Yukon Immunization Program Manual

Section 8 - Biological Products

Respiratory Syncytial Virus (RSV) Vaccine and Passive Immunizing Agents

SECTION 8 – BIOLOGICAL PRODUCTS

Contents

August 2024			
ABRYSVO™ Bivalent Respiratory Syncytial Virus Vaccine			
Manufacturer	Pfizer Canada Inc.	**Biological Classification**	Unadjuvanted Subunit Protein Vaccine
INDICATIONS	**Publicly Funded Indication**		**Standard Schedule**
	1. Individuals aged 75 years & up		**Dose 1: 0.5 mL IM**
	2. Individuals aged 60 years & up residing in long-term care		**Dose 1: 0.5 mL IM**
CONTRAINDICATIONS	• ABRYSVO™ should not be given to anyone with a history of severe allergic reaction (e.g., anaphylaxis) to any of its components. • Vaccination with ABRYSVO™ should be postponed in individuals suffering from an acute febrile illness.		
PRECAUTIONS & SPECIAL CONSIDERATIONS	• **RSV products must only be provided within the defined RSV season (generally November to April), as set by the Yukon CMOH each year. Clients should not be provided a dose outside of the established criteria and/or defined RSV season.** • **RSV vaccines must be given at least 4 weeks after receiving any other vaccines to help with identifying adverse events related to this product. Similarly, it is recommended to wait 4 weeks prior to giving any additional vaccines after receiving this product.** • Adverse event of note: may be slightly increased risk of GBS • The presence of a minor infection, such as a cold, should not result in the deferral of vaccination		
PREGNANCY AND LACTATION	• Although ABRYSVO™ is approved for use in those 32-36 weeks gestation, Yukon will only be providing this product to individuals aged 75 years and up (60 years and up if residing in LTC) • There are no data on the excretion of ABRYSVO™ in human or animal milk		
INTERCHANGEABILITY	• None		
RECONSTITUTION AND DILUTION	• To form ABRYSVO™, the lyophilized vaccine must be reconstituted using the vial adapter and only with the diluent provided. • Do not shake, swirl x 1 min. • Vial presentation – withdraw 0.5 ml of reconstituted product • for prefilled syringe, withdraw entire contents single dose (needle free reconstitution tool)		
ADMINISTRATION	• Each 0.5 mL dose is to be injected intramuscularly, into the deltoid muscle, with care to avoid injection into or near nerves and blood vessels.		

August 2024	
ABRYSVO™ Bivalent Respiratory Syncytial Virus Vaccine	
CONCURRENT ADMINISTRATION WITH OTHER VACCINES	• RSV vaccines should be given at least 4 weeks before or after other vaccines to help with identifying adverse events related to these new RSV vaccines.
SEROLOGICAL TESTING	• Serologic testing is not recommended before or after receiving ABRYSVO™
VACCINE COMPONENTS	• Each 0.5 mL dose of the reconstituted ABRYSVO™ includes the following ingredients: 60 mcg of each stabilized RSV prefusion F antigens (A and B), 22.5 mg mannitol, 0.08 mg polysorbate 80, 1.1 mg sodium chloride, 11.3 mg sucrose, 0.11 mg tromethamine, 1.04 mg trometamol hydrochloride, and sterile water as the diluent.
APPEARANCE	• ABRYSVO™ is a sterile, clear, and colorless solution.
BLOOD/ BLOOD PRODUCTS	• Does not contain blood or blood products.
BOVINE/ PORCINE PRODUCTS	• Does not contain bovine or porcine products.
LATEX	• The vial stopper, the tip cap and plunger stopper of the pre-filled syringe are not made with natural rubber latex.
EXPECTED REACTIONS	• **Local:** pain at the injection site, and • **Systemic:** fatigue, headache, muscle pain, nausea (pregnancy specific)
STORAGE AND HANDLING	• Store in a refrigerator between 2°C and 8°C • Store in original package to protect from light • Once reconstituted product can be stored at room temperature 15°C to 30°C for up to 4 hours. • Discard reconstituted vaccine if not used within 4 hours.
REFERENCES AND RESOURCES	National Advisory Committee on Immunization Statements Canadian Immunization Guide ABRYSVO™ Product Monograph

			August 2024
BEYFORTUS™ Nirsevimab Respiratory Syncytial Virus			
Manufacturer	Sanofi Pasteur Limited	**Biological Classification**	Passive Immunizing Agent (Human Monoclonal Antibody)

