Individuals undergoing dialysis treatment
• Individuals with a history of bronchopulmonary dysplasia</td></tr>
<tr><td>AVAILABLE FORMAT</td><td colspan="3">• Single-dose vial (lyophilized powder and diluent in prefilled syringe, with vial adapter)
• Supplied in cartons of 1 or 10 vials</td></tr>
<tr><td>CONTRAINDICATIONS</td><td colspan="3">• History of severe allergic reaction (e.g., anaphylaxis) to a previous dose of ABRYSVO™ or to any of its components.</td></tr>
</table>

Respiratory Syncytial Virus (RSV) Vaccine	**ABRYSVO™**
PRECAUTIONS & SPECIAL CONSIDERATIONS	• **Delay vaccination** in those with severe acute illness; minor illness is not a reason to defer. • **A small number of Guillain Barré syndrome cases** have been reported following RSV vaccination in adults aged 60 years and older. A causal relationship has not been established.
PREGNANCY AND LACTATION	• Although ABRYSVO™ is authorized in Canada for use during pregnancy at 32 to 36 weeks gestation, this indication is not publicly funded in Yukon. • No data is available on excretion in human or animal milk.
INTERCHANGEABILITY	Preferably complete with the same product; another RSV vaccine may be used if the previous product is unknown or unavailable
RECONSTITUTION AND DILUTION	1. Attach vial adapter 2. Reconstitute lyophilized vaccine component with the entire contents of the prefilled diluent syringe provided, using the vial adapter. 3. Gently swirl the vial until dissolved (less than 1 minute). **Do not shake.** 4. Withdraw full 0.5 mL dose for administration.
ADMINISTRATION	• **Dose:** 0.5 mL • **Route:** Intramuscular (IM) • **Preferred site:** deltoid preferred for adults • **After reconstitution:** administer the entire contents of the vial • Do not inject into the gluteal area or near major nerves or blood vessels.
CONCURRENT ADMINISTRATION WITH OTHER VACCINES	RSV vaccines may be administered concurrently with other vaccines; however, when possible, consider spacing RSV vaccines at least 6 weeks before or after non seasonal vaccines such as shingles or diphtheria tetanus vaccines to help avoid misattributing adverse events.
SEROLOGICAL TESTING	Serologic testing is **not recommended** before or after vaccination.

Respiratory Syncytial Virus (RSV) Vaccine	**ABRYSVO™**

VACCINE COMPONENTS	**Each 0.5 mL dose of the reconstituted ABRYSVO™ contains:**
	• Active ingredients:
	  ○ 60 mcg RSV subgroup A prefusion F protein
	  ○ 60 mcg RSV subgroup B prefusion F protein
	• Non-medicinal ingredients: mannitol, polysorbate 80, sodium chloride, sucrose, tromethamine, trometamol hydrochloride, sterile water (diluent)
	• No preservatives

APPEARANCE	Sterile, clear, colorless solution
BLOOD/ BLOOD PRODUCTS	Does not contain blood or blood products.
BOVINE/ PORCINE PRODUCTS	Does not contain bovine or porcine products.
LATEX	Product and packaging components are latex free.
EXPECTED REACTIONS	• **Local:** injection site pain, redness, swelling. • **Systemic:** headache, fatigue, myalgia, arthralgia. • Very rare: Guillain-Barré Syndrome (GBS).
STORAGE AND HANDLING	**Storage** • Store unreconstituted vials in refrigerator at 2 to 8 °C in original packaging; protect from light • Do not freeze, discard if frozen **After reconstitution** • Administer immediately; discard after 4 hours if unused **Handling** • Discard if particulate matter, discoloration, or freezing are observed • Do not shake
REFERENCES AND RESOURCES	
National Advisory Committee on Immunization Statements Canadian Immunization Guide Product Monograph	

<table>
<tr><th colspan="4">Respiratory Syncytial Virus (RSV) Passive Immunization — BEYFORTUS™ Nirsevimab</th></tr>
<tr><td>Manufacturer</td><td>Sanofi Pasteur Limited</td><td>Biological Classification</td><td>Passive Immunizing Agent (human monoclonal antibody)</td></tr>
<tr><td>Current Formulation</td><td colspan="3">2025-2026: Long-acting monoclonal antibody targeting RSV prefusion F protein.</td></tr>
<tr><td rowspan="4">INDICATIONS</td><td colspan="3">SCHEDULE</td></tr>
<tr><td colspan="2">1. All infants 8 months of age and younger, in their first RSV season:</td><td>Weighing less than 5kg :
• 1 Dose: 0.5 mL (50 mg/0.5 mL) IM