INDICATIONS	**Publicly Funded Indication**	**Standard Dose**
	1. All infants 8 months of age and younger in their first RSV season weighing **less** than 5 kg	A single 0.5 mL dose (50 mg/0.5 mL) IM injection (purple)
	2. All infants 8 months of age and younger in their first RSV season weighing **more** than 5 kg	A single 1 mL dose (100 mg/1 mL) IM injection (light blue
	3. Children up to 24 months of age who are at increased risk of severe RSV disease in their first or second RSV season.	A single dose of 200 mg (2 x 100 mg/1 mL), divided between two IM injection sites.

TABLE 1: INFANTS AT INCREASED RISK OF SEVERE RSV DISEASE

- All premature infants (i.e., born less than 37 wGA)
- 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 with respiratory involvement and/or growth delay
- Hemodynamically significant chronic cardiac disease
- Severe immunodeficiency
- Severe congenital airway anomalies impairing clearing of respiratory secretions
- Neuromuscular disease impairing clearing of respiratory secretions
- Down syndrome

CONTRAINDICATIONS	• BEYFORTUS™ nirsevimab injection is contraindicated in individuals with a history of severe hypersensitivity reactions, including anaphylaxis, to this drug or to any ingredient in the formulation, including any non-medicinal ingredient, or component of the container.
PRECAUTIONS & SPECIAL CONSIDERATIONS	• The presence of a minor infection, such as a cold, should not result in the deferral of vaccination • **RSV products must only be provided within the defined RSV season (generally November to April), as set by the Yukon CMOH each year. Clients should not be provided a dose outside of the established criteria and/or defined RSV season.**

August 2024	
BEYFORTUS™ Nirsevimab Respiratory Syncytial Virus	
PREGNANCY AND LACTATION	• BEYFORTUS™ is not indicated in this population
INTERCHANGEABILITY	• When available, BEYFORTUS should be given to eligible children as the preferred product over Synagis. However, infant RSV immunization this season should not be delayed while awaiting BEYFORTUS in children eligible for Synagis. Synagis remains an available product and should be initiated for eligible children if BEYFORTUS is not available or in stock. If a child started on Synagis they should receive BEYFORTUS when the next Synagis dose is due (i.e. 4 weeks later); once given BEYFORTUS they do not need to continue receiving Synagis.
RECONSTITUTION AND DILUTION	• No reconstitution is required for this product. Do not dilute.
ADMINISTRATION	• BEYFORTUS™ is administered intramuscularly, preferably in the anterolateral aspect of the thigh. The gluteal muscle should not be used routinely as an injection site because of the risk of damage to the sciatic nerve
CONCURRENT ADMINISTRATION WITH OTHER VACCINES	• BEYFORTUS 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 before or after receiving BEYFORTUS™
VACCINE COMPONENTS	• Nirsevimab, arginine hydrochloride, L-histidine, L-histidine hydrochloride, Polysorbate 80, Sucrose, and Water for injection
APPEARANCE	• BEYFORTUS™ is a clear to opalescent, colourless to yellow solution. Do not inject BEYFORTUS™ if the liquid is cloudy, discoloured, or it contains large particles or foreign particulate matter.
BLOOD/ BLOOD PRODUCTS	• BEYFORTUS™ is a long acting monoclonal antibody produced by recombinant DNA technology. It has no potential for transmitting blood-borne infectious diseases.
BOVINE/ PORCINE PRODUCTS	• Does not contain bovine or porcine products.
LATEX	• The vial stopper, the tip cap and plunger stopper of the pre-filled syringe are not made with natural rubber latex.
EXPECTED REACTIONS	• Rash, fever, redness, swelling, and pain where the injection is given

August 2024	
BEYFORTUS™ Nirsevimab Respiratory Syncytial Virus	
STORAGE AND HANDLING	• Store in a refrigerator between 2°C and 8°C • Store in original package to protect from light • Once reconstituted product can be stored at room temperature 15°C to 30°C for up to 8 hours. • Do not shake
REFERENCES AND RESOURCES	National Advisory Committee on Immunization Statements Canadian Immunization Guide BEYFORTUS® Product Monograph

August 2024			
SYNAGIS® Palivizumab Injection Respiratory Syncytial Virus			
Manufacturer	AstraZeneca Canada Inc.	**Biological Classification**	Passive Immunizing Agent (Human Monoclonal Antibody)
INDICATIONS	**Publicly Funded Indication**		**Standard Dose**
	1. Children up to 24 months of age who are at increased risk of severe RSV disease in their first or second RSV season (Table 1). **Must review Section 5 of the Immunization Manual for Synagis Program details**		15mg/kg of bodyweight **Dose per month during the defined RSV season**
TABLE 1: INFANTS AT INCREASED RISK OF SEVERE RSV DISEASE			
• All premature infants (i.e., born less than 37 wGA) • 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 with respiratory involvement and/or growth delay • Hemodynamically significant chronic cardiac disease • Severe immunodeficiency • Severe congenital airway anomalies impairing clearing of respiratory secretions • Neuromuscular disease impairing clearing of respiratory secretions • Down syndrome			
CONTRAINDICATIONS	• SYNAGIS® palivizumab injection is contraindicated in patients with known hypersensitivity to palivizumab injection or to any of its excipients. It is also contraindicated in patients with known hypersensitivity to other humanized monoclonal antibodies.		
PRECAUTIONS & SPECIAL CONSIDERATIONS	• The presence of a minor infection, such as a cold, should not result in the deferral of vaccination. • **RSV products must only be provided within the defined RSV season (generally November to April), as set by the Yukon CMOH each year. Clients should not be provided a dose outside of the established criteria and/or defined RSV season.**		
PREGNANCY AND LACTATION	• SYNAGIS® is not indicated in this population		

August 2024	
SYNAGIS® Palivizumab Injection Respiratory Syncytial Virus	
INTERCHANGEABILITY	• When available, BEYFORTUS should be given to eligible children as the preferred product over Synagis. However, infant RSV immunization this season should not be delayed while awaiting BEYFORTUS in children eligible for Synagis. Synagis remains an available product and should be initiated for eligible children if BEYFORTUS is not available or in stock. If a child started on Synagis they should receive BEYFORTUS when the next Synagis dose is due (i.e. 4 weeks later); once given BEYFORTUS they do not need to continue receiving Synagis.
RECONSTITUTION AND DILUTION	• No reconstitution is required for this product. Do not dilute.
ADMINISTRATION	• The dose per month = [patient weight (kg) x 15 mg/kg ÷ 100 mg/mL of SYNAGIS®. • Injection volumes over 1 mL should be given as a divided dose. • To prepare product - remove the tab portion of the vial cap and clean the stopper with 70% ethanol or equivalent. Insert the needle into the vial and withdraw an appropriate volume of solution into the syringe • SYNAGIS does not contain a preservative and should be administered immediately after drawing the dose into the syringe • SYNAGIS® is administered intramuscularly, preferably in the anterolateral aspect of the thigh. The gluteal muscle should not be used routinely as an injection site because of the risk of damage to the sciatic nerve.
CONCURRENT ADMINISTRATION WITH OTHER VACCINES	• Palivizumab 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 before or after receiving this vaccine.
VACCINE COMPONENTS	• Palivizumab, chloride, glycine, histidine and water for injection.
APPEARANCE	• SYNAGIS® is a clear to opalescent, colourless to yellow solution. Do not inject if the liquid is cloudy, discoloured, or it contains large particles or foreign particulate matter.
BLOOD/ BLOOD PRODUCTS	• Synagis® is a monoclonal antibody produced by recombinant DNA technology. It has no potential for transmitting blood-borne infectious diseases.
BOVINE/ PORCINE PRODUCTS	• Does not contain bovine or porcine products.
LATEX	• The vial stopper, the tip cap and plunger stopper of the pre-filled syringe are not made with natural rubber latex.

	August 2024
SYNAGIS® Palivizumab Injection Respiratory Syncytial Virus	
EXPECTED REACTIONS	• Fever, rash, redness or swelling at injection site.
STORAGE AND HANDLING	• Store in a refrigerator between 2°C and 8°C • Store in original package to protect from light • Once reconstituted product can be stored at room temperature 15°C to 30°C for up to 8 hours. • Do not shake • The single-use vial of SYNAGIS® solution for injection does not contain a preservative and should be administered immediately after drawing the dose into the syringe
REFERENCES AND RESOURCES	National Advisory Committee on Immunization Statements Canadian Immunization Guide SYNAGIS® Product Monograph