Weighing 5 kg or more :
• 1 Dose: 1 mL (100 mg/1 mL) IM</td></tr>
<tr><td colspan="2">2. High risk children under 24 months of age (see Table 1) in their second RSV season</td><td>Weighing 5 kg to less than 10 kg:
• 1 Dose: 1 mL (100 mg/1 mL) IM

Weighing 10 kg or more:
• 1 Dose: 2 mL (2 x 100 mg/1 mL) IM, given at 2 separate injection sites</td></tr>
<tr><td colspan="3">❶ BEYFORTUS™ delivery is restricted to the Yukon RSV season (generally November to April) as defined each year by the CMOH.
❶ For high-risk children weighing less than 5 kg entering their second RSV season, consult the Yukon Immunization Program for dosing guidance.</td></tr>
<tr><td>AVAILABLE FORMATS</td><td colspan="3">Prefilled syringes: 50 mg and 100 mg single use.</td></tr>
</table>

Table 1. Infants at increased risk of severe RSV disease

- Premature infants (born at less than 37 weeks gestational age)
- Chronic lung disease, including bronchopulmonary dysplasia, requiring ongoing assisted ventilation, oxygen therapy or chronic medical therapy in the 6 months prior to the start of the RSV season
- Cystic fibrosis
- Hemodynamically significant congenital heart disease
- Severe immunodeficiency
- Severe congenital airway anomalies impairing clearing of respiratory secretions
- Neuromuscular disease impairing clearing of respiratory secretions
- Down syndrome

CONTRAINDICATIONS	• Do not administer to clients older than 24 months of age. • BEYFORTUS™ Nirsevimab injection is contraindicated in individuals with a **history of severe hypersensitivity reactions**, including anaphylaxis, to this product or to any ingredient in the formulation or component of the container.

Respiratory Syncytial Virus (RSV) Passive Immunization	**BEYFORTUS™ Nirsevimab**
PRECAUTIONS & SPECIAL CONSIDERATIONS	• **Severe acute illness:** delay vaccination in those with severe acute illness; minor illness is not a reason to defer. • **Cardiopulmonary bypass surgery:** An additional dose of monoclonal antibody is recommended after surgery requiring cardiopulmonary bypass. If the client did not receive this dose, contact the Yukon Immunization Program. • Infants remain eligible for Beyfortus regardless of **maternal RSV immunization** during pregnancy.
PREGNANCY AND LACTATION	Product is not indicated in this population.
INTERCHANGEABILITY	Product is the preferred product for this population.
RECONSTITUTION AND DILUTION	No reconstitution is required for this product. Do not dilute.
ADMINISTRATION	• **Preferred site:** intramuscular (IM) injection, preferably in the anterolateral aspect of the thigh. • **Do not inject into the gluteal area** or anywhere near major nerves or blood vessels.
CONCURRENT ADMINISTRATION WITH OTHER VACCINES	Product can be administered at the same time as, or at any time before or after, other immunization products.
SEROLOGICAL TESTING	Serologic testing is not recommended.
VACCINE COMPONENTS	**Each prefilled syringe contains:** • **Active ingredient:** Nirsevimab • **Non-medicinal ingredients:** L-arginine hydrochloride, L-histidine, L-histidine hydrochloride, Polysorbate 80, Sucrose, and Water for injection • **No preservatives**

Respiratory Syncytial Virus (RSV) Passive Immunization	**BEYFORTUS™ Nirsevimab**
APPEARANCE	• BEYFORTUS™ is a clear to opalescent, colorless to yellow solution. • Do not administer if the liquid is cloudy, discoloured, or it contains large particles or foreign particulate matter.
BLOOD/ BLOOD PRODUCTS	Does not contain blood or blood products.
BOVINE/ PORCINE PRODUCTS	Does not contain bovine or porcine products.
LATEX	Product and packaging components are latex free.
EXPECTED REACTIONS	• **Local:** injection site pain, redness, swelling. • **Systemic:** rash, fever
STORAGE AND HANDLING	**Storage:**
	• Store in a refrigerator between 2°C and 8°C • Protect from light, store in original packaging
	Handling:
	• Do not freeze, shake or expose to heat. • Discard if dropped or damaged. • If required, product may be kept at room temperature (20 to 25 °C) for up to 8 hours before use; discard if not used within 8 hours

REFERENCES AND RESOURCES

National Advisory Committee on Immunization Statements
Canadian Immunization Guide
Product Monograph